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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91194218
Party	Plaintiff Illumina, Inc.
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Attachments	20120530 OPPOSER - PETITIONER'S MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT THEREOF.pdf (26 pages)(1972277 bytes) EXHIBIT I OF OPPOSER'S MOTION FOR SUMMARY JUDGMENT DEC OF KAREN POSSEMATO (5 PGS).pdf (5 pages)(327390 bytes) EXHIBIT A OF DEC OF KAREN POSSEMATO (45 PGS).pdf (45 pages)(4959242 bytes) EXHIBIT B (PART I OF II) OF DEC OF KAREN POSSEMATO (36 PGS).pdf (36 pages)(4242719 bytes) EXHIBIT B (PART II OF II) OF DEC OF KAREN POSSEMATO (34 PGS).pdf (34 pages)(7798947 bytes) EXHIBIT C OF DEC OF KAREN POSSEMATO (9 PGS).pdf (9 pages)(936110 bytes) EXHIBIT D OF DEC OF KAREN POSSEMATO (18 PGS).pdf (18 pages)(2379033 bytes) EXHIBIT E (PART I OF II) OF DEC OF KAREN POSSEMATO (21 PGS).pdf (21 pages)(2689120 bytes) EXHIBIT E (PART II OF II) OF DEC OF KAREN POSSEMATO (35 PGS).pdf (35 pages)(3775294 bytes) EXHIBIT F OF DEC OF KAREN POSSEMATO (30 PGS).pdf (30 pages)(4167274 bytes) EXHIBIT G OF DEC OF KAREN POSSEMATO (3 PGS).pdf (3 pages)(217694 bytes) EXHIBIT II OF OPPOSER'S MOTION FOR SUMMARY JUDGMENT DEC OF GREGORY HEATH (4 PGS).pdf (4 pages)(292114 bytes) EXHIBIT 1 OF DEC OF GREGORY F. HEATH (52 PGS).pdf (52 pages)(7516247 bytes) EXHIBIT 2 (PART I OF II) OF DEC OF GREGORY F. HEATH (43 PGS).pdf (43 pages)(7765083 bytes) EXHIBIT 2 (PART II OF II) OF DEC OF GREGORY F. HEATH (27 PGS).pdf (27 pages)(5419525 bytes) EXHIBIT 3 (PART I OF III) OF DEC OF GREGORY F. HEATH (21 PGS).pdf (21 pages)(7593274 bytes) EXHIBIT 3 (PART II OF III) OF DEC OF GREGORY F. HEATH (26 PGS).pdf (26 pages)(9231495 bytes) EXHIBIT 3 (PART III OF III) OF DEC OF GREGORY F. HEATH (39 PGS).pdf (39 pages)(9861821 bytes)

	EXHIBIT 4 (PART I OF II) OF DEC OF GREGORY F. HEATH (51 PGS).pdf (51 pages)(6803264 bytes) EXHIBIT 4 (PART II OF II) OF DEC OF GREGORY F. HEATH (55 PGS).pdf (55 pages)(9868981 bytes) EXHIBIT 5 (PART I OF VII) OF DEC OF GREGORY F. HEATH (30 PGS).pdf (30 pages)(10432252 bytes) EXHIBIT 5 (PART II OF VII) OF DEC OF GREGORY F. HEATH (30 PGS).pdf (30 pages)(9540676 bytes) EXHIBIT 5 (PART III OF VII) OF DEC OF GREGORY F. HEATH (34 PGS).pdf (34 pages)(9935731 bytes) EXHIBIT 5 (PART IV OF VII) OF DEC OF GREGORY F. HEATH (63 PGS).pdf (63 pages)(8802079 bytes) EXHIBIT 5 (PART V OF VII) OF DEC OF GREGORY F. HEATH (35 PGS).pdf (35 pages)(10014887 bytes) EXHIBIT 5 (PART VI OF VII) OF DEC OF GREGORY F. HEATH (41 PGS).pdf (41 pages)(6642850 bytes) EXHIBIT 5 (PART VII OF VII) OF DEC OF GREGORY F. HEATH (47 PGS).pdf (47 pages)(7187845 bytes) EXHIBIT III OF OPPOSER'S MOTION FOR SUMMARY JUDGMENT ILLUMINADX REG NO. 4053668 (6 PAGES).pdf (6 pages)(414057 bytes) EXHIBIT IV OF OPPOSER'S MOTION FOR SUMMARY JUDGMENT DEC OF CALVIN FAN W EXHBTS (35 PGS).pdf (35 pages)(5506652 bytes)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc.,	)	
	)	Opp. No. 91194218 (SN 77768176) (Parent)
Opposer/Petitioner,	)	
	)	Opp. No. 91194219 (SN 77775316)
v.	)	
	)	Can. No. 92053479 (RN 3887164)
Meridian Bioscience, Inc.,	)	
	)	Can. No. 92053482 (RN 3868081)
Applicant/Registrant.	)	

OPPOSER/PETITIONER'S MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT THEREOF

In accordance with Rule 56 of the Federal Rules of Civil Procedure and 37 C.F.R. Section 2.116(a), Opposer/Petitioner, Illumina, Inc. ("Illumina"), through its undersigned attorneys, hereby moves for summary judgment against Applicant/Registrant, Meridian Bioscience, Inc. ("Meridian"), on the claims of likelihood of confusion made in the Notices of Opposition and Petitions to Cancel.

TABLE OFCONTENTS

Table of Authorities..... ii

Index of Exhibits..... iv

I. Introduction..... 2

II. Undisputed Factual Background..... 2

III. Summary Judgment Standard..... 5

IV. Illumina is Entitled to Summary Judgment on its Claims of Likelihood of Confusion..... 6

A. Standing and Priority..... 6

B. Likelihood of Confusion..... 7

V. Conclusion..... 19

TABLE OF AUTHORITIES

Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986) 5

Bose Corp. v. QSC Audio Prods., Inc., 63 USPQ2d 1303, 1305 (Fed. Cir. 2002) 11

Brewski Beer Co. v. Brewski Brothers, Inc., 47 USPQ2d 1281 (TTAB 1998) 7

CAE Inc. v. Clean Air Engineering Inc., 60 USPQ2d 1449 (7th Cir. 2001) 16

Carlisle Chemical Works, Inc. v. Hardman & Holden Ltd., 168 USPQ 110 (CCPA 1970) 15

Cunningham v. Laser Golf Corp., 55 USPQ2d 1842 (Fed. Cir. 2000) 7

In re E. I. du Pont de Nemours & Co., 177 USPQ 563 (CCPA 1973) 8

Gen. Elec. Co. v. Raychem Corp., 184 USPQ 766 (TTAB 1974) 10

Federated Foods, Inc. v. Fort Howard Paper Co., 192 USPQ 24 (CCPA 1976) 8

Hercules Inc. v. Nat'l Patent Dev. Corp., 187 USPQ 668 (TTAB 1975) 10

Hercules Inc. v. Nat'l Starch & Chem. Corp., 223 USPQ 1244 (TTAB 1984) 10

J.C. Hall Co. v. Hallmark Cards, Inc., 144 USPQ 435 (CCPA 1965) 14

Jenn-Air Corporation v. Jenn Mfg. Inc., 208 USPQ 948 (TTAB 1980) 16

Kenner Parker Toys v. Rose Art Indus., 22 USPQ2d 1453 (Fed. Cir. 1992) 11

King Candy, Co. v. Eunice King's Kitchen, Inc., 182 USPQ 108 (CCPA 1974) 7

In re Lamson Oil Co., 6 USPQ2d 1041 (TTAB 1988) 8

Lipton Industries, Inc. v. Ralston Purina Co., 213 USPQ 185 (CCPA 1982) 7

In re Majestic Distilling Co., Inc., 65 USPQ2d 1201 (Fed. Cir. 2003) 8

Mason Eng'g & Designing Corp. v. Mateson Chem. Corp.,
225 USPQ 956 (TTAB 1985) 19

Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574 (1986) 5

Monsanto Co. v. Enviro-Chem Corp., 199 USPQ 590 (TTAB 1978) 14

In re National Data Corp., 224 USPQ 749 (Fed. Cir. 1985) 9

Optomechanisms, Inc. v. Optoelectronics, Inc., 175 USPQ 246 (TTAB 1972) 16

Palm Bay Imports Inc. v. Veuve Clicquot Ponsardin Maison Fondee En 1772,
73 USPQ2d 1689 (Fed. Cir. 2005) 8, 11

Pathfinder Commc'ns Corp. v. Midwest Commc'ns Co.,
224 USPQ 203 (N.D. Ind. 1984) 9

Pittsburgh Plate Glass Co. v. Rexall Drug & Chemical Co.,
152 USPQ 825 (TTAB 1967) 15

Presto Prods., Inc. v. Nice-Pak Prods., Inc., 9 USPQ2d 1895 (TTAB 1988) 9

Recot, Inc. v. M.C. Becton, 54 USPQ2d 1894 (Fed. Cir. 2000) 17

R.J. Reynolds Tobacco Co. v. R. Seelig & Hille, 201 USPQ 856 (TTAB 1978) 19

In re Research Trading Corp., 230 USPQ 49 (Fed. Cir. 1986) 15

San Fernando Elec. Mfg. Co. v. JFD Elec. Components Corp.,
196 USPQ 1 (CCPA 1977) 8

Spoons Rest. Inc. v. Morrison Inc., 23 USPQ2d 1735 (TTAB 1991) 8

The State Historical Society of Wisconsin v. Ringling Bros.-Barnum & Bailey Combined Shows, Inc., 190 USPQ 25 (TTAB 1976) 14

In re White Swan Ltd., 9 USPQ2d 1534 (TTAB 1988) 8

INDEX OF EXHIBITS

Exhibit I — Declaration of Karen Possemato, Senior Director, Corporate Marketing of Opposer Illumina, Inc.

- Exhibit A — Print-outs from www.illumina.com website
- Exhibit B — Representative examples of the use of the ILLUMINA mark
- Exhibit C — Representative examples of the use of the ILLUMICODE mark
- Exhibit D — Representative examples of the use of the ILLUMINOTES mark
- Exhibit E — Press releases of Illumina's publically reported financial results
- Exhibit F — Articles and excerpts of articles about Illumina
- Exhibit G — Press release about Illumina's acquisition of Epicentre

Exhibit II — Declaration of Gregory F. Heath, General Manager of Illumina's Diagnostics Business Unit

- Exhibit 1 — Press releases about Illumina's entry into Diagnostics
- Exhibit 2 — Representative examples of the use of ILLUMINADX
- Exhibit 3 — Press releases, articles and excerpts of articles about Illumina's efforts to obtain government approval for diagnostic products
- Exhibit 4 — Review articles and excerpts of articles regarding the transition from research markets to diagnostics markets
- Exhibit 5 — Advertisements and trade show exhibitor lists

Exhibit III — Title and status copies of United States Reg. No. 4053668

Exhibit IV — Declaration of Calvin Fan, Senior Patent Attorney of Opposer Illumina, Inc.

- Exhibit 1 — Print-outs from meridianbioscience.com
- Exhibit 2 — Article about Meridian

Exhibit 3 Excerpt from Meridian's 2010 Annual Report

Exhibit 4 Information about ILLUMIGENE and DisplaceAce

I. Introduction

Illumina has opposed two applications and is seeking to cancel two registrations owned by Meridian for marks that incorporate the prefix illumi-. The proceedings have been consolidated, and now after the parties have conducted some discovery, Illumina hereby requests summary judgment on the issue of likelihood of confusion.

II. Undisputed Factual Background

The relevant facts are fully set forth in the accompanying Declaration of Gregory F. Heath and the exhibits attached thereto. For the Board's convenience, the salient facts will be summarized here.

Illumina is a global company that develops, manufactures and markets genetic analysis tools and integrated systems for the analysis of genetic variation and function, and provides services related to the same. More specifically, Illumina develops and sells innovative array-based solutions for DNA and RNA analysis which serve as tools for disease research and diagnosis, drug development and for the development of molecular tests in the clinic. (Exhibit I, Declaration of Karen Possemato, Senior Director, Corporate Marketing of Opposer Illumina, Inc., ¶ 2; see Ex. A (ILLUM-0767-70)). Illumina's products and services serve life-sciences research, applied markets and the molecular diagnostics market. (Ex. I, ¶ 2, see Ex. F (ILLUM-0952)).

Since its founding in 1998, Illumina has extensively used ILLUMINA as a house and product mark for its products and services. (Ex. I, ¶ 3; see Ex. A (ILLUM-0775-9)). The first of

its products, an SNP genotyping system sold under the mark Illumina BeadLab™, was first sold in the United States starting in 2002. (Ex. I, ¶ 3; see Ex. A (ILLUM-0775-9)). Illumina has since developed a comprehensive line of products that address the scale of experimentation and the breadth of functional analysis required to achieve the goals of molecular medicine. (Ex. I, ¶ 3; see Ex. A (ILLUM-0769-70)). Currently, Illumina's product line includes leading-edge solutions for: DNA and RNA sequencing, genotyping, gene copy number variation, methylation studies, gene expression profiling, and low-multiplex analysis. (Ex. I, ¶ 3; see Ex. A (ILLUM-0769-70)).

Illumina's products and services serve a range of interconnected markets, including sequencing, genotyping, gene expression, and molecular diagnostics, and its products are used by a broad range of academic, government, pharmaceutical, biotechnology, and other leading institutions around the globe. (Ex. I, ¶ 3; ¶ 2; see Ex. A (ILLUM-0769-70)).

Illumina began development of products and services for the molecular diagnostic market in 2008, with the creation of a Diagnostics Business Unit within its company and hired Gregory F. Heath, Ph.D. in March of 2008 to serve as the General Manager of Illumina's Diagnostics Business Unit. (Exhibit II, Declaration of Gregory F. Heath, Senior Vice President of Opposer Illumina, Inc., ¶ 3; see Ex. 1 (ILLUM-0601-3)). After internal development of diagnostic products, Illumina publicly announced its intention to enter the market for molecular diagnostics in April 2010. (Ex. II, ¶ 3; Ex. 3 (ILLUM-0202-3)). Around May 2010, Illumina announced the launch of an in-vitro diagnostic device intended for the simultaneous detection of multiple analytes in a DNA sample utilizing its VeraCode® holographic microbead technology. This

system had just then been FDA cleared for in vitro diagnostic use. (Ex. II, ¶ 3; Ex. 3 (ILLUM-0204-5)). Illumina is currently developing the next generation of molecular tests, systems, and services that will facilitate earlier diagnosis, selection of appropriate therapies, and monitoring of disease progression. (Ex. II, ¶ 3; see Ex. 2 (ILLUM-0616-7)). Marketed and sold under the ILLUMINADX mark, Illumina's technologies enable sophisticated analysis of pathogens and subtle changes in patients' genes and chromosomes, allowing clinical laboratories and physicians to personalize disease management for improved healthcare. (Ex. II, ¶ 3; see Ex. 2 (ILLUM-0616-7)). In addition to molecular diagnostics, molecular cytogenetics and cancer discovery initiatives, the Illumina Clinical Services Laboratory currently offers physician-ordered genome sequencing services. (Ex. II, ¶ 3; see Ex. 2 (ILLUM-0617-23)).

Illumina has extensively registered its ILLUMINA mark in connection with its various products and services and is the owner of incontestable registrations nos. 2471539, 2632507 and 2756703. (Notice of Opposition, ¶ 4; Petitions for Cancellation, ¶ 3). Title and status copies of Illumina's registrations nos. 2471539, 2632507 and 2756703 were attached to the various Notices of Opposition and Petition to Cancel, and Illumina's registrations were thereby made of record pursuant to 37 C.F.R. § 2.122(d). (*Id.*). In addition, Illumina has registered and is seeking to further register the mark ILLUMINADX in connection with its products and services. Specifically, Illumina is the owner of recently-issued registration no. 4053668 and an allowed application serial no. 77747038 both for the mark ILLUMINADX. (Ex. III; Notice of Opposition, ¶ 4; Petition for Cancellation, ¶ 3). Lastly, Illumina uses the mark ILLUMICODE in

connection with DNA microarrays and the mark ILLUMINOTES in connection with newsletters featuring information in the life sciences field. (Ex. I, ¶ 6, ¶ 7; see Ex. D, E).

Meridian is an Ohio corporation organized and existing under the laws of Ohio and having a principal place of business at 3471 River Hills Drive, Cincinnati, OH 45244-3091, United States. According to its website, Meridian is a fully integrated life science company that manufactures, markets and distributes a broad range of innovative diagnostic test kits, purified reagents and biopharmaceutical enabling technologies. (Ex. IV, Declaration of Calvin Fan, Senior Patent Attorney of Opposer Illumina, Inc., ¶ 2; see Ex. 1). Meridian's diagnostic products had traditionally been immunoassays – tests that use antibodies for detection. Meridian has since begun developing much more sensitive "molecular" assays, which use DNA amplification for detection. (Ex. IV, ¶ 3; see Ex. 2).

Meridian has applied (serial nos. 77768176 and 77775316) to register the marks ILLUMIPRO and ILLUMIPRO-10 for "diagnostic machine, namely, a standalone closed heater and turbidity meter to be used for the amplification and detection of a closed tube molecular assay" and has registered (registration nos. 3868081 and 3887164) the marks ILLUMIGENE and ILLUMIGENE & Device for "diagnostic kits consisting of molecular assays for use in disease testing and treatment of gastrointestinal, viral, urinary, respiratory and infectious diseases."

III. Summary Judgment Standard

Summary judgment should be granted if the evidence shows "that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law."

Fed. R. Civ. P. 56(c). Once the moving party has shown that no genuine issue of fact exists, the burden shifts to the non-moving party to demonstrate the existence of a factual issue. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The non-moving party may not rest on the mere allegations or denials of the pleadings, but must instead set forth specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e). Disputed facts that do not resolve or affect the outcome of the litigation will not preclude the entry of summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (explaining that "the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact"). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial,'" and the moving party must prevail as a matter of law. *Anderson*, 477 U.S. at 587 (internal citations omitted).

IV. Illumina is Entitled to Summary Judgment on its Claims of Likelihood of Confusion

Illumina moves for summary judgment on the claims of likelihood of confusion under Section 2(d) of the Trademark Act.

A. Standing and Priority

There is no genuine issue of fact that Illumina acquired rights in its ILLUMINA mark prior to the date on which Meridian acquired rights in its own marks.

By virtue of its registration if its ILLUMINA mark and its registration and attempted registration of its ILLUMINADX mark, Illumina has shown that it has a personal stake in the

outcome of this proceeding. Therefore, Illumina has conclusively established its standing. *See Cunningham v. Laser Golf Corp.*, 55 USPQ2d 1842 (Fed. Cir. 2000); *Lipton Industries, Inc. v. Ralston Purina Co.*, 213 USPQ 185 (CCPA 1982).

Because its pleaded registrations have been made of record, Illumina's priority is not in issue in the opposition proceedings. *See Cunningham, supra*; and *King Candy, Co. v. Eunice King's Kitchen, Inc.*, 182 USPQ 108 (CCPA 1974).

With respect to the cancellation proceeding, the facts establish that Illumina's first use of its ILLUMINA mark was prior to Meridian's use of its registered marks and its filing of applications for its registered marks. *See Brewski Beer Co. v. Brewski Brothers, Inc.*, 47 USPQ2d 1281, 1284 (TTAB 1998). Illumina's registration nos. 2471539, 2632507 and 2756703 issued, based on actual use, on February 23, 2001, October 8, 2002 and August 26, 2003, respectively. The first application filed by Meridian for its registered marks was accorded a filing date of November 17, 2008—after Illumina's registrations became incontestable. Meridian has not claimed use of its registered marks prior to the filing date of its first application for the registered marks. Since the registrations for the ILLUMINA mark precede the filing dates of the applications which matured into the registrations sought to be cancelled and there are no claims by Meridian of earlier use of the registered marks, Illumina has conclusively established priority in the cancellations.

B. Likelihood of Confusion

The determination of the issue of likelihood of confusion is based on an analysis of all of

the probative facts in evidence that are relevant to the factors set forth in *In re E. I. du Pont de Nemours & Co.*, 177 USPQ 563 (CCPA 1973); *see also, In re Majestic Distilling Co., Inc.*, 65 USPQ2d 1201 (Fed. Cir. 2003). In the analysis of likelihood of confusion, key considerations are the similarities of the marks and the fact that the goods and/or services are related. *Federated Foods, Inc. v. Fort Howard Paper Co.*, 192 USPQ 24, 29 (CCPA 1976) ("The fundamental inquiry mandated by Section 2(d) goes to the cumulative effect of differences in the essential characteristics of the goods and differences in the marks").

To determine whether the marks are confusingly similar, the Board must consider the appearance, sound, connotation and commercial impression of each mark. *Palm Bay Imports Inc. v. Veuve Clicquot Ponsardin Maison Fondee En 1772*, 73 USPQ2d 1689, 1692 (Fed. Cir. 2005). In a particular case, any one of these means of comparison may be critical in finding the marks to be similar. *In re White Swan Ltd.*, 9 USPQ2d 1534, 1535 (TTAB 1988); and *In re Lamson Oil Co.*, 6 USPQ2d 1041, 1042 (TTAB 1988). The test is not whether the marks can be distinguished when subjected to a side-by-side comparison, but rather whether the marks are sufficiently similar in terms of their overall commercial impression that confusion as to the source of the goods and/or services offered under the respective marks is likely to result. *San Fernando Elec. Mfg. Co. v. JFD Elec. Components Corp.*, 196 USPQ 1, 3 (CCPA 1977); and *Spoons Rest. Inc. v. Morrison Inc.*, 23 USPQ2d 1735, 1741 (TTAB 1991), aff'd unpublished, No. 92-1086 (Fed. Cir. June 5, 1992).

In this case, Illumina's registered marks are ILLUMINA and ILLUMINADX. In

addition, Illumina also uses and owns the marks ILLUMICODE and ILLUMINOTES. Meridian's opposed marks both begin with the prefix ILLUMI– which is combined with the highly suggestive suffix –PRO in the one instance and the highly-suggestive suffix –PRO and the model number "10" in the second instance. Meridian's registered marks also both begin with the prefix ILLUMI– which is combined with the generic suffix –GENE in the one instance and with the generic suffix –GENE and the laudatory tagline MOLECULAR SIMPLIFIED in the second instance.

The involved marks share the first six letters in common and differ only in the letters comprising the endings of the marks. ILLUMI– is most likely to be seen by consumers as the dominant element in all of Meridian's marks as well as Illumina's marks, simply because it is the first element of the marks. *See Presto Prods., Inc. v. Nice-Pak Prods., Inc.*, 9 USPQ2d 1895 (TTAB 1988) ("[I]t is often the first part of a mark which is most likely to be impressed upon the mind of a purchaser and remembered."); *Pathfinder Commc'ns Corp. v. Midwest Commc'ns Co.*, 224 USPQ 203, 205 (N.D. Ind. 1984) (it is an "accepted fact" that "people perceive differences which occur at the end of words less clearly than when differences occur at the beginning of words"). Thus, the prefix ILLUMI– is the dominant element of the involved marks. In determining the commercial impressions created by the marks, more weight should be accorded to the fact that the marks share the same dominant element. *See In re National Data Corp.*, 224 USPQ 749, 751 (Fed. Cir. 1985) ("There is nothing improper in stating that, for rational reasons, more or less weight has been given to a particular feature of a mark, provided the ultimate

conclusion rests on consideration of the marks in their entireties. Indeed, this type of analysis appears to be unavoidable."). Thus, although the involved marks have different endings, the fact that the marks share the same beginning six letters outweighs those less appreciable differences. *See e.g.*, *Hercules Inc. v. Nat'l Starch & Chem. Corp.*, 223 USPQ 1244 (TTAB 1984) (NATROSOL for alkali-soluble cellulose ethers held likely to be confused with NATROL for polymeric dispersant for industrial use); *Hercules Inc. v. Nat'l Patent Dev. Corp.*, 187 USPQ 668 (TTAB 1975) (HYDROLYN for synthetic resin held likely to be confused with HYDRON for hydrophilic gels); and *Gen. Elec. Co. v. Raychem Corp.*, 184 USPQ 766 (TTAB 1974) (FLAMTROL for insulated wire likely to be confused with FLAMENOL for electric wires, cables and conductors).

In addition to being very similar in appearance, the involved marks are also very similar in sound. ILLUMIPRO and ILLUMIGENE are, like ILLUMINA, ILLUMICODE and ILLUMINOTES, four syllable terms with the suffixes (i.e., the wording added to the ILLUMI- prefix being a single syllable). Moreover, rather than distinguishing Meridian's marks from Illumina's marks, the endings of Meridian's marks serve to strengthen the association with Illumina's marks by indicating that the products sold by Meridian are (i) for "professional"[1] use or (ii) that they have something to do with "genes" or "genetics". Thus, when considered in their entireties, the general overall commercial impressions engendered by the involved marks is one of similarity rather than of contrast.

[1] "Pro" is an abbreviation of "professional". *See* Webster's II: New Riverside University Dictionary, p. 937.

It is well established that "a mark with extensive public recognition and renown deserves and receives more legal protection than an obscure or weak mark." *Kenner Parker Toys v. Rose Art Indus.*, 22 USPQ2d 1453, 1456 (Fed. Cir. 1992). In this case, the ILLUMINA mark has extensive public recognition and renown and is, therefore, entitled to a wide latitude of legal protection. *Id.* In determining fame for purposes of likelihood of confusion, the Board looks to the class of customers and potential customers of a product or service, and not the general public. *See Palm Bay Imports*, *supra* at 1694 (Fame for likelihood of confusion purposes arises "as long as a significant portion of the relevant consuming public . . . recognizes the mark as a source indicator."). "[T]he fame of a mark may be measured indirectly, among other things, by the volume of sales and advertising expenditures of the goods traveling under the mark, and by the length of time those indicia of commercial awareness have been evident." *Bose Corp. v. QSC Audio Prods., Inc.*, 63 USPQ2d 1303, 1305 (Fed. Cir. 2002).

Illumina is a publicly traded company (NASDAQ) with a market capitalization of around $6 billion. (Ex. I, ¶ 7). In 2011, Illumina reported revenue of just over $1 billion including $987.3 million attributable to products and $68.3 million attributable to services and other sources. (Ex. I, ¶ 7; see Ex. E (ILLUM-0881-94)). In 2010, Illumina reported revenue of $902.7 million including $842.5 million attributable to products and $60.2 million attributable to services and other sources. (Ex. I, ¶ 7; see Ex. E (ILLUM-0895-900)). In 2009, Illumina reported revenue of $666.3 million including $627.2 million attributable to products and $39 million attributable to services and other sources. (Ex. I, ¶ 7; see Ex. E (ILLUM-0901-9)). In

2008, Illumina reported revenue of $573.2 million including $532.4 million attributable to products. (Ex. I, ¶ 7; see Ex. E (ILLUM-0901-9)). In 2007, Illumina reported revenue of $366.8 million of which $326.7 million was attributable to products. (Ex. I, ¶ 7; see Ex. E (ILLUM-0910-23)).

Illumina is a well known technology company. (Ex. I, ¶ 8). It ranked fourth on Forbes' 2010 ranking of the fastest growing technology companies in America. (Ex. I, ¶ 8; see Ex. F (ILLUM-0924-7)). In fact, Illumina was on the Forbes top 25 list four times in the five year period between 2006 and 2010. (Ex. I, ¶ 8; see Ex. F (ILLUM-0924-8)). In 2009, Forbes stated that Illumina was the fastest-growing technology company in America, based on five-year annualized sales growth. (Ex. I, ¶ 8; see Ex. F (ILLUM-0928)).

In 2008, Illumina's products are widely considered to be "best in-class" and it enjoys a market share of about 60 percent in both sequencing and genotyping. (Ex. I, ¶ 8; see Ex. F (ILLUM-0929)).

Illumina heavily promotes its products and services nearly all of which bear the ILLUMINA or ILLUMINADX marks. (Ex. I, ¶ 3; see Ex. B). In 2011, Illumina reported "Selling, General & Administrative"[2] (SG&A) expenses of about $269 million. (Ex. I, ¶ 7; see Ex. E (ILLUM-0881-94)). In 2010, Illumina reported SG&A expenses of $221 million and in

[2] SG&A is the sum of all direct and indirect selling expenses and all general and administrative expenses of a company. Direct selling expenses are expenses that can be directly linked to the sale of a specific unit such as credit, warranty and advertising expenses. Indirect selling expenses are expenses which cannot be directly linked to the sale of a specific unit, but which are proportionally allocated to all units sold during a certain period, such as telephone, interest and postal charges. http://www.investopedia.com/terms/s/sga.asp#axzz1dstqCEvC.

2009 Illumina reported SG&A expenses of $176.3 million. (Ex. I, ¶ 7; see Ex. E (ILLUM-0895-909)). Thus, it is clear that Illumina has a significant budget for marketing and selling its products and services. More specifically, during the period of January 2008 and June 30, 2011, Illumina spent over $5 million to produce advertising and to purchase advertising space in media such as scientific and industry journals. (Ex. I, ¶ 9). During this time, Illumina spent over $4 million in direct marketing and electronic marketing and over $10 million in public relations and agency fees. (Ex. I, ¶ 9). To specifically promote Illumina's emerging diagnostics business, Illumina has spent over $750,000 since 2008. (Ex. I, ¶ 9). In addition, Illumina attends, has exhibited at, conducts seminars and workshops and sponsors events at several industry trade shows each year, such as the annual meeting for the Association for Molecular Pathology, and has spent over $6 million for event marketing such as trade show booths, seminars, and event sponsorships. (Ex. I, ¶ 9).

Given its leading market position, its high volume of sales and its extensive advertising and sales expenditures, the ILLUMINA mark is a famous mark in the life science and biotechnology industries. As a result, the ILLUMINA mark is entitled to a wide latitude of legal protection.

While the parties' goods and services were not previously directly competitive, the parties' goods and services are closely related. It is well settled that goods and/or services need not be identical or even competitive in nature in order to support a finding of likelihood of confusion. Instead, it is sufficient that the goods and/or services are related in some manner

and/or that the circumstances surrounding their marketing are such that they would be likely to be encountered by the same persons under situations that would give rise, because of the marks employed in connection therewith, to the mistaken belief that they originate from or are in some way associated with the same entity or provider. *See, e.g., Monsanto Co. v. Enviro-Chem Corp.*, 199 USPQ 590, 595-96 (TTAB 1978). The salient question to be determined is not whether the involved goods of the parties are likely to be confused, but rather whether there is a likelihood that the relevant purchasing public will be misled to believe that the goods offered under the involved marks originate from a common source. *See J.C. Hall Co. v. Hallmark Cards, Inc.*, 144 USPQ 435 (CCPA 1965); *The State Historical Society of Wisconsin v. Ringling Bros.-Barnum & Bailey Combined Shows, Inc.*, 190 USPQ 25 (TTAB 1976).

In this case, the parties market and sell the same types of products and services to the same types of organizations. Illumina markets its products and services to "genomic research centers, academic institutions, government laboratories, and clinical research organizations, as well as pharmaceutical, biotechnology, agrigenomics, and consumer genomics companies". (Ex. I, ¶ 3, see Ex. E, (ILLUM-0987)). Meridian "markets its products and technologies to hospitals, reference laboratories, research centers, veterinary testing centers, physician offices, diagnostics manufacturers and biotech companies". (Ex. IV, ¶ 4; see Exs. 2, 3). Thus, the parties market their products to many of the same types of organizations.

The parties sell scientific products that perform similar functions—they are used in applications in which genetic material is amplified for further analysis. While the organizations

that are targeted by the parties for their respective products and services tend to be large organizations, the typical purchasing agent at a laboratory, research center, hospital or biotechnology company would be likely to encounter both companies' products and services when making purchases on behalf of their respective organizations. Likewise, the parties are targeting the same physicians who are seeking to offer their patients "personalized medicine". Thus, a physician ordering tests using Meridian's products may also potentially use the physician-ordered genome sequencing services Illumina currently offers to physicians. (Compare Ex. II, ¶ 3 and Ex. IV., Ex.2). Because of the parties' use of confusingly similar marks, there is a high potential for such consumers to mistakenly believe that the parties' products and services originate from or are in some way associated with the same entity or provider.

While the organizations themselves are sophisticated, the actual purchasers (e.g., purchasing agents and physicians) may be and often are less sophisticated. Regardless of the sophistication of the purchasers of the parties' products and services, it is well established that even careful purchasers of goods can be confused as to source under circumstances where substantially similar marks are used on identical and substantially related goods and on closely related goods and services. *See In re Research Trading Corp.*, 230 USPQ 49, 50 (Fed. Cir. 1986) citing *Carlisle Chemical Works, Inc. v. Hardman & Holden Ltd.*, 168 USPQ 110, 112 (CCPA 1970) ("Human memories even of discriminating purchasers ... are not infallible."). Therefore, the expertise of purchases does not always assure an absence of confusion. *See Pittsburgh Plate Glass Co. v. Rexall Drug & Chemical Co.*, 152 USPQ 825 (TTAB 1967) and

Optomechanisms, Inc. v. Optoelectronics, Inc., 175 USPQ 246 (TTAB 1972).

To reach their customers, both parties advertise and promote their products through the same outlets, including trade shows, press releases and trade magazines. In many instances, there has been an overlap in the trade shows and trade magazines used by the parties' to promote their products and services. For example, both parties have exhibited at the Association for Molecular Pathology Annual Meeting trade shows, the American Association for Clinical Chemistry (AACC) Annual Meeting trade shows, the Clinical Lab Expo trade shows and the Deutsche Bank Annual Health Care conferences. (Ex. II; ¶ 7; see Ex. 5 (ILLUM-0662-763)). Thus, the parties employ the same marketing techniques to attract the same types of customers. *See Jenn-Air Corporation v. Jenn Mfg. Inc.*, 208 USPQ 948, 954 (TTAB 1980); *see also CAE Inc. v. Clean Air Engineering Inc.*, 60 USPQ2d 1449, 1464 (7th Cir. 2001) (and cases cited therein).

Lastly, the diagnostics market served by Meridian's products is within Illumina's natural expansion of trade. Thus, purchasers in the diagnostics market might reasonably expect that products for the diagnostics market bearing the same or similar marks emanate from Illumina in the normal expansion of its business. Advances in technology and reductions in the cost of the products incorporating Illumina's technologies made inevitable Illumina's expansion into the diagnostic market. Other companies such as Beckmann Coulter, Becton Dickinson, Gen-Probe, Luminex, Roche and Siemens, have long marketed and sold products and services, under the same house and product marks, in both the research and diagnostic markets. (Ex. II, ¶ 3; see Ex. 4). As a result of this fact, consumers are accustomed to seeing and purchasing products from

the same entities in both the research and diagnostic markets. *See Recot, Inc. v. M.C. Becton*, 54 USPQ2d 1894, 1898 (Fed. Cir. 2000) (lay evidence that several large companies produce and sell both applicant's and registrant's goods was considered to be "extremely pertinent" in evaluating whether a consumer would reasonably believe that the parties' goods originated from the same source).

In January of 2008, several months before Meridian filed the first of its applications, Illumina publically announced that it had created a Diagnostic Business Unit to develop diagnostic applications for its technology. (Ex. II, ¶ 3, see Ex. 1 (ILLUM-0558-600)). In March 2008, Illumina publically announced that it had hired Gregory F. Heath to serve as that unit's general manager. (Ex. II, ¶ 3, see Ex. 1 (ILLUM-0601-3)). In fact, Illumina had as far back as May 2006 announced its interest in developing and commercializing DNA-based diagnostics, and continued to make such announcements which were widely reported in the press. (Ex. II; see Ex. 1 (ILLUM-0606, 0612)). Although Illumina did not have government approval to sell its products for diagnostics purposes in November 2008 (when Meridian filed the first of its applications), Illumina was already in the process of obtaining such approval and had already announced that it was seeking FDA clearance and moving further into the diagnostics field in that same month. (Ex. II, ¶ 3, see Ex. 1 (ILLUM-0224-5)). In May 2010, Illumina did in fact receive FDA 510(k) Clearance for use of one of its systems for Molecular Diagnostic Tests. (Ex. II, ¶ 3; see Ex. 3 (ILLUM0204-5)).

Additionally, in January of 2011, Illumina acquired Epicentre Technologies Corporation.

Epicentre is a manufacturer of specialty enzymes and biological preparations for use in molecular biology research and medical diagnosis. (Ex. I, ¶ 10; see Ex. G (ILLUM-0953-4)). Epicentre manufactures an enzyme by the name of DisplaceAce, which unbeknownst to Illumina at the time of acquisition, is the key enzyme used in Meridian's goods sold under the disputed marks. In fact, the enzyme is specifically identified by Meridian in its application for FDA approval and thus Meridian's goods cannot be legally sold without Illumina's enzyme product. (Ex. IV, ¶ 5; see Ex. 4 (ILLUM-0992-1006)). This fact further shows that the natural zone of expansion, which has become a reality in this case, supports a finding of likelihood of confusion.

Recognizing Illumina's potential impact on the diagnostics market, Roche recently unsuccessfully attempted to acquire Illumina in order to capitalize on the applicability of Illumina's technology to the diagnostics market. (Ex. I, Ex. F (ILLUM-0938-46)). In rejecting the Roche acquisition, Illumina emphasized that "proprietary diagnostics represent a sizeable long-term growth opportunity for Illumina". (Ex. 1, Ex. F (ILLUM-0940)). Illumina continues to develop additional molecular tests, systems and services that will be used in an increasing array of diagnostic applications including diagnosis of disease selection of appropriate therapies, and monitoring of disease progression. (Ex. II, ¶ 3). Illumina's development of products to understand genes for diseases and detect them in human samples in scientific and medical research is inextricably linked to the application of these tools to individual patients in diagnostic use. Specifically, "Illumina is developing proprietary clinical content for the eventual development of diagnostics in the oncology field, including in ovarian, gastric and colorectal

cancers, as well as autoimmune diseases, genetic diseases and maternal fetal medicine". (Ex. 1; see Ex. F (ILLUM-0940)). Clearly, there is some overlap with the "disease testing and treating of gastrointestinal, viral, urinary, respiratory and infectious diseases" function of Meridian's goods. *See* Reg. No. 3868081 and 3887164. Thus, the diagnostic market served by Meridian's products was and continues to be a zone of natural expansion for Illumina.

By entering Illumina's zone of natural expansion at nearly the same time Illumina was expanding into that same market, Meridian's adoption and use of a confusingly similar mark is likely to cause confusion, to cause mistake and to deceive consumers in both the diagnostic and research markets. It has long been held that the protection accorded registered marks, even those that are not famous, includes a zone of natural expansion. *See Mason Eng'g & Designing Corp. v. Mateson Chem. Corp.*, 225 USPQ 956, 962 (TTAB 1985); *see also R.J. Reynolds Tobacco Co. v. R. Seelig & Hille*, 201 USPQ 856, 860 (TTAB 1978) (recognizing the common practice which is so prevalent today for large corporations, not only to expand their present line of products, but also to diversify their business to include new fields of endeavor).

V. Conclusion

For the foregoing reasons, Illumina requests that the Trademark Trial and Appeal Board grant its Motion for Summary Judgment on the issue of likelihood of confusion and thereby deny registration to Meridian's applications, Ser. Nos. 77768176 and 77775316, and ultimately cancel registrations, Reg. Nos. 3887164 and 3868081.

Respectfully submitted,

ILLUMINA, INC.

Dated this 30th day of May 2012

By:
James R. Menker

Opposer's/Petitioner's Attorneys

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Atlantic Beach, FL 32233
T: 904-247-2620
F: 202-280-1177
E-Mail: eastdocket@holleymenker.com

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing "OPPOSER/PETITIONER'S MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT THEREOF" was served on Applicant/Registrant's attorney, J. Michael Hurst of Keating Muething & Klekamp PLL, via first class mail to the address of record One East Fourth Street, Suite 1400, Cincinnati, OH 45202, today **May 30, 2012**.

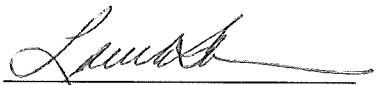
By: 
Laura K. Greer

EXHIBIT I

OF

OPPOSER/PETITIONER'S MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT THEREOF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc.,	)	
	)	Opp. No. 91194218 (SN 77768176) (Parent)
Opposer/Petitioner,	)	
	)	Opp. No. 91194219 (SN 77775316)
v.	)	
	)	Can. No. 92053479 (RN 3887164)
Meridian Bioscience, Inc.,	)	
	)	Can. No. 92053482 (RN 3868081)
Applicant/Registrant.	)	

DECLARATION OF KAREN POSSEMATO

I, Karen Possemato, declare as follows:

1. I have been employed with Illumina, Inc. ("Illumina") since 2004. In my current role as Senior Director, Corporate Marketing, I am responsible for building Illumina's marketing organization and developing the strategic and tactical marketing of the company. I am familiar with Illumina's use of the marks ILLUMINA, ILLUMINADX, ILLUMINOTES and ILLUMICODE.

2. Illumina is a global company that develops, manufactures and markets genetic analysis tools and integrated systems for the analysis of genetic variation and function, and provides services related to the same. More specifically, Illumina develops and sells innovative array- and sequencing-based solutions for DNA, RNA, and protein analysis that serve as tools for disease research and diagnosis, drug development and for the development of molecular tests in the clinic. Illumina products and services serve life-sciences research, applied markets and the

cf

molecular diagnostics market. True and correct copies of pages from Illumina's website <<www.illumina.com>> expounding on Illumina's commercial activities are attached hereto as Exhibit A.

3. Since its founding in 1998, Illumina has extensively used ILLUMINA as a house and product mark for its products and services. The first of Illumina's products, a SNP (single-nucleotide polymorphism) genotyping system was first sold under the mark Illumina BeadLab™ in the United States starting in 2002. Illumina has since developed a comprehensive line of products that address the scale of experimentation and the breadth of functional analysis required to achieve the goals of molecular medicine. Currently, Illumina's product line includes leading-edge solutions for: SNP genotyping, gene-copy number variation, DNA methylation studies, gene expression profiling, and low-multiplex analysis of DNA, RNA, and protein. Illumina's products and services serve a range of interconnected markets, including sequencing, genotyping, gene expression, and molecular diagnostics, and its products are used by a broad range of academic, government, pharmaceutical, biotechnology, and other leading institutions around the globe. All of the company's products and services are branded with the ILLUMINA mark. Representative examples of the use of the ILLUMINA mark are attached hereto as Exhibit B.

4. Illumina uses its ILLUMINA and ILLUMINADX marks in connection with its products and services that target the diagnostics market.

5. Since at least as early as August of 2002, Illumina has used and continues to use the mark ILLUMICODE in connection with DNA microarrays. Representative examples of the use of the ILLUMICODE mark are attached hereto as Exhibit C.

6. Since at least as early as April of 2006, Illumina has used and continues to use the

mark ILLUMINOTES in connection with newsletters featuring information in the life sciences field. Representative examples of the use of the ILLUMINOTES mark are attached hereto as Exhibit D.

7. Illumina is a publicly traded company (NASDAQ) with a market capitalization of over $6.4 billion. True and correct copies of press releases of Illumina's publicly reported annual financial results are attached hereto as Exhibit E.

8. Illumina is a well known technology company and has frequently been noted to be an industry leader. True and correct copies of articles discussing Illumina are attached hereto as Exhibit F.

9. Illumina has a significant budget for marketing and selling its products and services. During the period from January 2008 to June 2011, Illumina spent over $5 million to produce advertising and to purchase advertising space in media such as scientific and industry journals. During this time, Illumina also spent over $4 million in direct marketing and electronic marketing, and over $10 million in public relations and agency fees. Illumina appears at several industry trade shows each year, such as the annual meeting for the Association for Molecular Pathology, and spent over $6 million for event marketing such as trade shows, seminars, and sponsorships. The ILLUMINA mark has been featured in practically all of the company's advertising of the period. To specifically promote Illumina's emerging diagnostic business, Illumina has spent over $750,000 since 2008.

10. In January of 2011, Illumina acquired Epicentre Technologies Corporation. Epicentre is a manufacturer of specialty enzymes and biological preparations for use in molecular biology research and medical diagnostics. True and correct copy of printouts about this acquisition and the products now manufactured by Illumina are attached hereto as Exhibit G.

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 10 day of April 2012

Karen Possemato

Karen Possemato

EXHIBIT A

OF

DECLARATION OF KAREN POSSEMATO

illumina®

Illumina, Inc.

Quick Facts

Website: www.illumina.com
Ticker symbol: ILMN
Headquarters: San Diego, California, USA
Number of employees: 2,100+ globally
2010 revenue: $902.7 Million USD

Commercial Offices

- San Diego, CA
- Hayward, CA
- Cambridge, UK
- Beijing, China
- Tokyo, Japan
- Singapore
- Melbourne, Australia
- Sao Paulo, Brazil

Illumina Values

- Innovation is in our DNA
- We are relentless in the creation of great products
- We move fast and embrace change
- Deep collaboration allows us to compete in ways others cannot
- We are open—physically and philosophically

Illumina Management Team

Jay T. Flatley
President and CEO

Christian Henry
SVP, CFO, and GM, Life Sciences

Tristan B. Orpin
SVP and Chief Commercial Officer

Christian G. Cabou
SVP and General Counsel

Gregory F. Heath, Ph.D.
SVP and GM, Diagnostics

Mostafa Ronaghi, Ph.D.
SVP and Chief Technology Officer

Nicholas J. Naclerio, Ph.D.
SVP, Corporate Development

Kevin Harley
VP, Human Resources

About Illumina

Illumina is a leading developer, manufacturer, and marketer of life science tools and integrated systems for large-scale analysis of genetic variation and function. These systems are enabling studies that were not even imaginable just a few years ago, and moving us closer to the realization of personalized medicine. With rapid advances in technology taking place, it is mission-critical to offer solutions that are not only innovative, but flexible, and scalable, with industry-leading support and service. We strive to meet this challenge by placing a high value on collaborative interactions, rapid delivery of solutions, and meeting the needs of our customers.

Our customers include a broad range of academic, government, pharmaceutical, biotechnology, and other leading institutions around the globe.

Illumina's Vision

Illumina is a global company with a vision to be the leading provider of integrated solutions that advance the understanding of genetics and health. Our goal is to improve human health by enabling our customers to accelerate the collection, analysis, and application of biological information.

Leading-Edge Product and Services

Illumina has developed a comprehensive line of products that address the scale of experimentation and breadth of functional analysis to advance disease research, drug development, and the development of molecular tests. Our broad portfolio of leading-edge sequencing and array-based solutions address a range of genomic complexity and throughputs, enabling researchers to select the best solution for their scientific challenge.

Instruments

- HiSeq® systems
- Genome Analyzer$_{IIx}$
- MiSeq® system
- HiScanSQ™ system
- BeadXpress® Reader
- Eco™ Real-Time PCR system

Assays

- Sequencing by synthesis chemistry
- Infinium® genotyping and methylation assays
- GoldenGate® genotyping assay
- VeraCode® GoldenGate, methylation, gene expression, and protein analysis assays

Illumina, Inc. • 5200 Research Place, San Diego, CA 92122 USA • 1.800.809.4566 toll-free • 1.858.202.4566 tel • illumina.com

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Company

Illumina – Applying innovative technologies and revolutionary assays to the analysis of genetic variation and function

About Us

Learn how Illumina applies innovative technologies to the analysis of genetic variation and function.

Careers

Do exciting and challenging work and get a chance to change healthcare as we know it.

Newsroom

Read the latest news, find media contacts, and other related information.

Investors

Get stock information and financial reports for Illumina.

About Us

At Illumina, we apply innovative technologies for studying genetic variation and function, making studies possible that were not even imaginable just a few years ago. These revolutionary tools for DNA, RNA, and protein analysis are enabling rapid advances in disease research, drug development, and the development of molecular tests in the clinic.

Overview **Applications** **History**

Applications

Our core technologies, chemistries, systems, and software support the following applications:

- Sequencing
- SNP Genotyping and CNV Analysis
- Gene Regulation and

Core Technologies

- BeadArray Technology
- Sequencing Technology
- VeraCode Technology
- Oligator Technology
- Assay Technology

Cytogenetics

Cancer

Genomics

PCR Support

Customer Service

Training

Innovative technologies

At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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About us

Innovative technologies
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See our corporate overview video

Leading-edge products and services
Illumina has developed a comprehensive line of products that address the scale of experimentation and the breadth of functional analysis required to achieve the goals of molecular medicine. Our offering includes leading-edge solutions for:

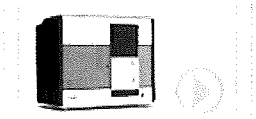
- SNP genotyping
- Copy number variation
- DNA methylation studies
- Gene expression profiling
- Low-multiplex analysis of DNA, RNA, and protein

Our products and services are used by a broad range of academic, government, pharmaceutical, biotechnology, and other leading institutions around the globe.

A collaborative approach
In concert with prospective customers and partners, Illumina takes a highly collaborative approach to business relationships. We're good listeners, value feedback, and believe in working together. Illumina is committed to providing our customers with world-class solutions, service, and support throughout their relationship with us to maximize their scientific success.

Building the illumina community
Staffed with a cohesive mix of high-performing scientists, engineers, managers, and support staff, Illumina is committed to building a team that delivers high-quality products and industry-leading service to the marketplace. Every employee is a critical part of the growing Illumina Community. Through our actions we strive to invite everyone associated with our company to become a part of this community. This includes customers, collaborators, suppliers, and industry colleagues.

See our corporate overview video


Sequencing Video: The Genome Analyzer

VeraCode Video: Technology Overview

Innovative technologies
At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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About us

Management Team

History

Vision

Technology

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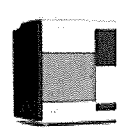
Vision

To be the leading provider of integrated solutions that advance the understanding of genetics and health

Purpose

To improve human health by enabling our customers to accelerate the collection, analysis and application of biological information



Sequencing \
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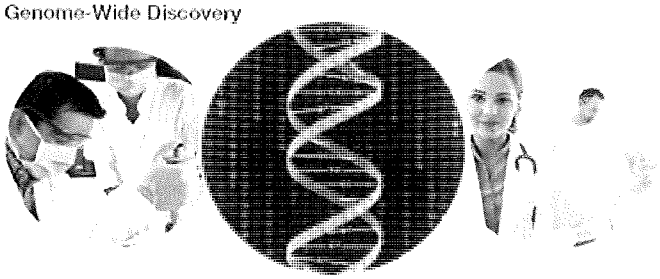
From Genome-Wide Discovery



To Targeted Validation and Beyond...

VeraCode Vi
Technology C

Life Sciences | **Personal Sequencing** | **Diagnostics** ようこそイルミナ株式会社へ

Applications

Sequencing
GWAS
SNP Genotyping & CNV Analysis
Gene Regulation & Epigenetic Analysis
Gene Expression Analysis
Protein Analysis
Real-Time PCR
Agrigenomics
Cytogenetics
Cancer Genomics

Systems

HiSeq Systems
Genome Analyzer IIx
MiSeq
HiScanSQ
iScan
BeadXpress
Eco Real-Time PCR System
Software
BaseSpace

Services

Genome Network
FastTrack Services
CSPro
Core Labs
Service Partnerships
Illumina Financial Solutions
Illumina Connect

Science

Publications
Researchers
Technology
iCommunity
Webinars

Support

Product Documentation
Product Literature
Software
BaseSpace
FAQs
DesignStudio
Assay Design Tool
Product Files
Eco Real-Time PCR Support
Customer Service
Training

Company

Careers
Contact Us
Events
About Us
Newsroom
Investor Relat
Privacy
Legal
California Transparency
Supply Chain

Innovative technologies

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ILLUM-0771

Company / **Technology**

About us

Management Team

History

Vision

Technology

Illumina Fact Sheet

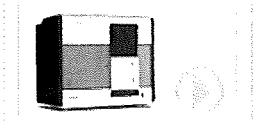
Technology

Our core technologies, assay chemistries, systems, and software support the following key applications:

- **SNP Genotyping**: A method of determining variation in genetic sequences
- **Gene Expression Profiling**: The analysis of which genes are active in a particular cell or group of cells
- **Epigenetics**: The process of profiling changes in genetic sequence function
- **Proteomics**: The process of determining which proteins are present in cells and how they interact

Our core technologies include:

- **BeadArray Technology**: A fundamentally different approach to high-density microarrays
- **Sequencing Technology**: A method for highly economical, scalable sequencing applications with unparalleled data density
- **VeraCode Technology**: Enabling a broad range of multiplexing options for RNA, DNA and protein applications
- **Oligator Technology**: World-class oligo manufacturing and quality fueling the Illumina product offering
- **Assay Technology**: Robust assay chemistries that provide industry-leading performance, specificity, and results
- **Real-Time PCR Technology**: A revolutionary approach to delivering superior performance for the most demanding qPCR applications at a fraction of the price.



Sequencing Video: The Genome Analyzer

VeraCode Video: Technology Overview

Innovative technologies

At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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illumina

Account Login

Returning Customer

* Username/Email:

* Password:

Forgot your password?

By clicking on the "Login" button you indicate that you agree with our Terms and Conditions.

LOGIN

New Customer

Why register?

- Place orders and track order status
- View and redeem quotes
- Design and order Illumina custom products
- Maintain favorite lists
- Manage subscriptions
- Register for upcoming webinars and view technical bullet

REGISTER

Innovative technologies

At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in techr taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and servic global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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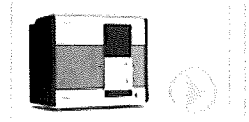
ILLUM-0774

Company / **History**

About us
Management Team
History
Vision
Technology
Illumina Fact Sheet

History

Illumina was founded in April of 1998 by David Walt, Ph.D., CW Group (Larry Bock), John Stuelpnagel, D.V.M., Anthony Czarnik, Ph.D., and Mark Chee, Ph.D. While working with CW Group, a venture capital firm, Larry and John uncovered what would become Illumina's BeadArray technology at Tufts University and negotiated an exclusive license to that technology. Headquartered in San Diego, California, Illumina completed its initial public offering in July, 2000.



Sequencing Video: The Genome Analyzer

Illumina began offering SNP genotyping services in 2001 and launched its first system, the Illumina BeadLab, in 2002, using GoldenGate Genotyping technology. The company acquired Solexa in 2006 and soon after launched the Genome Analyzer, the first of many Illumina sequencing systems based on the sequencing by synthesis technology.

VeraCode Video: Technology Overview

Illumina currently offers microarray-based products and services for an expanding range of genetic analysis sequencing, including SNP genotyping, gene expression, and protein analysis. Illumina's technologies are used by a broad range of academic, government, pharmaceutical, biotechnology, and other leading institutions around the globe.

Illumina timeline - see all dates

4/1/1998: Illumina founded
Illumina founded by David Walt, Ph.D., of Tufts University (inventor of BeadArray technology), Larry Bock of the CW Group, John Stuelpnagel, D.V.M., Anthony Czarnik, Ph.D., and Mark Chee, Ph.D.

11/1/1998: First substantial funding
Illumina begins with a staff of seven, secures a 10,000 sq. ft. facility in San Diego, CA, and begins developing core technology and intellectual property portfolio with initial funding of $8.6 million.

10/1/1999: Jay Flatley appointed CEO
Jay Flatley joins Illumina as President and Chief Executive Officer.

7/1/2000: Initial public offering
Illumina's IPO raises over $100 million.

Early 2001: FastTrack Genotyping Services launched
Illumina offers genotyping services using its production-scale systems and GoldenGate Genotyping Technology. The first services contract with GlaxoSmithKline comes through in May 2001.

Mid-2002: BeadLab system launched
Illumina's turnkey, fully-integrated production SNP genotyping system was introduced as a commercial solution for leading genotyping facilities around the world. More than 60% of the data for the International HapMap project Phase I was generated using this platform and the GoldenGate Assay.

9/1/2003: Gene Expression array launched
Illumina launches a second genetic analysis application, gene expression profiling. Illumina's gene expression arrays feature the world's first multi-sample chip formats and the industry's only 100% array QC.

Early 2004: BeadStation benchtop system launched
Illumina technology becomes available to core labs and researchers around the globe with the launch of the BeadStation system, a benchtop solution that runs both DNA and RNA analysis applications. The Illumina BeadStation brings scalability and flexibility to genetic analysis researchers through its modular format and integrated options.

1/1/2004: DASL Assay launched
Illumina launches the DASL Assay, a powerful new approach for generating gene expression profiles from partially degraded RNA samples such as those found in formalin-fixed, paraffin-embedded samples (a common method of preserving samples from biopsies). An estimated 400 million FFPE samples exist in the U.S. for cancer alone.

2/1/2005: CyVera acquisition
Illumina acquires CyVera Corporation, the developer of VeraCode Technology, a complementary, low-multiplex technology that is ideal for target validation and molecular test development.

2/5/2005: Whole-genome Gene Expression array launched
Illumina launches the world's first multi-sample, whole-genome expression microarrays. The Human-6 and HumanRef-8 BeadChips deliver industry-leading quality and pricing.

Mid-2005: Infinium whole-genome genotyping launched
Illumina launches the Infinium Assay, a revolutionary genotyping assay that provides intelligent SNP selection and unlimited access to the genome. The first Infinium product, the Human-1 Genotyping BeadChip, includes over 100,000 markers on a single BeadChip.

9/1/2005: Mouse whole-genome expression array launched
Illumina introduces the world's first whole-genome expression arrays for mouse, an important model organism.

1/1/2006: Infinium HumanHap300 BeadChip launched
Illumina announces the availability of the HumanHap300 Genotyping BeadChip, which leverages tag SNP content to deliver over 300,000 markers on a single microarray.

3/1/2006: Expansion of GoldenGate panels offered
Illumina expands its standard panel offering for GoldenGate genotyping with three new panels for the MHC region, cancer, and sample quality assessment.

3/1/2006: Infinium HumanHap550 BeadChip launched
Illumina announces the next BeadChip in its Infinium whole-genome genotyping offering, the HumanHap550 BeadChip, with over 550,000 markers on a single microarray.

6/1/2006: Infinium HumanHap550+ and iSelect products launched
Illumina announces custom content for Infinium genotyping with the HumanHap550+ and iSelect BeadChip.

6/1/2006: Infinium HumanHap650Y BeadChip launched
Illumina announces the third BeadChip in its Infinium whole-genome genotyping offering, the HumanHap650Y BeadChip, with over 650,000 markers on a single microarray and enriched content for African

ILLUM-0776

populations.

8/1/2006: Certified Service Provider (CSPro) program launched
Illumina announces a program certifying service labs around the world to provide genotyping and gene expression services using its BeadArray technology.

9/21/2006: Rat whole-genome Gene Expression array launched
Illumina introduces the world's first whole-genome expression arrays for rat, an important model organism.

11/1/2006: Solexa acquisition
Illumina announces the acquisition of Solexa, the developer of a genomic-scale sequencing technology. Combined, illumina now offers the ultimate tool set for genetic analysis.

1/10/2007: High-throughput DNA Methylation Cancer Panel launched
Illumina launched the GoldenGate Methylation Cancer Panel, capable of surveying up to 1,536 methylation sites across 96 samples simultaneously,

1/10/2007: Infinium Human1M and Human450S BeadChips launched
Combining an unprecedented level of content for both whole-genome and copy number variation analysis, the Human1M and Human450S BeadChips include additional unique, high-value genomic regions of interest - all on a single microarray chip.

1/29/2007: Illumina named fastest growing high-tech co. by Forbes
Illumina posted its first profitable 12-month period in five years, making its way to #1 on Forbes' fastest growing high-tech list.

3/12/2007: Infinium HumanCNV370-Duo BeadChip launched
Developed in collaboration with deCODE genetics, the HumanCNV370-Duo, is the world's first microarray designed to specifically target novel regions of the genome that show copy number variation.

3/21/2007: BeadXpress system launched
Utilizing uniquely inscribed digital microbeads, the VeraCode technology provides high-quality data, broad multiplexing capability, and assay flexibility. Researchers can assay tens to hundreds of analytes in a single sample at one time.

4/16/2007: Custom DNA Methylation launched
Using the custom DNA methylation panels investigators now have the option to select their favorite genes or gene regions to cost-effectively survey up to 1,536 methylation sites of choice across 96 samples simultaneously.

5/1/2007: IlluminaConnect launched
IlluminaConnect is a bioinformatics software partnership program established to advance data integration and analysis. This program offers Illumina customers seamless access to third-party bioinformatics providers of advanced data analysis applications for processing Illumina array data.

6/11/2007: Industry first controls database offered
iControlDB is the first industry-hosted genotyping control repository available for researchers conducting case-control whole-genome association studies.

7/24/2007: Digital Gene Expression launched
New Digital Gene Expression (DGE) applications including small RNA and Gene Expresion profiling use Illumina's Genome Analyzer to generate genome-wide sequencing-based expression profiles of messenger and small RNA.

8/2/2007: Infinium HumanHap550-Duo BeadChip introduced
The HumanHap550-Duo BeadChip is the Company's fourth multi-sample DNA Analysis solution for genome-wide association studies. The HumanHap550-Duo BeadChip provides the same content as the HumanHap550 BeadChip but in a dual-sample format, resulting in significantly greater throughput and lower cost per sample.

9/6/2007: Infinium HumanLinkage-12 BeadChip introduced
The HumanLinkage-12 BeadChip is Illumina's fifth multi-sample Infinium BeadChip and the Company's first standard panel to take advantage of a twelve-sample format for linkage analysis.

10/22/2007: MicroRNA Assay using BeadArray technology launched
Priced at $95 per sample, the MicroRNA Assay for Gene Expression profiling is the only tool available to allow rapid and reproducible miRNA expression profiling at a price less than half that of other commercially available methods.

10/25/2007: Infinium DNA Methylation BeadChip launched
New DNA Methylation BeadChip assays 27,000 CpG sites per sample, covering more than 14,000 well-annotated genes with single CpG resolution.

1/4/2008: Illumina announces corporate reorganization
Illumina reorganized its operating structure to further leverage the synergies between its sequencing and genotyping businesses.

1/7/2008: High-density product line introduced
The Infinium HD Human1M-Duo (two samples/chip) and the Human610-Quad (four samples/chip) feature up to 2.3 million single nucleotide polymorphisms (SNPs) per BeadChip, doubling sample throughput and reducing DNA input requirements by as much as 70 percent.

1/15/2008: Infinium BovineSNP50 BeadChip released
The Infinium BovineSNP50 BeadChip is a 12-sample genotyping product featuring 54,000 SNPs for detecting genetic variation in any breed of cattle.

2/6/2008: Illumina sequences first African human genome
Illumina scientists sequenced the genome of an anonymous African male (Yoruba from Ibadan, Nigeria), using the Genome Analyzer. This achievement establishes the direct utility of Illumina's sequencing technology for accurately sequencing large and complex genomes

Gene Expression Analysis
Protein Analysis
Real-Time PCR
Agrigenomics
Cytogenetics
Cancer Genomics
BeadXpress
Eco Real-Time PCR System
Software
BaseSpace
Illumina Financial Solutions
Illumina Connect
DesignStudio
Assay Design Tool
Product Files
Eco Real-Time PCR Support
Customer Service
Training
Privacy
Legal
California Transparency in Supply Chain

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Applications / Sequencing / **DNA Sequencing**

DNA Sequencing

Transcriptome Analysis

Gene Regulation Analysis

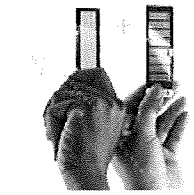
Illumina's sequencers powerfully combine the flexibility of single reads, short- and long-insert paired-end reads, enabling the broadest range of genomic applications. TruSeq sequencing chemistry supports this wide range of applications including whole-genome sequencing, targeted resequencing, *de novo* sequencing, amplicon sequencing, SNP discovery, identification of copy number variations, and chromosomal rearrangement. Nextera technology enables researchers to accelerate sample preparation and produce sequencing-ready libraries in less than 90 minutes.

Kits

- TruSeq DNA Sample Prep Kit
- TruSeq Exome Enrichment Kit
- TruSeq Custom Enrichment Kit
- TruSeq Custom Amplicon Kit
- Nextera DNA Sample Prep Kit

Applications

- Targeted Resequencing
- *De Novo* Sequencing
- Whole Human Genome Sequencing
- Sequencing Automation



Explore hybrid workflow options »
Expand the power of your study—next-gen sequencing and arrays.

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Whole-Genome Genotyping and Copy Number Variation Analysis

Custom Mid- to High-plex Genotyping

FFPE Sample Analysis

Focused Genotyping

SNP Discovery and Structural Variation Analysis

Cytogenetic Analysis

Linkage Analysis

Custom Low- to Mid-plex Genotyping

Since they were first developed in 2005, whole-genome genotyping (WGGT) arrays have become an important tool for discovering variants that contribute to human diseases and phenotypes. The two primary applications of this technology, genome-wide association studies (GWAS) and copy number variant (CNV) analysis, have helped researchers begin to unravel the complex genetic architecture behind diseases such as diabetes and Crohn's disease, and traits such as hair and eye color.

Illumina's WGGT Infinium BeadChips offer researchers the flexibility to genotype samples with hundreds of thousands to millions of markers that deliver dense genome-wide coverage with the most up-to-date content available from the scientific community. Markers on the BeadChips are strategically selected by Illumina scientists to provide maximum coverage of the genome for both association testing and copy number detection.

Keep up-to-date with recent discoveries by customizing Infinium iSelect HD BeadChips with Infinium Add-On Content. Whether it comes from publically available databases or new discoveries, allows researchers to combine existing marker sets with new, unique content on a single BeadChip, increasing efficiency and cost effectiveness in study design.

The Omni Family of Microarrays

The latest generation of Infinium WGGT products is The Omni Family of Microarrays. This flexible, complimentary family of microarrays represents a revolution in array design, delivering up to 5 million makers per sample and offering an unprecedented amount of customizability. Designed from next-generation sequencing data from international projects such as the 1000 Genomes Project, Omni microarrays deliver unrivaled coverage of the genome. Access to whole-genome sequencing data provides the most complete picture of the extent of variation, allowing Illumina scientists to select the most informative markers to provide superior power to detect trait- and disease-associated variants.

Learn More about the Omni Family of Microarrays

Omni Whole-Genome Arrays

BeadChip	Array Format	Markers per Sample
HumanOmni5-Quad	4	~ 4.3 million
HumanOmni2.5S	8	~ 2.5 million
HumanOmni2.5-8	8	~ 2.5 million
HumanOmni1S	8	~ 1.25 million
HumanOmni1-Quad	4	~ 1.1 million
HumanOmniExpress	12	~ 700,000
HumanCytoSNP-12	12	~ 300,000

Omni Semi-Custom Whole-Genome Arrays

BeadChip	Array Format	Markers per Sample

ILLUM-0782

BeadChip	Array Format	Markers per Sample
HumanOmni5-Quad+	4	~ 4.3 million (fixed) up to 500K (custom)
HumanOmni2.5S+	8	~2.5 million (fixed) up to 500K (custom)
HumanOmniExpress+	12	~700,000 (fixed) up to 200K (custom)

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Applications / Gene Regulation and Epigenetic Analysis / **Small RNA Discovery and Analysis**

Small RNA Discovery and Analysis

Sequencing-Based Methylation Analysis

DNA-Protein Interaction Analysis (ChIP-Seq)

Array-Based Methylation Analysis

Custom Low- to Mid-plex Methylation Analysis

Small RNA sequencing is a powerful application for Illumina Sequencing, enabling the discovery and profiling of microRNAs and other non-coding RNA on any organism, without prior genome annotation. Using low RNA inputs, you can profile the differential expression of known microRNAs as well as detect novel microRNA targets and wide-ranging sequence variation or "iso-miRs" miRBase accessions. With unprecedented sensitivity and dynamic range, Illumina's industry-leading small RNA sequencing methods allow for the most accurate detection and quantification of rare small RNA sequences.

LEARN MORE

Fully Supported Small RNA Analysis Applications

- **TruSeq Small RNA Sample Prep Kit:** Illumina's latest small RNA sample prep kit, with 48-sample indexing, enabling economical and high-throughput small RNA discovery and profiling.
- **Small RNA Sample Prep:** Illumina's original small RNA sequencing sample prep kit providing the ability to prepare 8 libraries for small RNA/microRNA analysis.

Highlights

- **Multiplex Enabling Sample Prep:** Enable high-throughput miRNA profiling using up to 48 unique indexes for multiplexed sequencing.
- **Simple, Fast Workflow:** Rapid library construction allows for the fastest RNA-to-data solution for rapid analysis and publication.
- **Strand-Specific Sequence Data:** Retain the original strand orientation information of microRNAs and other small RNAs, including piwi-interacting RNAs.
- **Low Input Requirements:** Requires 1.0 µg or less of total RNA for analysis of precious samples with high sensitivity, detecting as low as a single copy per cell.
- **Superior Data:** Achieve the highest quality data with the most accurate sequence detection across greater than six orders of dynamic range.
- **Broad Application:** Use for other RNA sequencing methods, including CLIP-Seq, RIP-Seq, or the strand specific analysis of messenger RNA fragments.
- **Universal Platform:** Analyze any small RNA sample from any species without any prior knowledge of sequence of secondary structure.

ILLUM-0784

Protein Analysis
Real-Time PCR
Agrigenomics
Cytogenetics
Cancer Genomics

Eco Real-Time PCR System
Software
BaseSpace

Solutions
Illumina Connect

Assay Design Tool
Product Files
Eco Real-Time PCR Support
Customer Service
Training

Privacy
Legal
California Transparency in Supply Chain

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Applications / Gene Expression Analysis / **Transcriptome Analysis**

Transcriptome Analysis

Whole-Genome Gene Expression

FFPE Sample Analysis

RNA sequencing has revolutionized the exploration of gene expression. Advances in the sequencing workflow, from sample preparation through data analysis, enable rapid profiling and deep investigation of the transcriptome. With RNA sequencing, you can characterize all transcriptional activity, coding and non-coding, in any organism without a priori assumptions.

Illumina's unique combination of long and short reads, single and paired-end sequencing, strand specificity, and capacity for tens of millions to billions of reads per run allows you to

- annotate coding SNPs
- discover transcript isoforms
- identify regulatory RNAs
- characterize splice junctions
- determine the relative abundance of transcripts

With the greatest daily output available for any sequencing system, transcript profiles can be generated in a single day. RNA sequencing reads can be aligned across splice junctions to identify isoforms, novel transcripts and gene fusions. Identify and quantify both rare and common transcripts, with over six orders of magnitude of dynamic range. Reveal the hidden world of non-coding RNA architecture without prior information.

Fully Supported Transcriptome Analysis Applications

- **TruSeq RNA Sample Prep Kits:** Illumina's latest high-throughput sample kits, providing robust indexing and a flexible, integrated workflow solution for economical RNA sequencing for discovery and profiling.
- **mRNA-Seq:** Illumina's original RNA sequencing sample prep kit providing the ability to prepare 8 libraries for full transcriptome analysis.
- **TruSeq Small RNA Sample Prep Kit:** Illumina's latest small RNA sample prep kit, with 48-sample indexing, enabling economical and high-throughput small RNA discovery and profiling.
- **Small RNA Sample Prep:** Illumina's original small RNA sequencing sample prep kit providing the ability to prepare 8 libraries for small RNA/microRNA analysis.

LEARN MORE

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Agrigenomics
Cytogenetics
Cancer Genomics
Software
BaseSpace
Eco Real-Time PCR Support
Customer Service
Training
California Transparency in Supply Chain

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Applications / Protein Analysis / **Protein Screening**

Protein Screening

VeraCode technology provides a simple and flexible solution for multiplexed protein assays. With VeraCode Carboxyl Bead Sets, any protein or peptide can be covalently attached to the highly stable microbead surface, enabling the development of standard "sandwich" immunoassays. The 48 unique Carboxyl bead types can be pooled in varying combinations to perform up to 48 immunoassays in a single reaction in a standard 96-well microplate.

Analytes can be labeled with standard fluorescent reporters such as phycoerythrin (R-PE), Cy3, Cy5, or AlexaFluor dyes. During analysis, the fluorescence and code inscription for each microbead are detected by the BeadXpress Reader.

It has been demonstrated that the BeadXpress Reader can detect protein concentrations as low as 10 pg/ml in a multiplexed VeraCode Carboxyl bead assay.

The VeraScan Software that comes with the BeadXpress Reader System provides users the flexibility they need to customize scanning protocols. Illumina's BeadStudio software provides users a forum for simple to complex data analysis that can be easily exported to third-party data analysis programs.

Learn more about Carboxyl Bead Sets.

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Applications / Real-Time PCR / qPCR

qPCR

Through the use of various fluorescent detection chemistries, Real-Time PCR (qPCR) enables the detection, amplification, and quantification of DNA sequences as a PCR reaction is proceeding. Unlike traditional PCR, samples are characterized at the point when amplification is first detected; as opposed to measuring the amount of product generated after PCR cycling is completed. This more precise and highly sensitive PCR method has applications in basic research and diagnostics, where it is used for gene expression and genotyping studies, and virus and pathogen detection.

Making qPCR Accessible

To achieve a higher level of detection, qPCR systems require powerful thermal and optical modules. For most qPCR systems, this translates into large instruments with price points to match. Making qPCR accessible to individual researchers, the compact Eco Real-Time PCR System packs loads of innovation into a small footprint that fits anywhere in the lab. A proprietary thermal system provides unrivaled temperature control and a sensitive optical system facilitates all four-color multiplex applications, enabling the system's ability to deliver the performance, data quality, and reproducibility of market-leading instruments at a fraction of the price. This revolutionary new system supports a range of demanding Real-Time PCR applications, including absolute quantification by standard curve, relative quantification using the ΔΔCq method with support for multiple reference gene normalization, allelic discrimination by end-point fluorescence, and gene scanning and genotyping by High Resolution Melt (HRM) curve analysis.

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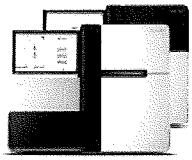
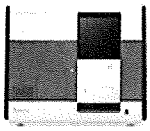
Systems

Sequencing



HiSeq Systems
Any application. Any study. Any budget.

GET MORE INFO



Genome Analyzer IIx
Most widely published and adopted next-gen system

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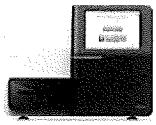
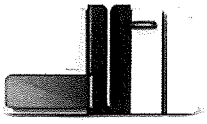


MiSeq
Prep, run, analyze in as little as 8 hours

GET A QUOTE

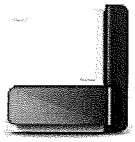
Sequencing + Arrays



HiScanSQ
High-throughput arrays with next-gen sequencing, one streamlined solution

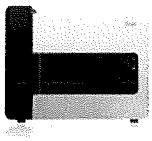
GET A QUOTE

Arrays - Low- to High-Plex



HiScan
Powerful array scanner; expandable to add next-gen sequencing

GET A QUOTE



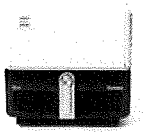
iScan
Dedicated array scanner; processes up to 96 multi-sample BeadChips per day

GET A QUOTE

BeadXpress
Broadest multiplexing range, assay versatility, superb data quality, and regulated device

GET A QUOTE

Real-Time PCR System



Eco Real-Time PCR System
High-performance thermal control & uniformity, open platform supporting variety of qPCR applications

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- Genomic copy number variation, human health, and disease. Wain LV et al. 2009.

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Featured Partner

iGenix, inc.

iGenix, Inc. provides Illumina BeadXpress lab services for genotyping, copy number variation assessment, methylation and expression studies, maximizing your research efficiency and data accuracy.

News and Events

- Illumina Receives FDA 510(k) Clearance for Its BeadXpress(R) Multiplex Analysis System
- Illumina Now Shipping HiScan(TM)SQ Platform
- Illumina Announces Its First Full Coverage DNA Sequencing of a Named Family

Cytogenetics

Cancer Genomics

Customer Service

Training

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Services

Proven Illumina technology. Proven expertise.

The Illumina family of genetic analysis services.

Applications

Offering the widest breadth of services in the industry, all powered by Illumina systems.

Illumina Genome Network

Providing whole human genome sequencing services without compromise.

FastTrack Services

Genotyping services performed by Illumina expert teams.

CSPro

Certified Illumina partners delivering industry-leading data quality for genetic analysis applications.

Services for a Broad Range of Applications

Whether you need to analyze DNA, RNA, or proteins, Illumina and its partners can assist you by quickly and affordably completing your studies on industry-leading Illumina platforms. Leverage the knowledge of expert teams for a wide range of applications, from sequencing and genotyping to gene expression profiling and methylation analysis; each focused on delivering the high-quality data that will move your research forward.

Applications

- Sequencing
- Genotyping and CNV Analysis
- Gene Regulation and Epigenetic Analysis
- Gene Expression Profiling
- Protein Analysis Screening

Innovative technologies
At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies

possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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Science

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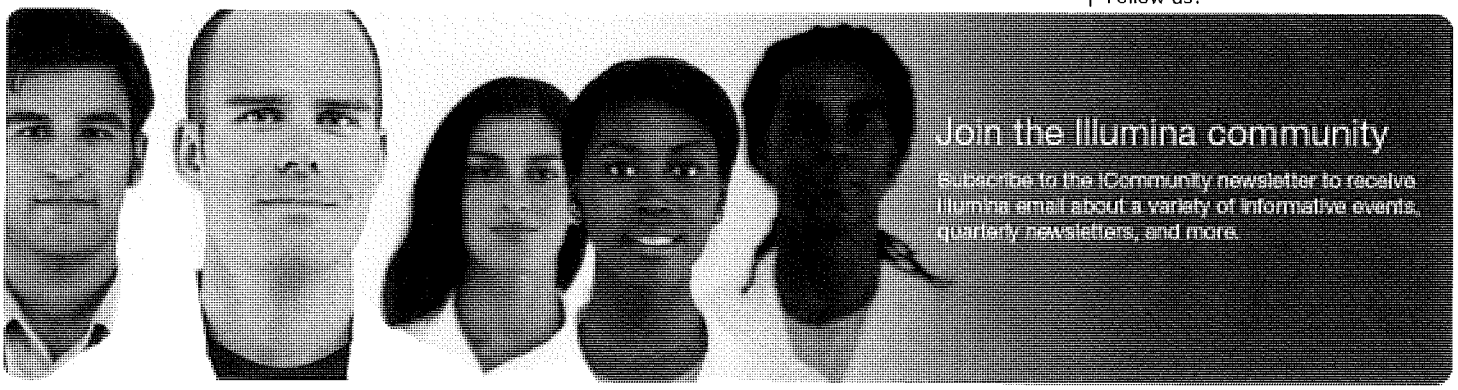

Publications

See how researchers are publishing at an unprecedented rate using Illumina technologies.

Researchers

Kevin Shianna, Ph.D.
Director, Genotyping Facility, Duke University

Discover other researcher's experiences using Illumina technologies.

iCommunity

Read how Illumina's customers are discovering more, and faster, everyday.

Webinars

Learn from respected scientists who share their real-life experiences using Illumina technology.

Publications

At Illumina, we enjoy seeing how researchers are successfully using our products for a wide range of genetic analysis applications. We are proud to share this list of publications from the growing community of Illumina customers, collaborators, and internal scientists. If we missed one, please send the citation to publications@illumina.com.

VIEW ALL FEATURED PUBLICATIONS

Featured Story

Population resequencing reveals local adaptation of Arabidopsis lyrata to serpentine soils Ecological adaptation on a genetic level is demonstrated by sequencing three candidate loci in Arabidopsis lyrata using the Illumina Genome Analyzer. More...

Search Publications List

Search our database of Illumina publications by:

- Sequencing Applications
- DNA Arrays
- RNA Arrays

Training

Innovative technologies
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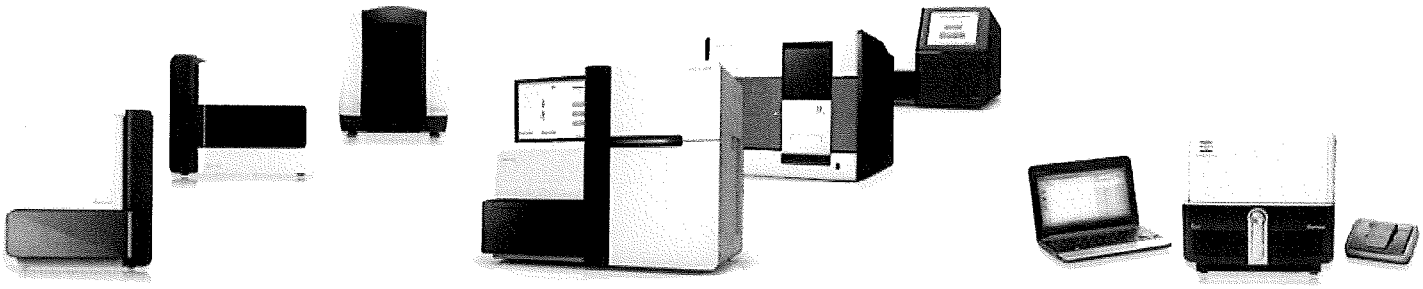
Support



Array

Get support for Illumina's BeadChips, scanners, and software.

VIEW SUPPORT

Sequencing

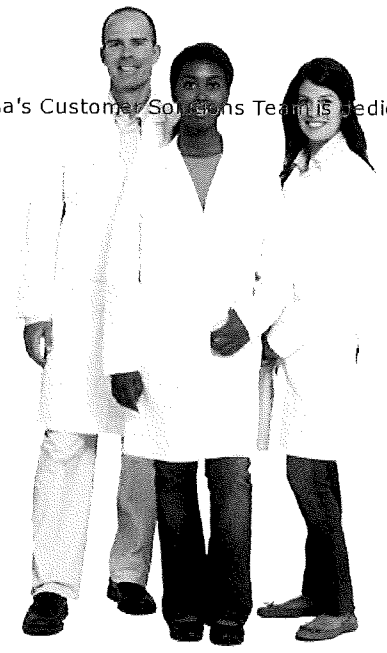
Get support for Illumina sequencing systems, kits, and software.

VIEW SUPPORT

Real-Time PCR

Get support for real-time PCR on Illumina's Eco system

VIEW SUPPORT



Customer Solutions

Illumina's Customer Solutions Team is dedicated to providing you with the resources you need to support your research. We strive to continuously exceed your expectations, so that you can maximize the impact of Illumina technology in your lab.

Scientists specializing in Illumina's technologies, scientific applications, software, and hardware systems are available even before your first system purchase.

Field Service Engineers expertly install and qualify your instrument to guarantee a fully functional system.

Field Application Scientists offer extensive training, enabling labs to quickly become proficient at generating industry-leading data quality at unparalleled throughput levels.

Technical Support Scientists are just a phone call or email away and can help you plan your project, diagnose a problem, and interpret results.

ILLUM-0798

Gene Regulation & Epigenetic Analysis
Gene Expression Analysis
Protein Analysis
Real-Time PCR
Agrigenomics
Cytogenetics
Cancer Genomics

HiScanSQ
iScan
BeadXpress
Eco Real-Time PCR System
Software
BaseSpace

Core Labs
Service Partnerships
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Innovative technologies
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Illumina® FastTrack Genotyping Services

Experience personalized service, industry-leading data quality, and guaranteed turnaround time with Illumina's FastTrack Genotyping Services for a wide range of SNP genotyping projects.

"Overall, our experience working with Illumina has been simply outstanding. The scientific and service staff of this organization are highly talented and committed individuals... The staff of Illumina went well beyond the normal service requirement in order to maximize information yield on these samples."

—PETER K. GREGERSON, M.D., Center Head, The Robert S. Boas Center for Genomics and Human Genetics

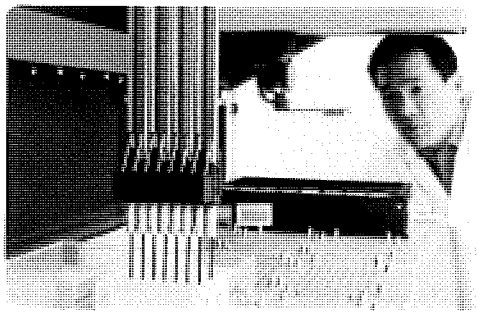
At Illumina, we work collaboratively with you to achieve your research objectives. Using Illumina's cutting-edge SNP genotyping technology, our in-house geneticists have consistently provided on-time, reliable genotyping services to academic and pharmaceutical customers since 2002. In collaboration with our customers, we have provided data for the study of many diseases through services projects, from various cancers to diabetes and schizophrenia. Using Illumina's FastTrack Services gives you the same competitive advantages as our installed base of customers: the ability to conduct whole-genome association studies, DNA copy number studies, linkage analysis, and fine mapping studies in a timely fashion at a reasonable cost.

In addition to the benefits you can realize by outsourcing your discovery efforts, you will also appreciate the professional design assistance and collaborative approach Illumina has proudly delivered since program inception. We highly value the quality outcome of your projects as much as your experience working with us.

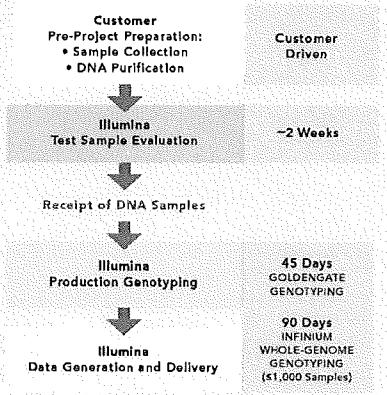
KEY HIGHLIGHTS OF PAST PERFORMANCE

- **Infinium® Service Projects:**
  Sample Success Rate: 99.5%
  Call Rate: 99.89%
- **GoldenGate® Service Projects:**
  DNA Success Rate: 97.6%
  Call Rate: 99.75%

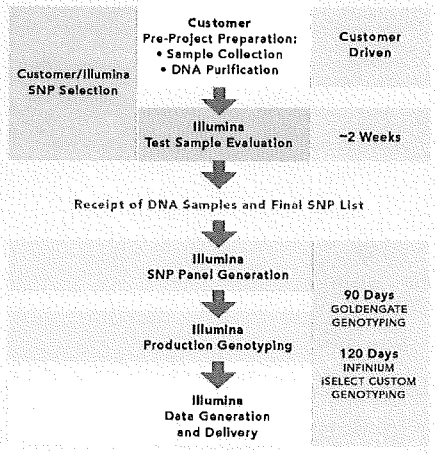
illumina®



STANDARD PANEL GENOTYPING PROJECT TIMELINE



CUSTOM PANEL GENOTYPING PROJECT TIMELINE



PERSONALIZED SERVICE WITH DEDICATED EXPERTS

- An expert molecular geneticist project manager assigned to each project
- Project completion and success ensured with guaranteed fast delivery
- Intensive customer engagement with proven process flow driven by best practices
- Each project dataset reviewed and QC'd by the services group
- Every sample and every SNP locus assigned a quality score
- Streamlined custom SNP selection from an up-to-date database of >1 million validated SNP markers
- Final annotated SNP lists specified with expected assay conversion rates

RELIABLE, PROVEN, FAST, AND ROBUST PROCESS

- Over 200 projects between 2002 and 2006, all delivered on time
- Guaranteed delivery date, with average study turnaround time <90 days
- Over 200,000 DNA samples genotyped, with nearly 100% success
- World-class Illumina BeadLab environment capable of generating over 75 million genotypes per day
- Expertise with large datasets—over 1 billion genotypes delivered for a single customer project
- Fully integrated custom Laboratory Information Management System (LIMS) tracking from sample input to data output and analysis
- Barcoded plates sent to customers to ensure accurate sample tracking
- Streamlined process for safe and secure dry ice sample shipment

INDUSTRY-LEADING DATA QUALITY

- Consistently impressive results from best-performing genotyping products, quality-driven processes, and professional expertise
- Maximal information value at every locus
- Illumina control samples included on every sample plate for extensive real-time QC and data review in LIMS environment
- Low sample input requirements

COMPREHENSIVE STUDY TYPES

- Industry's most flexible and comprehensive portfolio with Infinium and GoldenGate assays
- Standard and custom content
- Whole-genome and fine mapping studies
- Scalable multiplex levels—from 384 custom SNPs to 1 million standard SNPs per assay
- Wide sample size range—from 300 to several thousand
- Tag SNP selection available for any combination of the four HapMap populations
- All organisms supported; extensive experience with organisms such as human, cow, pig, chicken, mouse, dog, and corn
- Seamless transition to follow-on projects—from Infinium Whole-Genome Genotyping to iSelect Custom Genotyping, and then to targeted panels with Custom GoldenGate Genotyping—all with the same trusted team, quality data, and LIMS-driven process

SUMMARY

Take advantage of Illumina's full menu of FastTrack Genotyping Services. Our highly experienced FastTrack Project Managers are committed to working collaboratively with you from beginning to end, to ensure the highest quality data and fast turnaround. Enjoy the benefits of innovative technologies and personalized service from the genotyping market leader.

INFINIUM WHOLE-GENOME GENOTYPING PAST PERFORMANCE*

(Based on all contracts between January and September 2006 >11,500 BeadChips and 3.5 billion genotypes)

Infinium Service Projects	Average
Sample Success Rate	99.47%
Locus Success Rate	99.11%
Call Rate	99.89%
Reproducibility	99.99%
Heritability (Trios)	99.98%

* Performance for individual studies varies and depends on the DNA quality of the samples submitted and the quality of the SNPs selected

GOLDENGATE PAST PERFORMANCE*

Based on all contracts between January 2005 and June 2006 (>150,000 individual DNA samples from 100 projects)

GoldenGate Service Projects	Average
Custom Assay Development Success	
- Human only	92.8%
- All species	91.2%
DNA Success Rate	97.6%
Call Rate	99.75%
Reproducibility	>99.99%
Heritability	>99.99%

* Performance for individual studies varies and depends on the DNA quality of the samples submitted and the quality of the SNPs selected

NUMBER OF LOCI ASSAYED AND TURNAROUND TIME REQUIRED FOR FASTTRACK GENOTYPING SERVICES TO PROCESS STANDARD AND CUSTOM PANELS

Standard Panels	Number of Loci	Guaranteed Turnaround Time
GoldenGate Genotyping	~30–6000	45 days[1]
Infinium Whole-Genome Genotyping	300,000–1,000,000	90 days[1,2]
Custom Panels		
Custom GoldenGate Genotyping	384–8,000+	90 days[3]
Infinium iSelect™ Custom Genotyping	7,600–60,800	120 days[3]
Infinium Semi-Custom HumanHap300-Duo+ Genotyping	7,600–60,800[4]	120 days[2,3]
Infinium Semi-Custom HumanHap550+ Genotyping	7,600–121,600[5]	120 days[2,3]

[1] From DNA sample submission
[2] For up to 1,000 samples
[3] From date of final SNP list and DNA sample submission
[4] Add 7,600–60,800 custom loci to standard 300,000 loci per sample
[5] Add 7,600–121,600 custom loci to standard 550,000 loci

ORDERING INFORMATION

FASTTRACK GENOTYPING SERVICES STANDARD PANEL PROJECTS

CATALOG #	PRODUCT	Number of Loci	DNA Required per Sample (µg)	Volume Required per Sample (µl)
	Infinium Whole-Genome Genotyping Standard Panel Service Project			
FT-20-101	HumanHap300-Duo Genotyping BeadChip	>300,000	3	60
FT-20-102	HumanHap240S-Duo Genotyping BeadChip	>240,000	3	60
FT-20-104	HumanHap550 Genotyping BeadChip	>550,000	3	60
FT-20-105	HumanHap650Y Genotyping BeadChip	>650,000	3	60
FT-20-106	HumanHap450S DNA Analysis BeadChip	>450,000	3	60
FT-20-107	Human1M DNA Analysis BeadChip	>1,000,000	3	60
FT-20-108	HumanCNV370-Duo DNA Analysis BeadChip	>370,000	3	60
FT-20-111	HumanLinkage-12 DNA Analysis BeadChip	>6,000	1.5	30
FT-20-109[4]	BovineSNP50 Genotyping BeadChip	>50,000	1.5	30
FT-20-110[4]	CanineSNP20 Genotyping BeadChip	>20,000	1.5	30
FT-20-113[4]	CVDSNP60 Genotyping BeadChip	>60,000	1.5	30
FT-10-101	**GoldenGate Genotyping Standard Panel Service Project**			
	Linkage V Panel	6,056	4	80
	Mouse LD Linkage	377	2	40
	Mouse MD Linkage	1,449	2	40
	MHC Panel Set	2,360	4	80
	MHC Mapping Panel	1,293	2	40
	MHC Exon-Centric Panel	1,228	2	40
	Cancer SNP Panel	1,421	2	40

[4]These products are currently available for ordering, but will not be in use until late 2007

FASTTRACK GENOTYPING SERVICES CUSTOM PANEL PROJECTS

CATALOG #	PRODUCT	Number of Loci	DNA Required per Sample (µg)	Volume Required per Sample (µl)
FT-15-101	**Custom GoldenGate Genotyping Project**	up to 1,536	2	40
		1,632–4,608	4	80
		4,704–9,216	6	120
FT-25-101	**Infinium iSelect Custom Genotyping Project**	7,600–60,800	1.5	30
FT-25-102	**Infinum Semi-Custom HumanHap300-Duo+ Genotyping Project**	7,600–60,800[7]	3	60
FT-25-103	**Infinium Semi-Custom HumanHap550+ Genotyping Project**	7,600–121,600[8]	3	60

[7]Add 7,600–60,800 custom loci to the standard 300,000 loci per sample on the HumanHap300-Duo Genotyping BeadChip
[8]Add 7,600–121,600 custom loci to the standard 550,000 loci on the HumanHap550 Genotyping BeadChip

ADDITIONAL INFORMATION

Please visit www.illumina.com

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Announcing the new Cancer Analysis Service from the Illumina Genome Network.

Delivering the most accurate somatic mutation calls for comprehensive cancer studies.

OVERVIEW HIGH-QUALITY DATA CANCER ANALYSIS SERVICE PARTNERS SERVICE DETAILS PUBLICA

The Illumina Genome Network

The Illumina Genome Network links researchers interested in conducting large whole human genome sequencing project leading institutes worldwide that provide highly economical and rapid turnaround access to Illumina sequencing. Consisti CSPro-certified organizations with proven expertise in generating high-quality, economical human genome data, the Illur Genome Network enables researchers to complete their genome sequencing projects rapidly and confidently. Highest qu data with fast turnaround times: that is the promise of the Illumina Genome Network.

Entrust your study to some of the most recognized names in sequencing, all of whom rely upon the trusted and prover Illumina technology platform. Leverage their expertise to get fast access to comprehensive whole-genome assemblies, including:

- High quality variant calling of single nucleotide polymorphisms (SNPs) and insertions and deletions (Indels)
- Ability to identify Copy Number Variations (CNV) and other structural rearrangements
- Access to a comprehensive set of in-house and third-party analysis tools designed to support the system with the largest installed base in the industry
- Ability to reanalyze data sets over time

You can choose your Illumina Genome Network partner and create service packages based on your individual study requirements. Flexible turnaround times and a range of value-added services are available to meet the unique needs of e study. It's a quick and reliable way to get your sequencing study started on the Illumina sequencing technology platform

GET A QUOTE

Whole Human Genome Sequencing Services Brochure
Illumina Genome Network Data Sheet
Technical Note-Leveraging Whole Human Genome Sequencing in Cancer

High-Quality Data

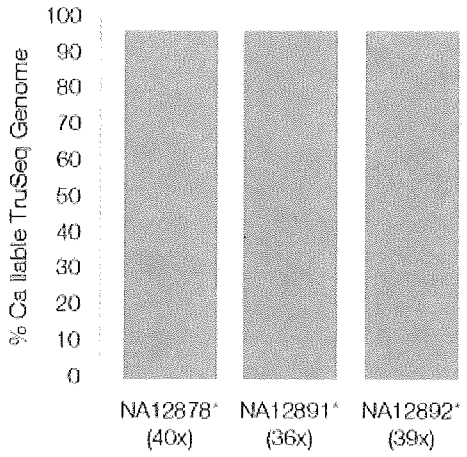
Sound research hinges on good data. While other service companies promise it, the Illumina Genome Network delivers h quality data, using industry-leading HiSeq 2000 systems, TruSeq reagents, and experienced scientists to cost-effectivel perform whole-human genome sequencing. We stand by the accuracy of our data. See how we compare.

More Useable Data

ILLUM-0804

Whole-genome sequencing involves more than obtaining high coverage depth and quality reads. It's the generation of u callable data for variant calling. The Illumina Genome Network runs each base pair through a usable genome test, provid

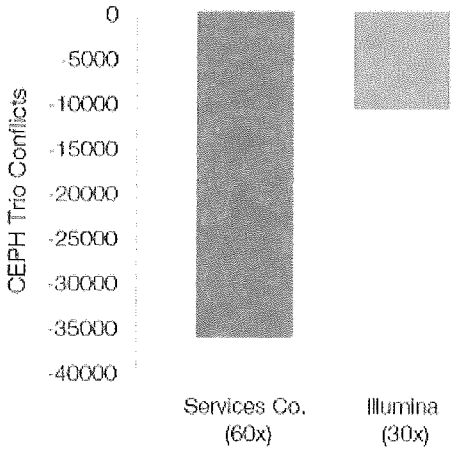
with the highest callable genome (>95%), even in the difficult-to-sequence regions (< 5%). Giving > 80% of all reads pa filter a quality score of Q30 or greater.



High Accuracy

Accuracy is vital for calling variants, especially the ones that are central to your research. The Illumina Genome Network the TruSeq genome, the most accurate genome in the industry. Don't take our word for it. See how the TruSeq genom delivers in the following tests:

1. Measuring consensus accuracy at the whole-genome level

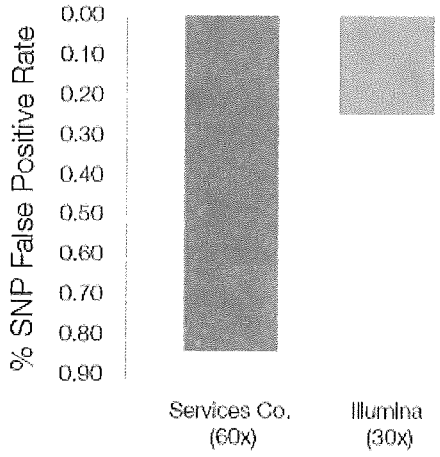


	Services co. (60X)	Illumina (30X)
Callable Sites Present in Trio (bp) "N-Excluded"	2,575,974,378	2,530,389,955
Mendelian Conflicts on Genotypes	35,843	10,801
Conflicts Per Mb	13.91	4.27

2. Analyzing consensus calls

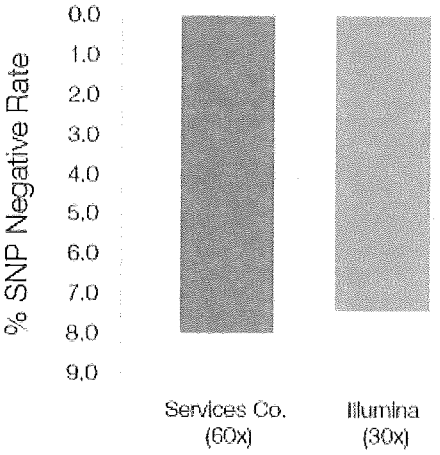
- More SNPs and fewer false positives (so you won't waste time chasing false leads)

ILLUM-0805



	Services co. (60X)	Illumina (30X)
Called SNPs in Any One of Trio	4,294,576	4,403,335
Mendelian Conflicts on Genotypes	35,843	10,801
False Positive Rate	0.83%	0.25%

- More SNPs and fewer false negatives (so you won't miss a variant)



	Services co. (60X)	Illumina (30X)
Called SNPs	3,466,755	3,536,295
Called SNPs from Gold Standard Set (95,005)	87,474	87,965
False Positive Rate	7.93%	7.41%

Analyzing SNP concordance

We run every sample on a HumanOmni-2.5 BeadChip. To support your further studies, we provide this genotyping data well as all WGS data files, as part of the final report.

Cancer Analysis Service

The experts of the Illumina Genome Network (IGN) now offer a Cancer Analysis Service, providing you with the high-con genomic data you need to decipher the mechanisms of cancer. Requiring the lowest sample input (5 µg) of any sequenc service, IGN delivers accurate, easily interpretable, and highly actionable whole-genome sequencing (WGS) data of tumo samples.

Cancer possesses significant heterogeneity at the genetic and histological levels. As a result, the variant calling method needs to properly model the complexities of multiple cancer sub-clones or normal sample contamination. IGN's Bayesian calling method provides the most accurate models for real-life tumor samples, recovering 97% of known SNVs, as comp 77% obtained by competing service offerings.

IGN's Cancer Analysis Service offers:

- Cost-effective solutions for small and large cohort studies, delivering at least 40× average post-alignment coverage of the no genome and at least 80× average post-alignment coverage of the tumor genome.
- Highly actionable WGS data for comprehensive cancer studies.
- Widely adopted data set formats (BAM and VCF) for streamlined analysis.
- Optimized software tools from Illumina informatics partners including Diagnomics, Ingenuity, and Knome, enabling downstrea and interrogation of IGN data sets.
- Smooth data integration with the results of follow-on projects, such as genotyping, RNA-Seq, and methylation studies, using systems and products, enabling a clearer understanding of cancer and the biological pathways it impacts.

IGN Cancer Analysis Service Data Sheet

IGN Cancer Analysis Service Combined Calling Method Poster

GET A QUOTE

The Illumina Genome Network Partners

CANADA'S MICHAEL SMITH GENOME SCIENCES CENTRE

BC Cancer Agency Genome Sciences Centre
100-570 West 7th Avenue
Vancouv er, BC V5Z 4S6 Canada

Email: igninfo@bcgsc.ca
Web: www.bcgsc.ca

Canada's Michael Smith Genome Sciences Centre (BCGSC) at the BC Cancer Agency leading international centre for genomics and bioinformatics research. Our mandate i advance knowledge about cancer and other diseases, to improve human health thro disease prevention, diagnosis and therapeutic approaches, and to realize the social a economic benefits of genomics research. Founded in 1999, BCGSC is the largest aca genome centre in Canada, and among the most productive in the world in the fields cancer genomics and bioinformatics. We collaborate locally, nationally and internatior with partners in all ares of genome sciences.

MACROGEN
Advancing through Genomics
Genomic Medicine Institute

Macrogen/Genomic Medicine Institute/Seoul National University
Rm 1002, 10th floor
World Merdian Venture Center
60-24, Gasan-dong, Geumchen-gu
Seoul, 153-781, South Korea

Phone: **+82.2.2113.7000**

Genomic Medicine Institute (GMI) was founded in 1997 with the mission of providing whole genome sequences and supporting the development of genomic technology fc future personalized medicine and taking a role as the institute of excellence for Genc Korea.

ILLUM-0807

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Email: chipinfo@macrogen.com
Web: www.macrogen.co.kr/eng

NCGR

NCGR (National Center for Genome Resources)
2935 Rodeo Park Drive East
Santa Fe, New Mexico 87505

Contact: **Patricia Mena, Customer Relations Manager**
Phone: **1.505.995.4444**
Fax: **1.505.995.4432**
Email: pmena@ncgr.org
Web: www.ncgr.org

NCGR, a non-profit research institute with extensive experience in Illumina DNA seq data generation and analyses, provides sequencing, genotyping, and analysis servic collaborative setting. Service offerings include whole-genome (including de novo), transcriptome, methylome, ChIP, smRNA, and exome (targeted or whole). Assistanc experimental design, custom data analysis, and visualization tools for de novo asser alignment, and variant detection are available. You can also contact us for Illumina genotyping services.

IGN SERVICE DETAILS

When you send your project to an Illumina Genome Network Partner, you will receive whole human genome sequencing performed at 30X average coverage, from short-insert paired end reads, using a single library. Data analysis will be perf using CASAVA (consensus sequence from ELAND alignment, called SNPs, and small indels). The delivered data set will in reads and quality scores for further downstream analysis.

The following specifications are guaranteed for each sample:

- Average autosomal minimum fold coverage of 30X
- Percent of non-N reference coverage >90% for non-cancer samples
- Paired end sequencing at 2×100bp
- At least 3,000,000 SNPs detected for non-cancer samples

Data will be delivered in standard formats for downstream visualization in Genome Studio or third-party open-source to follows:

- All pass filter reads, alignments, and quality scores in an archival BAM format file, suitable for visualization and downstream analysis
- SNP calls, insertions and deletions with respect to the reference sequence, as well as an allele call and confidence sc for every covered position in the reference
- Text reports for SNP calls for all SNPs in dbSNP for which sufficient coverage has been achieved
- Whole-genome genotyping array data and genotype report

Premium data analysis packages are also available through select Illumina Genome Network Providers. Please send quest directly to your Illumina Genome Network Partner.

WHOLE HUMAN GENOME SEQUENCING COMES OF AGE

In just 15 years, whole human genome sequencing has moved from an expensive, labor intensive, time consuming project costing $40 million, to a study that can be performed quickly and accurately by the Illumina Genome Network for $4,000 (50+ samples). Based on industry-leading TruSeq technology, Illumina sequencers are enabling whole genome sequencing (WGS) to become an integral part of human disease research, whether performed by researchers in their own laboratories, or by Illumina and its Illumina Genome Network partners.

Advances in Whole Hun Genome Sequencing
Click to enlarge »

See how whole human genome sequencing powered by Illumina sequencers is providing insight into the mechanisms of cancer and other life-threatening conditions, enabling researchers to visualize what's occurring a genomic level to develop better therapeutics and improved diagnostics.

RESEARCH AND DISCOVERY

Cancer

ILLUM-0808

REVIEWS AND COMMENTARIES

Reviews

Mendelian, Rare Disease

WHOLE HUMAN GENOME DATA ANALYSIS

Bioinformatics and Methods

OTHER INTERESTING WGS PUBLICATIONS

WGS and Methylation

Commentaries

ILLUMINA GENOME NETWORK PARTNER PUBLICATION

Partners

Innovative technologies
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EXHIBIT B

(PART I OF II)

OF

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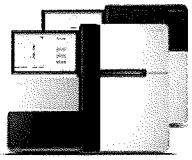

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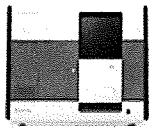

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Most widely published and adopted next-gen system

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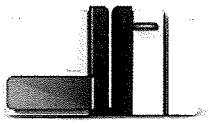

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HiScan
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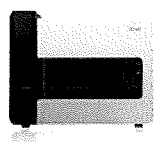

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Dedicated array scanner; processes up to 96 multi-sample BeadChips per day

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BeadXpress
Broadest multiplexing range, assay versatility, superb data quality, and regulated device

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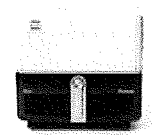
Real-Time PCR System



Eco Real-Time PCR System
High-performance thermal control & uniformity, open platform supporting variety of qPCR applications

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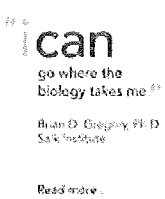

Science Publications

- Next is now: new technologies for sequencing of genomes, transcriptomes, and beyond. Lister R et al. 2009.
- Genomic copy number variation, human health, and disease. Wain LV et al. 2009.

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Featured Partner

iGenix, inc.

iGenix, Inc. provides Illumina BeadXpress lab services for genotyping, copy number variation assessment, methylation and expression studies, maximizing your research efficiency and data accuracy.

News and Events

- Illumina Receives FDA 510(k) Clearance for Its BeadXpress(R) Multiplex Analysis System
- Illumina Now Shipping HiScan(TM)SQ Platform
- Illumina Announces Its First Full Coverage DNA Sequencing of a Named Family

ILLUM-0810

Cytogenetics

Cancer Genomics

Customer Service

Training

Innovative technologies
At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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ILLUM-0811

Optimal Solution for low- to mid-plex molecular testing

Assay versatility
Superb data quality
Dual-color laser system

Systems / BeadXpress / **Technology**

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VeraCode Technology

Enabling a broad range of multiplexing options for RNA, DNA and protein applications

Watch the video »

Illumina's VeraCode technology leverages the power of digital holographic codes to provide a robust detection method for multiplex assays requiring high precision, accuracy, and speed.

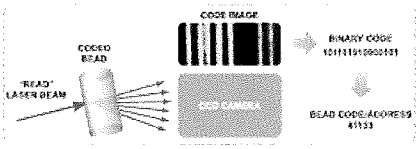
The truth is in the code

Comprised of cylindrical glass microbeads measuring 240 microns in length by 28 microns in diameter, VeraCode microbeads provide an ideal surface for numerous bioassays including genotyping, gene expression, and protein-based assays. Illumina's proprietary technology precisely embeds digital holographic elements within each microbead to create unique bead types. Each microbead can easily carry high-density codes (24-bit), for virtually unlimited development of bead types.

When excited by a laser, each VeraCode bead emits a unique code image, allowing for quick and specific detection by Illumina's BeadXpress Reader System. Depending on desired multiplex levels, assays are created by pooling microbeads with code diversities from one to several hundred. VeraCode beads are highly stable and the digital coding provides customizable tracking of not only the target(s) of interest, but also of critical identifiers such as sample ID, laboratory ID, and reagent kits.

Veracode technology highlights

- Unsurpassed multiplexing range
- Robust performance and customizable tracking
- Assay versatility
- Rapid sample throughput
- Two-color detection system



Life Sciences | Personal Sequencing | Diagnostics

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Applications

Sequencing
GWAS
SNP Genotyping & CNV Analysis
Gene Regulation & Epigenetic Analysis
Gene Expression Analysis
Protein Analysis
Real-Time PCR
Agrigenomics
Cytogenetics
Cancer Genomics

Systems

HiSeq Systems
Genome Analyzer IIx
MiSeq
HiScanSQ
iScan
BeadXpress
Eco Real-Time PCR System
Software
BaseSpace

Services

Genome Network
FastTrack Services
CSPro
Core Labs
Service
Partnerships
Illumina Financial Solutions
Illumina Connect

Science

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ILLUM-0814

Systems / BeadXpress / **Applications**

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Custom Low- to Mid-plex Genotyping

For profiling and validation studies requiring low to mid-plex genotyping, Illumina provides customized solutions that allow researchers to optimize the number of loci per sample and throughput level to best suit their study goals. Custom assay panels can be easily developed for any species and deployed with either BeadArray or Veracode technology.

More...

Custom Low- to Mid-plex Methylation Analysis

For methylation profiling studies requiring low- to mid-plex analysis, Illumina provides a customized solution that allows researchers to target CpG loci within genes or regions of interest. With the proven VeraCode GoldenGate Methylation Assay, customized probes can be easily developed for virtually any experimental design.

More...

Protein Screening

VeraCode technology provides a simple and flexible solution for multiplexed protein assays. With VeraCode Carboxyl Bead Sets, any protein or peptide can be covalently attached to the highly stable microbead surface, enabling the development of standard "sandwich" immunoassays. The 48 unique Carboxyl bead types can be pooled in varying combinations to perform up to 48 immunoassays in a single reaction in a standard 96-well microplate.

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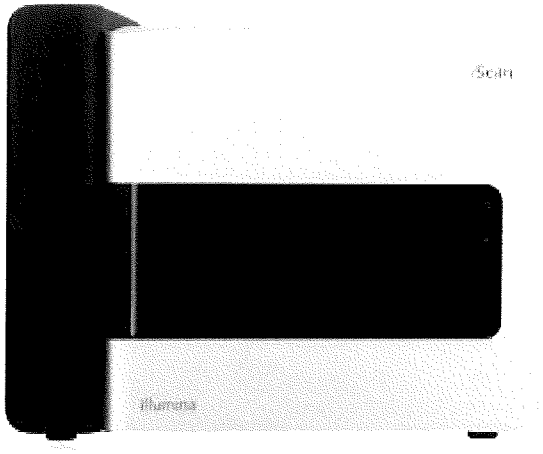

Cutting-edge array scanner

Highest Data Quality
Highest Sample Throughput
Flexible Platform

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Whole-Genome Genotyping and Copy Number Variation Analysis

Since they were first developed in 2005, whole-genome genotyping (WGGT) arrays have become an important tool for discovering variants that contribute to human diseases and phenotypes. The two primary applications of this technology, genome-wide association studies (GWAS) and copy number variant (CNV) analysis, have helped researchers begin to unravel the complex genetic architecture behind diseases such as diabetes and Crohn's disease, and traits such as hair and eye color.

Illumina's WGGT Infinium BeadChips offer researchers the flexibility to genotype samples with hundreds of thousands to millions of markers that deliver dense genome-wide coverage with the most up-to-date content available from the scientific community. Markers on the BeadChips are strategically selected by Illumina scientists to provide maximum coverage of the genome for both association testing and copy number detection.

The Omni Family of Microarrays

The latest generation of Infinium WGGT products is The Omni Family of Microarrays. This flexible, complimentary family of microarrays represents a revolution in array design, delivering up to 5 million makers per sample and offering an unprecedented amount of customizability. Designed from next-generation sequencing data from international projects such as the 1000 Genomes Project, Omni microarrays deliver unrivaled coverage of the genome. Access to whole-genome sequencing data provides the most complete picture of the extent of variation, allowing Illumina scientists to select the most informative markers to provide superior power to detect trait- and disease-associated variants.

More...

Custom Mid- to High-plex Genotyping

For researchers who want to study focused genomic regions of interest, or are interested in organisms for which there are no standard products, Illumina offers a broad range of custom genotyping options. Customized iSelect BeadChips can be easily developed to fit any experimental design, allowing customers to select the ideal solution for their loci multiplexing and sample throughput requirements. Convenient online tools and Illumina representatives are available to help you design and select your markers of interest, and choose the assay and customized products to best suit your research goals.

More...

Focused Genotyping

Focused genotyping supports a variety of applications such as candidate-gene studies in cancer, cardiovascular disease, and admixture mapping. Illumina also works closely with major animal consortia to develop genome-wide genotyping products for non-human organisms, including both animal and plant species.

More...

Cytogenetic Analysis

Structural variability is a substantial source of genetic variation that has a major influence on phenotypic variation. Cytogenetic analysis allows researchers to profile chromosomal aberrations such as amplifications, deletions, rearrangements, point mutations, copy number changes, and copy-neutral loss of heterozygosity (LOH) events.

More...

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Linkage Analysis

Linkage analysis provides researchers a powerful method for mapping the location of disease-causing loci by identifying genetic markers that are co-inherited with a phenotype of interest. Illumina's linkage analysis BeadChips present the optimal solution for identifying regions of statistically unequivocal linkage by delivering the information content, call rates, and accuracy that enable discovery of links between familial genotype and phenotype in both monogenic and polygenic disorders.

More...

Array-Based Methylation Analysis

DNA methylation plays a critical role in the regulation of gene expression and has been implicated in the etiology of many human diseases including cancer. Methylation profiling with BeadArray technology allows researchers to analyze the effects of aberrant methylation (either hyper- or hypomethylation) for a variety of applications. Illumina has developed a robust methylation profiling platform that provides quantitative methylation measurement at the single-CpG-site level, providing the highest resolution for understanding epigenetic changes.

More...

Transcriptome Analysis

RNA sequencing has revolutionized the exploration of gene expression. Advances in the sequencing workflow, from sample preparation through data analysis, enable rapid profiling and deep investigation of the transcriptome. With RNA sequencing, you can characterize all transcriptional activity, coding and non-coding, in any organism without a priori assumptions.

Illumina's unique combination of long and short reads, single and paired-end sequencing, strand specificity, and capacity for tens of millions to billions of reads per run allows you to

- annotate coding SNPs
- discover transcript isoforms
- identify regulatory RNAs
- characterize splice junctions
- determine the relative abundance of transcripts

With the greatest daily output available for any sequencing system, transcript profiles can be generated in a single day. RNA sequencing reads can be aligned across splice junctions to identify isoforms, novel transcripts and gene fusions. Identify and quantify both rare and common transcripts, with over six orders of magnitude of dynamic range. Reveal the hidden world of non-coding RNA architecture without prior information.

More...

FFPE Sample Analysis

Formalin-fixed, paraffin-embedded (FFPE) samples are preserved tissue samples that are generally associated with disease. Many of these samples represent clinical outcomes, which could provide a potential gold mine of information when linked with underlying expression profiles. FFPE samples generally contain partially degraded RNA, so transcription analysis is a challenge for many gene expression assays. By using unique PCR and labeling steps based on the proven GoldenGate chemistry, Illumina's DASL assays provide high-quality data from degraded RNA samples. The DASL assay is available in the Whole-Genome DASL Assay, a fixed content, whole-genome profiling panel.

More...

Gene Regulation & Epigenetic Analysis
Gene Expression Analysis
Protein Analysis
Real-Time PCR
Agrigenomics
Cytogenetics
Cancer Genomics

HiScanSQ
iScan
BeadXpress
Eco Real-Time PCR System
Software
BaseSpace

Service Partnerships
Illumina Financial Solutions
Illumina Connect

Webinars

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FAQs
DesignStudio
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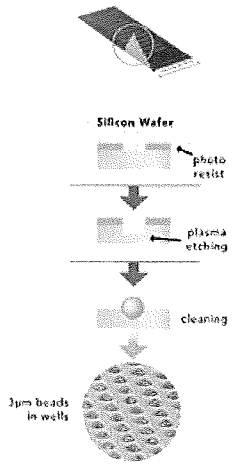
BeadArray Technology

A fundamentally different approach to high-density microarrays

Illumina's BeadArray Technology is based on 3-micron silica beads that self assemble in microwells on either of two substrates: fiber optic bundles or planar silica slides. When randomly assembled on one of these two substrates, the beads have a uniform spacing of ~5.7 microns. Each bead is covered with hundreds of thousands of copies of a specific oligonucleotide that act as the capture sequences in one of Illumina's assays. BeadArray technology is utilized in Illumina's iScan System for a broad range of DNA and RNA analysis applications. The original Infinium II Assay was great, but Infinium HD is remarkable. Most samples have an average call rate of 99.9% off the shelf, which makes downstream curation of data a whole lot easier. For those who aren't curating their data, there's much less downstream work because there is less likelihood of false positives and negatives due to the higher sample call rates. In addition to data quality, the ability to run four samples per chip clearly gets to the answers a lot faster.

BeadArray technology is deployed on either of two multi-sample array formats for DNA or RNA-analysis applications. With multi-sample BeadChip formats, uniform pits are etched into the surface of each substrate to a depth of approximately 3 microns prior to assembly. Beads are then randomly assembled and held in these microwells by Van der Waals forces and hydrostatic interactions with the walls of the well.

The Universal BeadChip format is used in Illumina's GoldenGate Genotyping and Focused Arrays applications. The BeadChip format is used in Illumina's Infinium Genotyping, DASL Gene Expression, and Focused Arrays applications.



Illumina multi-sample array formats

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Applications / **Genome-Wide Association Studies (GWAS)**

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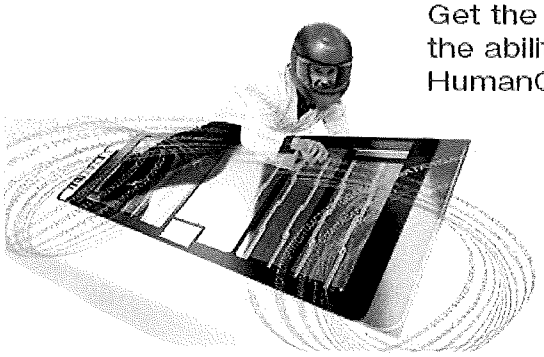

Get the highest-value content and the ability to customize with the new HumanOmni5-Quad BeadChip.

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Omni Arrays

Dig deeper into your research. Make new discoveries. Tailor your studies.

The new Omni5 harnesses over ten years of genomic research, capturing variation down to 1% MAF. With more than 4.3 million high-value markers. And room for 500k of your own.

It's the most powerful genotyping array for your whole-genome studies yet. Take a closer look at the Omni5.

Omni Roadmap. Delivered.

Since the Omni family of microarrays was launched in 2009, we've offered an expanding selection of flexible arrays featuring only the most informative common and progressively rare variants. Delivering the most powerful markers selected from the International HapMap Project and the 1000 Genomes Project. Built with input from thought leaders in the human genetics research community. To ensure these markers would most effectively advance your studies.

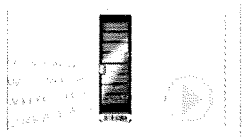
Now the Omni5 is here. This flagship array dramatically expands the catalog of rare variants, offering unprecedented coverage of the genome, including high-value regions that deliver the most power to identify variants associated with disease.

An array for any study. Any budget.

The Omni family gives you the flexibility to study the widest range of genetic variation—no matter your study size, sample population, research focus, or budget. Get the most comprehensive coverage of common and rare variants with the Omni5. Or, start smaller and build your variant collection with Omni products as your study grows.

Wherever you begin, you're guaranteed to be working with the most robust family of microarrays. All backed by the powerful Infinium Assay. With the highest-throughput. Intelligent tag-SNP selection. Cutting-edge content. All making the most of what this decade of genomic research has revealed. Giving you the power to effectively drive your next-gen GWAS studies—and discoveries.

View the collection of Omni products.

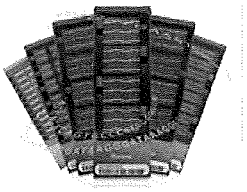


Video | Infinium Assay Driving Genomic Discovery

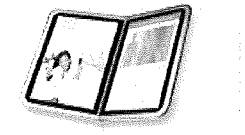
Discover the technology »
Watch the Infinium Arrays animation

Video | Next-Gen GWAS: Illumina's Omni Roadmap.

View the video »
Watch recent advancements in human genomics.



Launch the chip selector »
Select the best array for your research.



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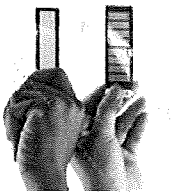
Read the e-book »
Read about the evolution of Omni arrays.



Explore hybrid workflow options »
Expand the power of your study—next-gen sequencing and arrays.

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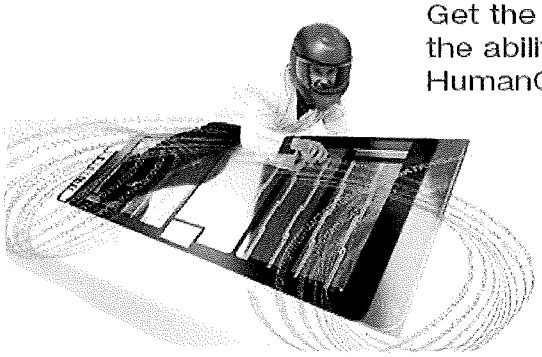
Applications / **Genome-Wide Association Studies (GWAS)**

Open-throttle genomics.



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Omni Overview Applications Omni BeadChips Infinium Overview Software Literature

Applications

Since they were first developed in 2005, whole-genome genotyping arrays have become an invaluable tool for discovering variants that contribute to human diseases and phenotypes. The two primary applications of this technology, genome-wide association studies (GWAS) and copy number variant (CNV) analysis, have helped researchers begin to unravel the complex genetic architecture behind diseases such as diabetes and Crohn's disease, and traits such as hair and eye color.

GWAS

GWAS has already proven very successful as an analytical approach to help researchers identify regions of the genome that harbor causative alleles for a trait or disease. This is accomplished by evaluating whole-genome genotypes across a large number of DNA samples and identifying those genetic variants that occur more frequently in people with a given trait or disease (cases), relative to those without the trait or disease (controls). Those variants that have statistically significant allele frequencies across the two groups of samples are said to be associated with that phenotype. Once an association is identified, it serves as an indicator to the region of the genome where causative variants are likely to exist. The use of GWAS to uncover these variants has proved immensely successful, identifying thousands of variants in hundreds of publications in a few short years. However, much remains to be discovered as researchers embark on a next-generation of GWAS, using new microarrays that allow detection of rarer variation and expand the catalog of diseases, traits, and populations studied.

Structural Variation Analysis

Structural Variation, is thought to be a significant contributor to the genetic basis of human disease. The same raw signal intensity data that is used to call genotypes can be used to identify regions where the genome contains either increased or decreased gene copy numbers. Furthermore, the added information of genotypes allows researchers to identify copy number neutral loss-of-heterozygosity. Dense marker spacing on the Omni microarrays, coupled with the sensitive Infinium assay and Illumina's high-precision array scanners, offer researchers a powerful solution for analyzing a range of structural variants.

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Analysis
Protein Analysis
Real-Time PCR
Agrigenomics
Cytogenetics
Cancer Genomics
BeadXpress
Eco Real-Time PCR System
Software
BaseSpace
Illumina Financial Solutions
Illumina Connect
DesignStudio
Assay Design Tool
Product Files
Eco Real-Time PCR Support
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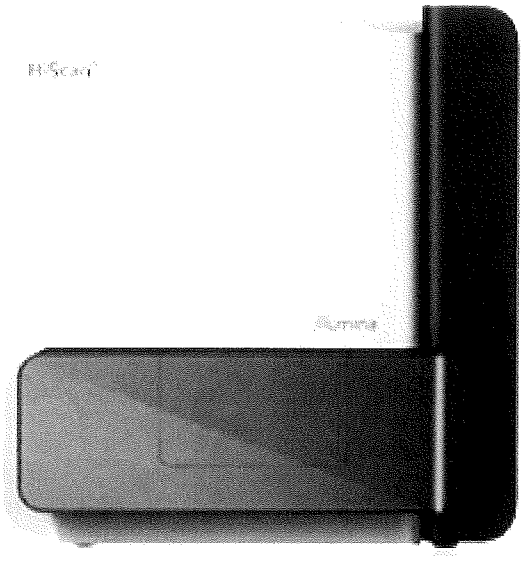

Powerful array scanner; expandable to add next-gen sequencing

Genome today, interpreted tomorrow

The world's most powerful sequencer, now with a rapid-run mode.

Coming mid-2012.

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Highest throughput.
Highest data quality.

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HiSeq™ Sequencing Systems

Redefining the trajectory of sequencing.

HiSeq System Highlights

- **High Accuracy and Unprecedented Output:** Generate up to 600 Gb per run with the highest yield of data greater than Q30.
- **Breakthrough User Experience:** Easily set up runs with simplified library prep, automated clonal amplification, pre-configured, plug-and-play reagents, simple flow cell loading, touch screen-enabled user interface, and integrated paired-end fluidics.
- **Unmatched Cost-Effectiveness:** Unrivalled output and ease of use with the industry's simplest sequencing workflow provide the lowest overall operating cost.
- **Flexibility:** HiSeq 1000 offers broader access to HiSeq technology, providing an easy upgrade path to the HiSeq 2000 as sequencing needs change.

Sequence at a Scale Never Before Possible

HiSeq Sequencing Systems combine Illumina's proven and widely-adopted, reversible terminator-based sequencing by synthesis (SBS) chemistry with innovative engineering. Comprised of the HiSeq 2000 (Figure 1) and HiSeq 1000 systems, this high-performance sequencing family combines human interaction design features and the easiest sequencing workflow, setting a new standard for simplicity and user experience.

The HiSeq 2000 sequencing system delivers the industry's highest sequencing output and fastest data generation rate. With the industry's simplest sequencing workflow and unmatched cost effectiveness, HiSeq 2000 has lowered the cost of whole-human genome sequencing to unrivaled levels.

Offering the same outstanding user experience and cost per data output (Gb), the HiSeq 1000 enables researchers to access HiSeq performance, with a built-in upgrade path should sequencing throughput needs change.

Unprecedented Output

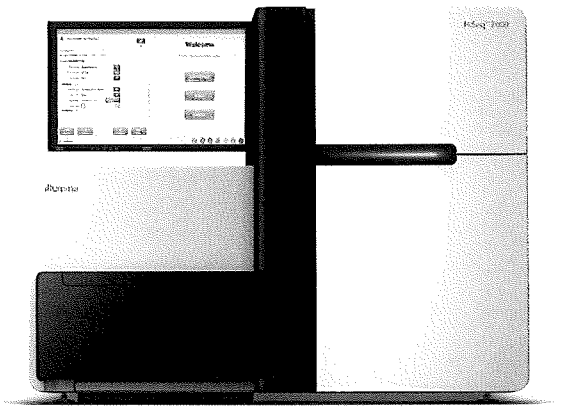
HiSeq Systems make it possible for individual labs to take on the largest and most complex sequencing studies at a lower cost. With cutting-edge scanning and imaging technology, clusters on both surfaces of the flow cell can be sequenced, dramatically increasing the number of reads, sequence output, and data generation rate. The ultra-high output and speed of the two flow cell HiSeq 2000 makes it possible to sequence > 5 human genomes at ~30× coverage simultaneously, up to 192 gene expression samples or 100 exome samples in a single run. The HiSeq 1000 System is an exceptionally powerful tool for researchers who do not require the throughput of a HiSeq 2000. It enables researchers to sequence > 2 human genomes at ~30× coverage or 96 gene expression samples in one run.

Breakthrough User Experience

Innovative design features make HiSeq Systems the easiest-to-use next-generation sequencing systems (Figure 2). Flow cells are loaded on the vacuum-controlled loading dock. Pre-configured, plug-and-play reagents sufficient for up to 200 cycles plus indexing, drop into racks in the machine's chiller compartment, requiring only two minutes of hands-on time. A simple touch screen user interface, including on-screen, step-by-step instructions with embedded multimedia help, simplifies run setup. Real-time progress indicators provide at-a-glance status, and remote monitoring allows a single user to check progress on multiple systems from any browser or internet-enabled phone.

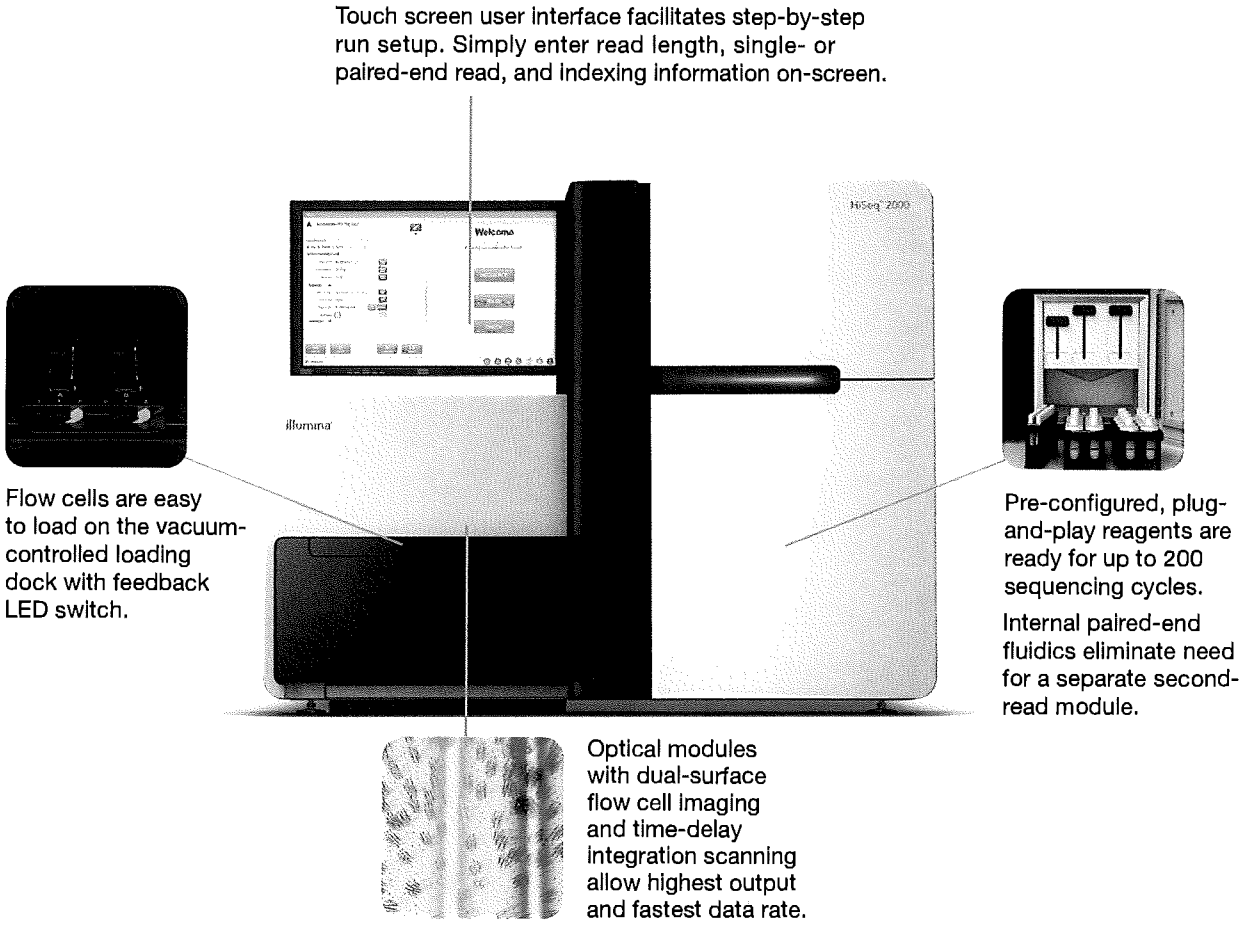
HiSeq 2000 can be operated in single or dual flow cell mode, offering unmatched experimental flexibility and instrument scalability. Its independently-operable flow cells allow applications requiring different read lengths to run simultaneously. The single flow cell HiSeq 1000 delivers the same user experience and output per flow cell, and can be easily upgraded to the dual flow cell HiSeq 2000 to meet growing research needs.

Figure 1: HiSeq 2000 System



Illumina's HiSeq 2000 sequencing system enables individual labs to take on larger and more complex studies, including routine human genome sequencing.

Figure 2: HiSeq 2000 Innovative Design Features



HiSeq Systems redefine the trajectory of sequencing. Innovative engineering and human interaction design features provide a breakthrough user experience and unmatched cost-effectiveness.

Figure 3: Next-Generation Sequencing Simplified

Library Preparation
~2 h [15 min hands-on (Nextera)]
< 6 h [< 3 h hands-on (TruSeq)]

Cluster Generation
~5 h (<10 min hands-on)

Sequencing by Synthesis
~1.5 to 11 days

CASAVA
2 days (30 min hands-on)

From simplified sample preparation kits and automated cluster generation, to streamlined sequencing by synthesis and complete data analysis, Illumina HiSeq sequencing systems offer the industry's simplest next-generation sequencing workflow.

TruSeq™ Chemistry

The TruSeq family of reagents represents the latest advancement of Illumina's SBS technology. Permeating the entire chemistry workflow, from sample preparation through DNA sequencing, TruSeq underlies Illumina sequencing and empowers it to deliver the industry's most accurate genomic data for a broad range of applications.

SBS technology enables massively parallel sequencing of millions of fragments using a proprietary reversible terminator-based method that detects single bases as they are incorporated into growing DNA strands. A fluorescently-labeled terminator is imaged as each dNTP is added and then cleaved to allow incorporation of the next base. Since all four reversible terminator-bound dNTPs are present during each sequencing cycle, natural competition minimizes incorporation bias. Base calls are made directly from signal intensity measurements during each cycle, which greatly reduces raw error rates compared to other technologies. The end result is highly accurate base-by-base sequencing that eliminates sequence-context specific errors, enabling robust base calling across the genome, including repetitive sequence regions and within homopolymers.

Powered by TruSeq chemistry, Illumina sequencing delivers the most accurate human genome at any level of coverage. The highest yield of error-free reads and most base calls above Q30 provide researchers the highest confidence in their data integrity to draw sound biological conclusions.

Easiest Sequencing Workflow

The Illumina sequencing workflow is based on three simple steps: libraries are prepared from virtually any nucleic acid sample, amplified to produce clonal clusters, and sequenced using massively parallel synthesis. Library preparation can be performed using Illumina's simplified TruSeq sample prep kits or Nextera's Illumina sequencer-compatible DNA Sample Prep Kits. Cluster generation occurs on the cBot automated cluster generation system, where hands-on time is less than ten minutes, compared to more than six hours of hands-on effort for emulsion PCR methods. The process of creating sequencing templates is complete in about four hours per flow cell. For sequencing, either one or two flow cells can be loaded on HiSeq 2000, enabling different experimental conditions to be run simultaneously. Pre-configured sequencing reagents are dropped in the instrument reagent racks prior to the start of the run.

Streamlined Data Analysis Solution

Accompanying the unprecedented sequencing output of HiSeq 2000 and HiSeq 1000 is Illumina's data analysis solution for transforming billions of bases of raw sequencing data into publishable, biologically meaningful results. HiSeq Control Software offers real-time analysis processing that automatically produces image intensities and quality-scored base calls on the instrument computer for alignment to a reference sequence and subsequent analysis. In combination with the Consensus Assessment of Sequence and Variation (CASAVA) software, GenomeStudio® data analysis software provides intuitive, graphical analysis. The optional IlluminaCompute system is available as a comprehensive and scalable computing architecture for genomic data processing and analysis. IlluminaCompute is an individually configured, pre-packaged data analysis solution consisting of scalable processing, scale-out storage, and comprehensive support for installation, training, and maintenance.

Installation and Support

Comprehensive installation and training is included with every HiSeq System purchase, along with on-going technical support, maintenance and service. Illumina's industry-leading support is available in North America, Europe, and Asia.

Easy Upgrade Path

HiSeq 1000 provides another entry point into the world of HiSeq high-performance sequencing, providing the scalability needed to accomodate expanding sequencing needs. HiSeq 1000 instrument upgrades are performed on-site, quickly transforming the system to a HiSeq 2000 to deliver the industry's highest sequencing output and fastest data generation rate.

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HiSeq System Information

HiSeq System Performance Parameters

Parameters	Single Flow Cell (HiSeq 2000 or 1000)*		Dual Flow Cell (HiSeq 2000 only)	
Read Length	Run Time	Output	Run Time	Output
1 × 35 bp	~1.5 days	47–52 Gb	~2 days	95–105 Gb
2 × 50 bp	~4.5 days	135–150 Gb	~5.5 days	270–300 Gb
2 × 100 bp	~8.5 days	270–300 Gb	~11 days	540–600 Gb
Reads	Up to 1.5 billion clusters passing filter, and up to 3 billion paired-end reads		Up to 3 billion clusters passing filter, and up to 6 billion paired-end reads.	
Throughput	Up to 35 Gb per day for a 2 × 100 bp run		Up to 55 Gb per day for a 2 × 100 bp run	
Performance	Greater than 85% bases higher than Q30 at 2 × 50 bp† Greater than 80% bases higher than Q30 at 2 × 100 bp†			

*HiSeq 2000 can be run as a single flow cell or dual flow cell system.

†Install specifications for HiSeq sequencers with an Illumina PhiX library and cluster densities between 610 – 678 K/mm² that pass filtering on a HiSeq system using TruSeq v3 Cluster and SBS kits for HiSeq. Performance may vary based on sample quality, cluster density, and other experimental factors. Paired 100 bp runs may vary in the range of 80 to 90% of bases above Q30 and paired 50 bp runs typically vary in the range of 85 to 95% bases above Q30 based on the above factors.

HiSeq System Specifications with Monitor and PC

Instrument Configuration
Computer and touch screen display
Installation setup and accessories
Data collection and analysis software

Instrument Control Computer
Base Unit: 2x Intel Xeon X5560 2.8 GHz CPU
Memory: 48 GB RAM
Hard Drive: 4x 1.0 TB 7200 RPM SATA
Operating System: Windows Vista

Note: Computer specifications will be regularly upgraded.
Contact your local account manager for current configuration.

Operating Environment
Temperature: 22°C ± 3°C
Humidity: Non-condensing 20%–80%
Altitude: Less than 2,000 m (6,500 ft)
Air Quality: Pollution degree rating of II
Ventilation: Maximum of 4,000 BTU/h
For Indoor Use Only

Laser
532 nm, 660 nm, 650 nm (barcode reader)

Dimensions
WxDxH: 118.6 cm x 76.0 cm x 94.0 cm (46.7 in x 30.0 in x 37.0 in)
Weight: 221.4 kg (488 lbs)
Crated Weight: 312 kg (688 lbs)

Power Requirements
100–240V AC 50/60Hz, 20A, 1500W
Illumina provides a region-specific uninterruptible power supply for all HiSeq instruments.

Product Safety
CE marked and ETL listed instrument

HiSeq Systems and Accessories

	Catalog No.
HiSeq 2000 Sequencing System	SY-401-1001
HiSeq 1000 Sequencing System	SY-405-1001
HiSeq 1000 to HiSeq 2000 Upgrade	SY-405-1002
cBot Clonal Amplification System	SY-301-2002

Accelerate Your Research with HiSeq Systems

HiSeq Systems redefine the trajectory of sequencing by combining innovative engineering with proven SBS chemistry to set new standards for output, simplicity, and cost-effectiveness. With the HiSeq 2000 and HiSeq 1000, the ability to process larger numbers of samples and to decode larger and more complex genomes means that virtually any sequencing project is now within reach.

Learn More

For more information about HiSeq 2000, HiSeq 1000, and Illumina sequencing, visit www.illumina.com/systems.

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MiSeq® System

Fully integrated, next-generation sequencing ecosystem for rapid genetic analysis.

MiSeq System Highlights

- **Sequencing at the touch of a button**
  Integrated and automated system requires no intervention, eliminating potential error
- **Most rapid variant detection for time-critical studies**
  Go from DNA to data in less than 8 hours
- **Proven data quality**
  Leverages the industry's most accurate TruSeq® chemistry for the highest confidence in your data
- **Optimized for key applications**
  Adjustable read lengths and imageable area provide ultimate experimental flexibility across a broad range of applications

Introduction

The MiSeq personal sequencing system enables researchers to go from sample to analyzed data in as little as eight hours with a revolutionary workflow and unmatched accuracy. Capable of generating up to 7.0 Gb per run, MiSeq is the only next-generation sequencer that integrates amplification, sequencing, and data analysis in a single instrument with a footprint of approximately 2 feet square (Figure 1). In contrast to sequencing systems that require emulsion PCR, the MiSeq system leverages Illumina's proven TruSeq chemistry, making it the ideal platform for any lab performing rapid and cost-effective genetic analysis for the widest range of applications.

Push Button Sequencing

The MiSeq system offers the easiest next-generation sequencing workflow. Perform simple instrument operation with an intuitive touch screen interface and plug-and-play reagents with RFID tracking and automated convenience. The compact, all-in-one MiSeq platform incorporates cluster generation, paired-end fluidics, and complete data analysis, eliminating the need for auxiliary hardware and saving valuable lab bench space. Seamless data upload to the BaseSpace™ cloud environment enables unparalleled analysis, collaboration, and security.

Fastest Turnaround Time

For results in hours rather than days, the MiSeq system delivers the simplest and fastest turnaround time of any next-generation personal sequencing system (Figure 2). Prepare your sequencing library in just 90 minutes with Nextera® sample prep reagents, then move to automated clonal amplification and sequencing in as little as three and a half hours directly on the MiSeq system. On the integrated instrument computer, data analysis from quality-scored base calls to variant calling and alignment is complete in less than two hours with no user intervention.

Proven Data Quality

Based on Illumina's proven sequencing by synthesis technology, massively parallel sequencing of millions of fragments occurs by a proprietary reversible terminator–based method that detects single bases as they are incorporated into growing DNA strands. A fluorescently labeled terminator is imaged as each dNTP is added and then cleaved to allow incorporation of the next base. Since all four reversible terminator–bound dNTPs are present during each sequencing cycle, natural competition minimizes incorporation bias. Base calls are made directly from signal intensity measurements during each cycle, greatly reducing raw error rates compared to other technologies. The end result is highly accurate base-by-base sequencing that eliminates sequence context–specific errors, enabling robust base calling, even within repetitive sequence regions and homopolymers. Illumina sequencing is powered by TruSeq technology, and delivers the highest data integrity, with the highest yield of error-free reads and the most base calls above Q30.

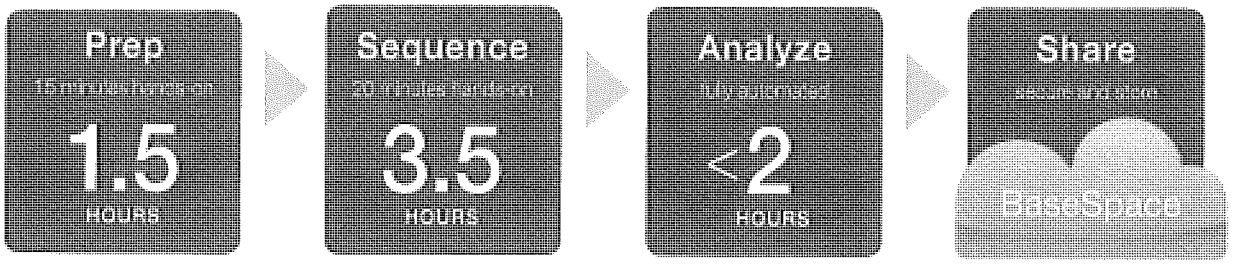
Optimized for Key Applications

Explore the broadest range of sequencing applications. Adjustable read lengths and imageable area and the choice of single or paired-end reads allow you to match experimental needs to your time requirements. Perform rapid and cost-effective capillary electrophoresis (CE) sequencing applications, as well as highly multiplexed amplicon sequencing with TruSeq Custom Amplicon, TruSeq Custom Enrichment, small genome resequencing and *de novo* sequencing, small RNA sequencing, library QC, and 16S metagenomics studies. For current next-generation sequencing users, complete sequencing projects in a fraction of time and cost using the MiSeq system.

Figure 1: MiSeq System

Illumina's compact MiSeq system is the ideal platform for rapid, cost-effective next-generation sequencing.

Figure 2: MiSeq Workflow



The MiSeq system's revolutionary workflow enables the fastest turnaround time of any next-generation personal sequencing system.

MiSeq System Performance Parameters

Read Length	Total Time from Prepped Library through Sequencing*	Output
1 × 35 bp	3.2–3.5 hours	440–550 Mb
2 × 25 bp	4.6–5.0 hours	640–800 Mb
2 × 100 bp	14.0–16.0 hours	2.5–3.1 Gb
2 × 150 bp	20.7–24.0 hours	3.7–4.6 Gb
2 × 250 bp**	>35 hours	6.0–7.0 Gb
Reads	12.0–15.0 million clusters passing filter, and 24.0–30.0 million paired-end reads	
Performance†	>90% bases higher than Q30 at 1 × 35 bp >90% bases higher than Q30 at 2 × 25 bp >85% bases higher than Q30 at 2 × 100 bp >75% bases higher than Q30 at 2 × 150 bp	

* Includes paired-end read, if applicable.

**Performance, output, amplification, and sequencing time for 2 x 250 bp read length depends on instrument upgrade, commercially available in the third quarter of 2012. Customers will be notified of upgrade availability. Upgrade dates are subject to change.

†The percentage of bases >Q30 is averaged across the entire run, not on a per-read or per-cycle basis.

Ordering Information

	Catalog No.
MiSeq system	SY-410-1001

Learn More

Go to www.illumina.com/miseq to learn more about the next revolution in personal sequencing.

MiSeq System Specifications

Instrument Configuration
RFID tracking for consumables
MiSeq Control Software
MiSeq Reporter Software

Instrument Control Computer (Internal)*
Base Unit: Intel Core i7-2710GE 2.10 GHz CPU
Memory: 16 GB RAM
Hard Drive: 750 GB
Operating System: Windows 7 embedded standard
*Computer specifications are subject to change.

Operating Environment
Temperature: 22°C ± 3°C
Humidity: Non-condensing 20%–80%
Altitude: Less than 2,000 m (6,500 ft)
Air Quality: Pollution degree rating of II
Ventilation: Maximum of 1,364 BTU/h
For Indoor Use Only

Light Emitting Diode (LED)
530 nm, 660 nm

Dimensions
W×D×H: 68.6 cm × 56.5 cm × 52.3 cm (27.0 in × 22.2 in × 20.6 in)
Weight: 54.5 kg (120 lbs)
Crated Weight: 90.9 kg (200 lbs)

Power Requirements
100–240V AC @ 50/60Hz, 10A, 400W

Radio Frequency Identifier (RFID)
Frequency: 13.56 MHz
Power: 100 mW

Product Safety and Compliance
NRTL certified IEC 61010-1
CE marked
FCC/IC approved

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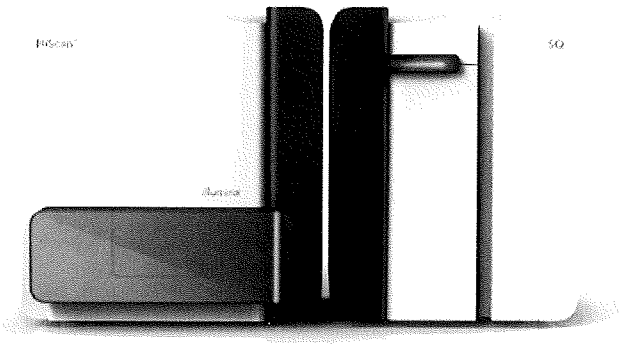

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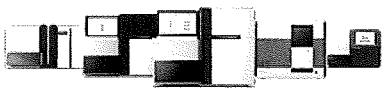

Compare Illumina sequencing systems »

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Gene Regulation & Epigenetic Analysis
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Protein Analysis
Real-Time PCR
Agrigenomics
Cytogenetics
Cancer Genomics

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Innovative technologies
At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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Eco

The Eco Real-Time PCR System

With the Eco system, Real-Time PCR technology is now within reach o individual researchers. Large, expensive thermal cyclers that take up a entire workspace are replaced with an affordable, compact system an Netbook computer that fit easily in any lab. Delivering unsurpassed da quality for 40-cycle runs in as little as 40 minutes, the Eco system revolutionizes qPCR accessibility for both new and experienced Real-Ti PCR users.

Sign up for a risk-free 7-day trial to evaluate the Eco in your lab

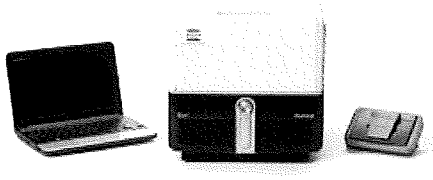
Free 7-Day Trial

Full-Featured, Open Platform

- Delivers high-precision (< 0.167 SD Cq)
- Provides sensitive fluorescence detection down to a single copy
- Delivers ±0.1°C well-to-well uniformity
- Supports most popular real-time PCR chemistries (calibrated for SYBR, FAM, HEX, VIC, ROX, and Cy5 dyes
- Real-time applications include:
  - ✓ Absolute quantification by standard curve
  - ✓ Relative quantification using ΔΔCq method with support for multiple reference gene normalization
  - ✓ Allelic discrimination by end-point fluorescence
  - ✓ SNP genotyping, mutation screening and methylation analysis by High-Resolution Melt (HRM) curve analysis

Learn about the Science »

High-performance Real-Time PCR System includes:



- Eco instrument
- Netbook computer pre-installed with Eco software and HRM module
- USB flash drive with Eco software
- Eco sample loading dock
- Starter pack of 10 plates, 40 seals, and one Evaluation Kit

US Price: **Only $13,900.00!**

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Specifications

ILLUM-0838

Instrument	
Thermal system	Single Peltier-based system

Block format	48-well block
Consumables	48-well Eco plates and optical Eco adhesive seals
Accessories	Eco sample loading dock
Sample volumes	5–20µl validated (optimized for standard 20µl protocols)
Average block ramp rate	5.5°C/sec
Temperature range	35–100°C
Temperature uniformity	± 0.1°C
Optical system	LED excitation (452–486 nm and 542–582 nm), four emission filters (505–545 nm, 562–596 nm, 604–644 nm, and 6€ 705 nm) and CCD camera
Calibrated dyes at shipment	SYBR, FAM, HEX, ROX, Cy5: factory-calibrated. Additional dyes within wavelength range of Eco filters are supported w no additional calibration required for implementation
Data collection	Data collected in all four filters for all wells regardless of plate setup; plate setup for data analysis can be altered aft run completion. Melt curve analysis supports continuous data acquisition in a single channel, providing increased data point collectio and reduced run times
Real-Time PCR run time (40 cycles)	Less than 40 minutes
Electrical	Voltage: 120VAC=10% Nominal current draw: 8A Frequency: 50/60 Hz=1% Peak Power 500VA, typical power is 180VA
Software	Eco System Software supports all chemistries and a variety of applications, including absolute quantification, relative quantification, allelic discrimination, and high resolution melt curve analysis (HRM)
Warranty	12-month warranty (includes parts and labor)

Instrument Physical

Instrument dimensions	12.6" closed (height) 14.5" open (height) 13.6" (depth) 12.2" (width) 32 cm closed (height) 36.8 cm open (height) 34.5 cm (depth) 31 cm (width)
Weight	30 lbs (13.6 Kg)

Performance

Sensitivity	1 copy
Dynamic range	9 logs linear range
Precision	Discriminates 5,000 and 10,000 template copies with 99% confidence

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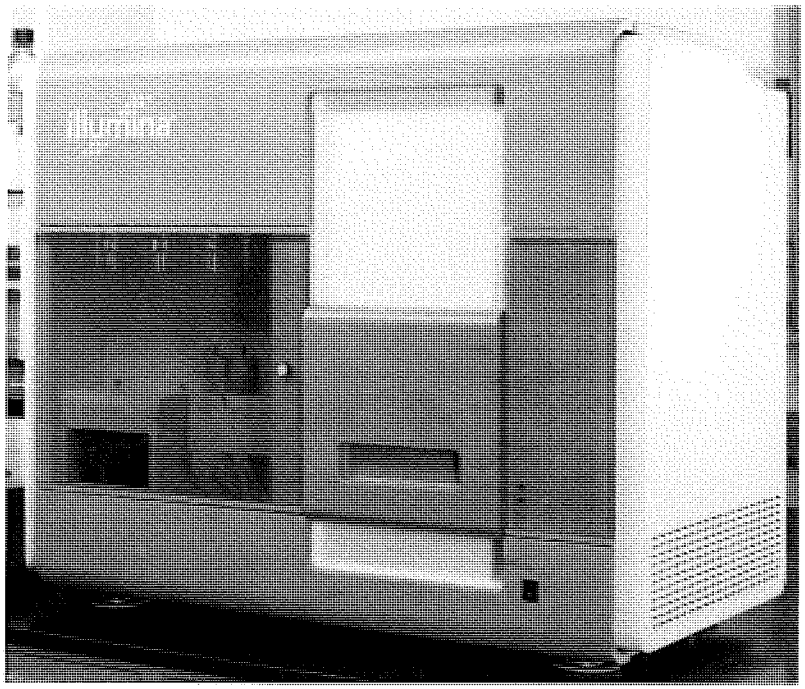

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making sense out of life

genotyping

SNP (single nucleotide polymorphism) genotyping is the process of determining which point mutations are present in each of the two copies of a gene or other portion of DNA sequence within a human or model organism. The use of genotyping analysis to obtain meaningful statistics on the impact of a single SNP or set of SNPs on individuals and population segments will require billions of tests or assays. Test scales may require, for example, 100,000 assays per individual for 1000 or more individuals involved in typical clinical trial.

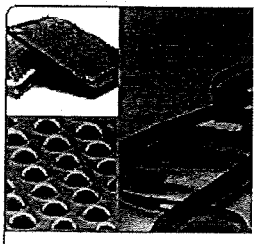
Large scale SNP genotyping, when commercially feasible, will be used for a variety of applications, including genomics-based drug development, clinical trial analysis, disease predisposition testing, and disease diagnosis. SNP genotyping can also be used outside of healthcare, for example in the selection and breeding of plants and animals with desirable commercial characteristics. These markets will require billions of SNP genotyping assays.

Our First Offerings

Illumina has partnered with Applera's Applied Biosystems Group to develop integrated solutions for high throughput SNP genotyping. The offering will include disposable Bead Array cassettes, reagent kits, instruments and related software.

SNP Genotyping Services

Our BeadArray™ platform and an advanced LIMS environment provide high throughput, accuracy and control to lower your genotyping cost per [illegible] [illegible] information



Illumina is developing a high-t SNP genotyping application.

NEWS & HIGHLIGHT

Interested in high volume supply of oligonucleotides?

We're always looking for qualified p

Background on genetic variation

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CUSTOM DNA SYNTHESIS

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services: genomic services with solexa sequencing technology

Even without a platform commitment, you can leverage the power of Solexa sequencing technology through our Illumina's Genomic Services. With years of experience delivering high-quality service, we offer a range of consultative and analytical capabilities, which can be tailored to meet your needs. Our proven track record of successfully executing high-value projects, and the access we provide to a team of seasoned professionals, will make using sequencing-by-synthesis technology convenient and affordable. Rely on Illumina's Genomics Services group to design and complete your projects in record time and at costs that no other technology can match.

applications offered

- Candidate gene and region resequencing
- Bacterial DNA resequencing
- Digital expression profiling
- Small RNA discovery

If your application of interest does not appear on the list, please contact us. We can often work with you to design the appropriate protocols and processes to handle your application.

The Genomics Services group can provide you with assistance across your entire workflow:

- Consultation on experimental design
- Sample preparation and QC
- Cluster generation
- Sequencing-by-synthesis using the Illumina Genome Analyzer
- Data analysis and bioinformatics consultation

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EXHIBIT B

(PART II OF II)

OF

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-25°C

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Label PN: 15010460.C

Patent Numbers: 7,057,026, 7,414,116, 7,427,673, 7,541,444, 7,592,435

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For MSDS information, please visit www.illumina.com/msds.

www.illumina.com

genetic energy™ inside

VeraCode® Universal Bead Set-5632
REF VC-910-5632
LOT 6187507-5632
LOT 6187507-5632
6 x 96 Samples
2012-06-21
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-25°C
For Laboratory Use
illuminaDx
2012-06-21
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San Diego, CA 92121 USA
Label P/N: 15007291 B
-25°C
For Laboratory Use
illuminaDx

Whole-Genome DASL® HT DAP- 24 Sample

BAG.DAP WG-DASL HT,HT12,v4,24

REF 15014439

LOT 12345678

Use in Pre-PCR Area Only

YYYY-MM-DD

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Label PN: 15018201.A

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Whole-Genome DASL® Assay Kit (96-Sample)

BOX.WG-DASL w/UDG, PRE.1 MCS3, 96

REF 15004150

LOT 1234567

Use in Pre-PCR Area Only

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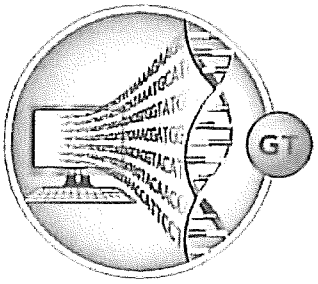
GenomeStudio™ Genotyping Module v1.0 Application & Documentation

Part # 11319324



CONTENTS

- GenomeStudio Framework Application
- GenomeStudio Framework Documentation
- GenomeStudio Genotyping Module Application
- GenomeStudio Genotyping Module Documentation

ILLUMINA PROPRIETARY

illumina®

Illumina® FastTrack Genotyping Services

Experience personalized service, industry-leading data quality, and guaranteed turnaround time with Illumina's FastTrack Genotyping Services for a wide range of SNP genotyping projects.

"Overall, our experience working with Illumina has been simply outstanding. The scientific and service staff of this organization are highly talented and committed individuals... The staff of Illumina went well beyond the normal service requirement in order to maximize information yield on these samples."

—PETER K. GREGERSON, M.D., Center Head, The Robert S. Boas Center for Genomics and Human Genetics

At Illumina, we work collaboratively with you to achieve your research objectives. Using Illumina's cutting-edge SNP genotyping technology, our in-house geneticists have consistently provided on-time, reliable genotyping services to academic and pharmaceutical customers since 2002. In collaboration with our customers, we have provided data for the study of many diseases through services projects, from various cancers to diabetes and schizophrenia. Using Illumina's FastTrack Services gives you the same competitive advantages as our installed base of customers: the ability to conduct whole-genome association studies, DNA copy number studies, linkage analysis, and fine mapping studies in a timely fashion at a reasonable cost.

In addition to the benefits you can realize by outsourcing your discovery efforts, you will also appreciate the professional design assistance and collaborative approach Illumina has proudly delivered since program inception. We highly value the quality outcome of your projects as much as your experience working with us.

KEY HIGHLIGHTS OF PAST PERFORMANCE

- **Infinium® Service Projects:**
  Sample Success Rate: 99.5%
  Call Rate: 99.89%
- **GoldenGate® Service Projects:**
  DNA Success Rate: 97.6%
  Call Rate: 99.75%

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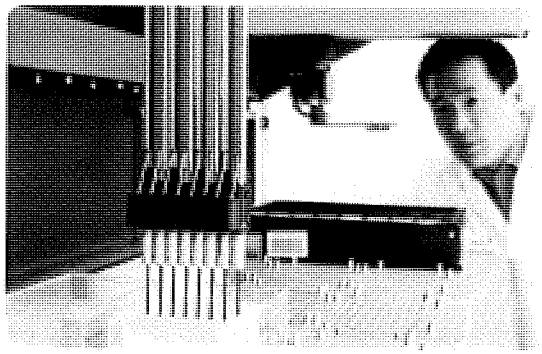
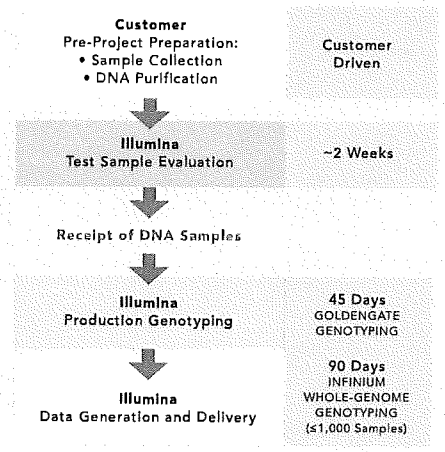
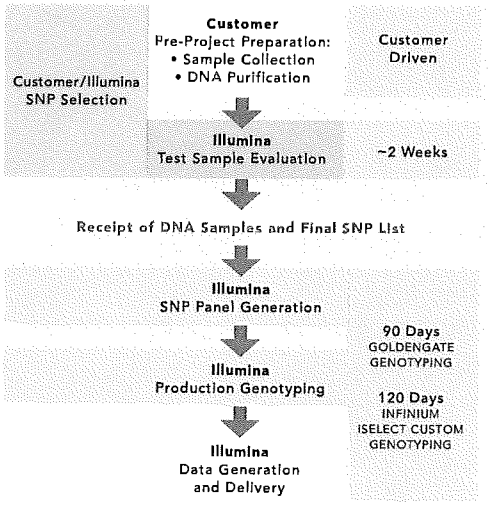


STANDARD PANEL GENOTYPING PROJECT TIMELINE



CUSTOM PANEL GENOTYPING PROJECT TIMELINE



PERSONALIZED SERVICE WITH DEDICATED EXPERTS

- An expert molecular geneticist project manager assigned to each project
- Project completion and success ensured with guaranteed fast delivery
- Intensive customer engagement with proven process flow driven by best practices
- Each project dataset reviewed and QC'd by the services group
- Every sample and every SNP locus assigned a quality score
- Streamlined custom SNP selection from an up-to-date database of >1 million validated SNP markers
- Final annotated SNP lists specified with expected assay conversion rates

RELIABLE, PROVEN, FAST, AND ROBUST PROCESS

- Over 200 projects between 2002 and 2006, all delivered on time
- Guaranteed delivery date, with average study turnaround time <90 days
- Over 200,000 DNA samples genotyped, with nearly 100% success
- World-class Illumina BeadLab environment capable of generating over 75 million genotypes per day
- Expertise with large datasets—over 1 billion genotypes delivered for a single customer project
- Fully integrated custom Laboratory Information Management System (LIMS) tracking from sample input to data output and analysis
- Barcoded plates sent to customers to ensure accurate sample tracking
- Streamlined process for safe and secure dry ice sample shipment

INDUSTRY-LEADING DATA QUALITY

- Consistently impressive results from best-performing genotyping products, quality-driven processes, and professional expertise
- Maximal information value at every locus
- Illumina control samples included on every sample plate for extensive real-time QC and data review in LIMS environment
- Low sample input requirements

COMPREHENSIVE STUDY TYPES

- Industry's most flexible and comprehensive portfolio with Infinium and GoldenGate assays
- Standard and custom content
- Whole-genome and fine mapping studies
- Scalable multiplex levels—from 384 custom SNPs to 1 million standard SNPs per assay
- Wide sample size range—from 300 to several thousand
- Tag SNP selection available for any combination of the four HapMap populations
- All organisms supported; extensive experience with organisms such as human, cow, pig, chicken, mouse, dog, and corn
- Seamless transition to follow-on projects—from Infinium Whole-Genome Genotyping to iSelect Custom Genotyping, and then to targeted panels with Custom GoldenGate Genotyping—all with the same trusted team, quality data, and LIMS-driven process

SUMMARY

Take advantage of Illumina's full menu of FastTrack Genotyping Services. Our highly experienced FastTrack Project Managers are committed to working collaboratively with you from beginning to end, to ensure the highest quality data and fast turnaround. Enjoy the benefits of innovative technologies and personalized service from the genotyping market leader.

INFINIUM WHOLE-GENOME GENOTYPING PAST PERFORMANCE*

(Based on all contracts between January and September 2006 >11,500 BeadChips and 3.5 billion genotypes)

Infinium Service Projects	Average
Sample Success Rate	99.47%
Locus Success Rate	99.11%
Call Rate	99.89%
Reproducibility	99.99%
Heritability (Trios)	99.98%

* Performance for individual studies varies and depends on the DNA quality of the samples submitted and the quality of the SNPs selected

GOLDENGATE PAST PERFORMANCE*

Based on all contracts between January 2005 and June 2006 (>150,000 individual DNA samples from 100 projects)

GoldenGate Service Projects	Average
Custom Assay Development Success	
- Human only	92.8%
- All species	91.2%
DNA Success Rate	97.6%
Call Rate	99.75%
Reproducibility	>99.99%
Heritability	>99.99%

* Performance for individual studies varies and depends on the DNA quality of the samples submitted and the quality of the SNPs selected

NUMBER OF LOCI ASSAYED AND TURNAROUND TIME REQUIRED FOR FASTTRACK GENOTYPING SERVICES TO PROCESS STANDARD AND CUSTOM PANELS

Standard Panels	Number of Loci	Guaranteed Turnaround Time
GoldenGate Genotyping	~30–6000	45 days[1]
Infinium Whole-Genome Genotyping	300,000–1,000,000	90 days[1,2]
Custom Panels		
Custom GoldenGate Genotyping	384–8,000+	90 days[3]
Infinium iSelect™ Custom Genotyping	7,600–60,800	120 days[3]
Infinium Semi-Custom HumanHap300-Duo+ Genotyping	7,600–60,800[4]	120 days[2,3]
Infinium Semi-Custom HumanHap550+ Genotyping	7,600–121,600[5]	120 days[2,3]

[1] From DNA sample submission
[2] For up to 1,000 samples
[3] From date of final SNP list and DNA sample submission
[4] Add 7,600–60,800 custom loci to standard 300,000 loci per sample
[5] Add 7,600–121,600 custom loci to standard 550,000 loci

ORDERING INFORMATION

FASTTRACK GENOTYPING SERVICES STANDARD PANEL PROJECTS

CATALOG #	Product	Number of Loci	DNA Required per Sample (µg)	Volume Required per Sample (µl)
	Infinium Whole-Genome Genotyping Standard Panel Service Project			
FT-20-101	HumanHap300-Duo Genotyping BeadChip	>300,000	3	60
FT-20-102	HumanHap240S-Duo Genotyping BeadChip	>240,000	3	60
FT-20-104	HumanHap550 Genotyping BeadChip	>550,000	3	60
FT-20-105	HumanHap650Y Genotyping BeadChip	>650,000	3	60
FT-20-106	HumanHap450S DNA Analysis BeadChip	>450,000	3	60
FT-20-107	Human1M DNA Analysis BeadChip	>1,000,000	3	60
FT-20-108	HumanCNV370-Duo DNA Analysis BeadChip	>370,000	3	60
FT-20-111	HumanLinkage-12 DNA Analysis BeadChip	>6,000	1.5	30
FT-20-109[6]	BovineSNP50 Genotyping BeadChip	>50,000	1.5	30
FT-20-110[6]	CanineSNP20 Genotyping BeadChip	>20,000	1.5	30
FT-20-113[6]	CVDSNP60 Genotyping BeadChip	>60,000	1.5	30
FT-10-101	**GoldenGate Genotyping Standard Panel Service Project**			
	Linkage V Panel	6,056	4	80
	Mouse LD Linkage	377	2	40
	Mouse MD Linkage	1,449	2	40
	MHC Panel Set	2,360	4	80
	MHC Mapping Panel	1,293	2	40
	MHC Exon-Centric Panel	1,228	2	40
	Cancer SNP Panel	1,421	2	40

[6]These products are currently available for ordering, but will not be in use until late 2007

FASTTRACK GENOTYPING SERVICES CUSTOM PANEL PROJECTS

CATALOG #	Product	Number of Loci	DNA Required per Sample (µg)	Volume Required per Sample (µl)
FT-15-101	**Custom GoldenGate Genotyping Project**	up to 1,536	2	40
		1,632–4,608	4	80
		4,704–9,216	6	120
FT-25-101	**Infinium iSelect Custom Genotyping Project**	7,600–60,800	1.5	30
FT-25-102	**Infinum Semi-Custom HumanHap300-Duo+ Genotyping Project**	7,600–60,800[7]	3	60
FT-25-103	**Infinium Semi-Custom HumanHap550+ Genotyping Project**	7,600–121,600[8]	3	60

[7]Add 7,600–60,800 custom loci to the standard 300,000 loci per sample on the HumanHap300-Duo Genotyping BeadChip
[8]Add 7,600–121,600 custom loci to the standard 550,000 loci on the HumanHap550 Genotyping BeadChip

ADDITIONAL INFORMATION

Please visit www.illumina.com

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Customer Solutions
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1.858.202.4566 (outside the U.S.)
techsupport@illumina.com
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Pub. No. 370-2006-025 21Jul07

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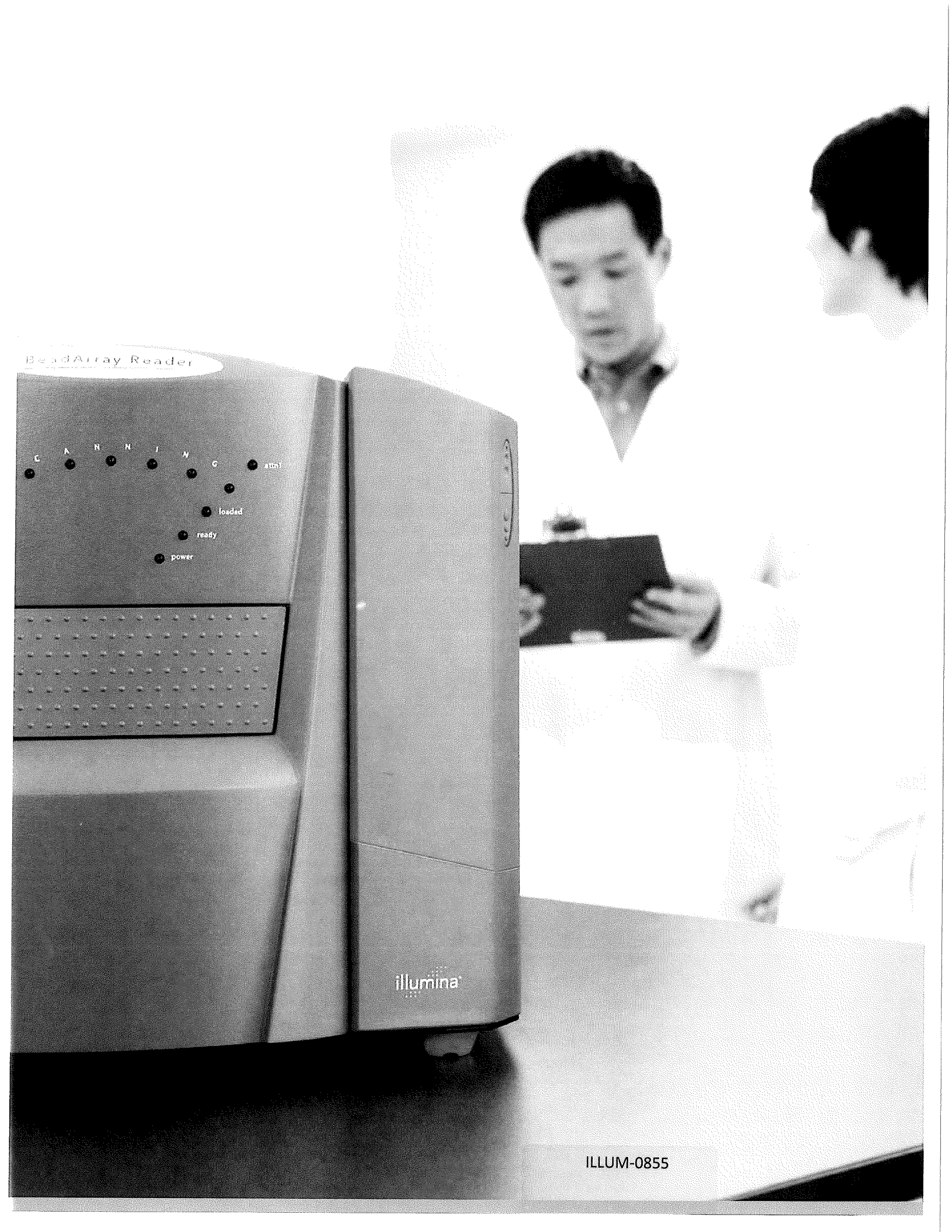
illumina® Product Guide 2006-07


BeadArray Reader
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Whole human genome sequencing services without compromise.

It's Tru. The most uniform coverage.

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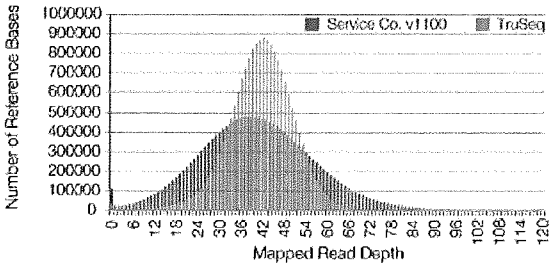

OVERVIEW HIGH-QUALITY DATA PARTNERS SERVICE DETAILS GET A QUOTE PUBLICATIONS

The Illumina Genome Network

The Illumina Genome Network links researchers interested in conducting large whole human genome sequencing projects with leading institutes worldwide that provide highly economical and rapid turnaround access to Illumina sequencing. Consisting of CSPro-certified organizations with proven expertise in generating high-quality, economical human genome data, the Illumina Genome Network enables researchers to complete their genome sequencing projects rapidly and confidently. Highest quality data with fast turnaround times: that is the promise of the Illumina Genome Network.

Entrust your study to some of the most recognized names in sequencing, all of whom rely upon the trusted and proven Illumina technology platform. Leverage their expertise to get fast access to comprehensive whole-genome assemblies, including:

- High quality variant calling of single nucleotide polymorphisms (SNPs) and insertions and deletions (Indels)
- Ability to identify Copy Number Variations (CNV) and other structural rearrangements
- Access to a comprehensive set of in-house and third-party analysis tools designed to support the system with the largest installed base in the industry
- Ability to reanalyze data sets over time

You can choose your Illumina Genome Network partner and create service packages based on your individual study requirements. Flexible turnaround times and a range of value-added services are available to meet the unique needs of every study. It's a quick and reliable way to get your sequencing study started on the Illumina sequencing technology platform.

GET A QUOTE

Whole Human Genome Sequencing Services Brochure
Illumina Genome Network Data Sheet
Technical Note-Leveraging Whole Human Genome Sequencing in Cancer

Life Sciences | **Personal Sequencing** | Diagnostics
ようこそイルミナ株式会社へ 中文网站

Applications	Systems	Services	Science	Support	Company
Sequencing	HiSeq 2000	Genome Network	Publications	Product Documentation	Careers
GWAS	HiSeq 1000	FastTrack Services	Researchers	Product Literature	Contact Us
SNP Genotyping & CNV Analysis	Genome Analyzer IIx	CSPro	Technology	Software	Events
Gene Regulation & Epigenetic Analysis	MiSeq	Core Labs	iCommunity	BaseSpace	About Us
Gene Expression Analysis	HiScanSQ	Service Partnerships	Webinars	FAQs	Newsroom
	iScan	Illumina Financial Solutions		DesignStudio	Investor Relations
	BeadXpress			Assay Design Tool	Privacy
	Eco Real-Time PCR System			Product Files	Legal
					California Transparency

ILLUM-0959

Protein Analysis
Real-Time PCR
Agrigenomics
Cytogenetics
Cancer Genomics
Software
BaseSpace
Illumina Connect
Eco Real-Time PCR Support
Customer Service
Training
In Supply Chain

Innovative technologies
At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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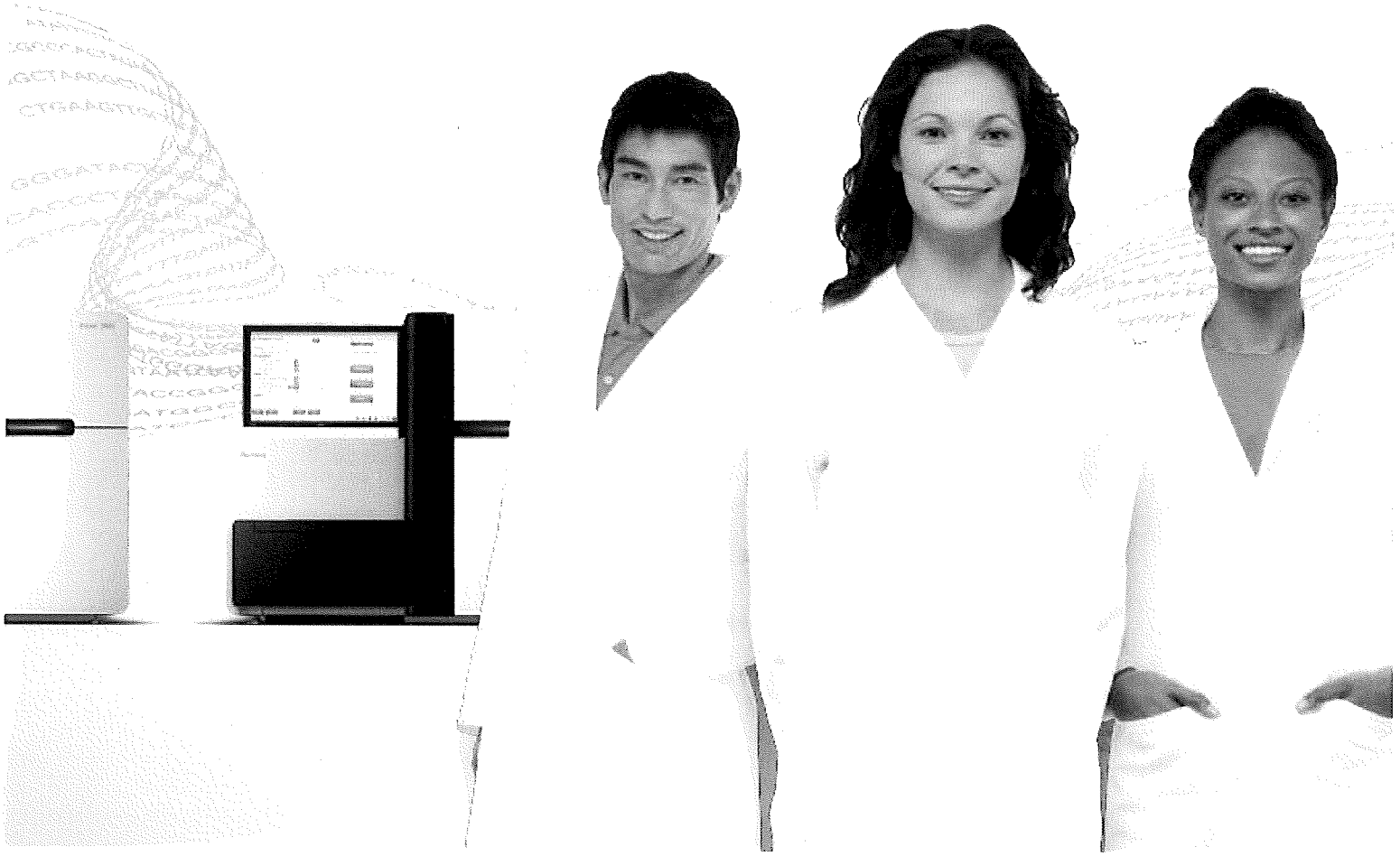
Whole human genome sequencing services.

Powered by TruSeq®.

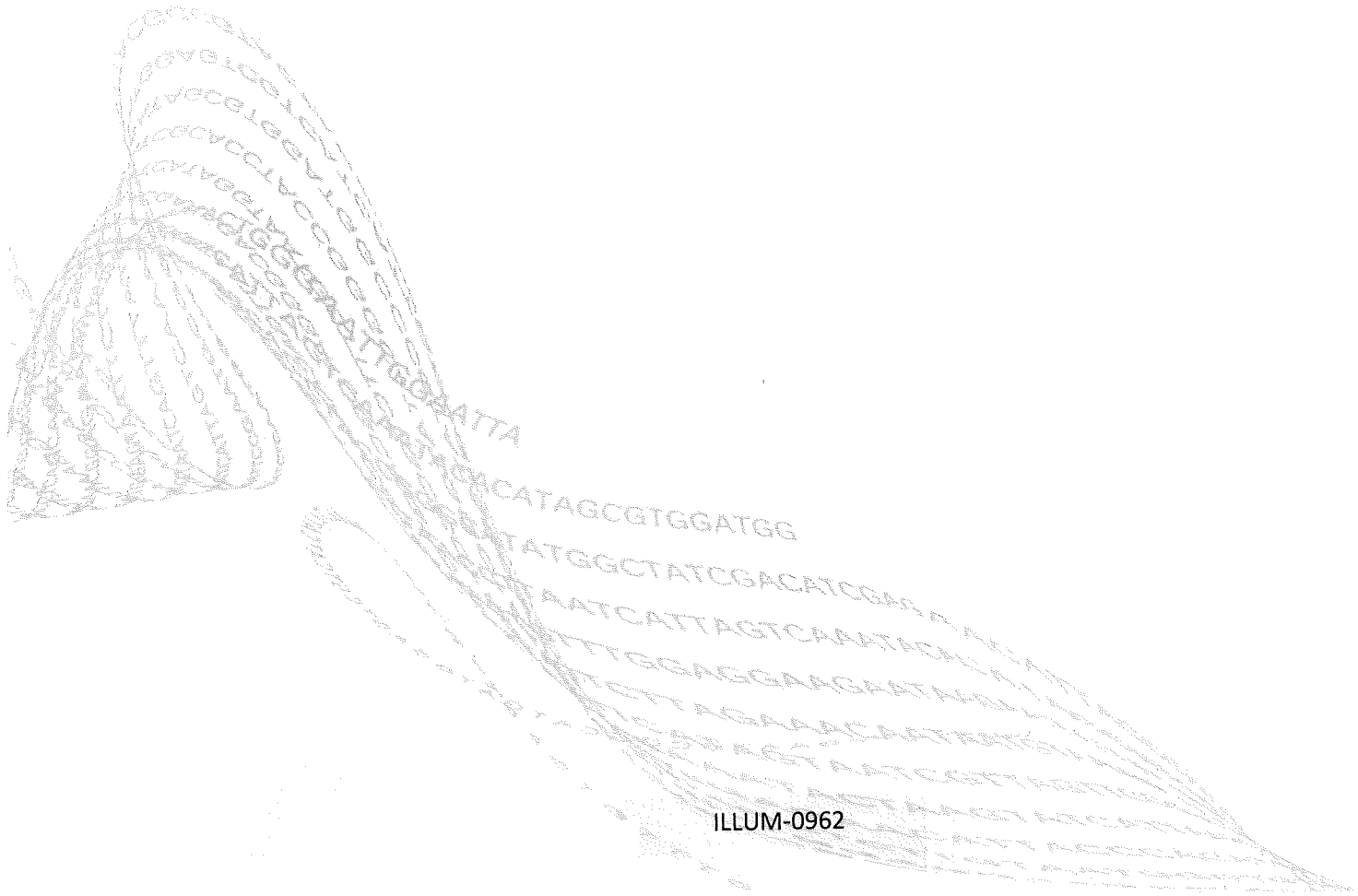


illumina®

Now is the time to take your research further. Faster.

As whole human genome sequencing becomes more accessible, the ability to study the entire genome accelerates opportunities for discovery. Fueling a new generation of genomic studies.

Only Illumina offers access to the most accurate, most complete whole human genome sequencing data. Giving you the clearest picture of the genome. Empowering your research like never before.



The only complete research solution.

You've got the samples, but not the dedicated resources or time. You need an experienced service partner to perform whole human genome sequencing to advance your studies.

Illumina offers the only end-to-end research solution, with guaranteed access to industry-leading TruSeq technology through our sequencing platforms, network of partners, and our own FastTrack Services. From discovery to validation, we provide support for every step of your project.

Once your whole human genome sequencing project is complete, we'll help you with follow-on studies. Whether it's targeted exome sequencing, SNP discovery, or RNA-Seq, you'll get the in-depth genomic information you need to accelerate your research.

And since your data will be delivered in the format most compatible with popular analysis tools, you can easily continue with any secondary studies of your own.

Our network of partners with one focus—to perform whole human genome sequencing projects on Illumina systems.

Our CLIA-approved and CAP-accredited in-house services, offering sequencing and genotyping.

Certified service labs producing validated Illumina data.

Whole human genome sequencing services. Without compromise.

When you use the Illumina Genome Network, you get the highest data quality with the fastest turnaround, to decrease your time-to-publish. All of your data is delivered in industry-standard format to streamline collaborations and allow integrated follow-on studies. And everything is completed at a competitive price, so you can sequence more samples for less.

The Illumina Genome Network delivers the following key analysis results and metrics:

- **Sequence data:** Aligned and non-aligned reads in archival BAM format
- **Variant information:** SNP, indel, CNV, and SV (e.g., large insertion, large deletion) variant calls in VCF format
- **Sample report:** Summary of sample and genome quality metrics in PDF format
- **SNP concordance:** All genotyping and WGS data files are provided (Figure 1)

Greater confidence in results.

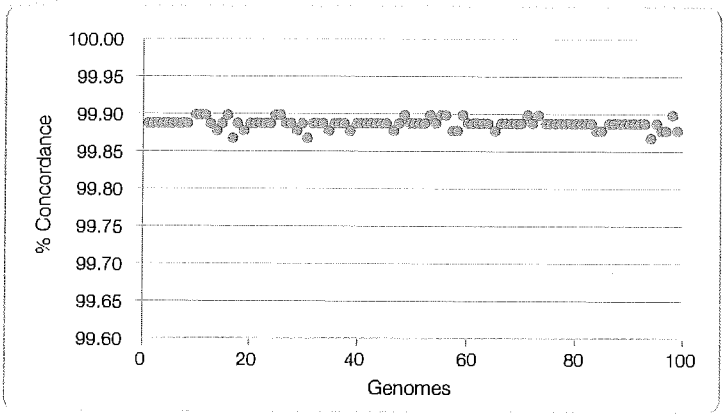


Figure 1. Independent confirmation with HumanOmni 2.5 BeadChip shows SNP concordance > 99% for every sample.

Proven TruSeq technology. Most accurate genome at any coverage.

Illumina platforms make up the largest installed base of next-generation sequencing systems worldwide—referenced in over 2,100 peer-reviewed publications, and counting. They're the most trusted and widely adopted for a reason: our proven TruSeq technology, delivering the highest data accuracy in the industry for variant calling (Figure 2).

Whole-genome sequencing involves more than obtaining high coverage depth and quality reads. That's why we run each base pair through a usable genome test (Figure 3), resulting in the highest callable genome with quality scores of Q30 or more on > 80% of all reads passing filter. This holds true even within the difficult-to-sequence regions of the genome.

Highest accuracy. More usable data.

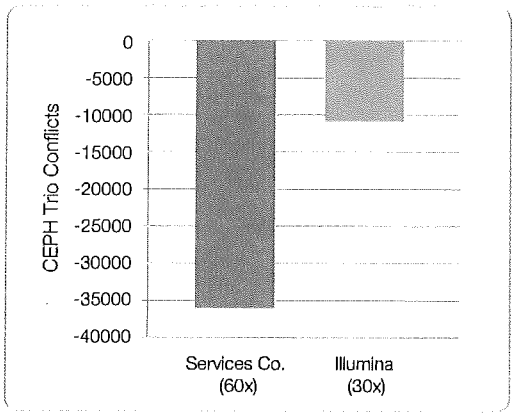


Figure 2. Services Co. data contains over 35,000 consensus conflicts or errors within the genome.

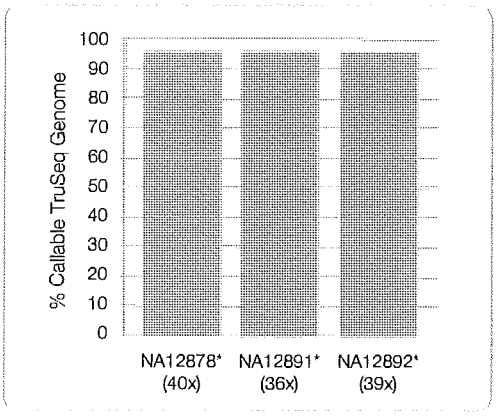


Figure 3. More usable data: > 95% of the NCBI reference genome.

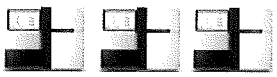
*Sequencing performed on an Illumina HiSeq system.

Guaranteed access to the highest quality data.

It's easy to secure the most accurate, research-ready data that meets your needs, budget, and timelines. Whether you own an Illumina system or use our sequencing services, your research will always be powered by TruSeq.

TruSeq

Accessing the TruSeq genome.



HiSeq® systems—used for the largest and most complex sequencing studies.

Whole human genome sequencing service.

Illumina sequencing and genotyping services.

Certified service labs producing validated Illumina data.

Perform your next whole human genome sequencing study with Illumina.

Learn more at
www.illumina.com/WGS

Illumina Genome Network

FastTrack SERVICES FROM ILLUMINA

Illumina CERTIFIED SERVICE PROVIDER CSPro

Learn more at www.illumina.com/services

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ILLUM-0968

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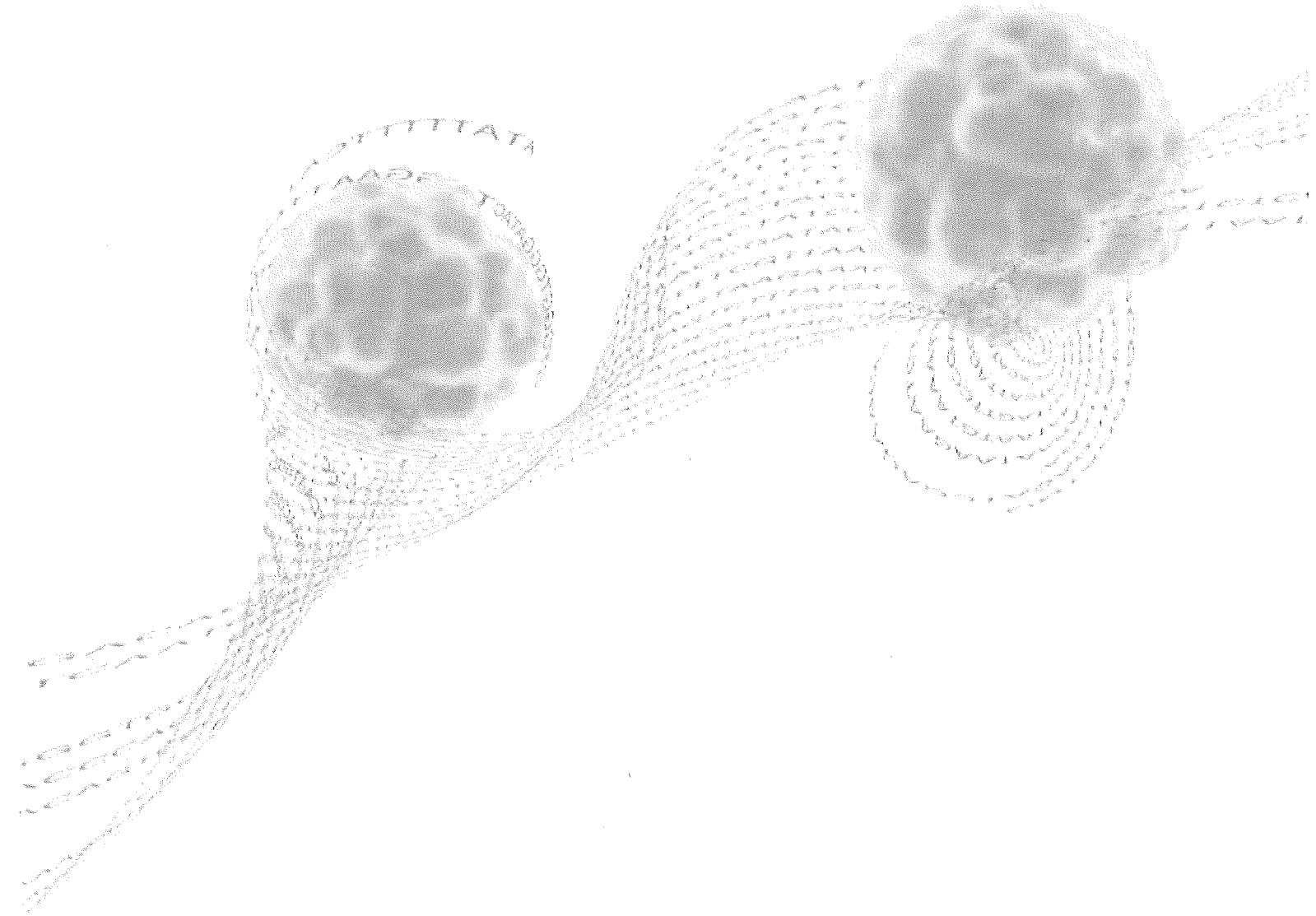
Cancer Genomics

Transforming our understanding of cancer



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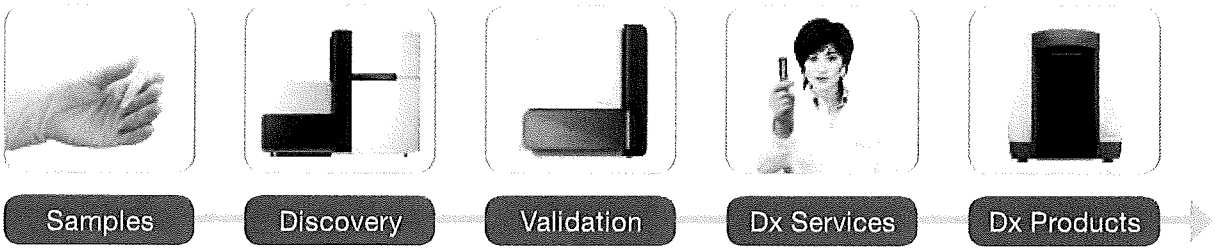
Accelerating translational medicine.

Technology enhances understanding. Drives discovery.

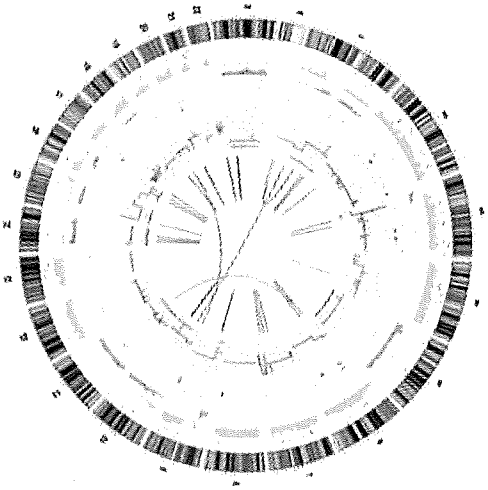


Illumina's cancer discovery initiative.

Our belief in the power of Illumina technology is so strong that we work side by side with researchers to obtain samples for our cancer discovery work. Using whole-genome sequencing, we are exploring how biomarker discovery can lead to early detection, resistance to therapy, and prognosis in ovarian, gastric, and colorectal cancer. Discovering how analyzing subtle changes in genes and chromosomes will change diagnostics forever. Ultimately leading to novel diagnostic services and products as shown in the continuum above.

Illumina's clinical services lab.

Innovative. Comprehensive. The first choice for doctor-ordered Individual Genome Sequencing services. The first to generate a complete human sequence in a clinical laboratory. Fully CLIA-certified and CAP-accredited for high-complexity molecular testing.



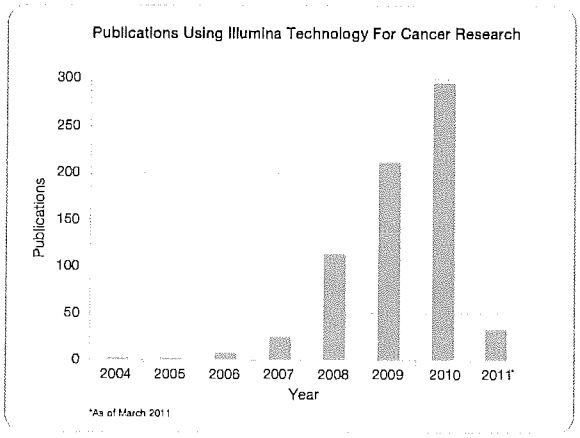
When taking a genome-wide approach to cancer, researchers can use a circus plot to visualize the extensive rearrangements and variations that are common to cancer. This plot shows variations found in a melanoma cell line, marking each chromosome on the outside ring, then showing validated indels, density of substitutions, coding substitutions, copy number variants, loss of heterozygosity, to reveal the intrachromosomal and interchromosomal structural variants in the middle of the plot

Empowering cancer research.

Sequencing. Microarrays. Real-time PCR. Technology is fueling a new era of cancer discovery and validation.

The growing Illumina community is a part of this revolution. Taking advantage of simplified workflows and streamlined platforms. Advancing research. Increasing our understanding. Publishing results.

The Illumina community is discovering more. Publishing more.



2008

- First publication describing whole-genome sequencing on human cancer[1]
- Accurate human whole-genome sequencing using reversible terminator chemistry[2]

2009

- Demonstrates the power of second-generation transcriptome sequencing for identifying rearrangements in coding genes[3]
- The largest collection of samples (24) for a single cancer type to be whole-genome sequenced, documenting large sample-to-sample variability[4]

2010

- Next-generation sequencing technology provides new insights into the mechanisms of cancer progression and a greater understanding of diagnosis and treatment options[5-7]

2011

- Discovery of causative gene mutations for a rare skin cancer condition[9]

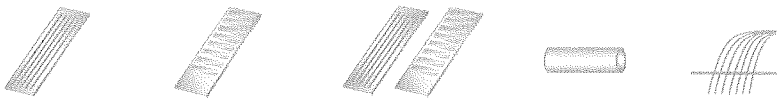
Transforming diagnostics.

New technologies. New discoveries. New hope. With innovation, insight, and commitment, the Illumina community is leading the way toward a brighter future in cancer diagnostics, therapy, and personalized treatment.

- New developments provide hope for earlier detection and better prognoses
- Novel biomarkers may lead to future treatments tailored to an individual's genetic disposition
- Individual Genome Sequencing services provide genetic information that will facilitate clinical decision making in cancer and medicine

Learn more about Illumina at www.illumina.com/cancer

Comprehensive cancer research portfolio



	Next-Gen Sequencing	Next-Gen Genotyping	Sequencing + Arrays	Multiplexed Analysis	Real-Time PCR
Find Structural Variation					
CNV Screening	■	+	+		•
CNV Discovery	■	+	+		
Detect Chromosomal Rearrangements					
Breakpoint Mapping	■		■		
Insertions, Deletions, and Translocations	■	+	+	+	•
Characterize Epigenetic Changes					
DNA Methylation Biomarker Panels		•	•	+	•
DNA Methylation Discovery	■		■		
ChIP-Sequencing (DNA-Protein Binding)	•		•		
Changes in Transcription Factor and Histone Binding	•		•		
Identify Variants in Gene Regions					
Whole-Genome Genotyping	■	+	+		
Custom/Focused Genotyping	+	+	+	+	•
SNP Discovery	■		■		
Whole-Genome Resequencing	■		■		
Exome Resequencing	■		■		
Custom Targeted Resequencing	■		■		
Custom Amplicon Resequencing	■		■		
Profile Gene Expression					
Whole-Genome Expression	+	+	+		
Focused Gene Expression					•
MicroRNA and Small RNA Profiling	+		+		•
MicroRNA and Small RNA Discovery	+		+		

• Illumina-supported intact samples
+ Illumina-supported intact and degraded (FFPE) samples
■ Customer-demonstrated intact and degraded (FFPE) samples

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The BeadXpress System is FDA cleared for use as an in vitro diagnostic only with FDA cleared VeraCode tests.
The Illumina Eco Real-Time PCR System, Infinium HD BeadChips, HiSeq Systems, and HiScan Systems are **FOR RESEARCH USE ONLY.**

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ILLUM-0972

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Genome-Wide DNA Analysis BeadChips

Illumina has created a comprehensive portfolio of DNA Analysis tools by deploying industry-leading content on multi-sample Infinium® HD BeadChips. Unmatched power provides researchers the fastest path to discoveries and publication.

Infinium HD Beadchip Highlights

- **Proven Content:** Publish with confidence using a foundation of well-validated assays and markers
- **Powerful Cytogenetics:** Get high-resolution analysis with dense and uniform marker spacing with minimal gaps
- **High Density:** Assay nearly 1.2 million loci per sample
- **Multi-Sample Format:** Increase sample throughput to finish projects faster
- **Low Sample Input:** Interrogate limited sample sources, down to 200 ng of DNA per sample

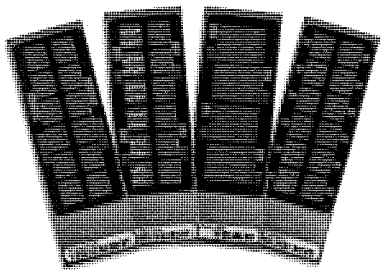
Comprehensive Analysis Platform

Illumina is a leader in the field of genetic analysis with innovative tools for DNA analysis, RNA analysis, and high-throughput sequencing. With the newest generation of high-density Infinium HD products, Illumina continues to provide the most comprehensive and powerful family of DNA Analysis BeadChips, taking genotyping and copy number variation (CNV) analysis to the next level.

Infinium HD technology expands the limits of density to provide industry-leading multiplexing in multi-sample formats, while maintaining the high data quality and simple assay workflow common to all Illumina products. Furthermore, Infinium HD BeadChips have low DNA input requirements, expanding the range of sample sources that can be used for a study.

The Infinium HD products include the HumanCytoSNP-12, Human660W-Quad, Human1M-Duo, and HumanOmni1-Quad BeadChips (Figure 1). This family of Illumina BeadChips provides a broad spectrum of whole-genome DNA Analysis products to support a variety of experimental designs. Researchers have the flexibility to use panels of 300,000 to nearly 1,200,000 markers per sample, depending on their study goals. All of these BeadChips provide powerful and integrated genome-wide SNP genotyping and structural variant detection. The 12-sample HumanCytoSNP-12 is a streamlined whole-genome scanning panel for high sample throughput analysis of genetic and structural variation, including cytogenetic abnormalities. The powerful Human660W-Quad BeadChip has an ideal combination of high-coverage genome-wide SNP and CNV markers in a high-throughput format. The two-sample Human1M-Duo BeadChip provides comprehensive access to the genome with nearly 1.2 million markers covering genome-wide SNPs, CNV-targeted markers, and high-value functional regions. The four-sample HumanOmni1-Quad offers the best combination of power and throughput, featuring over one million strategically selected markers that deliver dense genome-wide coverage and extensive disease-associated content, including data from the 1000 Genomes Project. The unparalleled content and assay technology of Infinium HD BeadChips provide the fastest path to discoveries and publication.

Figure 1: Infinium HD Beadchips



Infinium HD BeadChips provide a broad range of powerful content options in high-throughput formats for processing two, four, or 12 samples simultaneously.

Powerful Markers

Genome-wide association studies (GWAS) rely on genotyping SNPs near a disease locus to identify genetic links to disease. As highlighted in a study from University of Michigan researchers comparing different array platforms, Illumina's marker selection strategy is demonstrably better for GWAS studies[1]. Infinium BeadChips offer benefits in terms of several critical parameters that together contribute to the statistical power in an experiment: genomic coverage, array efficiency, genic coverage, call rate, and call accuracy[2].

The power to detect an association depends on the linkage disequilibrium (r^2) between the genotyped marker and the adjacent disease-causing SNP. A high r^2 between two SNPs indicates that the two SNPs can act as good proxies (tag SNPs) for each other[3]. Because the Infinium HD Assay chemistry—like the Infinium II Assay—affords flexible marker selection, Illumina scientists are able to rationally select loci that provide the highest information content, while using fewer SNPs. Illumina has taken advantage of this flexibility by selecting powerful tag SNPs and other high-value regions for markers. A result of this strategy is that the ~300,000 markers on the HumanCytoSNP-12 provide nearly the same genomic coverage in the Caucasian (CEU) population as a competing 924,000-marker array.

Compared to microarrays with randomly selected SNP content, Illumina's DNA Analysis BeadChips offer the industry's highest statistical power per sample by reducing the correction factor for multiple testing by almost 40%. Higher power means fewer samples are needed to identify significant genetic variations. Studies can be completed faster and more economically to support rapid publication in top-tier journals (for examples, browse customer citations at www.illumina.com/publications).

ILLUM-0973

Comprehensive Coverage

Illumina DNA Analysis BeadChips provide optimized panels for surveying genetic variants[1,4]. All genome-wide Infinium DNA Analysis products start with a broad set of tag SNPs and other valuable SNPs from the International HapMap Project and NCBI's dbSNP to provide high genomic coverage and uniformity across the genome. All genome-wide DNA Analysis products also include a set of additional CNV-targeted markers designed to increase coverage of regions underrepresented by tag SNPs.

In the Illumina portfolio, individual BeadChips offer slightly different content and numbers of markers to provide flexible options for using the optimal content panel in any study design (Table 1).

HumanCytoSNP-12 DNA Analysis BeadChip Content

The HumanCytoSNP-12 BeadChip represents the most efficiency-optimized DNA Analysis content selection strategy. It includes a complete panel of genome-wide tag SNPs and additional markers targeting all regions of known cytogenetic importance.

Illumina scientists employed 200,000 "best of the best" SNPs that have the highest tagging power. This content maintains the exceptional genome-wide SNP coverage that Illumina is known for (70% in CEU at $r^2 > 0.8$) because of the efficient marker design strategy[2]. At the same time, a set of 220,000 markers provides extra utility for cytogenetic analysis. This includes dense coverage of ~250 genomic regions commonly studied in cytogenetics labs and targeted coverage in additional genes, subtelomeric regions, pericentromeric regions, and sex chromosomes[5].

Furthermore, the HumanCytoSNP-12 takes advantage of the industry's first 12-sample whole-genome BeadChip and Illumina's high-density array technology to provide the highest throughput and most cost-effective BeadChip.

Human660W-Quad DNA Analysis BeadChip Content

The Human660W-Quad BeadChip offers comprehensive genomic coverage across many populations and the majority of known variation in regions of the genome based on HapMap data.

The Human660W-Quad BeadChip builds on the content of the highly successful HumanHap550 BeadChip. The broad, evenly spaced whole-genome marker set provides high genomic coverage for powerful GWAS. In addition, the Human660W-Quad BeadChip provides 87%, 85%, and 56% coverage of CEU, CHB+JPT, and YRI populations at $r^2 > 0.8$ (Figure 2).

For equally powerful CNV and cytogenetic analysis, this dense backbone content is combined with an additional ~100,000 markers that target observed common CNVs.

The entire panel of 657,000 markers provides exceptional genomic coverage and identification of known and novel structural variants, combined with an efficient multi-sample format.

Human1M-Duo DNA Analysis BeadChip Content

With nearly 1.2 million markers per sample, the Human1M-Duo provides a powerful combination of quality, coverage, and throughput. The comprehensive set of markers on the Human1M-Duo BeadChip provides access to dense genome-wide tag SNP coverage as well as additional content targeted to high-value genomic regions of interest. Other probes are located in SNP deserts to fill in gaps.

The uniform genome-wide coverage results in a median spacing between markers of 1.5 kb (mean = 2.4 kb) and few large gaps for high-resolution CNV identification and cytogenetics analysis. Ensuring no regions are skipped, the 90th percentile largest gap between SNPs on the Human1M-Duo BeadChip is 6 kb. The result of this comprehensive design strategy is 95%, 93%, and 76% coverage of CEU, CHB+JPT, and YRI populations at $r^2 > 0.8$.

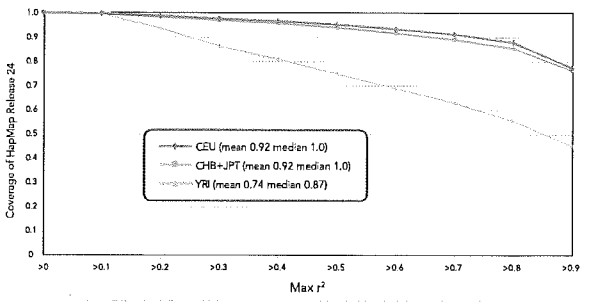
In addition to the broad coverage crucial for successful whole-genome association studies, the Human1M-Duo BeadChip targets other high-value content. Gene-centric markers selected in and around genes target both synonymous and non-synonymous SNPs to increase genic coverage. In addition, more than 10,000 markers are included for the major histocompatibility complex (MHC) region, which contains a high density of genes often associated with autoimmune and infectious diseases.

The BeadChip also features ~60,000 CNV-targeted markers, developed in collaboration with deCODE Genetics, for regions likely to contain undiscovered CNV. Novel CNV-specific probes and the dense uniform genome-wide SNP coverage support unbiased discovery and analysis of copy number polymorphisms.

HumanOmni1-Quad DNA Analysis BeadChip Content

The HumanOmni1-Quad BeadChip provides an unparalleled, extensive view of the genome, in a highthroughput, cost-effective format. A complete optimization of the BeadChip design increases the available complexity, allowing nearly five million markers to be assayed across four different samples in parallel, while reducing the amount of required DNA to 200 ng. Each BeadChip features over one million

Figure 2: Human660W-Quad Genomic Coverage



The Human660W-Quad BeadChip content covers the majority of common variation in three distinct populations. Graphs are estimated, based on the HapMap release 24 data set of > 2.3 million common SNPs.

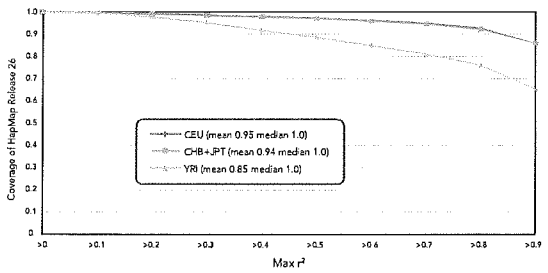
available assays per sample, containing carefully selected content that delivers dense coverage of the human genome and targets regions known to play a role in human disease. This comprehensive collection of genomic markers offers the best combination of power, price and throughput available for genome-wide association studies.

With recently released data from all three HapMap phases, intelligent tag SNP selection has been optimized to maintain comprehensive genomic coverage, while reducing SNP redundancy. This has enabled the inclusion of additional content carefully chosen to target high-value regions of the genome, such as the MHC region and new coding variants identified by the 1000 Genomes Project. The redesigned SNP selection strategy has maintained high genomic coverage rates of 93%, 92%, and 76% at $r^2 > 0.8$ for the CEU, CHB+JPT, and YRI populations, respectively (Figure 3). High density markers with a median spacing of 1.5 kb and the fewest number of large gaps for any BeadChip ensure the highest level of resolution for CNV identification in the industry.

The HumanOmni1-Quad is the only BeadChip to include cutting-edge content derived from the 1000 Genomes Project. This large international effort is dramatically increasing the information we have about genetic variation across human populations6. Already, the project has uncovered millions of rare and novel SNPs that will drive the next generation of microarrays. For the HumanOmni1-Quad, SNPs selected from the 1000 Genomes Project focus on regions already identified in GWAS to be associated with human disease. This content includes ~18,000 SNPs targeting four 1Mb regions known to be associated to three or more human diseases; over 50,000 SNPs predicted to be non-synonymous; 62,000 SNPs covering an additional 100 intervals surrounding published peak markers from the NHGRI GWAS database; and the remaining 950 top single-marker associated SNPs from the GWAS database.

With high-throughput processing, comprehensive genomic coverage and the ability to capture a vast amount of genetic variation, the HumanOmni1-Quad BeadChip lets you make more meaningful discoveries and take the fastest path to publication.

Figure 3: Humanomni1-Quad Genomic Coverage



The HumanOmni1-Quad BeadChip content covers the majority of HapMap common variation in three distinct populations. Graphs are based on the HapMap release
26 data set of > 2.3 million common SNPs.

Sensitive Structural Variant Detection

Dense Uniform Markers

An important goal during the design of Infinium HD content panels was the uniform distribution of SNP markers to create the best panels for detecting structural variation, including loss of heterozygosity. With the fewest large gaps across the whole genome, the HumanOmni1-Quad BeadChip is an ideal tool for CNV researchers to use for discovery and high-resolution breakpoint mapping (Figure 4).

Intelligent Targeted Content

Of course, some regions of the genome are naturally underrepresented by tag SNPs. Illumina scientists have leveraged the flexible Infinium Assay design to generate marker sets that provide the industry's best CNV detection panels.

The HumanCytoSNP-12 BeadChip is optimized to efficiently detect cytogenetic abnormalities that are the most relevant to human disease. Its content panel targets common regions shown to be important for cytogenetic analysis5 and a dense backbone of coverage across the remainder of the genome.

The Human660W-Quad contains a set of ~100,000 markers that are highly informative for analyzing common CNV regions. These markers were identified in a high-density screen for CNVs that occur in two or more HapMap samples, which was conducted in collaboration with The Centre for Applied Genomics at the Hospital for Sick Children in Toronto, the Wellcome Trust Sanger Institute in the United Kingdom, and Harvard Medical School/Brigham and Women's Hospital in Boston.

The Human1M-Duo features content developed in collaboration with deCODE Genetics to blanket the "unSNPable genome" with additional non-polymorphic markers[7]. This includes difficult-to-analyze regions like megasatellites and segmental duplications, which are targeted with both SNPs and non-polymorphic probes. Many of these regions have been validated with other approaches, such as TaqMan and Southern blotting, to confirm variance in copy number in several representative populations.

The HumanOmni1-Quad includes extensive high-value content focused on disease-associated regions: cSNPs, eSNPs, indels, SNPs in mRNA splice sites, miRNA binding sites, introns, promoter regions, ADME genes, disease-associated SNPs, mitochondrial DNA, AIMs, ABO blood typing SNPs, PAR, Y-chromosome, MHC region, and HLA complex. The BeadChip also provides high CNV coverage (Figure 4), featuring 5,000+ rare CNV regions in addition to all the common CNV content available on the Human660W-Quad.

CNV-targeted probes share the same rational design strategy with all SNPs. All markers on Infinium HD BeadChips have high feature redundancy, yielding low overall noise, and all markers are used for reliable and sensitive detection of changes in copy number. The consistent marker design allows all markers to be analyzed together using GenomeStudio® Software. Completely integrated genotyping and copy number studies maximize analytical efficiency[8-10].

The resulting rationally designed content on Infinium HD BeadChips supports the industry's most powerful SNP genotyping and CNV identification[3,1].

ILLUM-0975

Table 1: Comprehensive Coverage of High-Value Regions

	HUMANCytoSNP-12 v2.1	HUMAN660w-QUAD v1	HUMAN1M-DUO v3	HumanOmni1-Quad v1
Overview	**Efficient coverage for cost-effective GWAS and cytogenetic screening**	**High genomic coverage of common SNPs and CNV regions**	**Genome-wide coverage and additional high-value regions**	**Comprehensive genome-wide coverage and additional high-value regions, including new content from 1,000 Genomes Project**
Number of Markers per Sample	299,140	657,366	1,199,187	1,140,419
Number of Samples per BeadChip	12	4	2	4
DNA Input Requirement (per sample)	200 ng	200 ng	400 ng	200 ng
Scan Times per Sample (minutes)#	3	9	18	13
Genomic Coverage				
CEU (Mean / Median / r^2 > 0.8)	0.81 / 0.94 / 0.70	0.92 / 1.0 / 0.87	0.96 / 1.0 / 0.95	0.95 /1.0 / 0.93
CHB+JPT	0.83 / 0.94 / 0.73	0.92 / 1.0 / 0.85	0.95 / 1.0 / 0.93	0.94 / 1.0 / 0.92
YRI	0.55 / 0.52 / 0.32	0.74 / 0.87 / 0.56	0.86 / 1.0 / 0.76	0.85 / 1.0 / 0.76
Minor Allele Frequency*				
CEU (Mean / Median)	0.22 / 0.21	0.24 / 0.23	0.20 / 0.18	0.19 / 0.17
CHB+JPT	0.21 / 0.19	0.21 / 0.20	0.18 / 0.16	0.18 / 0.15
YRI	0.21 / 0.19	0.22 / 0.21	0.20 / 0.17	0.20 / 0.18
Spacing (kb)				
(Mean / Median)	9.7 / 6.2	4.4 / 2.3	2.4 / 1.5	2.4/ 1.2
90th %ile Largest Gap	18.7	10.6	6.0	6.4
Marker Categories				
Markers Within 10 kb of a RefSeq Gene	148,987	332,756	672,002	618,959
Non-Synonymous SNPs§	2,420	10,051	21,877	32,110
MHC† / ADME‡ / Indel SNPs	760 / 2,388 / 0	3,177 / 8,440 / 0	10,415 / 20,493 / 483	19,081 / 22,429 / 459
Sex Chromosome (X / Y / PAR Loci)	15,400 / 2,972 / 770	16,509 / 44 / 15	45,591 / 4,637 / 979	27,493 / 2,322 / 1,157
Mitochondrial SNPs	0	135	138	27

Scan times are approximations based on the iScan platform

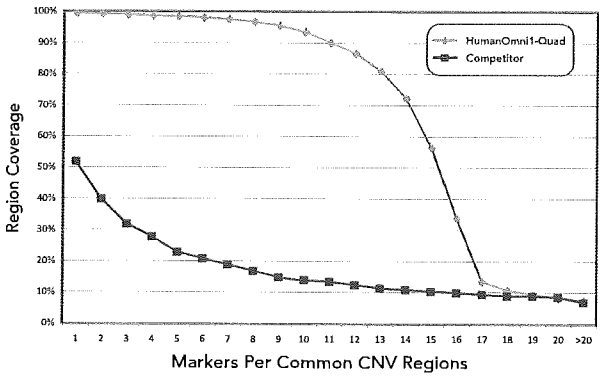
*Based on HapMap rel 24 for HumanCytoSNP-12, Human660W-Quad, and HumanOmni1-Quad, and rel 23 for Human1M-Duo

§Based on RefSeq and Ensembl databases

†As defined by de Bakker, 2006

‡Within 10 kb of 333 known ADME-related gene

Figure 4: Outstanding Coverage of Common CNVS



The intelligent marker selection used for all Illumina BeadChips results in substantially better coverage of important regions compared to greater numbers of randomly selected markers.

Custom Content Options

Illumina offers the option of adding custom-designed content to the broad genome-wide standard SNP content on the Human1M-Duo and Human660W-Quad BeadChips. The results are semi-custom Human1M-Duo+ and HumanHap550-Quad+ BeadChips. With assistance from Illumina scientists and a proprietary Assay Design Tool, researchers can include an additional panel of up to 60,800 SNPs to the powerful standard content.

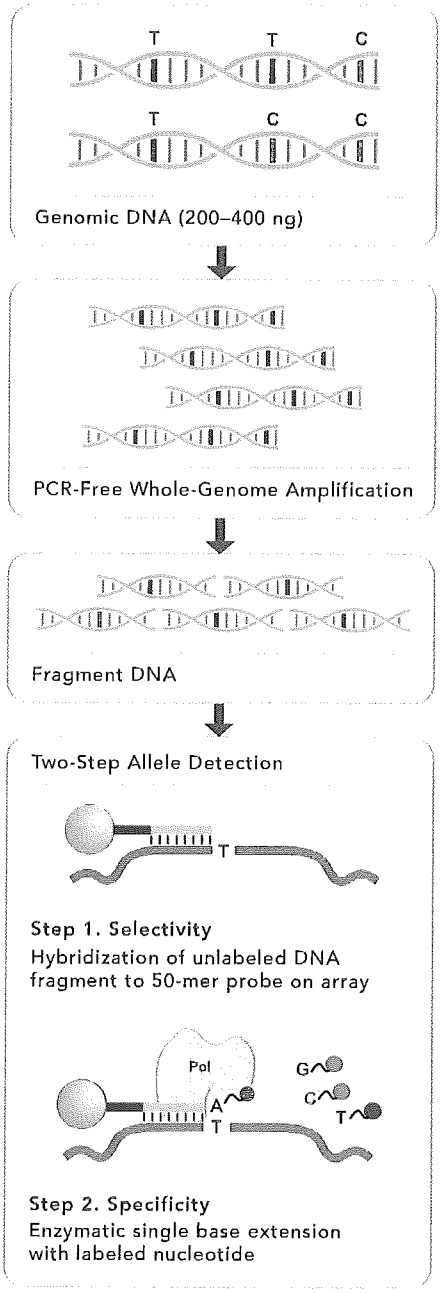
Streamlined Assay Workflow

The Infinium HD Assay can be scaled to unlimited multiplexing without compromising data quality, unlike many alternative PCR-dependent assays. The simple, streamlined workflow is common across all products, no matter how many SNPs are being interrogated. Likewise, the data acquisition process and analysis are the same.

The Infinium HD Assay protocol (Figure 5) features single-tube sample preparation and whole-genome amplification without PCR or ligation steps, significantly reducing labor and sample handling errors. After hybridizing unlabeled DNA sample to the BeadChip, two-step allele detection provides high call rates and accuracy. Selectivity and specificity are accomplished in two steps. Target hybridization to bead-bound 50-mer oligos provides high selectivity while enzymatic single-base extension provides powerful specificity. The single-base extension also incorporates a labeled nucleotide for assay readout. The staining reagent is optimized to provide a higher signal, and more balanced intensities between red and green channels. These features contribute to industry-leading accuracy, high call rates, and copy number data with lower noise.

The iScan System uses advanced optics for high-resolution detection and high-throughput readout of assay results. With this system and 12-sample BeadChips, researchers can scan each sample in three minutes (Table 1).

Figure 5: Infinium HD Assay



Multi-Sample Format

The efficient multi-sample format of Illumina BeadChips cost-effectively increases sample throughput. Reduced handling, more efficient scanning, and higher density assays contribute to higher sample throughput rates so projects are finished faster. Also, by effectively eliminating array-to-array variability, the multi-sample format is ideal for analyzing matched samples.

Low DNA Input Requirement

Infinium HD BeadChips require low quantities of input DNA, providing opportunities to use more limited sample sources (Table 1). Four- or 12-sample Infinium HD BeadChips require only 200 ng DNA per sample, and two-sample BeadChips require 400 ng DNA per sample.

High Quality Data

All of the assays on the HumanOmni1-Quad, Human1M-Duo, Human660W-Quad, and HumanCytoSNP-12 DNA Analysis BeadChips use Infinium HD chemistry. These BeadChips have undergone the same rigorous functional testing that ensures strong and reproducible performance of all Illumina products. One assessment of data quality was the analysis of a diverse panel of HapMap reference samples (Table 2). As shown in Table 2, the Infinium HD BeadChips perform extremely well, producing high call frequencies and excellent reproducibility.

Successful genome-wide association studies depend, in part, on the high call rates that Illumina DNA Analysis BeadChips exhibit. Since complex disease traits often have relatively small gene effects, potential associations may be missed if an assayed SNP, in LD with a disease SNP, has a low call rate. Data from the Infinium HD DNA Analysis BeadChips show strong reproducibility (> 99.9%) and concordance with the International HapMap Project (> 99.2%). Additionally, these BeadChips provide precise copy number metrics with low overall noise levels (Table 2), allowing reliable detection of single changes in copy number.

Internal Quality Controls

All products based on the Infinium HD Assay have several sample-dependent and sample-independent internal controls so researchers have confidence that they are producing the highest quality data. The performance of all controls can be monitored easily with the GenomeStudio Genotyping Module integrated Controls Dashboard.

Analysis Software

Illumina's GenomeStudio Data Analysis Software offers integrated genotyping and copy number tools and a graphical Genome Viewer. GenomeStudio Software has an open plug-in interface to integrate third-party applications for more downstream data analysis options. The illumina•Connect[11] program leverages this open architecture and has made numerous plug-ins available to support genotyping and copy number analysis.

iControlDB

Illumina hosts a database of genotypic and phenotypic data generated by researchers using Illumina genotyping products, which can be used to supplement controls in case-control association studies[12]. Access to the thousands of controls in the free iControlDB database allow researchers to increase the power of an association study and decrease overall project costs.

Automation

As with most of Illumina's standard DNA Analysis products, an optional Laboratory Information Management System (LIMS) and robotic automation accurately and efficiently track samples to provide workflow management and overall project management. This system, custom designed for Infinium workflows, allows labs to maximize their throughput with a completely integrated microarray solution.

Services

Illumina FastTrack Genotyping Services are available to analyze samples in a timely fashion at a reasonable cost using any Infinium DNA Analysis BeadChip. This option allows researchers to acquire high-quality data for limited studies or before purchasing their own equipment.

Summary

Illumina whole-genome DNA Analysis BeadChips are high-quality tools for SNP genotyping and analysis of structural variants. This genetic analysis platform offers a range of solutions with different numbers of markers per sample and different numbers of samples per BeadChip. All Illumina BeadChips offer the highest data quality and most complete genomic coverage in the industry. By choosing a BeadChip that matches the study design, researchers can confidently pursue the fastest path to discoveries and publication.

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Table 2: Genotyping Data Quality of DNA Analysis Beadchips Using Reference Samples

HumanCytosnp-12 BeadChip (283 DNA Samples, 15 Replicates, 56 Trios)

Genotyping Parameter	Value from Reference Samples	Product Specification	CNV Analysis Parameter	Value from Reference Samples	Expected**
Call Frequency	99.71%	> 99% average	Log R Ratio†	0.10	< 0.30
Reproducibility	100.00%	> 99.9%	B Allele Frequency†§	0.03	< 0.04
Mendelian Inconsistencies	0.02%	< 0.1%			
HapMap Concordance	99.77%	N/A			

Human660W-Quad BeadChip (283 DNA Samples, 15 Replicates, 58 Trios)

Genotyping Parameter	Value from Reference Samples	Product Specification	CNV Analysis Parameter	Value from Reference Samples	Expected**
Call Frequency	99.96%	> 99% average	Log R Ratio†	0.16	< 0.30
Reproducibility	100.00%	> 99.9%	B Allele Frequency†§	0.03	< 0.04
Mendelian Inconsistencies	0.04%	< 0.1%			
HapMap Concordance	99.76%	N/A			

Human1M-Duo BeadChip (284 DNA Samples, 15 Replicates, 58 Trios)

Genotyping Parameter	Value from Reference Samples	Product Specification	CNV Analysis Parameter	Value from Reference Samples	Expected**
Call Frequency	99.83%	> 99% average	Log R Ratio†	0.15	< 0.30
Reproducibility	100.00%	> 99.9%	B Allele Frequency†§	0.03	< 0.04
Mendelian Inconsistencies	0.05%	< 0.1%			
HapMap Concordance	99.63%	N/A			

HumanOmni1-Quad BeadChip (282 DNA SAMPLES, 15 REPLICATES, 56 TRIOS)

Genotyping Parameter	Value from Reference Samples	Product Specification	CNV Analysis Parameter	Value from Reference Samples	Expected**
Call Frequency	99.87%	> 99% average	Log R Ratio†	0.13	< 0.30
Reproducibility	100.00%	> 99.9%	B Allele Frequency†§	0.03	< 0.04
Mendelian Inconsistencies	0.02%	< 0.1%			
HapMap Concordance	99.64%	N/A			

*Based on CEU trios using loci with MAF ≥ 0.01; given as the frequency of markers with minor allele undertransmitted relative to the expected 50%

**Values expected for typical projects, excluding tumor samples or any samples prepared not following standard Illumina protocols

†Excludes sex chromosomes, mtDNA, and intensity-only loci

§Heterozygotes only

Ordering Information

Product	BeadChips	Samples	Catalog No.
HumanCytoSNP-12 v2.1 BeadChips and Reagents	1	12	WG-320-2101
	2	24	WG-320-2102
	4	48	WG-320-2103
	24	288	WG-320-2104
	96	1,152	WG-320-2105
Human660W-Quad v1 BeadChips and Reagents	4	16	WG-311-1501
	12	48	WG-311-1502
	24	96	WG-311-1503
	96	384	WG-311-1504
Human1M-Duo v3 BeadChips and Reagents	8	16	WG-311-1105
	24	48	WG-311-1102
	48	96	WG-311-1103
	192	384	WG-311-1104
HumanOmni1-Quad v1 BeadChips and Reagents	4	16	WG-311-1110
	12	48	WG-311-1111
	24	96	WG-311-1112
	96	384	WG-311-1113

Additional Information

Visit www.illumina.com/infinium or contact us at the address below to learn more about Illumina DNA Analysis BeadChips. Related technical notes13,14 are available at www.illumina.com/literature.

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ILLUM-0980

EXHIBIT C

OF

DECLARATION OF KAREN POSSEMATO

GoldenGate® Indexing Assay Increases Sample Throughput

By combining sample indexing within the robust GoldenGate Assay, automation capabilities, and positive sample tracking with LIMS support, GoldenGate Indexing provides the highest level of throughput at the most affordable cost for low- to mid-plex custom genotyping screening.

Highlights

- **Highest Throughput:** Greater than 2,000 samples per day
- **Highly Flexible:** Advanced multiplexing enables analysis of 96, 192, or 384 loci per sample
- **Fully Integrated:** Automated platform incorporating LIMS
- **Proven Technology:** Robust assay used in genotyping centers worldwide with average call rates > 99%

Introduction

The GoldenGate Genotyping Assay is a highly successful genotyping technology proven in labs worldwide. In fact, it was used to make major contributions in the HapMap Project. Building on this strong foundation, the GoldenGate Indexing Assay allows researchers to pool multiple samples, increasing the number of samples that can be analyzed in a single run. With advanced automation and updates to Illumina LIMS (Laboratory Information Management System) to accommodate this new step, along with positive sample tracking, researchers now have the ability to screen up to 16 times as many samples per reaction as they could with the standard GoldenGate Assay. This dramatically increases throughput from 288 samples per day to greater than 2,000. Overall, researchers will realize a significant decrease in cost while maximizing throughput for low-complexity sample screening.

How GoldenGate Indexing works

GoldenGate Indexing, based on Illumina's BeadArray™ technology, maximizes the throughput of the original GoldenGate Assay (Figures 1 and 2). BeadArray technology uses illumiCodes, unique 23-bp single-stranded DNA oligos, to correctly identify each DNA sample as well as the loci being interrogated. Because each illumiCode is distinctive, multiplexing is possible. Current plexity ranges for GoldenGate Indexing include 96-plex, 192-plex, and 384-plex.

IllumiCodes Enable Pooling

During sample preparation, primers containing illumiCodes and universal primer sites are hybridized to the DNA. Individual samples can be processed using oligonucleotide assay pools containing non-overlapping illumiCodes. This enables pooling of multiple samples into a single well. Since the illumiCodes are discreet within the well, each sample can be independently examined during downstream analysis.

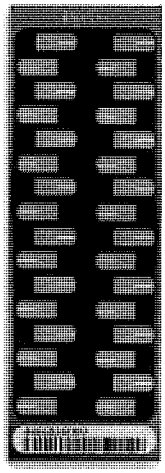
Amplification and Signal Reading

Prepared samples are amplified using universal PCR primers labeled with Cy3 and Cy5 fluorescent dyes. The resulting fluorescently labeled PCR products are hybridized to a Universal BeadChip. The BeadChip contains randomly assembled universal beads, each displaying an illumiCode corresponding to a specific loci. DNA will bind to the bead containing the complementary illumiCode. Unbound DNA is removed and the remaining fluorescence signal levels read on the iScan system or BeadArray Reader for individual SNP genotype readout. This information is then analyzed for automated genotype clustering and calling. The entire assay can be completed in as few as three days.

Illumina LIMS and Automation Control

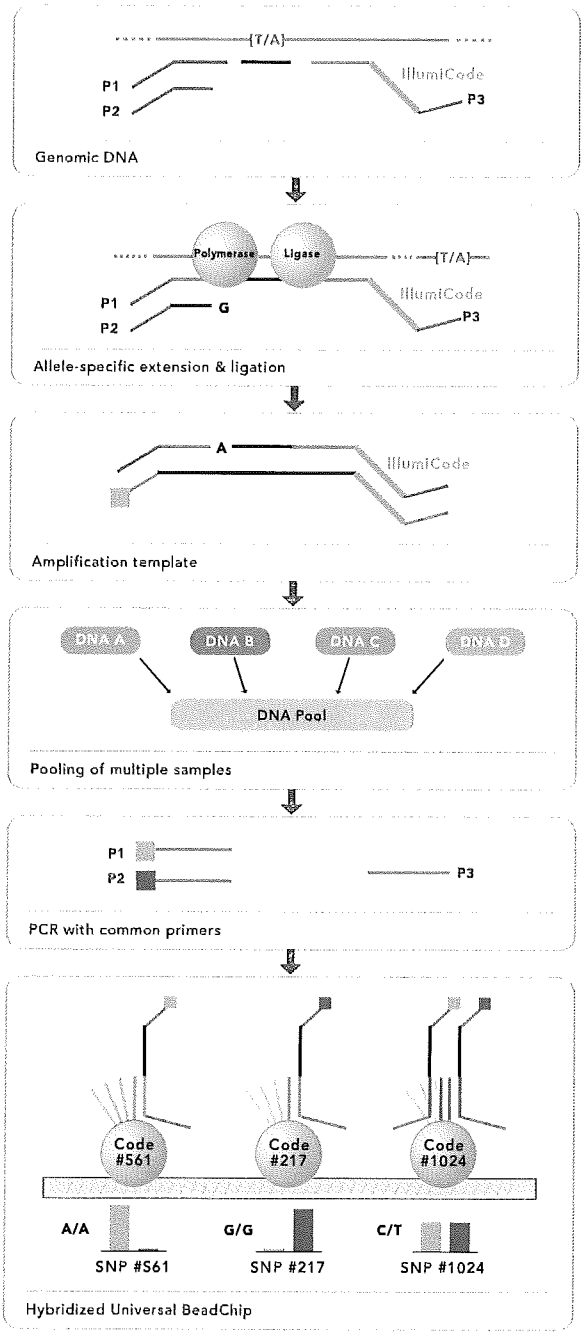
The GoldenGate Indexing assay is highly automated, maximizing throughput. Robotic liquid handlers automatically process samples through each step of the assay, enabling the assay to run with minimal hands-on operation. Pre-amplification steps are performed via a larger 96-tip–based robot, and post-amplification steps via a standard 8-tip robot.

Figure 1: Universal-32 beadchip



GoldenGate Indexing Assay products are hybridized onto the Universal-32 BeadChip for individual SNP genotype readout.

Figure2: Goldengate Indexing Assay Workflow



In the GoldenGate Indexing assay, a unique set of illumiCodes is used to identify each sample, allowing multiple samples to be pooled prior to amplification. This, along with automation capabilities, greatly increases the assay throughput.

Illumina's integrated LIMS delivers state-of-the-art management and tracking to ensure the highest quality data, efficient data acquisition, and significant savings in time and lab resources. As a ready-to-use solution, Illumina LIMS includes the server hardware and software needed to accurately manage and enforce assay workflow. Illumina LIMS provides the excellent project management capabilities needed to effectively manage samples from receipt through analysis.

Positive sample tracking by Illumina LIMS is achieved by direct control of the automated liquid handling robots, ensuring samples are automatically processed and queued to the proper step and eliminating error due to manual mishandling. LIMS tracks time-stamped lab transactions with associated user information by offering user authentication either through Illumina LIMS or through existing Windows password authentication. In addition, LIMS uses a barcode system for accurate sample identification in downstream analysis. Illumina provides software updates to accommodate new product formats and workflows, saving the time and cost of in-house software development. By managing time-consuming and error-prone sample/data handling from beginning to end, the LIMS environment greatly increases confidence and efficiency in genotyping studies.

Reliable Analysis

GoldenGate Indexing Assay results can be analyzed in the genotyping module of GenomeStudio™ data analysis software. This module recognizes each illumiCode and displays individual genotyping data for the pooled samples. In addition, GenomeStudio software features the ability to normalize raw data and perform clustering and automated genotyping calling.

Data Quality

GoldenGate Indexing Assays produce the same high-quality data as the original GoldenGate Assay. This ensures that important SNPs are captured and a high call accuracy is achieved (Table 1).

Summary

GoldenGate Indexing provides a fully automated, affordable assay for high-throughput low- to mid-plex genotype screening. Using a proven assay, researchers can now screen thousands of samples in just a few days, while still obtaining the high-quality data they require.

Additional Information

To learn how you can access the power of the GoldenGate Indexing Assay, visit www.illumina.com or contact us at the address below.

Figure 1: Specifications for the Goldengate Indexing Assay

Parameter	Specification
Average Call Rate	> 99%
Reproducibility	> 99.9%
Mendialian Inconsistencies	< 0.1%

Ordering Information

Product	Plexity	No. of Samples Indexed	No. of Samples Processed per Kit	Catalog No.
GoldenGate Indexing Assay Kit, Custom	96	16	768	GT-222-1003
	192	8	768	GT-222-1004
	384	4	768	GT-222-1005

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FGED SOCIETY

Minimum Information About a Microarray Experiment - MIAME

MIAME describes the **Minimum Information About a Microarray Experiment** that is needed to enable the interpretation of the results of the experiment unambiguously and potentially to reproduce the experiment. [Brazma et al., Nature Genetics]

The six most critical elements contributing towards MIAME are:

1. The raw data for each hybridisation (e.g., CEL or GPR files)
2. The final processed (normalised) data for the set of hybridisations in the experiment (study) (e.g., the gene expression data matrix used to draw the conclusions from the study)
3. The essential sample annotation including experimental factors and their values (e.g., compound and dose in a dose response experiment)
4. The experimental design including sample data relationships (e.g., which raw data file relates to which sample, which hybridisations are technical, which are biological replicates)
5. Sufficient annotation of the array (e.g., gene identifiers, genomic coordinates, probe oligonucleotide sequences or reference commercial array catalog number)
6. The essential laboratory and data processing protocols (e.g., what normalisation method has been used to obtain the final processed data)

For more details, see MIAME 2.0.

MIAME does not specify a particular format, however, obviously the data are more usable, if it is encoded in a way that the essential information specified by MIAME can be accessed easily. FGED recommends the use of MAGE-TAB format, which is based on spreadsheets, or MAGE-ML.

MIAME also does not specify any particular terminology, however for automated data exchange the use of standard controlled vocabularies and ontologies are desirable. FGED recommends the use of MGED Ontology for the description of the key experimental concepts, and where possible ontologies developed by the respective community for describing terms such as anatomy, disease, chemical compounds etc (see OBO page for more detail).

MIAME In Practice

The public repositories ArrayExpress at the EBI (UK), GEO at NCBI (US) and CIBEX at DDBJ (Japan) are designed to accept, hold and distribute MIAME compliant microarray data.

There is a number of software tools supporting MIAME requirements under development.

Open letter to the scientific journals about submitting MIAME compliant data [RTF 14kb] [HTML 12kb].

These journals require MIAME compliant data as a condition for publishing microarray based papers.

ArrayExpress service to journals [PDF 508kb].

MIAME extensions or related activities

- MIBBI Project.
- MIAME CGH checklist [DOC 72kb] [PDF 61kb]
- MIAME ChIP-on-chip checklist [DOC 92kb] [PDF 64kb]
- MIAME proposal for random arrays [DOC 66kb] [PDF 141kb]
- MIAME/Tox and MIAME/Env
- MIAME/Plant Whitepaper:

ILLUM-0859

A MIAME plant specification white paper has been produced and submitted to Plant Methods. [PDF 51kb] [Commentary PDF 25kb] [PPT 23kb]

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As a microarray manufacturer Illumina fully appreciates the importance of MIAME as a standard necessary for meaningful interpretation and verification of microarray experiments. Our goal is to become a MIAME compliant platform when we release our gene expression related products. Therefore, I created this document to introduce the MIAME workgroup to some concepts which we think can extend the current version of the standard and enable compliance by our customers. I include a description of the Illumina array, and I would like to seek from your workgroup comments of whether they consider such description to be MIAME compliant.

Terms Needed in the Description of the Illumina Microarray Platform

- Random Array – this concept implies that features assemble at random locations on each physical array manufactured. In terms of changes to the Array Description part of MIAME, it would require an additional array property – 'Array Geometry'. Describing array geometry as Random will allow us to introduce a Virtual Array Geometry placing all features present in the array onto a fixed virtual rectangular grid which makes it analogous to an ordered array. This will spare our customers the need to submit array description data with every physical array they use (it is impossible to reproduce feature locations so it does not affect verification of experiments ability). Also, virtual arrays can be helpful in describing flow cytometry gene expression data.
- Universal Array – this concept is not unique to Illumina and implies that probes on the array are used indirectly as address readout reporters rather than direct hybridization target quantifiers. This notion can help to create a placeholder for additional sequence information required to interpret microarray data. In case of Illumina we refer to address reporters as IllumiCode capture sequences.
- Generalized Reporter – this concept allows characterization of various parts of the sequence generated on the array. In particular, we propose to split reporter sequence into hybridizing part and auxiliary part. In figure 1a below, the reporter's hybridizing sequence coincides with the gene specific portion while the auxiliary sequence functions as an IllumiCode capture sequence. Another possible function for the auxiliary sequence is to provide padding between the substrate and the gene specific sequence.

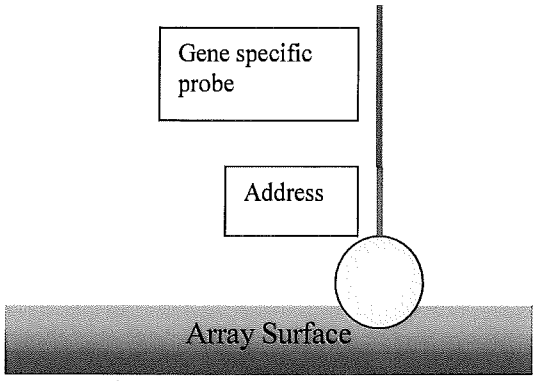

Figure 1.a

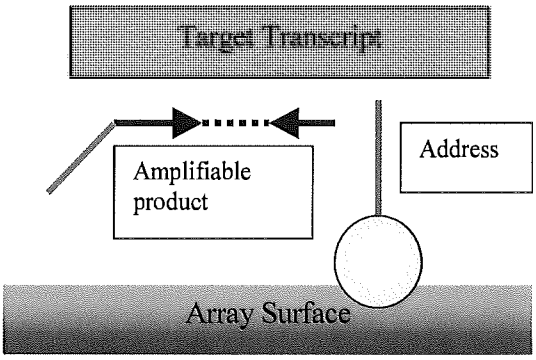

Figure 1.b

Figure 1b represents a typical universal array. In this case the sequence hybridizing to the gene specific part is not attached to the array. The reporter sequence does not have an auxiliary part, however, it serves as IllumiCode capture sequences. This could be described through an additional reporter sequence property - 'hybridization type'. It would be included in the experiment description part of MIAME. Illumina plans to release probe sequence information for gene specific portions, however, for intellectual property considerations we cannot release sequences for our IllumiCode capture sequences.

- Probe orientation – As a minor addition, we think MIAME should add additional reporter sequence property describing orientation (3' outward or inward) of probes with respect to the array surface.

To summarize these concepts here is the proposed content of Illumina's array description: Blue font represents additions either new to the current MIAME content or having new interpretation.

1. **Array related information**
   Array Design Name= IlluminaTest
   Platform Type= DNA Oligonucleotide
   Surface and Coating Specification= silica beads, diameter=3μm.
   Physical Dimension= hexagon, diameter=1.5mm
   Array Geometry= Random (means that locations described below are virtual)
   Number of Features on the Array= Number of distinct feature types (number of replicates per distinct feature is random)
   Availability= provided by Illumina Inc.
2. **(a) For each reporter type**
   Reporter Type = synthetic DNA oligonucleotide
   Number of strands = 1
   (b) For each reporter type
   Identifier = illumina's unique identifier
   Hybridization type = Universal or Specific
   Auxiliary sequence function = (None, padding, address, etc.)
   Auxiliary sequence position = proximal to surface (if exists)

Auxiliary sequence length= sequence length if exists, 0 otherwise
Specific sequence=AGCT… (gene specific portion of the sequence if exists)
Sequence orientation= 5' proximal to surface

3. **(a) For each feature type**
   Dimension = diameter 3μm
   (b) For each feature
   Reporter identifier
   Location on the virtual array.
4. **For each composite sequence**
   List of reporters
   Reference sequence
   Gene name
5. **Control Elements**
   Position of the feature on virtual array
   Control type
   Control qualifier

In the Experiment Description section we propose to introduce the following descriptor:

For each universal reporter:
Specific sequence
Element of the array expected to hybridize to it

In terms of raw data, Illumina will provide customers with gene expression data tables which would list for all features described in array descriptor:

- Feature Identifier
- Average Intensity
- Number of Beads
- Bead to Bead Standard Deviation
- Detection p-value.

In addition, customers will have raw images, so they will be able to examine images for scratches, intensity gradients, etc. We will make our extraction algorithms and normalization routines public.

EXHIBIT D

OF

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Illuminotes

April 2011

Product News

New TruSeq™ Enrichment Demo Kits

New demo kits allow customers to try TruSeq Exome Enrichment on their own samples. Limited to one per laboratory, the kit provides TruSeq DNA Sample Preparation and TruSeq Exome Enrichment reagents for up to 24 samples. Contact your local Account Manager or Illumina customer support for more information.

Final Order Date for RatRef-12

The final order date for RatRef-12 BeadChips is May 31, 2011, or while supplies last, with a final shipment date of June 30, 2011. Contact your local Account Manager or Illumina customer support for assistance in transitioning to RNA sequencing and the TruSeq RNA Sample Prep Kit for your next gene expression profiling experiment.

Final Order Date for Human660W-Quad, Human610-Quad, Human1M-Duo, Human1MDuo+, and HumanHap550-Quad+ BeadChips

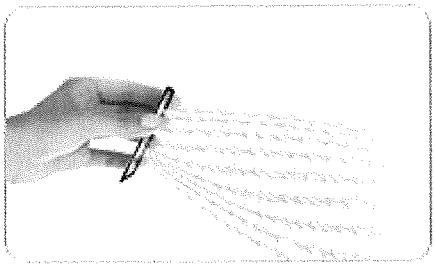
The final order date for these Infinium® BeadChips is April 29, 2011, or while supplies last, with a final shipment date of June 30, 2011. Contact your local Account Manager or Illumina customer support for assistance in transitioning to the Omni family of microarrays for GWAS projects.

Customer Satisfaction

Enhanced HiSeq™ Flow Cell QC and Manufacturing

We are continually improving and updating our processes to deliver the highest quality products. Our commitment to customer satisfaction also involves listening to your concerns and correcting product issues. This new section of Illuminotes is devoted to communicating those solutions to you in a timely fashion.

Recently, some HiSeq customers experienced issues with flow cell performance. We made modifications to our HiSeq flow cell quality control and manufacturing processes, resolving the edge-effect issues and supporting more uniform clustering. Since February 2011, all shipped HiSeq Cluster Kits have contained updated flow cells. We are continuing to replace the flow cells of impacted customers. For more



Start Using RNA Sequencing

Learn how other researchers are benefiting from RNA-Seq by signing up for Illumina's three-part RNA Sequencing webinar series.

New Products

- MiSeq™ Personal Sequencing System
- Infinium DNA Restoration Solution
- TruSeq DNA Fragmentation and Size Selection Automation

Illumina Seminar Series

Registration is open for these upcoming seminars:

Sequencing Seminars

- Berlin – May 3
- Lausanne – May 4
- Uppsala – May 11
- Copenhagen – May 12
- Brussels – May 18
- Amsterdam – May 19
- Paris – June 15
- Milan – June 16
- Barcelona – June 22
- Rome – June 23

ILLUM-0864

information, contact Illumina technical support.

iDEA Challenge Conference

Register Now for the iDEA Conference - June 14-15, 2011 San Diego, CA
The iDEA Conference will showcase innovative ideas for the visualization and analysis of Illumina datasets from around the world, highlighted by the announcement of the six iDEA Challenge award winners. Space is limited, so register today!

Product Literature

Optimize Targeted Resequencing
Maximize the efficiency of your targeted resequencing studies with the new TruSeq Exome Enrichment Kit. An updated data sheet provides details about the kit, its workflow, input requirements, and data accuracy, while a new technical note discusses how to optimize coverage for highly sensitive variant calling.

RNA-Seq Analysis Demystified
A new data sheet provides a broad overview of RNA-Seq data analysis, demystifing the tools—from Illumina and third-parties—to make your studies successful. See a comparison of microarray and RNA-Seq data in a new white paper, comparing the ability of each platform to detect and quantify differential gene expression across two well-annotated samples.

Documentation

The following new documentation is available:

- HiSeq 1000 User Guide and Quick Reference Guide
- Infinium HD DNA Restoration Protocol Instructions
- Infinium HD FFPE QC Instructions, Assay Guide, Experienced User Card, and Lab Tracking Form
- Sample Stats Report Plug-in for GenomeStudio® Software
- GC Content Polynomial Fit C# Script for GenomeStudio Software

The following documentation has been updated recently:

- HiSeq Lab Tracking Form
- cnvPartition CNV Analysis Plug-in for GenomeStudio Software
- TruSeq Small RNA Sample Preparation Guide,

- London – June 28
- Glasgow –June 29
- Birmingham – July 5
- Leeds – July 6

Illumina Regional User Group Meetings
Illumina is hosting 13 regional user group meetings in North America, providing customers with a forum to share results, receive updates on the latest applications and products, and exchange best practices to get the most from their Illumina systems.

Registration is open for the following meetings:

April 26 - San Diego, California
June 1 - New York, New York
June 7 - Bethesda, Maryland
June 9 - Boston, Massachusetts

July 2011 (specific dates TBD)
- San Francisco Bay Area, California
- Seattle, Washington
- Los Angeles, California
- St. Louis, Missouri
- Toronto, Ontario, Canada
- Houston, Texas
- Philadelphia, Pennsylvania

Upcoming Events

-
European Molecular Biology Laboratory (EMBL) Advanced Course–Next-Gen Sequencing Data Analysis
May 3-4
Heidelberg, Germany

-
International Friedreich's Ataxia Scientific Conference
May 5-7
Illkirch, France

- Leena Pelonen-Palotie Symposium–A Global View of Disease Genetics
May 18-19

ILLUM-0865

Experienced User Card, and Lab Tracking Form
- VeraCode ADME Core Panel Guide and Lab Tracking Form

View or download PDFs of all current Illumina documentation here using your iCom login. To register for an iCom account click here.

Experimental Protocols

Protocols Provide New Application Options
Your research might benefit from experimental applications of Illumina technology. The following protocols are now available:

- Ultra-Low-Input mRNA-Seq Guide
- Directional mRNA-Seq Sample Preparation Guide
- DSN Normalization Sample Preparation Application Note

Please note that these protocols are not supported by Illumina Technical Support or Field Application scientists, and may prove challenging to even the most experienced user.

iCommunity Newsletter

March iCommunity Now Online
Learn how customers are using Illumina products to enhance their research. The March iCommunity includes articles about adaptive immune system research, autism discoveries, breast cancer diagnostics, and sheep breeding selection. Subscribe today!

Recent Publications

Jones SJ, Laskin J et al. (2010)) Evolution of an adenocarcinoma in response to selection by targeted kinase inhibitors. Genome Biol 11: R82.

Goudie DR, D'Alessandro M et al. (2011) Multiple self-healing squamous epithelioma is caused by a disease-specific spectrum of mutations in TGFBR1. Nat Genet [Epub ahead of print].

Bonnefond A, Durand E et al. (2010) Molecular diagnosis of neonatal diabetes mellitus using next-generation sequencing of the whole exome. PLoS ONE 5: e13630.

Gardy JL, Johnston JC et al. (2011) Whole-genome sequencing and social-network analysis of a

Helsinki, Finland

- European Symposium on Bio-Organic Chemistry (ESBOC)
May 20-22
Gregynog, Wales,
United Kingdom

-
European Society of Human Genetics (ESHG)
May 28-31
Amsterdam, the Netherlands

Attend the Illumina Technology Workshop:
Sunday, May 29
6:00pm-8:15pm
Booth #244

- Genetic Epidemiology
May 30-June 1
Paris, France

- International Rapeseed Congress
June 5-9
Prague, Czech Republic

-
Copenhagenomics: Genomics Conference on Improving Human Health
June 9-10
Copenhagen, Denmark

- Infectious Disease Research Network (IDRN)–Microbial Community Profiling Workshop
June 20
London, United Kingdom

-
International Committee for Animal Recording (ICAR)
June 22-24
Bourg-en-Bresse, France

View Webinar Archives

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tuberculosis outbreak. N Engl J Med 364: 730-739.

Rosenthal AZ, Matson EG et al. (2011) RNA-seq reveals cooperative metabolic interactions between two termite-gut spirochete species in co-culture. ISME J [Epub ahead of print].

Polymenidou M, Lagier-Tourenne C et al. (2011) Long pre-mRNA depletion and RNA missplicing contribute to neuronal vulnerability from loss of TDP-43. Nat Neurosci [Epub ahead of print].

Wang W, Barnaby JY et al. (2011) Timing of plant immune responses by a central circadian regulator. Nature 470: 110-114.

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ILLUM-0867

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Illuminotes

June 2011

Product News

New GWAS Manifests Available

New build 37 manifests (April Release 2011) for all current Illumina standard GWAS microarrays, including the latest updates to marker names and positions, are now available. For further information, please contact Illumina technical support.

Discover, Develop, and Deploy with Illumina's Agrigenomics Toolset

Illumina systems and products support multiple agrigenomics applications to advance research and commercial efforts, including enhancing breeding programs (see our new video).

Product Literature

MiSeq™ Sequencing Data Available!

Download the MiSeq poster presented at the 2011 Cold Spring Harbor Biology of Genomes Meeting and an accompanying presentation describing amplicon sequencing from FFPE samples, metagenomic sequencing, de novo sequencing, and more. An application note describing the amplicon sequencing experiments in more detail is also available.

Customer Satisfaction

Product Labeling Improvements

We are enhancing the information content of our packaging and recently developed an easier to read product label format, incorporating expiration date detail and internationally recognized symbols for product information. This new labeling format now appears on TruSeq reagent kits and will soon be standard for all new Illumina products.

Documentation

The following new documentation is available:

- Version Compatibility Reference Guide for HiSeq™ Sequencing Components

TruSeq™

Sequencing Data Accuracy Comparison

A side-by-side analysis of the data quality generated using Illumina sequencing and a competing services company technology is now available. Analysis was performed using transparent, reproducible methods and publically available data sets.

New Products

- Infinium® HD HumanOmni2.5 and HumanOmni5 BeadChips
- TruSeq v3 Reagent Kits
- MiSeq Personal Sequencing System
- Infinium DNA Restoration Solution
- TruSeq DNA Fragmentation and Size Selection Automation

Illumina Seminar Series

Registration is open for these upcoming seminars:

Sequencing Seminars

- Barcelona – June 22
- Rome – June 23
- London – June 28
- Glasgow –June 29

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- TruSeq Sample Preparation Best Practices and Troubleshooting Guide
- GenomeStudio® 2011.1 Online Help (covers Framework and Methylation Module)
- Infinium LCG Assay Protocol Guide, Experienced User Cards, and Lab Tracking Form for use with HumanOmni2.5-8 BeadChip
- Infinium Multi-Use LCG Assay Protocol Guide, Experienced User Cards, and Lab Tracking Form for use with HumanOmni2.5-8 Multi-Use BeadChip
- HumanOmni2.5-8 BeadChip Product Information Sheet
- HumanOmni2.5-8 Multi-Use BeadChip Product Information Sheet

The following documentation has been updated recently:

- TruSeq DNA Sample Preparation Guide, Experienced User Cards, and Lab Tracking Forms (includes new gel-free protocol option)
- TruSeq Enrichment Guide, Experienced User Card, and Lab Tracking Form (includes new custom enrichment kit)
- CASAVA v1.8 User Guide and Quick Reference Guide
- Eco™ Real-Time PCR System User Guide
- Infinium HD HumanMethylation450 BeadChip Assay Protocol Guide, Experienced User Cards, and Lab Tracking Form (with Illumina LIMS support)

View or download PDFs of all current Illumina documentation here using your iCom login. To register for an iCom account click here.

Recent Publications

Totoki Y, Tatsuno K, et al. (2011) High-resolution characterization of a hepatocellular carcinoma genome. Nat Gen 43: 464-469.

Feldman AL, Dogan A, et al. (2011) Discovery of recurrent t(6;7)(p25.3;q32.3) translocations in ALK-negative anaplastic large cell lymphomas by massively parallel genomic sequencing. Blood 117: 915-919.

Jiao Y, Shi C, et al. (2011) DAXX/ATRX, MEN1, and mTOR Pathway Genes Are Frequently Altered in Pancreatic Neuroendocrine Tumors. Science 331: 1199-1203. Reviewed by Elsässer SJ, Allis CD and Lewis PW (2011) Cancer. New epigenetic drivers of cancers. Science 331: 1145-1146.

Shi CY, Yang H, et al. (2011) Deep sequencing of the Camellia sinensis transcriptome revealed candidate genes for major metabolic pathways of tea-specific compounds. BMC Genomics 12:131.

- Birmingham – July 5
- Leeds – July 6

Illumina Regional User Group Meetings

Illumina is hosting regional user group meetings in North America, providing customers with a forum to share results, receive updates on the latest applications and products, and exchange best practices to get the most from their Illumina systems.

Registration is open for the following meetings:

San Francisco - August 3

Boston - September 8

Dates still to be determined for the following cities:

- Seattle, Washington
- Los Angeles, California
- St. Louis, Missouri
- Toronto, Ontario, Canada
- Houston, Texas
- Philadelphia, Pennsylvania

Upcoming Events

- Infectious Disease Research Network (IDRN)–Microbial Community Profiling Workshop
  June 20
  London, United Kingdom

- International Committee for Animal Recording (ICAR)
  June 22-24
  Bourg-en-Bresse, France

- Berlin Summer Meeting
  June 23-25
  Berlin, Germany

- JOBIM
  June 28-July 1
  Paris, France

ILLUM-0869

Wenping H, Yuan Z, et al. (2011) De novo transcriptome sequencing in Salvia miltiorrhiza to identify genes involved in the biosynthesis of active ingredients. Genomics. (Epub ahead of print.)

Shan L, Yang HC, et al. (2011) Influence of host gene transcription level and orientation on HIV-1 latency in a primary-cell model. J Virol 85: 5384-5393.

Yu H, Xie W, et al. (2011) Gains in QTL detection using an ultra-high density SNP map based on population sequencing relative to traditional RFLP/SSR markers. PLoS One 6: e17595.

Bomar L, Maltz M, et al. (2011) Directed culturing of microorganisms using metatranscriptomics. MBio 2: e00012-00011.

View additional publications

- EU Cytogenetics Conference
  July 2-5
  Porto, Portugal

- ICGEB DNA Tumour Virus Meeting
  July 17-22
  Trieste, Italy

- CeBiTec Symposium
  July 18-20
  Bielefeld, Germany

- 50 Years of X Inactivation Research
  July 20-24
  Oxford, United Kingdom

- The Leena Peltonen School of Human Genetics
  August 21-25
  Hinxton, United Kingdom

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Illuminotes

August 2011

Customer Satisfaction

Automated Filling Technologies Enhance Reagent Manufacturing

To improve product lead time and quality, Illumina is transitioning to automated filling technologies in our reagent manufacturing operation. Our new systems ensure consistent reagent fill levels within and across manufactured lots, label accuracy and proper capping.

Product News

TruSeq™ RNA and DNA Sample Prep Kits v2 Offer More Indexed Adapters

TruSeq RNA and DNA Sample Preparation Kits v2 now offer 24 indexed adapters, supporting higher levels of multiplexing and optimized fill volumes for manual and automated deployment.

LIMS Supports Infinium® HumanMethylation450 BeadChip

Illumina's state-of-the-art LIMS is now available for the HumanMethylation450 BeadChip, providing positive sample tracking, component verification, project and data management, lab workflow management, and reporting.

Customer Input

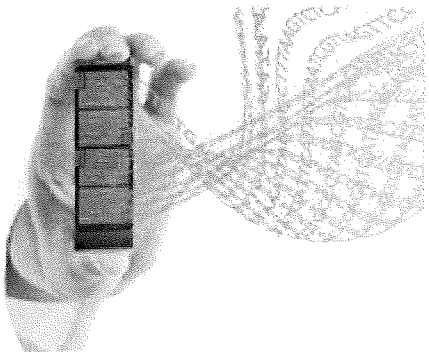
Interested in Methylation?

We are currently assessing the level of customer interest in and capturing guidance for the design of an Infinium mouse methylation array. If you would be interested in such a product we would appreciate hearing from you.

Documentation

The following new documentation is available:

- TruSeq DNA Sample Preparation v2 Guide, and Low-Throughput and High-Throughput Experienced User Cards and Lab Tracking Forms



HumanOmni5-Quad BeadChip Now Shipping

Delivering the most comprehensive coverage of the genome, the HumanOmni5-Quad BeadChip also provides the flexibility to add up to 500K custom markers for targeted applications and population-specific studies.

New Products

-TruSeq Custom Enrichment Kits

-MiSeq™ Personal Sequencing System

-TruSeq DNA Fragmentation and Size Selection Automation

-GenomeStudio® Supports Polyploidy Genotyping and More

Illumina User Group Meetings

Illumina is hosting user group meetings in North America and Europe, providing customers with a forum to share results, receive updates on the latest applications and products, and exchange best practices to get the most from their Illumina systems.

ILLUM-0871

- TruSeq RNA Sample Preparation v2 Guide, and Low-Throughput and High-Throughput Experienced User Cards and Lab Tracking Forms

The following documentation has been updated recently:

- HiScanSQ™ System User Guide and Quick Reference Guide

View or download PDFs of all current Illumina documentation here using your Illumina online account login. To register for an online account click here.

Product Literature

Optimize Analysis Efficiency of Whole-Genome Genotyping
A new tech note demonstrates how to minimize sample processing time for high- and low-throughput environments.

Online Training

Online Courses Available
Two new courses have been added to the Illumina customer Online Learning Portal:

- DesignStudio™ Software
- CASAVA Software

If you need an online learning account, please contact your local account manager or Illumina customer support.

Recent Publications

Avrani S, Wurtzel O, Sharon I, Sorek R, Lindell D. (2011) Genomic island variability facilitates Prochlorococcus – virus coexistence. Nature 474:604-608.

Barchi L, Lanteri S, Portis E, Acquadro A, Valè, et al. (2011) Identification of SNP and SSR markers in eggplant using RAD tag sequencing. BMC Genomics 12:304-313.

Ju YS, Kim JI, Kim S, Hong D, Park H, et al. (2011) Extensive genomic and transcriptional diversity identified through massively parallel DNA and RNA sequencing of eighteen Korean individuals. Nat Genet. 43:745-752.

Larman HB, Zhao Z, Laserson U, Li MZ, Ciccia A, et al. (2011) Autoantigen discovery with a synthetic human peptidome. Nat Biotechnol. 29:535-541.

North American User Group Meetings

* St. Louis – August 23-24
* Boston – September 8
* Seattle – September 13
* Nashville – September 15
Los Angeles – October 20
Houston – November 8
Philadelphia – November 10
Toronto, Ontario, Canada – December 15

European User Group Meetings

* Heidelberg, Germany – September 13-14
* Copenhagen, Denmark – September 20-21
* Nice, France – October 17-18

Agrigenomics User Group Meeting

* St. Louis – August 25

*Registration is open

Upcoming Events

-
The Leena Peltonen School of Human Genetics
August 21-25
Hinxton, United Kingdom

- UK Next-Generation Sequencing
August 30 - September 1
Nottingham, United Kingdom

- Eucarpia Fodder Crops and Amenity Grasses Section Meeting
September 4-8
Dublin, Ireland

- Spanish Society of Biochemistry and Molecular Biology (SEBBM)
September 5-8
Barcelona, Spain

- MipTec
September 20-22
Basel, Switzerland

ILLUM-0872

Li M, Wang IX, Li Y, Bruzel A, Richards AL, et al. (2011) Widespread RNA and DNA sequence differences in the human transcriptome. Science 333:53-58.

Li Y, Sidore C, Kang HM, Boehnke M, Abecasis GR. (2011) Low-coverage sequencing: Implications for design of complex trait association studies. Genome Res. 21:940-951.

Morin RD, Mendez-Lago M, Mungall Aj, Goya R, Mungall KL, et al. (2011) Frequent mutation of histone-modifying genes in non-Hodgkin lymphoma. Nature [Epub ahead of print].

Toung JM, Morley M, Li M, Cheung VG. (2011) RNA-sequence analysis of human B-cells. Genome Res. 21:991-998.

View additional publications

- International Congress on Human Genetics/American Society of Human Genetics (ICHG/ASHG)
October 11-15
Montreal, Quebec, Canada
Visit Illumina at Booth #708

Attend the Illumina Technology Workshops:

Illumina Sequencing Solutions for Every Need. Every Budget. Every Lab.
Wednesday, October 12
12:45pm at the Westin Hotel

Using Multiple Illumina Technologies for Comprehensive Genomic Analysis
Thursday, October 13
12:45pm at the Westin Hotel

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Illuminotes

September 2011

Product News

New Tools for Epigenetics Studies

Planning an epigenetic study? Illumina offers a broad range of products for robust interrogation of multiple forms of epigenetic regulation. Learn more about our rapidly growing portfolio, including:

- Protocols and data analysis software for whole-genome bisulfite sequencing (WGBS) and reduced representation bisulfite sequencing (RRBS)
- Protocols enabling FFPE samples to be run on the Infinium HumanMethylation450 BeadChip
- Data analysis software for small RNA

Webinar

Designing TruSeq Custom Enrichment Content

Learn best practices for designing TruSeq Custom Enrichment content and obtain an in-depth review of how to modify your custom projects in GenomeStudio software.

Documentation

The following new documentation is available:

- MiSeq System Site Preparation Guide, Safety and Compliance Guide, User Guide, and Quick Reference Guide
- MiSeq Reagent Preparation Guide
- MiSeq Sample Sheet Quick Reference Guide
- Infinium HD FFPE Methylation Experienced User Cards
- Using Passive Reference Dyes for Normalization and Troubleshooting in qPCR Technical Note
- Sequencing Analysis Workflow Help
- Flicker User Guide
- Bisulfite Sequencing Analysis Software User Guide

The following documentation has been updated recently:

- Infinium HD FFPE QC Instructions and DNA Restoration Protocol

TruSeq™

TruSeq Custom Enrichment Trial Kit Available

The TruSeq Custom Enrichment Kit provides a cost-effective, scalable, custom targeted sequencing solution. View the design coordinates and gene list for this in-solution capture assay. Contact your Account Manager to order a trial kit.

New Products

-MiSeq™ Personal Sequencing System

-TruSeq DNA Fragmentation and Size Selection Automation

-GenomeStudio® Software Supports Polyploidy Genotyping and More

Illumina User Group Meetings

Illumina is hosting user group meetings in North America and Europe, providing customers with a forum to share results, receive updates on the latest applications and products, and exchange best practices to get the most from their Illumina systems.

Registration is open for the following meetings:

North American User Group Meetings

ILLUM-0874

View or download PDFs of all current Illumina documentation here using your Illumina online account login. To register for an online account click here.

We'd Like Your Opinion
How does Illumina rate when it comes to documentation? Complete our survey and earn a chance to win an **iPod Shuffle**.

Demonstrated Protocols

New Methylation Analysis Protocol
Your research might benefit from experimental applications of Illumina technology. The following Illumina demonstrated protocols are now available:

- Whole-Genome Bisulfite Sequencing for Methylation Analysis Guide
- Reduced Representation Bisulfite Sequencing for Methylation Analysis Guide

Please note that this protocol is not supported by Illumina Technical Support or Field Application scientists, and may prove challenging to even the most experienced user.

Recent Publications

Holbrook JD, Parker JS, et al. (2011) Deep sequencing of gastric carcinoma reveals somatic mutations relevant to personalized medicine. J Transl Med 9: 119.

Bass AJ, Lawrence MS, Brace LE, et al. (2011) Genomic sequencing of colorectal adenocarcinomas identifies a recurrent VTI1A-TCF7L2 fusion. Nat Genet. [Epub ahead of print]

Mutreja A, Kim DW, Thomson NR, et al. (2011) Evidence for several waves of global transmission in the seventh cholera pandemic. Nature. [Epub ahead of print]

Gracheva EO, Cordero-Morales JF, et al. (2011) Ganglion-specific splicing of TRPV1 underlies infrared sensation in vampire bats. Nature 476: 88-91.

Belgard TG, Marques AC, et al. (2011) A transcriptomic atlas of mouse neocortical layers. Neuron 71: 605-616.

Mercer TR, Neph S, et al. (2011) The human mitochondrial transcriptome. Cell 146: 645-658.

Jabbari A, Suarez-Farinas M, et al. (2011) Transcriptional profiling of psoriasis using RNA-Seq reveals previously unidentified differentially expressed genes. J Invest Dermatol. [Epub ahead of print]

Robinson T, Campino SG, et al. (2011) Drug-resistant genotypes and multi-clonality in *Plasmodium falciparum*

Los Angeles – October 20

European User Group Meetings

Nice, France – October 17-18
Cambridge, United Kingdom – October 20-21

Upcoming Events

- MipTec
  September 20-22
  Basel, Switzerland

- Annual National Genome Research Network (NGFN) Meeting
  September 26-28
  Berlin, Germany

- System Genetics: from man to microbe from genotype to phenotype
  September 29-30
  Groningen, Netherlands

- International Symposium on Human Identification (ISHI)
  October 3-6
  Washington, DC

- International Symposium on Animal Functional Genomics
  October 10-12
  Dublin, Ireland

-
  International Congress on Human Genetics/American Society of Human Genetics (ICHG/ASHG)
  October 11-15
  Monteral, Quebec, Canada
  Visit Illumina at Booth #708

  Attend the Illumina Technology Workshops:

  Illumina Sequencing Solutions for Every Need. Every Budget. Every Lab.
  Wednesday, October 12
  12:45pm at the Westin Hotel

  Using Multiple Illumina Technologies for Comprehensive Genomic Analysis
  Thursday, October 13
  12:45pm at the Westin Hotel

ILLUM-0875

- Epigenetics: from Bases to

analysed by direct genome sequencing from peripheral blood of malaria patients. PLoS One 6:e23204.

Raffan E and Semple RK (2011) Next generation sequencing--implications for clinical practice. Br Med Bull. 99: 53-71.

View additional publications

Pathology
October 12-14
Paris, France

- National Cancer Research Institute (NCRI) Cancer Conference
November 6-8
Liverpool, United Kingdom

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Illuminotes

November 2011

Customer Satisfaction

Enhanced MyIllumina Simplifies Product Ordering, Tracking, and More
Click MyIllumina in the upper right-hand corner of any Illumina webpage and you can:

- Place orders
- View order history
- Convert quotes to orders
- View Support Bulletins
- Use Lot Tracker to view lots and expiration dates of current and previous orders, and recent shipments
- Create and manage custom projects with DesignStudio™ software

Register for a MyIllumina account today!

New Products

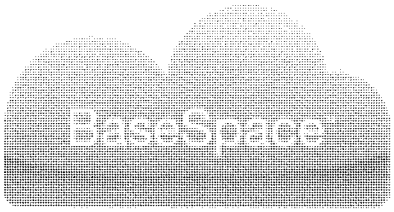
Ribo-Zero™ Gold Kit Enhances rRNA Removal
The new Ribo-Zero Gold Kit for human, mouse, or rat from Epicentre (an Illumina company) removes both cytoplasmic and mitochondrial rRNA, resulting in improved RNA-Seq results and fewer wasted reads.

CASAVA Supports Nextera™ Dual Indexing
Enhanced CASAVA 1.8.2 sequence analysis software supports Nextera dual-indexed libraries on HiSeq® systems and is now available for download.

Product News

Discontinuation of RUO VeraCode Universal Capture and Carboxyl Beads
Effective immediately, orders for RUO-labeled VeraCode Universal Capture and Carboxyl Beads will be fulfilled with high-quality, FDA-registered General Purpose Reagent (GPR) beads. For more information contact your local Account Manager.

Final Order Date for mRNA-Seq and DGE Small RNA Sample Preparation Kits
The final order date for these sequencing sample preparation kits is December 31, 2011, with a final shipment date of February 1, 2012. Contact your local Account Manager for assistance in transitioning to the TruSeq family of sample preparation kits for



BaseSpace™ Takes MiSeq® Data into the Cloud
BaseSpace is a secure and customizable cloud computing environment that offers streamlined MiSeq data analysis and real-time sharing capabilities without the need for onsite computing infrastructure.

New Products

-MiSeq System

-TruSeq™ Custom Amplicon Kit

-Nextera DNA Sample Preparation Kits

-Infinium® HumanExome BeadChips

-Infinium BovineLD BeadChip

-TruSeq DNA Fragmentation and Size Selection Automation

Illumina Sequencing Seminar Series
Registration is open for these upcoming seminars:

November 24 – Glasgow, United Kingdom

Illumina User Group Meetings
Illumina is hosting user group meetings in North America and Europe, providing customers with a forum to share results, receive

ILLUM-0877

sequencing projects.

Product Literature

Case Studies: HiSeq 2000 System and TruSeq Exome Enrichment Kits Empower Research
Researchers at the Oklahoma Medical Research Foundation and the Genome Technology Access Center at Washington University are using the HiSeq 2000 System and TruSeq Exome Enrichment Kits to discover mutations linked with lupus, cancer, and other diseases.

Enhanced CASAVA Offers Improved Accuracy for ELAND and Variant Calling
A new technical note describes the improved alignment and variant calling accuracy of CASAVA 1.8 sequence analysis software.

Estimating Coverage for Sequencing Applications
An updated technical note provides information on how to estimate the sequencing coverage required for an experiment.

Documentation

The following new documentation is available:

- BaseSpace Help

The following documentation has been updated recently:

- Estimating Sequencing Coverage Technical Note
- Whole-Genome Bisulfite Sequencing for Methylation Analysis Guide
- Cluster Station User Guide
- Version Compatibility Reference
- TruSeq Enrichment Guide, Analysis Guide, Experienced User Card, and Lab Tracking Form

View or download PDFs of all current Illumina documentation here using your MyIllumina account login. To register for a MyIllumina account click here.

Online Training

MiSeq and TruSeq Online Courses Available
Several new courses have been added to the Illumina Customer Online Learning Portal, from Introductory Sequencing and Getting Started with MiSeq, to TruSeq Sample Preparation and Custom Amplicon modules. You'll need a MyIllumina account to enroll. Register for a MyIllumina account or contact your local Account Manager for assistance.

Recent Publications

Bos KI, Schuenemann VJ, Golding GB, Burbano HA,

updates on the latest applications and products, and exchange best practices to get the most from their Illumina systems.

Registration is open for the following meetings:

North American User Group Meetings

Toronto, Ontario, Canada – December 15

Upcoming Events

- Association for Molecular Pathology (AMP)
  November 17-19
  Grapevine, Texas

- Australasian Biospecimen Network Association (ABNA)
  November 18
  Perth, Australia

- New Zealand Microbiological Society (NZMS)
  November 23-25
  Palmerston North, New Zealand

- Functional Genomics & Systems Biology
  November 29-December 1
  Hinxton, United Kingdom

- 4th International Barcode of Life
  November 30-December 3
  Adelaide, Australia

- Plant & Animal Genome Conference (PAG)
  January 14-18
  San Diego, California

- Norwegian Biochemical Society Winter Meeting
  January 19-22
  Storefjell, Norway

- Advances in Genome Biology and Technology (AGBT)
  February 15-18
  Marco Island, Florida

Waglechner N, et al. (2011) A draft genome of *Yersinia pestis* from victims of the Black Death. Nature 478: 506-510.

Wang D, Wang H, Zhou Y, Zhang Q, Zhang F, et al. (2011) Genome sequencing reveals unique mutations in characteristic metabolic pathways and the transfer of virulence genes between *V. mimicus* and *V. cholerae*. PLoS ONE 6: e21299.

Lu R, Neff NF, Quake SR, and Weissman IL (2011) Tracking single hematopoietic stem cells *in vivo* using high-throughput sequencing in conjunction with viral genetic barcoding. Nat Biotechnol 29: 928-933.

Castellarin M, Warren RL, Freeman JD, Dreolini L, Krzywinski M, et al. (2011) *Fusobacterium nucleatum* infection is prevalent in human colorectal carcinoma. Genome Research.

Baillie JK, Barnett MW, Upton KR, Gerhardt DJ, Richmond TA, et al. (2011) Somatic retrotransposition alters the genetic landscape of the human brain. Nature. [Epub ahead of print]

Wang K, Kan J, Yuen ST, Shi ST, Chu KM, et al. (2011)Exome sequencing identifies frequent mutation of ARID1A in molecular subtypes of gastric cancer. Nat Genet. [Epub ahead of print]

Myllykangas S, Buenrostro JD, Natsoulis G, Bell JM, and Ji HP. (2011) Efficient targeted resequencing of human germline and cancer genomes by oligonucleotide-selective sequencing. Nat Biotechnol 29: 1024-1027.

Maher B (2011) Human genetics: Genomes on prescription. Nature 478: 22-24.

Virgin HW and Todd JA (2011) Metagenomics and personalized medicine. Cell 147: 44-56.

Brown CT, Davis-Richardson AG, Giongo A, Gano KA, Crabb DB, et al. (2011) Gut microbiome metagenomics analysis suggests a functional model for the development of autoimmunity for type 1 diabetes. PLoS ONE 6: e25792.

Cooper GM and Shendure J (2011) Needles in stacks of needles: finding disease-causal variants in a wealth of genomic data. Nat Rev Genet 12: 628-640.

View Additional Publications

- International Symposium of the Association of Biomolecular Resource Facilities (ABRF)
March 17-20
Orlando, Florida

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EXHIBIT E

(PART I OF II)

OF

DECLARATION OF KAREN POSSEMATO

illumina

Illumina Reports Financial Results for Fourth Quarter and Fiscal Year 2011

SAN DIEGO--(BUSINESS WIRE)--Feb. 7, 2012-- ILLUMINA REPORTS FINANCIAL RESULTS FOR FOURTH QUARTER AND FISCAL YEAR 2011

Illumina, Inc. (NASDAQ:ILMN) today announced its financial results for the fourth quarter and fiscal year of 2011.

Fourth quarter 2011 results:

Revenue of $250 million, a 4% decrease compared to the $261 million in the fourth quarter of 2010.

GAAP net income for the quarter of $11.7 million, or $0.09 per diluted share, compared to net income of $38.4 million, or $0.25 per diluted share, for the fourth quarter of 2010.

Non-GAAP net income for the quarter of $43.5 million, or $0.35 per diluted share, compared to $40.9 million, or $0.29 per diluted share, for the fourth quarter of 2010 (see the table entitled "Itemized Reconciliation Between GAAP and Non-GAAP Net Income" for a reconciliation of these GAAP and non-GAAP financial measures).

Record cash flow from operations of $108 million and record free cash flow of $81 million for the quarter.

Excluding a very large sequencing equipment order in the fourth quarter of 2009, record orders during the quarter and a book-to-bill ratio of 1.2.

As a result of our strong book-to-bill ratio we exited the year with a backlog of $251 million.

Gross margin in the fourth quarter of 2011 was 68.2% compared to 63.6% in the prior year period. Excluding the effect of non-cash charges associated with stock compensation and the amortization of acquired intangibles, non-GAAP gross margin was 70.2% for the fourth quarter of 2011 compared to 65.1% in the prior year period.

Research and development (R&D) expenses for the fourth quarter of 2011 were $45.5 million compared to $45.8 million in the fourth quarter of 2010. R&D expenses included $7.3 million and $7.0 million of non-cash stock compensation expense in the fourth quarters of 2011 and 2010, respectively. Excluding these charges and contingent compensation expense, R&D expenses as a percentage of revenue were 15.0% compared to 14.5% in the prior year period.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2011 were $60.9 million compared to $62.0 million for the fourth quarter of 2010. SG&A expenses included $12.7 million and $11.3 million of non-cash stock compensation expense in the fourth quarters of 2011 and 2010, respectively. SG&A expenses in the fourth quarter of 2011 also included $2.3 million in legal settlement gain and amortization of acquired intangibles. Excluding these items, SG&A expenses as a percentage of revenue were 20.1% compared to 19.4% in the prior year period.

The company generated $108.3 million in cash flow from operations during the fourth quarter of 2011 compared to $81.5 million in the prior year period. Depreciation and amortization expenses were $18.5 million and capital expenditures were $27.1 million during the fourth quarter of 2011. The company

ended the fourth quarter of 2011 with $1.2 billion in cash, cash equivalents and short-term investments compared to $894.3 million as of January 2, 2011.

Fiscal 2011 results:

Revenue of $1.056 billion, a 17% increase over the $902.7 million reported in fiscal 2010.

GAAP net income of $86.6 million, or $0.62 per diluted share, compared to $124.9 million or $0.87 per share in fiscal 2010.

Non-GAAP net income of $176.0 million, or $1.30 per diluted share, compared to $142.2 million, or $1.06 per diluted share in fiscal 2010 (see table entitled "An Itemized Reconciliation Between GAAP and Non-GAAP Net Income" for a reconciliation of these GAAP and non-GAAP financial measures).

Record cash flow from operations of $358 million.

Gross margin for fiscal 2011 was 67.2% compared to 66.6% in fiscal 2010. Excluding the effect of non-cash charges associated with stock compensation and the amortization of acquired intangibles, non-GAAP gross margin was 69.0% in fiscal 2011 compared to 68.1% in fiscal 2010.

R&D expenses for fiscal 2011 were $196.9 million compared to $177.9 million in fiscal 2010. R&D expenses for fiscal 2011 included non-cash stock compensation expense of $32.1 million compared to $25.4 million in fiscal 2010. R&D expenses also included contingent compensation expense of $4.8 million in fiscal 2011 and $3.7 million in fiscal 2010. Excluding these charges, R&D expenses as a percentage of revenue were 15.2% compared to 16.5% in fiscal 2010.

SG&A expenses for fiscal 2011 were $261.8 million compared to $220.5 million in fiscal 2010. SG&A expenses included $52.3 million and $40.4 million of non-cash stock compensation expense in fiscal 2011 and 2010, respectively. SG&A expenses in fiscal 2011 also included $2.3 million in legal settlement gain, $1.3 million of contingent compensation expense and amortization of acquired intangibles. Excluding these items, SG&A expenses as a percentage of revenue were 19.9%, consistent with fiscal 2010.

The company generated $358.1 million in cash flow from operations in fiscal 2011 compared to $272.6 million in fiscal 2010. Depreciation and amortization expenses for fiscal 2011 were $68.3 million and capital expenditures were $77.8 million.

Highlights since our last earnings release

Announced the HiSeq 2500, a new multi-mode next-generation sequencer which enables researchers and clinicians to sequence an entire human genome in approximately a day (120Gb/run). Alternatively, the instrument can be operated in the standard 600Gb-run mode. Existing HiSeq 2000 instruments are upgradable through a simple, field-based upgrade priced at $50,000. The system and upgrades will be available in the second half of 2012.

Announced significant enhancements to the MiSeq platform that enable read-lengths of up to 2 x 250 base pairs per run, faster cycle times, and threefold higher throughput (up to 7Gb per run) compared to the original MiSeq launched just over four months ago.

Announced a ground-breaking partnership with Siemens Healthcare Diagnostics to use the MiSeq platform for Siemens' molecular HIV tests and to establish new standards based on the use of next-generation sequencing for the identification of infectious diseases and potential treatment paths.

Appointed Marc Stapley, formerly Pfizer's Senior Vice President of Finance, as Chief Financial Officer.

Further strengthened Illumina's management team by appointing Dr. Daniel Grosu to the newly created position of Chief Medical Officer and Laura Lauman to the position of Vice President of Marketing.

Promoted Matt Posard to the newly created position of Senior Vice President and General Manager of our Translational and Consumer Genomics Business Unit; promoted Omead Ostadan, formerly our Vice President of Marketing, to the position of Senior Vice President Product Development.

Expanded the Illumina Genome Network by adding the British Columbia Cancer Agency to the growing list of prestigious participants.

Financial outlook and guidance

The non-GAAP financial guidance discussed below excludes various one-time or specified non-cash charges. Please see our Reconciliation of Non-GAAP Financial Guidance included in this release for a reconciliation of the GAAP and Non-GAAP financial measures.

We currently expect revenue for 2012 between $1.10 billion and $1.175 billion, representing year-over-year growth between 4% and 11%. We expect our non-GAAP gross margin percentage to approximate 70% for the year. We expect non-GAAP earnings per fully diluted share between $1.40 and $1.50. We expect the full-year pro forma tax rate to be approximately 33% and stock compensation expense to be approximately $105 million. The Company expects full-year weighted average diluted shares outstanding for the measurement of pro forma amounts to be approximately 135 million shares.

For the first quarter of 2012, we expect revenues between $250 and $260 million and a non-GAAP gross margin percentage of approximately 69%. We expect non-GAAP earnings per fully diluted share of $0.29 to $0.32, assuming approximately 133 million shares. We expect stock compensation expense during the first quarter of approximately $25 million.

Quarterly conference call information

The conference call will begin at 2:00 pm Pacific Time (5:00 pm Eastern Time) on Tuesday, February 7, 2012. Interested parties may listen to the call by dialing 888-455-2265 (passcode: 8701498), or if outside North America by dialing +1-719-457-2637 (passcode: 8701498). Individuals may access the live teleconference in the Investor Relations section of Illumina's web site under the "Company" tab at http://www.illumina.com.

A replay of the conference call will be available from 5:00 pm Pacific Time (8:00 pm Eastern Time) on February 7, 2012 through February 14, 2012 by dialing 888-203-1112 (passcode: 8701498), or if outside North America by dialing +1-719-457-0820 (passcode: 8701498).

Statement regarding use of non-GAAP financial measures

The company reports non-GAAP results for diluted net income per share, net income, gross margins, operating expenses, operating margins, other income, and free cash flow in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP.

The company's financial measures under GAAP include substantial charges related to stock compensation expense, headquarter relocation expense, non-cash interest expense associated with the company's convertible debt instruments that may be settled in cash, restructuring charges, amortization expense related to acquired intangible assets, loss on the extinguishment of convertible debt, contingent compensation expense, legal settlement gain, and acquisition related gain or expense.

Per share amounts also include the double dilution associated with the accounting treatment of the company's 0.625% convertible senior notes outstanding and the corresponding call option overlay. Management believes that presentation of operating results that excludes these items and per share double dilution provides useful supplemental information to investors and facilitates the analysis of the company's core operating results and comparison of operating results across reporting periods. Management also believes that this supplemental non-GAAP information is therefore useful to investors in analyzing and assessing the company's past and future operating performance.

The company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP results are presented in the tables of this release.

Use of forward looking statements

This release contains projections, information about our financial outlook, earnings guidance, and other forward-looking statements that involve risks and uncertainties. These forward-looking statements are based on our expectations as of the date of this release and may differ materially from actual future events or results. Among the important factors that could cause actual results to differ materially from those in any forward-looking statements are (i) our ability to develop and commercialize further our sequencing, array, PCR, and consumables technologies and to deploy new products and applications, and expand the markets, for our technology platforms; (ii) our ability to manufacture robust instrumentation and consumables; (iii) our expectations and beliefs regarding future conduct and growth of the business and the markets in which we operate; (iv) challenges inherent in developing, manufacturing, and launching new products and services; (v) business disruptions associated with the tender offer commenced by CKH Acquisition Corporation, a wholly owned subsidiary of Roche Holding Ltd; (vi) our ability to maintain our revenue and profitability during periods of research funding reduction or uncertainty and adverse economic and business conditions, including as a result of slowing economic growth in the United States or worldwide, together with other factors detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We undertake no obligation, and do not intend, to update these forward-looking statements, to review or confirm analysts' expectations, or to provide interim reports or updates on the progress of the current financial quarter.

About Illumina

Illumina (http://www.illumina.com) is a leading developer, manufacturer, and marketer of life science tools and integrated systems for the analysis of genetic variation and function. We provide innovative sequencing and array-based solutions for genotyping, copy number variation analysis, methylation studies, gene expression profiling, and low-multiplex analysis of DNA, RNA, and protein. We also provide tools and services that are fueling advances in consumer genomics and diagnostics. Our technology and products accelerate genetic analysis research and its application, paving the way for molecular medicine and ultimately transforming healthcare.

Additional Information and Where to Find It

This communication does not constitute an offer to buy or a solicitation of an offer to sell any securities. In response to the tender offer commenced by CKH Acquisition Corporation, a wholly owned subsidiary of Roche Holding Ltd, Illumina has filed a solicitation/recommendation statement on Schedule

14D-9 with the SEC. INVESTORS AND SECURITY HOLDERS OF ILLUMINA ARE URGED TO READ THE SOLICITATION/RECOMMENDATION STATEMENT AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY (WHEN THEY BECOME AVAILABLE) BECAUSE THEY CONTAIN IMPORTANT INFORMATION. Investors and security holders will be able to obtain free copies of these documents (when they become available) and other documents filed with the SEC by Illumina through the web site maintained by the SEC at http://www.sec.gov. Investors and security holders also will be able to obtain free copies of these documents, and other documents filed with the SEC by Illumina, from Illumina by directing a request to Illumina, Inc., Attn: Investor Relations, Kevin Williams, MD, kwilliams@illumina.com.

In addition, Illumina will file a proxy statement and a WHITE proxy card with the SEC. The definitive proxy statement will be mailed to security holders of Illumina. INVESTORS AND SECURITY HOLDERS OF ILLUMINA ARE URGED TO READ THE PROXY STATEMENT AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY (WHEN THEY BECOME AVAILABLE) BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and security holders will be able to obtain free copies of these documents (when they become available) and other documents filed with the SEC by Illumina through the web site maintained by the SEC at http://www.sec.gov. Investors and security holders also will be able to obtain free copies of the proxy statement, and other documents filed with the SEC by Illumina, from Illumina by directing a request to Illumina, Inc., Attn: Investor Relations, Kevin Williams, MD, kwilliams@illumina.com.

Certain Information Regarding Participants in the Solicitation

Illumina and certain of its directors and executive officers may be deemed to be participants in the solicitation of proxies in connection with Illumina's 2012 Annual Meeting of Stockholders under the rules of the SEC. Security holders may obtain information regarding the names, affiliations and direct and indirect interests (by security holdings or otherwise) of Illumina's directors and executive officers in (i) Illumina's Annual Report on Form 10-K for the year ended January 2, 2011, which was filed with the SEC on February 28, 2011, and (ii) Illumina's proxy statement for its 2011 Annual Meeting of Stockholders, which was filed with the SEC on March 24, 2011. To the extent that Illumina's directors' and executive officers' holdings of Illumina's securities have changed from the amounts printed in the proxy statement for the 2011 Annual Meeting of Stockholders, such changes have been or will be reflected on Statements of Changes in Beneficial Ownership on Form 4 filed with the SEC. These documents can be obtained free of charge from the sources indicated above. Additional information regarding the interests of these participants in any proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will also be included in any proxy statement and other relevant materials to be filed with the SEC when they become available.

Illumina, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

	January 1, 2012 (unaudited)	January 2, 2011	
ASSETS			
Current assets:			
Cash and cash equivalents	$ 302,978	$ 248,947	
Short-term investments	886,590	645,342	ILLUM-0885
Accounts receivable, net	173,886	165,598	

Inventory, net	128,781	142,211
Deferred tax assets, current portion	23,188	19,378
Prepaid expenses and other current assets	29,196	36,922
Total current assets	1,544,619	1,258,398
Property and equipment, net	143,483	129,874
Goodwill	321,853	278,206
Intangible assets, net	106,475	91,462
Deferred tax assets, long-term portion	19,675	39,497
Other assets	59,735	41,676
Total assets	$ 2,195,840	$ 1,839,113
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 49,806	$ 66,744
Accrued liabilities	187,774	156,164
Long-term debt, current portion	-	311,609
Total current liabilities	237,580	534,517
Long-term debt	807,369	-
Other long-term liabilities	69,954	28,531
Conversion option subject to cash settlement	5,722	78,390
Stockholders' equity	1,075,215	1,197,675
Total liabilities and stockholders' equity	$ 2,195,840	$ 1,839,113

Illumina, Inc.
Condensed Consolidated Statements of Income
(In thousands, except per share amounts)
(unaudited)

	Three Months Ended		Year Ended	
	January 1, 2012	January 2, 2011	January 1, 2012	January 2, 2011
Revenue:				
Product revenue	$ 230,396	$ 245,626	$ 987,280	$ 842,510
Service and other revenue	19,675	15,672	68,255	60,231
Total revenue	250,071	261,298	1,055,535	902,741
Cost of Revenue:				
Cost of product revenue (a)	69,509	87,183	308,228	271,997
Cost of service and other revenue (a)	6,940	5,694	26,118	21,399
Amortization of acquired intangible assets	3,036	2,295	12,091	7,805
Total cost of revenue	79,485	95,172	346,437	301,201
Gross profit	170,586	166,126	709,098	601,540
Operating Expenses:				
Research and development (a)	45,513	45,800	196,913	177,947

ILLUM-0886

Selling, general and administrative (a)	60,918	62,034	261,843	220,454
Headquarter relocation expense	30,243	-	41,826	-
Restructuring charges	8,136	-	8,136	-
Acquisition related (gain) expense, net	(1,523)	(10,376)	919	(8,515)
Total operating expenses	143,287	97,458	509,637	389,886
Income from operations	27,299	68,668	199,461	211,654
Other expense, net	(7,077)	(17,886)	(66,416)	(26,275)
Income before income taxes	20,222	50,782	133,045	185,379
Provision for income taxes	8,502	12,342	46,417	60,488
Net income	$ 11,720	$ 38,440	$ 86,628	$ 124,891
Net income per basic share	$ 0.10	$ 0.31	$ 0.70	$ 1.01
Net income per diluted share	$ 0.09	$ 0.25	$ 0.62	$ 0.87
Shares used in calculating basic net income per share	121,541	125,876	123,399	123,581
Shares used in calculating diluted net income per share	124,888	151,171	138,937	143,433

(a) Includes total stock-based compensation expense for stock based awards:

	Three Months Ended		Year Ended	
	January 1, 2012	January 2, 2011	January 1, 2012	January 2, 2011
Cost of product revenue	$ 1,684	$ 1,508	$ 6,951	$ 5,378
Cost of service and other revenue	159	76	695	470
Research and development	7,295	6,977	32,105	25,428
Selling, general and administrative	12,678	11,279	52,341	40,369
Stock-based compensation expense before taxes	$ 21,816	$ 19,840	$ 92,092	$ 71,645

Illumina, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Three Months Ended		Year Ended	
	January 1, 2012	January 2, 2011	January 1, 2012	January 2, 2011
Net cash provided by operating activities	$ 108,300	$ 81,481	$ 358,140	$ 272,573
Net cash used in investing activities	(42,960)	(70,056)	(400,999)	(285,053)
Net cash provided by financing activities	7,848	26,543	97,016	116,474
Effect of exchange rate changes on cash and cash				

equivalents	(56)	212	(126)	320
Net increase in cash and cash equivalents	73,132	38,180	54,031	104,314
Cash and cash equivalents, beginning of period	229,846	210,767	248,947	144,633
Cash and cash equivalents, end of period	$302,978	$248,947	$ 302,978	$ 248,947
Calculation of free cash flow **(a)**:				
Net cash provided by operating activities	$108,300	$ 81,481	$ 358,140	$ 272,573
Purchases of property and equipment	(27,114)	(12,384)	(77,800)	(49,818)
Free cash flow	$ 81,186	$ 69,097	$ 280,340	$ 222,755

(a) Free cash flow, which is a non-GAAP financial measure, is calculated as net cash provided by operating activities reduced by purchases of property and equipment. Free cash flow is useful to management as it is one of the metrics used to evaluate our performance and to compare us with other companies in our industry. However, our calculation of free cash flow may not be comparable to similar measures used by other companies.

Illumina, Inc.
Results of Operations - Non-GAAP
(In thousands, except per share amounts)
(unaudited)

ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP NET INCOME PER SHARE:

	Three Months Ended		Year Ended	
	January 1, 2012	January 2, 2011	January 1, 2012	January 2, 2011
GAAP net income per share - diluted	**$ 0.09**	**$ 0.25**	**$ 0.62**	**$ 0.87**
Pro forma impact of weighted average shares **(a)**	-	0.01	0.03	0.06
Adjustments to net income:				
Headquarter relocation expense **(b)**	0.24	-	0.31	-
Non-cash interest expense **(c)**	0.07	0.04	0.24	0.16
Restructuring charges	0.07	-	0.06	-
Amortization of acquired intangible assets	0.02	0.02	0.09	0.06
Legal settlement gain	(0.02)	-	(0.02)	-
Acquisition related (gain) expense, net **(d)**	(0.01)	(0.07)	0.01	(0.09)
Contingent compensation expense **(e)**	0.01	0.01	0.04	0.03
Loss on extinguishment of debt	-	-	0.28	-
Impairment loss related to a cost-method investment	-	0.09	-	0.10
Incremental non-GAAP tax expense **(f)**	(0.12)	(0.06)	(0.36)	(0.13)
Non-GAAP net income per share - diluted **(g)**	$ 0.35	$ 0.29	$ 1.30	$ 1.06
Shares used in calculating non-GAAP diluted net income				

per share	124,409	140,080	135,154	134,375

ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP NET INCOME:

GAAP net income	**$ 11,720**	**$ 38,440**	**$ 86,628**	**$124,891**
Headquarter relocation expense **(b)**	30,243	-	41,826	-
Non-cash interest expense **(c)**	8,542	5,363	32,495	20,832
Restructuring charges	8,136	-	8,136	-
Amortization of acquired intangible assets	3,188	2,295	12,689	7,805
Legal settlement gain	(2,300)	-	(2,300)	-
Acquisition related (gain) expense, net **(d)**	(1,523)	(10,376)	919	(11,429)
Contingent compensation expense **(e)**	732	919	6,057	3,675
Loss on extinguishment of debt	-	-	37,611	-
Impairment loss related to a cost-method investment	-	13,223	-	13,223
Incremental non-GAAP tax expense **(f)**	(15,215)	(9,014)	(48,053)	(16,813)
Non-GAAP net income **(g)**	$ 43,523	$ 40,850	$176,008	$ 142,184

ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP DILUTED NUMBER OF SHARES:

Weighted average shares used in calculation of GAAP diluted net income per share	124,888	151,171	138,937	143,433
Weighted average dilutive potential common shares issuable of redeemable convertible senior notes **(a)**	(479)	(11,091)	(3,783)	(9,058)
Weighted average shares used in calculation of Non-GAAP diluted net income per share	124,409	140,080	135,154	134,375

(a) Pro forma impact of weighted average shares represents the impact of double dilution associated with the accounting treatment of the company's outstanding convertible debt and the corresponding call option overlay.

(b) The Company relocated its headquarters to a new facility in San Diego, California during the second half of 2011. Headquarter relocation expense in Q4 2011 and fiscal year 2011 are primarily non-cash in nature and includes a cease-use loss upon vacating certain buildings of our prior headquarters, accelerated depreciation expense, and double rent expense during the transition to our new headquarter facility.

(c) Non-cash interest expense is calculated in accordance with the authoritative accounting guidance for convertible debt instruments that may be settled in cash.

(d) Acquisition related (gain) expense, net includes the following current year and prior year adjustments:

2011 adjustments:

- IPR&D charge of $5.4 million related to milestone payments for a prior acquisition
- Gain of $4.5 million for changes in fair value of contingent consideration, $1.5 million of which was recorded in Q4 2011

2010 adjustments:

- IPR&D charge of $1.3 million related to milestone payments for a prior acquisition

- Acquisition expenses of $0.5 million
- Gain on acquisition of $2.9 million recorded for the difference between the carrying value of a cost-method investment prior to acquisition and the fair value of that investment at the time of acquisition

- Gain of $10.4 million recorded in Q4 2010 for changes in fair value of contingent consideration

(e) Contingent compensation expense represents contingent consideration for post-combination services associated with acquisitions.

(f) Incremental non-GAAP tax expense reflects the increase to GAAP tax expense related to the non-GAAP adjustments listed above.

(g) Non-GAAP net income per share and net income exclude the effect of the pro forma adjustments as detailed above. Non-GAAP diluted net income per share and net income are key drivers of our core operating performance and major factors in management's bonus compensation each year. Management has excluded the effects of these items in these measures to assist investors in analyzing and assessing our past and future core operating performance.

Illumina, Inc.
Results of Operations - Non-GAAP (continued)
(Dollars in thousands)
(unaudited)

ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP RESULTS OF OPERATIONS AS A PERCENT OF REVENUE:

	Three Months Ended				Year Ended			
	January 1, 2012		January 2, 2011		January 1, 2012		January 2, 2011	
GAAP gross profit	**$170,586**	**68.2%**	**$166,126**	**63.6%**	**$709,098**	**67.2%**	**$601,540**	**66.6%**
Stock-based compensation expense	1,843	0.7%	1,584	0.6%	7,646	0.7%	5,848	0.6%
Amortization of acquired intangible assets	3,036	1.2%	2,295	0.9%	12,091	1.1%	7,805	0.9%
Non-GAAP gross profit	$ 175,465	70.2%	$ 170,005	65.1%	$ 728,835	69.0%	$ 615,193	68.1%
Research and development expense	**$ 45,513**	**18.2%**	**$ 45,800**	**17.5%**	**$196,913**	**18.7%**	**$177,947**	**19.7%**
Stock-based compensation								

expense	(7,295)	(2.9%)	(6,977)	(2.7%)	(32,105)	(3.0%)	(25,428)	(2.8%)
Contingent compensation expense **(a)**	(732)	(0.3%)	(919)	(0.4%)	(4,799)	(0.5%)	(3,675)	(0.4%)
Non-GAAP research and development expense	$ 37,486	15.0%	$ 37,904	14.5%	$ 160,009	15.2%	$ 148,844	16.5%
Selling, general and administrative expense	**$ 60,918**	**24.4%**	**$ 62,034**	**23.7%**	**$261,843**	**24.8%**	**$220,454**	**24.4%**
Stock-based compensation expense	(12,678)	(5.1%)	(11,279)	(4.3%)	(52,341)	(5.0%)	(40,369)	(4.5%)
Legal settlement gain	2,300	0.9%	-	-	2,300	0.2%	-	-
Contingent compensation expense **(a)**	-	-	-	-	(1,258)	(0.1%)	-	-
Amortization of acquired intangible assets	(152)	(0.1%)	-	-	(598)	(0.1%)	-	-
Non-GAAP selling, general and administrative expense	$ 50,388	20.1%	$ 50,755	19.4%	$ 209,946	19.9%	$ 180,085	19.9%
GAAP operating profit	**$ 27,299**	**10.9%**	**$ 68,668**	**26.3%**	**$199,461**	**18.9%**	**$211,654**	**23.4%**
Stock-based compensation expense	21,816	8.7%	19,840	7.6%	92,092	8.7%	71,645	7.9%
Headquarter relocation expense **(b)**	30,243	12.1%	-	-	41,826	4.0%	-	-
Amortization of acquired intangible assets	3,188	1.3%	2,295	0.9%	12,689	1.2%	7,805	0.9%
Restructuring charges	8,136	3.3%	-	-	8,136	0.8%	-	-
Contingent compensation expense **(a)**	732	0.3%	919	0.4%	6,057	0.6%	3,675	0.4%
Legal settlement gain	(2,300)	(0.9%)	-	-	(2,300)	(0.2%)	-	-

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Acquisition related (gain) expense, net **(c)**	(1,523)	(0.6%)	(10,376)	-4.0%	919	0.1%	(8,515)	-0.9%
Non-GAAP operating profit **(d)**	$ 87,591	35.0%	$ 81,346	31.1%	$ 358,880	34.0%	$ 286,264	31.7%
GAAP other expense, net	**$ (7,077)**	**(2.8%)**	**$(17,886)**	**(6.8%)**	**$(66,416)**	**(6.3%)**	**$(26,275)**	**(2.9%)**
Loss on extinguishment of debt	-	-	-	-	37,611	3.6%	-	-
Acquisition related gain **(c)**	-	-	-	-	-	-	(2,914)	(0.3%)
Impairment loss related to a cost-method investment	-	-	13,223	5.1%	-	-	13,223	1.5%
Non-cash interest expense **(e)**	8,542	3.4%	5,363	2.1%	32,495	3.1%	20,832	2.3%
Non-GAAP other income, net **(d)**	$ 1,465	0.6%	$ 700	0.3%	$ 3,690	0.3%	$ 4,866	0.5%

(a) Contingent compensation expense represents contingent consideration for post-combination services associated with acquisitions.

(b) Headquarter relocation expense in Q4 2011 and fiscal year 2011 are primarily non-cash in nature and includes a cease-use loss upon vacating certain buildings of our prior headquarters, accelerated depreciation expense, and double rent expense during the transition to our new headquarter facility.

(c) Acquisition related (gain) expense, net includes the following current year and prior year adjustments:

2011 adjustments:

- IPR&D charge of $5.4 million related to milestone payments for a prior acquisition
- Gain of $4.5 million for changes in fair value of contingent consideration, $1.5 million of which was recorded in Q4 2011

2010 adjustments:

- IPR&D charge of $1.3 million related to milestone payments for a prior acquisition
- Acquisition expenses of $0.5 million

- Gain on acquisition of $2.9 million recorded for the difference between the carrying value of a cost-method investment prior to acquisition and the fair value of that investment at the time of acquisition
- Gain of $10.4 million recorded in Q4 2010 for changes in fair value of contingent consideration

(d) Non-GAAP operating profit, and non-GAAP other income, net, exclude the effects of the pro forma adjustments as detailed above. Management has excluded the effects of these items in these

measures to assist investors in analyzing and assessing our past and future core operating performance. Non-GAAP gross profit, included within the non-GAAP operating profit, is a key measure of the effectiveness and efficiency of our manufacturing processes, product mix and the average selling prices of our products and services.

(e) Non-cash interest expense is calculated in accordance with the authoritative accounting guidance for convertible debt instruments that may be settled in cash.

Illumina, Inc.
Reconciliation of Non-GAAP Financial Guidance

The financial guidance provided below is an estimate based on information available as of February 7, 2012. The company's future performance and financial results are subject to risks and uncertainties, and actual results could differ materially from the guidance set forth below. Some of the factors that could affect the company's financial results are stated above in this press release. More information on potential factors that could affect the company's financial results is included from time to time in the company's public reports filed with the SEC, including the company's Form 10-K for the fiscal year ended January 1, 2012 to be filed with the SEC, and the company's Form 10-Q for the fiscal quarters ended April 3, 2011, July 3, 2011, and October 2, 2011. The company assumes no obligation to update any forward-looking statements or information, which speak as of their respective dates.

	Fiscal Year 2012	Q1 2012
Gross Margin		
Non-GAAP gross margin	70%	69%
Stock-based compensation expense	(1%)	(1%)
Amortization of acquired intangible assets	(1%)	(1%)
GAAP gross margin	68%	67%
Diluted net income per share		
Non-GAAP diluted net income per share	$1.40 - $1.50	$0.29 - $0.32
Non-cash interest expense **(a)**	(0.16)	(0.04)
Headquarter relocation expense **(b)**	(0.11)	--
Amortization of intangible assets	(0.06)	(0.02)
Contingent compensation expense **(c)**	(0.03)	(0.01)
Restructuring charges	(0.03)	(0.02)
Pro forma impact of weighted average shares **(d)**	(0.01)	--
GAAP diluted net income per share	**$1.00 - $1.10**	**$0.20 - $0.23**

(a) Non-cash interest expense is calculated in accordance with the authoritative accounting guidance for convertible debt instruments that may be settled in cash.

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(b) We expect to incur additional headquarter relocation expenses during the first half of 2012, the majority of which are non-cash in nature. These expenses include items such as additional cease-use loss upon vacating our former headquarter facilities, accelerated depreciation of certain property and

equipment, and double rent expense during the transition to the new facility.

(c) Contingent compensation expense represents contingent consideration for post-combination services associated with acquisitions.

(d) Pro forma impact of weighted average shares represents the estimated impact of double dilution associated with the accounting treatment of the company's outstanding convertible debt and the corresponding call option overlay.

Source: Illumina, Inc.

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Illumina Reports Financial Results for Fourth Quarter and Fiscal Year 2010

SAN DIEGO, Feb 08, 2011 (BUSINESS WIRE) -- Illumina, Inc. (NASDAQ:ILMN) today announced its financial results for the fourth quarter and fiscal year of 2010.

Fourth quarter 2010 results:

- Revenue of $261.3 million, a 45% increase over the $180.6 million reported in the fourth quarter of 2009.
- GAAP net income of $38.4 million, or $0.25 per diluted share, compared to net income of $11.7 million, or $0.09 per diluted share, for the fourth quarter of 2009.
- Non-GAAP net income of $40.9 million, or $0.29 per diluted share, compared to $27.0 million, or $0.21 per diluted share, for the fourth quarter of 2009 (see the table entitled "An Itemized Reconciliation Between GAAP and Non-GAAP Net Income" for a reconciliation of these GAAP and non-GAAP financial measures).

Gross margin in the fourth quarter of 2010 was 63.6% compared to 69.5% in the comparable period of 2009. Excluding the effect of non-cash charges associated with stock compensation and the amortization of intangibles, non-GAAP gross margin was 65.1% for the fourth quarter of 2010 compared to 71.2% in the prior year period.

Research and development (R&D) expenses for the fourth quarter of 2010 were $45.8 million compared to $40.4 million in the fourth quarter of 2009. R&D expenses included $7.0 million and $5.6 million of non-cash stock compensation expense in the fourth quarter of 2010 and 2009, respectively. R&D expenses in both periods also included $0.9 million of accrued contingent compensation. Excluding these charges, R&D expenses as a percentage of revenue were 14.4% compared to 18.8% in the prior year period.

Selling, general, and administrative (SG&A) expenses for the fourth quarter of 2010 were $62.0 million compared to $49.5 million for the fourth quarter of 2009. SG&A expenses included $11.3 million and $9.6 million of non-cash stock compensation expense in the fourth quarter of 2010 and 2009, respectively. Excluding these charges, SG&A expenses as a percentage of revenue were 19.4% compared to 22.1% in the prior year period.

The company generated $81.5 million in cash flow from operations during the fourth quarter of 2010 compared to $61.3 million in the prior year period. Depreciation and amortization expenses were $12.1 million and capital expenditures were $12.4 million during the fourth quarter. The company ended the fourth quarter with $894.3 million in cash and short-term investments compared to $806.8 million as of October 3, 2010 and $693.5 million as of January 3, 2010.

Fiscal 2010 results:

- Revenue of $902.7 million, a 35% increase over the $666.3 million reported in fiscal 2009.
- GAAP net income of $124.9 million, or $0.87 per diluted share, compared to $72.3 million or $0.53 per share in fiscal 2009.
- Non-GAAP net income of $142.2 million, or $1.06 per diluted share, compared to $104.2 million, or $0.80 per diluted share, in fiscal 2009 (see the table entitled "An Itemized Reconciliation Between GAAP and Non-GAAP Net Income" for a reconciliation of these GAAP and non-GAAP financial measures).

Gross margin for fiscal 2010 was 66.6% compared to 68.1% in fiscal 2009. Excluding the effect of non-cash charges associated with stock compensation and the amortization of intangibles, non-GAAP gross margin was 68.1% in fiscal 2010 compared to 69.9% in fiscal 2009.

R&D expenses for fiscal 2010 were $177.9 million compared to $140.6 million in fiscal 2009. R&D expenses for fiscal 2010 included non-cash stock compensation expense of $25.4 million compared to $20.0 million in fiscal 2009. R&D expenses in both periods included $3.7 million of accrued contingent compensation and in fiscal 2009 included $2.0 million of acquired research and development. Excluding these charges, R&D expenses as a percentage of revenue were 16.5% compared to 17.3% in fiscal 2009.

SG&A expenses for fiscal 2010 were $221.0 million compared to $176.3 million in fiscal 2009. SG&A expenses included $40.4 million and $35.6 million of non-cash stock compensation expense in fiscal 2010 and 2009, respectively. SG&A expenses in fiscal 2010 also included $0.5 million of acquisition related transaction expense. Excluding these charges, SG&A expenses as a percentage of revenue were 19.9% compared to 21.1% in fiscal 2009.

The company generated $272.6 million in cash from operations in fiscal 2010 compared to $172.2 million in fiscal 2009. Depreciation and amortization expenses for fiscal 2010 were $42.6 million and capital expenditures were $49.8 million.

Highlights since our last earnings release:

ILLUM-0895

- Announced MiSeq, a low-cost personal sequencing system that is capable of beginning with purified DNA and ending with analyzed data in as few as eight hours, or generating in excess of 1 gigabase per run in just over a day.

- Completed the acquisition of Epicentre Biotechnologies, a leading provider of nucleic acid sample preparation reagents and specialty enzymes used in sequencing and microarray applications.
- Launched the TruSeq sample preparation kits for DNA, RNA, and small RNA applications and the TruSeq Exome Enrichment Kit, for use across the company's portfolio of sequencing platforms.
- Launched the next generation of iSelect custom genotyping products that allow researchers to design custom arrays containing from 3,000 up to 1,000,000 markers, with the flexibility to add supplemental content to their array designs.
- Entered into a lease agreement to relocate the company's corporate headquarters to a larger facility in San Diego with an expected commencement date in Q4 2011.
- Received ISO 13485 certification in our San Diego, Chesterford and Singapore facilities.

Financial outlook and guidance

The non-GAAP financial guidance discussed below excludes the following items (see the table entitled "Reconciliation of Non-GAAP Financial Guidance" for a reconciliation of these GAAP and non-GAAP financial measures):

- Charges associated with relocating the company's corporate headquarters including an estimated non-cash charge related to a cease-use loss to account for the remaining lease payments on the company's current headquarters reduced by estimated sublease proceeds, accelerated depreciation on existing leasehold improvements abandoned upon the relocation to the new facility, and anticipated double rent expense incurred during the transition to the new facility.
- Incremental non-cash interest expense associated with the company's convertible debt instruments that may be settled in cash and the double dilution associated with the accounting treatment of the company's outstanding convertible debt and the corresponding call option overlay.
- Amortization expense related to intangible assets.
- In-process research and development and contingent compensation expense.

The company expects:

- Revenue growth for fiscal 2011 of approximately 20% from fiscal 2010 revenue of $902.7 million.
- Gross margin to improve over the course of the year to approximately 70% for the full year.
- Non-GAAP earnings per diluted share to grow more than 30% from 2010 non-GAAP earnings per diluted share of $1.06.
- Stock compensation expense of approximately $101 million or a tax adjusted amount of $0.49 per fully diluted pro forma share.
- Full-year weighted-average diluted shares outstanding for the measurement of pro forma results of approximately 145 million.

Quarterly conference call information

The conference call will begin at 2:30pm Pacific Time (5:30pm Eastern Time) on Tuesday, February 8, 2011. Interested parties may listen to the call by dialing 800.561.2813 (passcode: 53294883), or if outside North America, by dialing +1.617.614.3529 (passcode: 53294883). Individuals may access the live teleconference in the Investor Relations section of Illumina's web site under the "Company" tab at www.illumina.com.

A replay of the conference call will be available from 6:30pm Pacific Time (9:30pm Eastern Time) on February 8, 2011 through February 15, 2011 by dialing 888.286.8010, or if outside North America, by dialing +1.617.801.6888 (passcode: 87212455).

Statement regarding use of non-GAAP financial measures

The company reports non-GAAP results for diluted net income per share, net income, gross margins, operating margins, other income, and free cash flow in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP.

The company's financial measures under GAAP include substantial non-cash and other charges related to stock compensation expense, the impairment of a cost-method investment, a gain recorded for the change in fair value of contingent consideration, expenses related to our new lease, including a cease use loss, accelerated depreciation, and anticipated double rent expense, incremental interest expense associated with the company's convertible debt instruments that may be settled in cash, a gain on the acquisition of an investee accounted for using the cost method of accounting prior to acquisition, amortization expense related to intangible assets, in-process research and development and contingent compensation expense, acquisition related transaction expenses, expense related to acquired research and development, and a gain on the extinguishment of debt. Per share amounts also include the double dilution associated with the accounting treatment of the company's convertible debt outstanding and the corresponding call option overlay. Management believes that presentation of operating results that excludes these charges and per share double dilution provides useful supplemental information to investors and facilitates the analysis of the company's core operating results and comparison of operating results across reporting periods. Management also believes that this supplemental non-GAAP information is therefore useful to investors in analyzing and assessing the company's past and future operating performance.

The company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP results are presented in the tables of this release.

Use of forward looking statements

ILLUM-0896

This release contains projections, information about our financial outlook, earnings guidance, and other forward-looking statements that involve risks and uncertainties. These forward-looking statements are based on our expectations as of the date of this release and may differ materially from actual future events or results. Among the important factors that could cause actual results to differ materially from those in any forward-looking statements are (i) our ability to develop and commercialize further our BeadArray(TM), VeraCode(R), and Solexa(R) technologies and to deploy new sequencing, gene expression, and genotyping products and applications for our technology platforms, (ii) our

ability to increase our manufacturing capacity and produce robust instrumentation and reagents, and (iii) reductions in the funding levels to our primary customers, including as a result of the timing and amount of funding provided by the American Recovery and Reinvestment Act of

2009, together with other factors detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We undertake no obligation, and do not intend, to update these forward-looking statements, to review or confirm analysts' expectations, or to provide interim reports or updates on the progress of the current financial quarter.

About Illumina

Illumina (www.illumina.com) is a leading developer, manufacturer, and marketer of life science tools and integrated systems for large-scale analysis of genetic variation and function. We provide innovative sequencing and array-based solutions for genotyping, copy number variation analysis, methylation studies, gene expression profiling, and low-multiplex analysis of DNA, RNA and protein. We also provide tools and services that are fueling advances in consumer genomics and diagnostics. Our technology and products accelerate genetic analysis research and its application, paving the way for molecular medicine and ultimately transforming healthcare.

Illumina, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

	January 2, 2011	January 3, 2010
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 248,947	$ 144,633
Short-term investments	645,342	548,894
Accounts receivable, net	165,598	157,751
Inventory, net	142,211	92,776
Deferred tax assets, current portion	19,378	20,021
Prepaid expenses and other current assets	36,922	17,515
Total current assets	1,258,398	981,590
Property and equipment, net	129,874	117,188
Goodwill	278,206	213,452
Intangible assets, net	70,024	43,788
Deferred tax assets, long-term portion	39,497	47,371
Other assets	63,114	26,548
Total assets	$ 1,839,113	$ 1,429,937
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 66,744	$ 52,781
Accrued liabilities	156,164	98,253
Long-term debt, current portion	311,609	290,202
Total current liabilities	534,517	441,236
Other long-term liabilities	28,531	24,656
Conversion option subject to cash settlement	78,390	99,797
Stockholders' equity	1,197,675	864,248
Total liabilities and stockholders' equity	$ 1,839,113	$ 1,429,937

Illumina, Inc.
Condensed Consolidated Statements of Income
(In thousands, except per share amounts)
(unaudited)

	Three Months Ended		Years Ended	
	January 2, 2011	January 3, 2010	January 2, 2011	January 3, 2010
Revenue:				
Product revenue	$ 245,626	$ 167,532	$ 842,510	$ 627,240
Service and other revenue	15,672	13,032	60,231	39,084
Total revenue	261,298	180,564	902,741	666,324
Cost of Revenue:				
Cost of product revenue **(a)**	87,183	48,337	271,997	190,714
Cost of service and other revenue **(a)**	5,694	5,031	21,399	15,055
Amortization of intangible assets	2,295	1,670	7,805	6,680
Total cost of revenue	95,172	55,038	301,201	212,449
Gross profit	166,126	125,526	601,540	453,875
Operating Expenses:				
Research and development **(a)**	45,800	40,368	177,947	140,616
Selling, general and administrative **(a)**	62,034	49,471	220,990	176,337
Acquisition related (gain) expense, net	(10,376)	10,000	(9,051)	11,325
Total operating expenses	97,458	99,839	389,886	328,278
Income from operations	68,668	25,687	211,654	125,597
Other expense, net	(17,886)	(3,399)	(26,275)	(11,472)
Income before income taxes	50,782	22,288	185,379	114,125
Provision for income taxes	12,342	10,583	60,488	41,844
Net income	$ 38,440	$ 11,705	$ 124,891	$ 72,281

ILLUM-0897

Net income per basic share	$ 0.31	$ 0.10	$ 1.01	$ 0.59
Net income per diluted share	$ 0.25	$ 0.09	$ 0.87	$ 0.53
Shares used in calculating basic net income per share	125,876	122,818	123,581	123,154
Shares used in calculating diluted net income per share	151,171	136,095	143,433	137,096

(a) Includes total stock-based compensation expense for stock based awards:

	Three Months Ended		Years Ended	
	January 2, 2011	January 3, 2010	January 2, 2011	January 3, 2010
Cost of product revenue	$ 1,508	$ 1,160	$ 5,378	$ 4,776
Cost of service and other revenue	76	117	470	514
Research and development	6,977	5,571	25,428	19,960
Selling, general and administrative	11,279	9,629	40,369	35,561
Stock-based compensation expense before taxes	$ 19,840	$ 16,477	$ 71,645	$ 60,811

Illumina, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Three Months Ended		Years Ended	
	January 2, 2011	January 3, 2010	January 2, 2011	January 3, 2010
Net cash provided by operating activities	$ 81,481	$ 61,290	$ 272,573	$ 172,191
Net cash (used in) provided by investing activities	(70,056)	15,553	(285,053)	(256,569)
Net cash provided by (used in) financing activities	26,543	(171,149)	116,474	(98,862)
Effect of exchange rate changes on cash and cash equivalents	212	411	320	849
Net increase (decrease) in cash and cash equivalents	38,180	(93,895)	104,314	(182,391)
Cash and cash equivalents, beginning of period	210,767	238,528	144,633	327,024
Cash and cash equivalents, end of period	$ 248,947	$ 144,633	$ 248,947	$ 144,633
Calculation of free cash flow **(a)**:				
Net cash provided by operating activities	$ 81,481	$ 61,290	$ 272,573	$ 172,191
Purchases of property and equipment	(12,384)	(6,385)	(49,818)	(52,673)
Free cash flow	$ 69,097	$ 54,905	$ 222,755	$ 119,518

(a) Free cash flow, which is a non-GAAP financial measure, is calculated as net cash provided by operating activities reduced by purchases of property and equipment. Free cash flow is useful to management as it is one of the metrics used to evaluate our performance and to compare us with other companies in our industry. However, our calculation of free cash flow may not be comparable to similar measures used by other companies.

Illumina, Inc.
Results of Operations - Non-GAAP
(In thousands, except per share amounts)
(unaudited)

AN ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP NET INCOME PER SHARE:

	Three Months Ended		Years Ended	
	January 2, 2011	January 3, 2010	January 2, 2011	January 3, 2010
GAAP net income per share - diluted	**$ 0.25**	**$ 0.09**	**$ 0.87**	**$ 0.53**
Pro forma impact of weighted average shares	0.01	-	0.06	0.03
Adjustments to net income:				
Losses (gains) in other expense, net **(a)**	0.09	-	0.08	(0.01)
Acquisition related (gain) expense, net **(b)**	(0.07)	0.08	(0.07)	0.09
Non-cash interest expense **(c)**	0.04	0.04	0.16	0.15
Amortization of intangible assets	0.02	0.01	0.06	0.05
Other pro forma adjustments **(d)**	0.01	0.01	0.03	0.04
Incremental non-GAAP tax expense **(e)**	(0.06)	(0.02)	(0.13)	(0.08)
Non-GAAP net income per share - diluted **(f)**	$ 0.29	$ 0.21	$ 1.06	$ 0.80
Shares used in calculating non-GAAP diluted net income per share	140,080	129,698	134,375	130,599
AN ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP NET INCOME:				
GAAP net income	**$ 38,440**	**$ 11,705**	**$ 124,891**	**$ 72,281**
Losses (gains) in other expense, net **(a)**	13,223	-	10,309	(767)
Acquisition related (gain) expense, net **(b)**	(10,376)	10,000	(9,051)	11,325
Non-cash interest expense **(c)**	5,363	5,331	20,832	19,656
Amortization of intangible assets	2,295	1,670	7,805	6,680
Other pro forma adjustments **(d)**	919	919	4,211	5,675
Incremental non-GAAP tax expense **(e)**	(9,014)	(2,598)	(16,813)	(10,675)
Non-GAAP net income **(f)**	$ 40,850	$ 27,027	$ 142,184	$ 104,175

(a) Losses (gains) in other expense, net include a $13.2 million impairment loss in Q4 2010 related to a cost-method investment, a $2.9 million gain recognized in Q2 2010 on our cost-method investment in Helixis, Inc. upon our acquisition of its remaining shares, and a $10.0 million gain in Q1 2009 on the extinguishment of debt.

(b) Acquisition related (gain) expense, net includes a gain in Q4 2010 of $10.4 million related to a change in the fair value of contingent consideration and an acquired in-process research and development charge in Q2 2010 of $1.3 million related to a milestone payment for a

ILLUM-0898

consideration and an acquired in-process research and development charge in Q2 2010 of $1.3 million related to a milestone payment for a prior acquisition. Prior year adjustments include acquired in-process research and development charges related to milestone payments for prior acquisitions. These acquisition related gain and expenses are included in operating expenses in our consolidated statements of income.

(c) Non-cash interest expense is calculated in accordance with the authoritative accounting guidance for convertible debt instruments that may be settled in cash.

(d) Other pro forma adjustments include compensation expenses of $0.9 million for each of the three-month periods presented and $3.7 million for each of the years presented. These compensation expenses represent contingent consideration for post-combination services associated with a prior acquisition and are included in research and development expenses in our consolidated statements of income. Other pro forma adjustments also include $0.5 million in acquisition related transaction expense recorded in Q2 2010 as a component of selling, general and administrative expense, and $2.0 million in acquired research and development expense recorded in Q1 2009 as a component of research and development expense.

(e) Incremental non-GAAP tax expense reflects the increase to GAAP tax expense related to the non-GAAP adjustments listed above, with the exception of the acquisition related (gain) expense, net which has no impact on the provision for income taxes.

(f) Non-GAAP net income per share and net income exclude the effect of the pro forma adjustments as detailed above. Non-GAAP diluted net income per share and net income are key drivers of our core operating performance and major factors in management's bonus compensation each year. Management has excluded the effects of these items in these measures to assist investors in analyzing and assessing our past and future core operating performance.

Illumina, Inc.
Results of Operations - Non-GAAP (continued)
(unaudited)

AN ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP RESULTS OF OPERATIONS AS A PERCENT OF REVENUE:

	Three Months Ended				Years Ended			
	January 2, 2011		January 3, 2010		January 2, 2011		January 3, 2010	
GAAP gross profit	**$ 166,126**	**63.6%**	**$ 125,526**	**69.5%**	**$ 601,540**	**66.6%**	**$ 453,875**	**68.1%**
Stock-based compensation expense	1,584	0.6%	1,277	0.7%	5,848	0.6%	5,290	0.8%
Amortization of intangible assets	2,295	0.9%	1,670	0.9%	7,805	0.9%	6,680	1.0%
Non-GAAP gross profit	$ 170,005	65.1%	$ 128,473	71.2%	$ 615,193	68.1%	$ 465,845	69.9%
Research and development expense	**$ 45,800**	**17.5%**	**$ 40,368**	**22.4%**	**$ 177,947**	**19.7%**	**$ 140,616**	**21.1%**
Stock-based compensation expense	(6,977)	(2.7%)	(5,571)	(3.1%)	(25,428)	(2.8%)	(19,960)	(3.0%)
Compensation Expense **(a)**	(919)	(0.4%)	(919)	(0.5%)	(3,675)	(0.4%)	(3,675)	(0.6%)
Acquired research and development	-	-	-	-	-	-	(2,000)	(0.3%)
Non-GAAP research and development expense	$ 37,904	14.4%	$ 33,878	18.8%	$ 148,844	16.5%	$ 114,981	17.3%
Selling, general and administrative expense	**$ 62,034**	**23.7%**	**$ 49,471**	**27.4%**	**$ 220,990**	**24.5%**	**$ 176,337**	**26.5%**
Stock-based compensation expense	(11,279)	(4.3%)	(9,629)	(5.3%)	(40,369)	(4.5%)	(35,561)	(5.3%)
Transaction expense related to acquisition	-	-	-	-	(536)	(0.1%)	-	-
Non-GAAP selling, general and administrative expense	$ 50,755	19.4%	$ 39,842	22.1%	$ 180,085	19.9%	$ 140,776	21.1%
GAAP operating profit	**$ 68,668**	**26.3%**	**$ 25,687**	**14.2%**	**$ 211,654**	**23.4%**	**$ 125,597**	**18.8%**
Stock-based compensation expense	19,840	7.6%	16,477	9.1%	71,645	7.9%	60,811	9.1%
Acquisition related (gain) expense, net **(b)**	(10,376)	(4.0%)	10,000	5.5%	(9,051)	(1.0%)	11,325	1.7%
Amortization of intangible assets	2,295	0.9%	1,670	0.9%	7,805	0.9%	6,680	1.0%
Other pro forma adjustments **(c)**	919	0.4%	919	0.5%	4,211	0.5%	5,675	0.9%
Non-GAAP operating profit **(d)**	$ 81,346	31.3%	$ 54,753	30.3%	$ 286,264	31.7%	$ 210,088	31.5%
GAAP other expense, net	**$ (17,886)**	**(6.8%)**	**$ (3,399)**	**(1.9%)**	**$ (26,275)**	**(2.9%)**	**$ (11,472)**	**(1.7%)**
Losses (gains) in other expense, net **(f)**	13,223	5.1%	-	0.0%	10,309	1.1%	(767)	(0.1%)
Non-cash interest expense **(e)**	5,363	2.1%	5,331	3.0%	20,832	2.3%	19,656	2.9%
Non-GAAP other income, net **(d)**	$ 700	0.3%	$ 1,932	1.1%	$ 4,866	0.5%	$ 7,417	1.1%

(a) Compensation expense represents contingent consideration for post-combination services associated with a prior acquisition. This expense is included in research and development in our statements of income.

(b) Acquisition related (gain) expense, net includes a gain in Q4 2010 of $10.4 million related to a change in the fair value of contingent consideration and an acquired in-process research and development charge in Q2 2010 of $1.3 million related to a milestone payment for a prior acquisition. Prior year adjustments include acquired in-process research and development charges related to milestone payments for prior acquisitions. These acquisition related gain and expenses are included in operating expenses in our consolidated statements of income.

(c) Other pro forma adjustments include compensation expenses of $0.9 million for each of the three-month periods presented and $3.7 million for each of the years presented. These compensation expenses represent contingent consideration for post-combination services associated with a prior acquisition and are included in research and development expenses in our consolidated statements of income. Other pro forma adjustments also include $0.5 million in acquisition related transaction expense recorded in Q2 2010 as a component of selling, general and administrative expense, and $2.0 million in acquired research and development expense recorded in Q1 2009 as a component of research and development expense.

(d) Non-GAAP operating profit, and non-GAAP other income, net, exclude the effects of the pro forma adjustments as detailed above. Management has excluded the effects of these items in these measures to assist investors in analyzing and assessing our past and future core operating performance. Non-GAAP gross profit, included within the non-GAAP operating profit, is a key measure of the effectiveness and efficiency of our manufacturing processes, product mix and the average selling prices of our products and services.

(e) Non-cash interest expense is calculated in accordance with the authoritative accounting guidance for convertible debt instruments that may be settled in cash.

(f) Losses (gains) in other expense, net include a $13.2 million impairment loss in Q4 2010 related to a cost-method investment, a $2.9 million gain recognized in Q2 2010 on our cost-method investment in Helixis, Inc. upon our acquisition of its remaining shares, and a $0.8 million gain in Q1 2009 on the extinguishment of debt.

ILLUM-0899

Illumina, Inc.
Reconciliation of Non-GAAP Financial Guidance

The financial guidance provided below assumes an estimated non-GAAP diluted net income per share of $1.40 and is based on information available as of February 8, 2011. The company's future performance and financial results are subject to risks and uncertainties, and actual

results could differ materially from the guidance set forth below. Some of the factors that could affect the company's financial results are stated above in this press release. More information on potential factors that could affect the company's financial results is included from time to time in the company's public reports filed with the SEC, including the company's Form 10-K for the fiscal year ended January 3, 2010, the company's Form 10-Q for the fiscal quarters ended April 4, 2010, July 4, 2010 and October 3, 2010 and the company's Form 10-K for the fiscal year ended January 2, 2011 to be filed with the SEC. The company assumes no obligation to update any forward-looking statements or information, which speak as of their respective dates.

	Diluted net income per share
Fiscal Year 2011	
Non-GAAP	$ 1.40
Lease related expenses **(a)**	($0.18)
Non-cash interest expense **(b)**	($0.09)
Pro forma impact of weighted average shares **(c)**	($0.06)
Amortization of intangible assets	($0.04)
Other non-GAAP adjustments **(d)**	($0.02)
GAAP	**$ 1.01**

(a) Under the terms of a lease agreement executed by the company in Q4 2010, the company's headquarters will be relocated to a new location during the second half of 2011. Lease related expenses reflect non-cash cease-use loss to account for the remaining lease payments on the company's current headquarters reduced by estimated sublease proceeds, accelerated depreciation on existing leasehold improvements abandoned upon the relocation to the new facility, and anticipated double rent expense incurred during the transition to the new facility.

(b) Non-cash interest expense is calculated in accordance with the authoritative accounting guidance for convertible debt instruments that may be settled in cash.

(c) Pro forma impact of weighted average shares represents the estimated impact of double dilution associated with the accounting treatment of the company's outstanding convertible debt and the corresponding call option overlay.

(d) Other non-GAAP adjustments reflect the estimated impact on diluted net income per share for fiscal year 2011 from compensation expense for contingent consideration and acquired in-process research and development.

SOURCE: Illumina, Inc.

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EXHIBIT E

(PART II OF II)

OF

DECLARATION OF KAREN POSSEMATO

illumina®

Illumina Reports Financial Results for Fourth Quarter and Fiscal Year 2009

SAN DIEGO, Feb 04, 2010 (BUSINESS WIRE) -- Illumina, Inc. (NASDAQ:ILMN) today announced its financial results for the fourth quarter and fiscal year of 2009.

Fourth quarter 2009 results:

Revenue of $180.6 million, a 12% increase over the $160.9 million reported in the fourth quarter of 2008.

GAAP net income for the quarter of $11.7 million, or $0.09 per diluted share, compared to net income of $26.1 million, or $0.20 per diluted share in the comparable period of 2008. Net income for the fourth quarter of 2009 included non-cash charges of $16.5 million in stock compensation expense, $10 million of acquired in-process research and development expense associated with the acquisition of Avantome, Inc., $5.3 million in non-cash interest expense, and other items listed in the table entitled "An Itemized Reconciliation Between GAAP and Non-GAAP Net Income."

Non-GAAP net income for the fourth quarter of 2009 of $37.8 million, or $0.29 per diluted share, compared to $39.4 million, or $0.31 per diluted share, for the fourth quarter of 2008. Net income in the prior year period included a one-time benefit of approximately $2.2 million from the retroactive extension of the US R&D tax credit.

Gross margin in the fourth quarter of 2009 was 69.5% compared to 64.4% in the comparable period of 2008. Excluding the effect of non-cash charges associated with stock compensation and the amortization of intangibles, non-GAAP gross margin was 71.2% for the fourth quarter of 2009 compared to 66.7% in the prior year period.

It should be noted that due to the structure of our financial reporting calendar, the company incurred an additional week of operating activity in the fourth quarter of 2009 as compared to both sequential and prior year periods.

Research and development (R&D) expenses for the fourth quarter of 2009 were $40.4 million compared to $28.3 million in the fourth quarter of 2008. R&D expenses include $5.6 million and $3.8 million of non-cash stock compensation expense in the fourth quarter of 2009 and 2008, respectively. R&D expenses in both periods also include $0.9 million of accrued contingent compensation associated with the Avantome acquisition. Excluding these charges, R&D expenses as a percentage of revenues were 18.8% compared to 14.7% in the prior year period.

Selling, general, and administrative (SG&A) expenses for the fourth quarter of 2009 were $49.5 million compared to $39.2 million for the fourth quarter of 2008. SG&A expenses include $9.6 million and $6.9 million of non-cash stock compensation expense in the fourth quarter of 2009 and 2008, respectively. Excluding these charges, SG&A expenses as a percentage of revenues were 22.1% compared to 20.1% in the prior year period.

The company generated $61.3 million in cash flow from operations during the fourth quarter of 2009 compared to $50.1 million in the prior year period. Depreciation and amortization expenses were $7.9 million and capital expenditures were $6.4 million during the fourth quarter. The company ended the fourth quarter with $693.5 million in cash and investments compared to $815.4 million as of September 27, 2009. During the quarter, the company purchased over 6 million shares of its common stock for approximately $175 million completing both outstanding share repurchase programs.

Fiscal 2009 results:

Revenue of $666.3 million, a 16% increase over the $573.2 million reported in fiscal 2008.

GAAP net income of $72.3 million, or $0.53 per diluted share, compared to $39.4 million or $0.30 per share in 2008. 2009 GAAP net income included non-cash charges of $60.8 million related to stock compensation expense, $19.7 million in non-cash interest expense, $11.3 million of in-process research and development primarily associated with the acquisition of Avantome, Inc., and other items listed in the table entitled "An Itemized Reconciliation Between GAAP and Non-GAAP Net Income."

Non-GAAP net income of $144.9 million, or $1.11 per diluted share, compared to $118.0 million, or $0.93 per diluted share in fiscal 2008.

Gross margin for fiscal 2009 was 68.1%, compared to 61.6% in fiscal 2008. Excluding non-cash charges associated with stock compensation, the amortization of intangibles, and the impairment of manufacturing equipment, non-GAAP gross margin was 69.9% in fiscal 2009 compared to 65.0% in fiscal 2008.

R&D expenses for fiscal 2009 were $140.6 million compared to $100.0 million in fiscal 2008. R&D expenses for 2009 included non-cash stock compensation expense of $20.0 million compared to $14.1 million in 2008. R&D expenses also included $3.7 million and $1.5 million of accrued contingent compensation associated with the acquisition of Avantome, Inc. in 2009 and 2008 respectively. SG&A expenses for fiscal 2009 were $176.3 million compared to $148.0 million in 2008 and included $35.6 million and $28.5 million of non-cash stock compensation expense respectively.

The company generated $174.5 million in cash from operations in 2009 compared to $87.9 million in 2008. The 2008 amount included $54.5 million in litigation settlement payments, without which the company generated $142.4 million in cash from operations. Depreciation and amortization expenses for 2009 were $31.3 million and capital expenditures were $52.7 million.

Highlights since our last earnings release:

Launched HiSeq 2000, the next generation sequencing system, capable of generating 200Gb of data per run using two flowcells and dual surface imaging.

Announced that the BGI purchased 128 HiSeq2000 systems, representing the largest order for next-generation sequencing systems to date.

Launched the Genome Analyzer IIe, a lower-priced sequencing by synthesis sequencing system ideal for smaller labs and expected to generate output up to 40Gb of data per run.

Launched the OmniExpress, a 12 sample BeadChip incorporating Illumina's 3rd generation array technology and containing over 700,000 variants per sample, or a total of 8.4 million total markers. Customers can process over 1,400 samples per week at a list price $250 per sample.

Launched the BovineHD, a 12 sample BeadChip for agricultural livestock with over 700,000 loci from more than 20 different bovine breeds.

Announced that The Broad Institute purchased an additional 30 Genome Analyzers bringing its installed base to 89 systems.

Financial Outlook and Guidance ILLUM-0902

The non-GAAP financial guidance discussed below excludes the incremental interest expense associated with the company's convertible debt instruments that may be settled in cash, the amortization expense related to intangible assets, contingent compensation expense and the accrual of in-process research and development related to the Avantome acquisition, and the double dilution associated with the accounting treatment of the company's outstanding convertible debt and the corresponding call option overlay (see table which reconciles these non-GAAP financial measures to the

related GAAP measures).

The company expects:

Revenue growth for the full year 2010 of approximately 20% from 2009 revenue of $666 million.

Gross margins in the mid to high 60s.

Non-GAAP earnings per share between $0.90 and $1.00.

Full year pro forma tax rate of approximately 34%.

Stock compensation expense of approximately $73 million or a tax adjusted amount of $0.36 per fully diluted pro forma share.

Full-year weighted-average diluted shares outstanding for the measurement of pro forma results of approximately 132 million.

Quarterly Conference Call Information

The conference call will begin at 2:00 p.m. Pacific Time (5:00 p.m. Eastern Time) on Thursday, February 4, 2010. Interested parties may listen to the call by dialing 866-788-0546 (passcode: 47715520), or if outside North America, by dialing +1-857-350-1684 (passcode: 47715520). Individuals may access the live teleconference under the "Corporate/Investor Information" tab of Illumina's web site at http://www.illumina.com.

A replay of the conference call will be available from 5:00 p.m. Pacific Time (8:00 p.m. Eastern Time) on February 4, 2010 through February 11, 2010 by dialing 888-286-8010, or if outside North America, by dialing +1-617-801-6888 (passcode: 71521642).

Statement Regarding Use of Non-GAAP Financial Measures

The company reports non-GAAP results for diluted net income per share, net income, gross margins, operating margins, cash flow from operations and free cash flow in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP.

The company's financial results under GAAP include substantial non-cash charges related to stock compensation expense, incremental interest expense and gain on debt extinguishment associated with the company's convertible debt instruments that may be settled in cash, expense related to in-process and acquired research and development, the amortization expense related to intangible assets, compensation expense related to contingent consideration due to stockholders of Avantome, Inc., and charges for the impairment of manufacturing equipment. Per share amounts also include the double dilution associated with the accounting treatment of the company's convertible debt outstanding and the corresponding call option overlay. Management believes that presentation of operating results that excludes these non-cash charges provides useful supplemental information to investors and facilitates the analysis of the company's core operating results and comparison of operating results across reporting periods. Management also believes that this supplemental non-GAAP information is therefore useful to investors in analyzing and assessing the company's past and future operating performance.

The company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP results are presented in the tables of this release.

ILLUM-0903

Use of Forward-Looking Statements

This release contains projections, information about our financial outlook, earnings guidance, and other forward-looking statements that involve risks and uncertainties. These forward-looking statements are made based on our expectations as of the date of this release and may differ materially from actual future events or results. Among the important factors that could cause actual results to differ materially from those in any forward-looking statements are (i) our ability to develop and commercialize further our BeadArray(TM), VeraCode(R), and Solexa(R) technologies and to deploy new sequencing, gene expression, and genotyping products and applications for our technology platforms, (ii) our ability to manufacture robust instrumentation and reagents technology, and (iii) reductions in the funding levels to our primary customers, including as a result of the timing and amount of funding provided by the American Recovery and Reinvestment Act of 2009, together with other factors detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q or in information disclosed in public conference calls, the date and time of which are released beforehand. We undertake no obligation, and do not intend, to update these forward-looking statements, to review or confirm analysts' expectations, or to provide interim reports or updates on the progress of the current financial quarter.

About Illumina

Illumina (http://www.illumina.com) is a leading developer, manufacturer, and marketer of next-generation life-science tools and integrated systems for the analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations, and biotechnology companies. Our tools provide researchers around the world with the performance, throughput, cost effectiveness, and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information from advances in genomics and proteomics. We believe this information will enable researchers to correlate genetic variation and biological function, which will enhance drug discovery and clinical research, allow diseases to be detected earlier, and permit better choices of drugs for individual patients.

Illumina, Inc.
Condensed Consolidated Balance Sheets
(In thousands)
(unaudited)

	January 3, 2010	December 28, 2008 (a)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 144,633	$ 327,024
Short-term investments	548,894	313,051
Accounts receivable, net	157,751	133,266
Inventory, net	92,776	73,431
Deferred tax assets, current portion	20,021	8,635
Prepaid expenses and other current assets	17,515	14,154
Total current assets	981,590	869,561
Property and equipment, net	117,188	89,436
Long-term investments	-	55,900
Goodwill (b)	213,452	228,734
Intangible assets, net	43,788	47,755
Deferred tax assets, long-term portion	47,371	30,960
Other assets	26,548	4,825

ILLUM-0904

Total assets	$ 1,429,937	$ 1,327,171
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 52,781	$ 29,204
Accrued liabilities	98,253	80,355
Long-term debt, current portion	290,202	276,889
Total current liabilities	441,236	386,448
Other long-term liabilities	24,656	18,946
Conversion option subject to cash settlement	99,797	123,110
Stockholders' equity	864,248	798,667
Total liabilities and stockholders' equity	$ 1,429,937	$ 1,327,171

(a) Adjusted for the required retroactive adoption of authoritative accounting guidance for convertible debt instruments that may be settled in cash upon conversion.
(b) Reclassified a portion of goodwill to deferred tax assets to reflect the tax effect of Solexa's pre-acquisition net operating losses that can be utilized by Illumina.

Illumina, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(unaudited)

	Three Months Ended		Year Ended	
	January 3, 2010	December 28, 2008 (a)	January 3, 2010	December 28, 2008 (a)
Revenue:				
Product revenue	$167,532	$ 152,836	$627,240	$ 532,390
Service and other revenue	13,032	8,091	39,084	40,835
Total revenue	180,564	160,927	666,324	573,225
Costs and expenses:				
Cost of product revenue (excluding impairment of manufacturing equipment and amortization of intangible assets) **(b)**	48,337	52,107	190,714	192,868
Cost of service and other revenue **(b)**	5,031	2,547	15,055	12,756
Research and development **(b)**	40,368	28,339	140,616	99,963
Selling, general and administrative **(b)**	49,471	39,205	176,337	148,014
Impairment of manufacturing equipment	-	-	-	4,069
Amortization of intangible assets	1,670	2,653	6,680	10,438
Acquired in-process research and development	10,000	-	11,325	24,660
Total costs and expenses	154,877	124,851	540,727	492,768
Income from operations	25,687	36,076	125,597	80,457
Interest and other income (expense), net	(3,399)	(1,096)	(11,472)	(7,770)
Income before income taxes	22,288	34,980	114,125	72,687
Provision for income taxes	10,583	8,888	41,844	33,271
Net income	$ 11,705	$ 26,092	$ 72,281	$ 39,416
Net income per basic share	$ 0.10	$ 0.21	$ 0.59	$ 0.34
Net income per diluted share	$ 0.09	$ 0.20	$ 0.53	$ 0.30
Shares used in calculating basic net income per share	122,818	122,447	123,154	116,855
Shares used in calculating diluted net income per share	136,095	131,301	137,096	133,607

(a) Adjusted for the required retroactive adoption of authoritative accounting guidance for convertible debt instruments that may be settled in cash upon conversion.
(b) Includes total stock-based compensation expense for employee stock options and stock purchases:

ILLUM-0905

	Three Months Ended	Year Ended

	January 3, 2010	December 28, 2008	January 3, 2010	December 28, 2008
Cost of product revenue	$ 1,160	$ 976	$ 4,776	$ 4,710
Cost of service and other revenue	117	112	514	400
Research and development	5,571	3,797	19,960	14,086
Selling, general and administrative	9,629	6,933	35,561	28,492
Stock-based compensation expense before taxes	$ 16,477	$ 11,818	$ 60,811	$ 47,688

Illumina, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Three Months Ended		Year Ended	
	January 3, 2010	December 28, 2008	January 3, 2010	December 28, 2008
Net cash provided by operating activities	$ 61,328	$ 50,117	$ 174,496	$ 87,882
Net cash provided by (used) in investing activities	16,404	(31,222)	(255,718)	(277,249)
Net cash (used in) provided by financing activities	(171,149)	(49,414)	(98,862)	337,672
Effect of foreign currency translation on cash and cash equivalents	(478)	2,324	(2,307)	3,778
Net (decrease) increase in cash and cash equivalents	(93,895)	(28,195)	(182,391)	152,083
Cash and cash equivalents, beginning of period	238,528	355,219	327,024	174,941
Cash and cash equivalents, end of period	$ 144,633	$ 327,024	$ 144,633	$ 327,024
Calculation of free cash flow **(a)**:				
Net cash provided by operating activities	$ 61,328	$ 50,117	$ 174,496	$ 87,882
Purchases of property and equipment	(6,385)	(14,554)	(52,673)	(59,693)
Free cash flow	$ 54,943	$ 35,563	$ 121,823	$ 28,189

(a) Free cash flow, which is a non-GAAP financial measure, is calculated as net cash provided by operating activities reduced by purchases of property and equipment. Free cash flow is useful to management as it is one of the metrics used to evaluate our performance and to compare us with other companies in our industry. However, our calculation of free cash flow may not be comparable to similar measures used by other companies.

Illumina, Inc.
Results of Operations - Non-GAAP
(In thousands, except per share amounts)
(unaudited)

AN ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP NET INCOME PER SHARE:

	Three Months Ended		Year Ended	
	January 3, 2010	December 28, 2008	January 3, 2010	December 28, 2008
GAAP net income per share - diluted	**$ 0.09**	**$ 0.20**	**$ 0.53**	**$ 0.30**
Pro forma impact of weighted average shares	-	0.01	0.03	0.01
Adjustments to net income:				
Pro forma impact of stock-based compensation expense	0.08	0.06	0.31	0.25
Pro forma impact of non-cash interest expense **(a)**	0.03	0.02	0.09	0.09
Other pro forma adjustments	0.09	0.02	0.15	0.28
Non-GAAP net income per share - diluted **(b)**	$ 0.29	$ 0.31	$ 1.11	$ 0.93
Shares used in calculating non-GAAP diluted net income per share	129,698	128,044	130,599	126,836

AN ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP NET INCOME:

ILLUM-0906

GAAP net income	**$ 11,705**	**$ 26,092**	**$ 72,281**	**$ 39,416**
Stock-based compensation expense	16,477	11,818	60,811	47,688

Non-cash interest expense **(a)**	5,331	4,689	19,656	18,219
Acquired in-process research and development expense	10,000	-	11,325	24,660
Amortization of intangible assets	1,670	2,653	6,680	10,438
Compensation expense **(c)**	919	919	3,675	1,531
Acquired research and development	-	-	2,000	-
Gain on extinguishment of debt	-	-	(767)	-
Impairment of manufacturing equipment	-	-	-	4,069
Pro forma impact on tax expense:				
stock-based compensation	(5,744)	(4,397)	(20,121)	(15,844)
non-cash interest expense **(a)**	(2,082)	(1,842)	(7,691)	$ (7,158)
other pro forma adjustments	(516)	(499)	(2,984)	$ (5,014)
Incremental non-GAAP tax expense **(d)**	(8,342)	(6,738)	(30,796)	$ (28,016)
Non-GAAP net income **(b)**	$ 37,760	$ 39,433	$ 144,865	$ 118,005

(a) Non-cash interest expense is calculated in accordance with the authoritative accounting guidance for convertible debt instruments that may be settled in cash.

(b) Non-GAAP net income per share and net income exclude the effect of the pro forma adjustments as detailed above. Non-GAAP diluted net income per share and net income are key drivers of our core operating performance and major factors in management's bonus compensation each year. Management has excluded the effects of these items in these measures to assist investors in analyzing and assessing our past and future core operating performance.

(c) Compensation expense represents the contingent consideration due to stockholders of Avantome, Inc. for post-combination services for a three year period contingent upon the primary stockholders' continued employment. This expense is included within research and development on our statements of operations.

(d) Incremental non-GAAP tax expense reflects the increase to GAAP tax expense related to the non-GAAP adjustments listed above.

Illumina, Inc.
Results of Operations - Non-GAAP (continued)
(unaudited)

AN ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP RESULTS OF OPERATIONS AS A PERCENT OF REVENUE:

	Three Months Ended				Year Ended			
	January 3, 2010		December 28, 2008		January 3, 2010		December 28, 2008	
GAAP gross profit	**$125,526**	**69.5%**	**$103,620**	**64.4%**	**$453,875**	**68.1%**	**$353,094**	**61.6%**
Stock-based compensation expense	1,277	0.7%	1,088	0.7%	5,290	0.8%	5,110	0.9%
Amortization of intangible assets	1,670	0.9%	2,653	1.6%	6,680	1.0%	10,438	1.8%
Impairment of manufacturing equipment	-	-	-	-	-	-	4,069	0.7%
Non-GAAP gross profit	$128,473	71.2%	$107,361	66.7%	$465,845	69.9%	$372,711	65.0%
Research and development expense	**$ 40,368**	**22.4%**	**$ 28,339**	**17.6%**	**$140,616**	**21.1%**	**$ 99,963**	**17.4%**
Stock-based compensation expense	(5,571)	(3.1%)	(3,797)	(2.4%)	(19,960)	(3.0%)	(14,086)	(2.5%)
Compensation expense **(a)**	(919)	(0.5%)	(919)	(0.6%)	(3,675)	(0.6%)	(1,531)	(0.3%)
Acquired research and development	-	-	-	-	(2,000)	(0.3%)	-	-
Non-GAAP research and development expense	$ 33,878	18.8%	$ 23,623	14.7%	$114,981	17.3%	$ 84,346	14.7%
Selling, general and administrative expense	**$ 49,471**	**27.4%**	**$ 39,205**	**24.4%**	**$176,337**	**26.5%**	**$148,014**	**25.8%**
Stock-based compensation expense	(9,629)	(5.3%)	(6,933)	(4.3%)	(35,561)	(5.3%)	(28,492)	(5.0%)
Non-GAAP selling, general and administrative expense	$ 39,842	22.1%	$ 32,272	20.1%	$140,776	21.1%	$119,522	20.9%
GAAP operating profit	**$ 25,687**	**14.2%**	**$ 36,076**	**22.4%**	**$125,597**	**18.8%**	**$ 80,457**	**14.0%**
Stock-based compensation expense	16,477	9.1%	11,818	7.3%	60,811	9.1%	47,688	8.3%
Acquired in-process research and development	10,000	5.5%	-	-	11,325	1.7%	24,660	4.3%
Amortization of intangible assets	1,670	0.9%	2,653	1.6%	6,680	1.0%	10,438	1.8%
Compensation expense **(a)**	919	0.5%	919	0.6%	3,675	0.6%	1,531	0.3%
Acquired research and development	-	-	-	-	2,000	0.3%	-	-
Impairment of manufacturing equipment	-	-	-	-	-	-	4,069	0.7%
Non-GAAP operating profit **(b)**	$ 54,753	30.3%	$ 51,466	32.0%	$210,088	31.5%	$168,843	29.5%

ILLUM-0907

(a) Compensation expense represents the contingent consideration due to stockholders of Avantome, Inc. for post-combination services for a three year period contingent upon the primary stockholders' continued employment. This expense is included within research and development on our statements of operations.
(b) Non-GAAP operating profit excludes the effect of the pro forma adjustments as detailed above. Management has excluded the effects of these items in these measures to assist investors in analyzing and assessing our past and future core operating performance. Non-GAAP gross profit, included within the non-GAAP operating profit, is a key measure of the effectiveness and efficiency of our manufacturing processes, product mix and the average selling prices of our products and services.

Illumina, Inc.
Condensed Consolidated Statements of Cash Flow - Non-GAAP
(unaudited)

AN ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP CASH FLOW FROM OPERATING ACTIVITIES:

	Three Months Ended		Year Ended	
	January 3, 2010	December 28, 2008	January 3, 2010	December 28, 2008
Net cash provided by operating activities	$ 61,328	$ 50,117	$ 174,496	$ 87,882
Litigation settlements paid in cash (a)	-	-	-	54,536
Non-GAAP net cash provided by operating activities (b)	$ 61,328	$ 50,117	$ 174,496	$ 142,418

(a) The company made payments of $90.5 million during the first quarter of 2008 associated with two litigation settlement agreements. Of the total $90.5 million payments, $54.5 million was charged to expense during the fourth quarter of 2007 and $36.0 million was recorded as an intangible asset.
(b) Non-GAAP cash provided by operating activities is a key driver of our core operating performance. Management has excluded the cash effect of the litigation settlement payments to assist investors in analyzing and assessing our past and future core operating performance.

Illumina, Inc.
Reconciliation of Non-GAAP Financial Guidance

The financial guidance provided below is an estimate based on information available as ofFebruary 4, 2010. The company's future performance and financial results are subject to risks and uncertainties, and actual results could differ materially from the guidance set forth below. Some of the factors that could affect the company's financial results are stated above in this press release. More information on potential factors that could affect the company's financial results is included from time to time in the company's public reports filed with the SEC, including the company's Form 10-K for the fiscal year ended December 28, 2008, the company's Form 10-Q for the fiscal quarters ended March 29, 2009, June 28, 2009 and September 27, 2009 and the company's Form 10-K for the fiscal year ended January 3, 2010 to be filed with the SEC. The company assumes no obligation to update any forward-looking statements or information, which speak as of their respective dates.

	Diluted net income per share
Fiscal Year 2010	
Non-GAAP	$0.90 - $1.00
Non-cash interest expense (a)	($0.10)
Other non-GAAP adjustments (b)	($0.11)
GAAP	**$0.69 - $0.79**

(a) Non-cash interest expense is calculated in accordance with the authoritative accounting guidance for convertible debt instruments that may be settled in cash.
(b) Other non-GAAP adjustments reflect the estimated impact on diluted net income per share for fiscal year 2010 from the amortization of intangible assets, compensation expense for the contingent consideration due to stockholders of Avantome, Inc., acquired in-process research and development and the adjustment to the number of diluted shares due to the double dilution associated with the accounting treatment of the company's convertible debt outstanding and the corresponding call option overlay.

SOURCE: Illumina, Inc.

ILLUM-0908

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Illumina Reports Financial Results for Fourth Quarter and Fiscal 2007

Fourth Quarter Revenue Increases 86% Over Prior Year and 15%

Sequentially; Annual Revenue Increases 99% Over Prior Year

SAN DIEGO--(BUSINESS WIRE)--Feb. 4, 2008--Illumina, Inc. (NASDAQ:ILMN) today announced its financial results for the fourth quarter and fiscal 2007.

For the fourth quarter of 2007, Illumina reported revenue of $112.6 million, an 86% increase over the $60.4 million reported in the fourth quarter of 2006 and a 15% increase over revenue of $97.5 million in the third quarter of 2007. This represents the Company's 26th consecutive quarter of revenue growth. The Company reported a GAAP net loss for the fourth quarter of $4.1 million, or $0.07 per share, compared to net income of $17.1 million, or $0.34 per diluted share in the comparable period of 2006. The GAAP net loss was attributable to the recognition of litigation settlement expenses during the quarter in the amount of $54.5 million, $54 million of which represents the majority of a total payment of $90 million to settle all ongoing legal disputes between the Company and Affymetrix, Inc. The GAAP loss also included non-cash charges of $0.7 million associated with the amortization of acquired intangible assets, and $9.6 million in non-cash stock compensation expense associated with SFAS No. 123R. These GAAP expenses were partially offset by a net tax benefit of approximately $25.3 million primarily attributable to the reversal of the Company's valuation allowance. Excluding the impact of these items and the net pro forma tax expense, Illumina's net income on a non-GAAP basis was $22.5 million, or $0.38 per diluted share, for the fourth quarter of 2007, compared to $21.2 million, or $0.42 per diluted share, for the fourth quarter of 2006.

Gross margin in the fourth quarter of 2007 was 64.4%, compared to 66.7% in the comparable period of 2006. Excluding the effect of the non-cash charges associated with the acquisition of Solexa and stock compensation mentioned above, non-GAAP gross margin was 65.5% for the fourth quarter of 2007, compared to 67.5% in the prior year period. The year-over-year decrease in gross margin was primarily attributable to a change in product mix.

Research and development (R&D) expenses for the fourth quarter of 2007 were $20.1 million, compared to $8.8 million in the fourth quarter of 2006. R&D expenses include $3.0 million and $1.1 million of non-cash stock compensation expense in the fourth quarter of 2007 and 2006, respectively. Excluding these non-cash charges, R&D expenses as a percentage of revenues were 15.2%, compared to 12.8% in the prior year period.

Selling, general and administrative (SG&A) expenses for the quarter were $30.0 million, compared to $14.9 million for the fourth quarter of 2006. SG&A expenses include $5.4 million and $2.5 million of non-cash stock compensation expense in the fourth quarter of 2007 and 2006, respectively. Excluding these non-cash charges, SG&A expenses as a percentage of revenues were 21.9%, compared to 20.6% in the prior year period.

ILLUM-0910

The Company generated $11.6 million in cash from operations during the fourth quarter of 2007, compared to $8.8 million in the comparable quarter of 2006. Depreciation and amortization expenses were $4.0 million and capital expenditures were $9.1 million during the quarter. The Company ended the quarter with $386.1 million in cash and short-term investments, compared to $352.9 million as of

September 30, 2007.

Fiscal 2007

For the fiscal year 2007, the Company reported revenue of $366.8 million, a 99% increase over the $184.6 million reported in fiscal 2006. On a GAAP basis, the Company reported a net loss of $278.4 million or $5.14 per diluted share. The GAAP net loss included the aforementioned litigation settlement expense of $54.5 million and non-cash charges of $306.8 million associated with the acquisition of Solexa and $33.7 million related to stock compensation expense, partially offset by a net tax benefit in the amount of $10.4 million primarily attributable to the release of the Company's valuation allowance. Excluding the impact of the settlement payment and the non-cash items listed above and the net pro forma tax expense, Illumina's non-GAAP net income would have been $71.9 million, or $1.23 per diluted share, compared to $54.3 million, or $1.11 per diluted share in fiscal 2006.

Gross margin for fiscal 2007 was 63.9%, compared to 67.9% in fiscal 2006. Excluding non-cash charges associated with stock compensation and certain charges related to the Solexa acquisition, non-GAAP gross margin would have been 65.3% in fiscal 2007 compared to 68.7% in fiscal 2006. The year-over-year decrease in gross margin was primarily attributable to a change in product mix.

R&D expenses for fiscal 2007 were $73.9 million compared to $33.4 million in fiscal 2006. R&D expenses for 2007 included non-cash charges of $0.2 million for an inventory valuation step-up related to the Solexa acquisition and $10.0 million of stock compensation expense, compared to $3.9 million of stock compensation expense in 2006. SG&A expenses for fiscal 2007 were $101.3 million compared to $54.1 million in 2006 and included $19.4 million and $8.9 million of non-cash stock compensation expense respectively.

The Company generated $56.0 million in cash from operations in 2007. Depreciation and amortization expenses for the year were $14.9 million and capital expenditures were $24.3 million.

Highlights since our last earnings release:

-- Entered into a settlement agreement with Affymetrix to resolve all outstanding patent litigation between the companies. Without admitting liability, Illumina agreed to make a one-time payment to Affymetrix of $90 million to dismiss with prejudice all lawsuits it had brought against Illumina. Affymetrix also granted Illumina a perpetual covenant not to sue for making, using or selling any of Illumina's current products, evolutions of those products and services related thereto. In addition, Affymetrix extended the covenant not to sue for four years for making, using or selling Illumina products or services that are based on future technology developments. The covenant not to sue covers all fields other than photolithography.

-- Announced a reorganization of the Company's operating structure into a Life Sciences Business Unit and a Diagnostics Business Unit. Additionally, the Company announced the resignation of John West, Senior Vice President and General

Manager of Sequencing and announced that John Stuelpnagel, Senior Vice President, COO and General Manager, Arrays will step off the Board and move to part time status on April 1, 2008. The Company also announced the hiring of General Managers for both the Life Sciences and the Diagnostics Business Units.

-- Introduced the Infinium HD Human1M-Duo and Human610-Quad BeadChips for DNA analysis. The new Infinium HD products contain up to 2.4 million markers per chip, doubling sample throughput and reducing DNA input requirements by as much as 70 percent.

-- Announced that Erasmus Medical Center in Rotterdam has purchased Infinium HD Human610-Quad BeadChips for the analysis of 10,000 samples to identify early environmental and genetic causes of normal and abnormal growth, development, and health from fetal life until young adulthood.

-- Released two non-human Infinium genotyping products: the BovineSNP50 and the CanineSNP20 BeadChips. Both chips are 12-sample genotyping products available for detecting genetic variation in any breed of cattle and dog, respectively. Content for the BovineSNP50 BeadChip features more than 54,000 SNPs, including 24,000 SNPs discovered using Illumina's Genome Analyzer.

-- Launched a 12-sample Infinium DNA Methylation BeadChip for use in epigenetic research powered by Illumina's Infinium Assay. This new tool allows researchers to assay approximately 27,000 CpG sites per sample. Earlier this year Illumina also introduced methylation products using the GoldenGate Assay. Together, these tools represented the industry's first array-based products combining high-sample throughput, high multiplexing, and single-site CpG resolution for DNA methylation profiling.

Financial Outlook and Guidance

The non-GAAP financial guidance discussed below excludes the effect of non-cash stock compensation expense and amortization expense related to intangible assets recorded in conjunction with the Solexa acquisition and litigation settlement with Affymetrix. (see table which reconciles these non-GAAP financial measures to the related GAAP measures). ILLUM-0912

We expect revenue for 2008 between $500 and $525 million, representing year over year growth of 36% - 43%, exceeding the high end of our long term operating model. We expect gross margin percentage to range in the mid 60s. We expect earnings per fully diluted share of $1.45 to $1.60.

For the first quarter of 2008, we expect revenues between $110 and $115 million. We expect earnings

per fully diluted share of $0.33 to $0.36.

We expect the full year pro forma tax rate to be approximately 36%, higher in the first half of the year and lower in the second half of the year as the Company begins to ramp its Singapore operations.

The Company expects full year total shares outstanding for the measurement of pro forma amounts to be approximately 62 million.

Quarterly Conference Call Information

Our conference call will begin at 2:00 pm Pacific Time (5:00 pm Eastern Time) on February 4, 2008. Interested parties may listen to the call by dialing 866.713.8565 (passcode: 33681070), or if outside North America, by dialing +1.617.597.5324 (passcode: 33681070). Individuals may access the live webcast under the "Corporate/Investor Information" tab of Illumina's web site at www.illumina.com.

A replay of the conference call will be available from 4:00 pm Pacific Time (7:00 pm Eastern Time) on February 4, 2008 through February 11, 2008 by dialing 888.286.8010, or if outside North America, by dialing +1. 617.801.6888 (passcode: 57638190).

About Illumina

Illumina is a leading developer, manufacturer and marketer of next-generation life science tools and integrated systems for the large scale analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations and biotechnology companies. Our tools provide researchers around the world with the performance, throughput, cost effectiveness and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information from advances in genomics and proteomics. We believe this information will enable researchers to correlate genetic variation and biological function, which will enhance drug discovery and clinical research, allow diseases to be detected earlier and permit better choices of drugs for individual patients.

Statement Regarding Use of Non-GAAP Financial Measures

The Company has reported non-GAAP results for diluted net income per share, net income, gross margins and free cash flow in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP.

The Company's financial results under GAAP include substantial non-cash charges related to stock compensation expense, its acquisition of Solexa, Inc. in January 2007, and the settlement of its litigation with Affymetrix in January 2008. Management believes that presentation of operating results that exclude these non-cash charges provides useful supplemental information to investors that facilitates analysis of the Company's core operating results and comparison of operating results across reporting periods. Management believes that this supplemental non-GAAP information is therefore useful to investors in analyzing and assessing the Company's past and future operating performance.

ILLUM-0913

The Company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP results are presented in the

tables of this release.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: this release may contain forward-looking statements that involve risks and uncertainties. Among the important factors that could cause actual results to differ materially from those in any forward-looking statements are our ability (i) to integrate effectively our recent acquisition of Solexa, Inc., (ii) to develop and commercialize further our BeadArray(TM), VeraCode(TM) and Solexa(R) technologies and to deploy new gene expression and genotyping products and applications for our technology platforms, (iii) to manufacture robust micro arrays and Oligator(R) oligonucleotides, (iv) to integrate and scale our VeraCode technology, (v) to scale further oligo synthesis output and technology to satisfy market demand derived from our collaboration with Invitrogen, together with other factors detailed in our filings with the Securities and Exchange Commission including our recent filings on Forms 10-K and 10-Q or in information disclosed in public conference calls, the date and time of which are released beforehand. We disclaim any intent or obligation to update these forward-looking statements beyond the date of this release.

Illumina, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

	December 30, 2007	December 31, 2006 (1)
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$174,941	$ 38,386
Short-term investments	211,141	92,418
Accounts receivable, net	83,119	39,984
Inventory, net	53,980	20,169
Deferred tax assets - current portion	26,934	-
Prepaid expenses and other current assets	12,640	2,769
Total current assets	562,755	193,726
Property and equipment, net	46,274	25,634
Investment in Solexa	-	67,784
Goodwill	228,734	2,125
Intangible assets, net	57,971	-
Deferred tax assets - long term portion	80,245	-
Other assets, net	11,753	11,315

ILLUM-0914

Total assets	$987,732	$300,584
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 24,311	$ 9,853
Litigation settlements payable	90,536	-
Accrued liabilities and current portion of long-term debt	50,868	23,923
Total current liabilities	165,715	33,776
Long-term debt	400,000	-
Other long-term liabilities	10,339	19,466
Stockholders' equity	411,678	247,342
Total liabilities and stockholders' equity	$987,732	$300,584

(1) The condensed consolidated balance sheet as of December 31, 2006 has been derived from the audited financial statements as of that date.

Illumina, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended		Year Ended	
	December 30, 2007	December 31, 2006	December 30, 2007	December 31, 2006
Revenue:				
Product	$101,116	$49,229	$ 326,699	$155,811

ILLUM-0915

Service and other	11,489	11,206	40,100	28,775
Total revenue	112,605	60,435	366,799	184,586
Costs and expenses:				
Cost of revenue (including non-cash stock compensation expense of $1,226, $507, $4,324 and $1,524, respectively)	40,098	20,119	132,436	59,344
Research and development (including non-cash stock compensation expense of $2,983, $1,101, $10,016 and $3,891, respectively)	20,050	8,826	73,943	33,373
Selling, general and administrative (including non-cash stock compensation expense of $5,407, $2,484, $19,406 and $8,889, respectively)	30,020	14,914	101,256	54,057
Amortization of acquired intangible assets	662	-	2,429	-
Acquired in-process research and development	-	-	303,400	-
Litigation settlements	54,536	-	54,536	-

ILLUM-0916

Total costs and expenses	145,366	43,859	668,000	146,774
Income (loss) from operations	(32,761)	16,576	(301,201)	37,812
Interest and other income, net	3,373	1,388	12,416	4,808
Income (loss) before income taxes	(29,388)	17,964	(288,785)	42,620
Provision (benefit) for income taxes	(25,337)	822	(10,426)	2,652
Net income (loss)	$ (4,051)	$17,142	$(278,359)	$ 39,968
Net income (loss) per basic share	$ (0.07)	$ 0.37	$ (5.14)	$ 0.90
Net income (loss) per diluted share	(0.07)	0.34	(5.14)	0.82
Shares used in calculating basic net income (loss) per share	55,055	46,699	54,154	44,501
Shares used in calculating diluted net income (loss) per share	55,055	51,003	54,154	48,754

ILLUM-0917

Illumina, Inc.

Condensed Consolidated Statements of Cash Flow
(In thousands)
(Unaudited)

	Three Months Ended		Year Ended	
	December 30, 2007	December 31, 2006	December 30, 2007	December 31, 2006
Net cash provided by operating activities	$ 11,578	$ 8,781	$ 56,019	$ 39,000
Net cash provided by (used in) investing activities	68,382	(18,369)	(67,686)	(160,735)
Net cash provided by financing activities	30,719	3,788	148,567	109,296
Effect of foreign currency translation on cash and cash equivalents	155	20	(345)	3
Increase (decrease) in cash and cash equivalents	110,834	(5,780)	136,555	(12,436)
Cash and cash equivalents, beginning of period	64,107	44,166	38,386	50,822
Cash and cash equivalents, end of period	$174,941	$ 38,386	$174,941	$ 38,386

Calculation of Free Cash Flow

ILLUM-0918

(a):

Net cash provided by operating activities	$ 11,578	$ 8,781	$ 56,019	$ 39,000
Purchases of property and equipment	(9,087)	(1,637)	(24,343)	(15,114)
Cash paid for intangible assets	-	(85)	(85)	(100)
Free cash flow	$ 2,491	$ 7,059	$ 31,591	$ 23,786

(a) Free cash flow, which is a non-GAAP financial measure, is calculated as net cash provided by operating activities reduced by purchases of property and equipment and cash paid for intangible assets. Free cash flow is useful to management as it is one of the metrics used to evaluate our performance and to compare the Company with other companies in our industry. However, our calculation of free cash flow may not be comparable to similar measures used by other companies.

Illumina, Inc.
Results of Operations - Non-GAAP
(In thousands, except per share amounts)
(Unaudited)

AN ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP NET INCOME (LOSS) PER SHARE IS AS FOLLOWS:

	Three Months Ended		Year Ended	
	December 30, 2007	December 31, 2006	December 30, 2007	December 31, 2006
GAAP net income (loss) per share - diluted	$ (0.07)	$ 0.34	$ (5.14)	$ 0.82
Pro forma impact on weighted average shares	-	-	0.37	-
Adjustment to net income (loss), as detailed below	0.45	0.08	6.00	0.29

ILLUM-0919

Non-GAAP net income per share - diluted (a)	$ 0.38	$ 0.42	$ 1.23	$ 1.11
Shares used in calculating non-GAAP diluted net income per share	58,878	51,003	58,430	48,754

AN ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP NET INCOME (LOSS) IS AS FOLLOWS:

GAAP net income (loss)	$ (4,051)	$17,142	$(278,359)	$39,968
Non-cash stock compensation expense	9,616	4,092	33,746	14,304
Amortization of acquired intangible assets	662	-	2,429	-
Amortization of inventory revaluation costs	-	-	942	-
Acquired in-process research and development expense	-	-	303,400	-
Litigation settlements	54,536	-	54,536	-
Pro forma tax expense (b)	(38,291)	-	(44,751)	-
Non-GAAP net income (a)	$ 22,472	$21,234	$ 71,943	$54,272

(a) Non-GAAP diluted net income per share and net income excludes the effect of non-cash stock compensation expense, as well as the amortization of acquired intangible assets, amortization of inventory revaluation costs on products sold that were previously written-up under purchase accounting rules and acquired in-process research and development expense related to the Company's acquisition of Solexa, Inc. in January 2007, and the charge recorded by the Company in Q4 2007 related to the settlement of its litigation with Affymetrix in January 2008. Management regards non-GAAP net income and non-GAAP diluted net income per share as key indicators of the Company's core operating performance and are major factors in determining

management's bonus compensation each year. Management has excluded the effects of these items in these measures to assist investors in analyzing and assessing our past and future core operating performance.

(b) Pro forma tax expense is higher than GAAP tax expense primarily due to the litigation settlement and certain acquisition related costs, such as amortization of acquired intangible assets, inventory revaluation costs and acquired in-process research and development expense, which are deducted for GAAP purposes but excluded for pro forma purposes. In addition, the impact of the Company's release of its valuation allowance has been excluded for pro forma purposes. GAAP net income (loss) for the three and twelve months ended December 30, 2007 also includes non-cash stock compensation expense, which is deducted for GAAP purposes but excluded for pro forma purposes. These adjustments produce a GAAP-only tax benefit, which is added back for pro forma purposes.

Illumina, Inc.
Results of Operations - Non-GAAP (continued)
(Unaudited)

AN ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP GROSS MARGIN IS AS FOLLOWS:

	Three Months Ended		Year Ended	
	December 30, 2007	December 31, 2006	December 30, 2007	December 31, 2006
GAAP gross margin (a)	64.4%	66.7%	63.9%	67.9%
Non-cash stock compensation expense	1.1%	0.8%	1.2%	0.8%
Amortization of inventory revaluation costs	-	-	0.2%	-
Non-GAAP gross margin (b)	65.5%	67.5%	65.3%	68.7%

(a) In Q4 2007, the Company began to classify research revenue as part of services and other revenue. This reclassification is also reflected in the prior periods shown in the table above.

ILLUM-0921

(b) Non-GAAP gross margin excludes the effect of non-cash stock compensation expense and the amortization of inventory revaluation costs. Management regards non-GAAP gross margin as a key measure of the effectiveness and efficiency of the Company's manufacturing processes, product mix and the average selling prices of the Company's products and services.

Illumina, Inc.
Reconciliation of GAAP to Non-GAAP Financial Guidance Summary
(In thousands, except per share amounts)

The financial guidance provided below is an estimate based on information available as of February 4, 2008. The Company's future performance and financial results are subject to risks and uncertainties, and actual results could differ materially from the guidance set forth below. Some of the factors that could affect the Company's financial results are stated above in this press release. More information on potential factors that could affect the Company's financial results is included from time to time in the Company's public reports filed with the SEC, including the Company's Form 10-K for the fiscal year ended December 30, 2007 to be filed with the SEC. The Company assumes no obligation to update any forward-looking statements or information, which speak as of their respective dates.

Fiscal Year 2008 Financial Guidance Summary

	GAAP	Non-GAAP Adjustments		Non-GAAP
Revenue	$500 - 525 million			$500 - 525 million
Diluted net income per share	$0.73 - 0.88	$0.72	(a)	$1.45 - 1.60

Q1 2008 Financial Guidance Summary

	GAAP	Non-GAAP Adjustments		Non-GAAP
Revenue	$110 - 115 million			$110 - 115 million
Diluted net income per share	$0.14 - 0.17	$0.19	(a)	$0.33 - 0.36

ILLUM-0922

(a) These adjustments reflect the estimated impact on net income and diluted net income per share for fiscal year 2008 and Q1 2008 from the non-GAAP adjustments related to non-cash stock compensation expense, as well as the amortization of acquired intangible assets and amortization of the intangible asset recorded by the Company in Q4 2007 related to the settlement of its litigation with Affymetrix in January 2008.

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1-858-202-4507
pfromen@illumina.com

SOURCE: Illumina, Inc.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended January 2, 2011

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to .

Commission file number: 000-30361

Illumina, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**33-0804655**
(State or other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
9885 Towne Centre Drive, San Diego, California	**92121**
(Address of Principal Executive Offices)	*(zip code)*

Registrant's telephone number, including area code:
(858) 202-4500
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Exchange on Which Registered
Common Stock, $0.01 par value (including associated Preferred Stock Purchase Rights)	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☑	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

As of February 4, 2011, there were 127,626,004 shares (excluding 24,868,929 shares held in treasury) of the Registrant's Common Stock outstanding. The aggregate market value of the Common Stock held by non-affiliates of the Registrant as of July 4, 2010 (the last business day of the Registrant's most recently completed second fiscal quarter), based on the closing price for the Common Stock on The NASDAQ Global Select Market on that date, was $3,554,527,753. This amount excludes an aggregate of 41,715,009 shares of Common Stock held by officers and directors and each person known by the Registrant to own 10% or more of the outstanding Common Stock. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the Registrant, or that the Registrant is controlled by or under common control with such person.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for the annual meeting of stockholders expected to be held on May 10, 2011 are incorporated by reference into Items 10 through 14 of Part III of this Report.

ILLUMINA, INC.

FORM 10-K
FOR THE FISCAL YEAR ENDED JANUARY 2, 2011

TABLE OF CONTENTS

		Page
	PART I	
Item 1	Business	4
Item 1A	Risk Factors	17
Item 1B	Unresolved Staff Comments	27
Item 2	Properties	28
Item 3	Legal Proceedings	28
Item 4	Reserved	28
	PART II	
Item 5	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	29
Item 6	Selected Financial Data	30
Item 7	Management's Discussion and Analysis of Financial Condition and Results of Operations	31
Item 7A	Quantitative and Qualitative Disclosures about Market Risk	46
Item 8	Financial Statements and Supplementary Data	49
Item 9	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	84
Item 9A	Controls and Procedures	84
Item 9B	Other Information	86
	PART III	
Item 10	Directors, Executive Officers and Corporate Governance	86
Item 11	Executive Compensation	86
Item 12	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	86
Item 13	Certain Relationships and Related Transactions, and Director Independence	87
Item 14	Principal Accountant Fees and Services	87
	PART IV	
Item 15	Exhibits and Financial Statement Schedule	87
Signatures		92

EX-10.35
EX-21.1
EX-23.1
EX-31.1
EX-31.2
EX-32.1
EX-32.2
EX-101 INSTANCE DOCUMENT
EX-101 SCHEMA DOCUMENT
EX-101 CALCULATION LINKBASE DOCUMENT
EX-101 LABELS LINKBASE DOCUMENT
EX-101 PRESENTATION LINKBASE DOCUMENT
EX-101 DEFINITION LINKBASE DOCUMENT

Table of Contents

Special Note Regarding Forward-Looking Statements

This annual report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements discuss our current expectations concerning future results or events, including our future financial performance. We make these forward-looking statements in reliance on the safe harbor protections provided under the Private Securities Litigation Reform Act of 1995. These statements include, among others:

- statements concerning our expectations as to our future financial performance, results of operations, or other operational results or metrics;
- statements concerning the benefits that we expect will result from our business activities and certain transactions we have completed, such as product introductions, increased revenue, decreased expeuses, and avoided expenses and expenditures; and
- statements of our expectations, beliefs, future plans and strategies, anticipated developments (including new products), and other matters that are not historical facts.

These statements may be made expressly in this document or may be incorporated by reference to other documents we have filed or will file with the Securities and Exchange Commission, or SEC. You can identify many of these statements by looking for words such as "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology and similar references to future periods. These forward-looking statements are subject to numerous assumptions, risks, and uncertainties that may cause actual results or events to be materially different from any future results or events expressed or implied by us in those statements. Many of the factors that will determine or effect these results or events are beyond our ability to control or project. Specific factors that could cause actual results or events to differ from those in the forward-looking statements include:

- our ability to develop and commercialize further our sequencing, BeadArray™, VeraCode®, Eco™, and reagents technologies and to deploy new sequencing, genotyping, gene expression, and diagnostics products and applications for our technology platforms;
- our ability to manufacture robust instrumentation and consumables;
- reductions in the funding levels to our primary customers, including as the result of timing and amount of funding provided by the American Recovery and Reinvestment Act of 2009; and
- other factors detailed in our filings with the SEC, including the risks, uncertainties, and assumptions described in Item 1A "Risk Factors" below, or in information disclosed in public conference calls, the date and time of which are released beforehand.

Our forward-looking statements speak only as of the date of this annual report. We undertake no obligation, and do not intend, to publicly update or revise forward-looking statements, to review or confirm analysts' expectations, or to provide interim reports or updates on the progress of any current financial quarter, whether as a result of new information, future events, or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained in this annual report. Given these uncertainties, we caution investors not to unduly rely on our forward-looking statements.

Available Information

Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports are available free of charge on our website, *www.illumina.com*. The information on our website is not incorporated by reference into this report. Such reports are made available as soon as reasonably practicable after filing with, or furnishing to, the SEC. The SEC also maintains an Internet site at *www.sec.gov* that contains reports, proxy and information statements, and other information regarding issuers

that electronically file with the SEC. Copies of our annual report on Form 10-K will be made available, free of charge, upon written request.

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Unless the context requires otherwise, references in this annual report on Form 10-K to "Illumina," the "Company," "we," "us," and "our" refer to Illumina, Inc. and its subsidiaries.

PART I

ITEM 1. *Business*

Overview

We are a leading developer, manufacturer, and marketer of life science tools and integrated systems for the analysis of genetic variation and function. We were incorporated in California in April 1998 and reincorporated in Delaware in July 2000. Our principal executive offices are located at 9885 Towne Centre Drive, San Diego, California 92121. Our telephone number is (858) 202-4500.

Using our proprietary technologies, we provide a comprehensive line of genetic analysis solutions, with products and services that serve a broad range of highly interconnected markets, including sequencing, genotyping, gene expression, and molecular diagnostics. Our customers include leading genomic research centers, academic institutions, government laboratories, and clinical research organizations, as well as pharmaceutical, biotechnology, agrigenomics, and consumer genomics companies.

Our broad portfolio of systems, consumables, and analysis tools are designed to simplify genetic analysis. This portfolio addresses a range of genomic complexity, price points, and throughputs, enabling researchers to select the best solution for their scientific challenge. In 2007, through our acquisition of Solexa, Inc., we acquired our proprietary sequencing by synthesis (SBS) technology that is at the heart of our leading-edge sequencing instruments. These systems can be used to efficiently perform a range of nucleic acid (DNA, RNA) analyses on large numbers of samples. For more focused studies, our array-based solutions provide ideal tools to perform genome-wide association studies (GWAS) involving single-nucleotide polymorphism (SNP) genotyping and copy number variation (CNV) analyses, as well as gene expression profiling, and other DNA, RNA, and protein studies. To further enhance our genetic analysis workflows, in January 2011 we acquired Epicentre Technologies Corporation, a leading provider of nucleic acid sample preparation reagents and specialty enzymes for sequencing and microarray applications. In 2010, through our acquisition of Helixis, Inc., we expanded our portfolio to include real-time polymerase chain reaction (PCR), one of the most widely used technologies in life sciences. Our new Eco Real-Time PCR System provides researchers with an affordable, full-featured system to perform targeted validation studies.

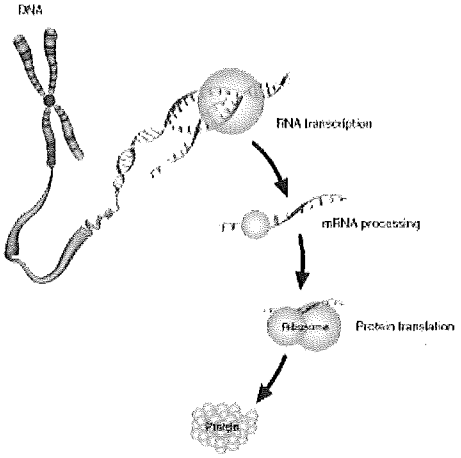
Our operating structure is divided into two business segments, the Life Sciences Business Unit and the Diagnostics Business Unit. During 2010, our Diagnostics Business Unit had limited business activity and, accordingly, operating results for both units are reported on an aggregate basis as one operating segment. At each reporting period end, we will reassess our reportable operating segments, particularly as we continue to develop our molecular diagnostics business.

Industry Background

Genetics Primer

The instruction set for all living cells is encoded in deoxyribonucleic acid, or DNA, with the complete set of DNA for any organism referred to as its genome. DNA contains small regions called genes, which comprise a string of nucleotide bases labeled A, C, G, and T, representing adenine, cytosine, guanine, and thymine, respectively. These nucleotide bases are present in a precise order known as the DNA sequence. When a gene is "expressed," a partial copy of its DNA sequence — called messenger RNA (mRNA) — is used as a template

to direct the synthesis of a protein. Proteins in turn, direct all cellular function. The illustration below is a simplified gene expression schematic.



Variations among organisms are due in large part to differences in their DNA sequences. Changes caused by insertions, deletions, inversions, or duplications of nucleotide bases may result in certain genes becoming over-expressed (excessive protein production), under-expressed (reduced protein production), or silenced altogether, sometimes triggering changes in cellular function. These changes can be the result of heredity, but most often occur at random. The most common form of variation in humans is called a single-nucleotide polymorphism (SNP), which is a variation in a single position of a nucleotide base in a DNA sequence. Copy number variations (CNVs) occur when there are fewer or more copies of certain genes.

In humans, genetic variation accounts for many of the physical differences we see (height, hair, eye color, etc.). More importantly, these genetic variations can have medical consequences affecting disease susceptibility, including predisposition to complex genetic diseases such as cancer, diabetes, cardiovascular disease, and Alzheimer's disease. They can also impact an individual's response to certain drug treatments, causing them to respond well, not respond at all, or experience adverse side effects — an area of study known as pharmacogenomics.

Scientists are studying these variations and their consequences in humans, as well as a broad range of animals, plants, and microorganisms. Researchers investigating human, viral, and bacterial genetic variation are helping us to better understand the mechanisms of disease and develop more effective therapeutics and diagnostics. Greater insight into genetic variation in plants (e.g., food and biofuel crops) and animals (e.g., livestock and domestic animals) is enabling scientists to improve crop yields and animal breeding programs.

The methods for studying genetic variation and biological function include sequencing, SNP genotyping, CNV analysis, gene expression profiling, and gene regulation analysis, each of which is addressed by our breadth of products and services.

Life Sciences Research Primer

Life science research encompasses the study of all living things, from humans, animals, and plants, to viruses and bacteria. It is being performed in government, university, pharmaceutical, biotechnology, and agrigenomics laboratories around the world, where scientists are seeking to expand our knowledge of the biological functions essential for life. Beginning at the genetic level, where our tools are used to elucidate the correlation between gene sequence and biological processes, life science research expands to include the study of the cells, tissues, organs, systems, and other components that make up living organisms. This research

supports development of new, more effective clinical diagnostics and medicines to improve human health, as well as advances in agriculture and animal husbandry to meet the world's growing needs for food and energy.

Molecular Diagnostics Primer

Molecular diagnostic assays (or tests) are designed to identify the biological indicators linked with disease and drug metabolism, providing physicians with information to more effectively diagnose, treat, and monitor both acute and chronic disease conditions. They are an integral part of personalized healthcare, where the unique makeup of each individual will be taken into account in diagnosing disease and managing treatment through the use of more tailored therapies. Biological indicators that can be measured by these assays include protein or gene expression, methylation levels, copy number variations, and the presence or absence of a specific gene or group of genes.

There are molecular diagnostic assays on the market for infectious disease, cancer, and heart disease, as well as molecular-based drug metabolism assays to help physicians select the most effective therapy with the fewest side effects. Our innovative technologies and products are contributing to the development of a wide-range of potential molecular diagnostic assays. Our own efforts in this area are currently focused on the identification of certain genetic markers with potential diagnostic and therapeutic utility.

Growing news coverage about the clinical relevance of newly discovered genetic markers has prompted consumers' interest in having their personal genomes analyzed, sparking the development of the consumer genomics market. We believe there are distinct medical benefits, especially for people with family histories of certain diseases, of knowing your disease predisposition. Several companies, including Illumina, now offer personal sequencing or genotyping services, working with physician groups and genetic counselors to interpret the results for consumers.

We believe the growth in consumer genomics and the use of molecular diagnostic assays will trigger a fundamental shift in the practice of medicine and the economics of the pharmaceutical industry by facilitating an increased emphasis on preventative and predictive molecular medicine, ushering in the era of personalized medicine.

Our Principal Markets

From the company's inception, we have believed that the analysis of genetic variation and function will play an increasingly important role in molecular biology, and that by empowering genetic analysis, our tools will advance disease research, drug development, and the creation of molecular tests. In addition to developing sequencing- and array-based solutions for life science, applied, and consumer genomics markets, we are making inroads into the emerging market of molecular diagnostics.

Life Sciences Research Market

The life sciences research market consists of laboratories generally associated with universities, medical research centers, government institutions, as well as biotechnology and pharmaceutical companies. Researchers at these institutions are using our products and services in a broad spectrum of scientific activities, such as: next-generation sequencing, mid-to-high-complexity genotyping and gene expression (for whole-genome discovery and profiling), and low complexity genotyping and gene expression (for high-throughput targeted screening). DNA sequencing is growing the most rapidly among these three areas due to the creation of next-generation sequencing technologies, such as SBS. It is fueled by private and public funding, new global initiatives to broadly characterize genetic variation, and the migration of legacy genetic applications to sequencing-based technologies.

Applied Markets

We provide products and services for various other markets, which we refer to as "applied markets." The largest among these is the "Agbio" market, where government and corporate researchers use our sequencing- and array-based tools to accelerate and enhance agricultural research. For example, we currently offer

microarrays that contain SNPs for custom and focused genotyping of seeds and crops (such as maize) and livestock (such as cattle, horses, pigs, and sheep). Customers use them to perform selective breeding, accelerating and enhancing the process over traditional methods such as cross-breeding.

Molecular Diagnostics Market

Molecular diagnostics makes up the fastest growing segment in the clinical diagnostics market, with the primary growth drivers being the continued discovery of genetic markers with proven clinical utility, the increasing adoption of genetic-based diagnostic tests, and the expansion of reimbursement programs to include a greater number of approved molecular diagnostic tests. We believe our BeadXpress instrument platform, using our VeraCode technology, is ideally suited to provide a cost-effective, high-throughput, mid- to low-multiplex solution to the molecular diagnostic market. In April 2010, we obtained 510(K) approval for the BeadXpress platform from the U.S. Food and Drug Administration (FDA). We have initiated development of a variety of clinical diagnostic testing panels for this platform and are continuing research into the potential development of cancer diagnostic panels, initially focusing on ovarian, gastric, and colorectal cancers. During the fourth quarter of 2009, we made an FDA pre-IDE (investigational device exemption) submission for a cytogenetics test intended to be used on our iScan instrument platform as an aid in the postnatal diagnosis of chromosomal abnormalities known to be associated with developmental delay and mental retardation. Following completion of the required clinical trial, we intend to seek FDA clearance for the iScan instrument platform and related consumables.

Consumer Genomics Markets

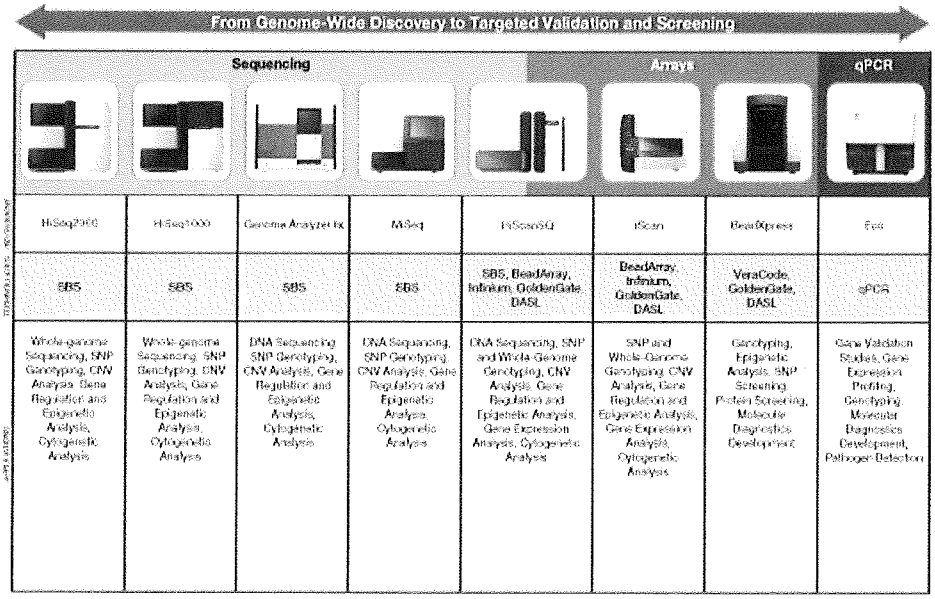
New sequencing and genotyping technologies, such as those developed by Illumina, are driving down the cost of performing analyses which are increasingly valuable in diagnosing disease and evaluating disease risk. Consumer genomics is a nascent market, but one we believe has the potential for high growth as the cost per analysis continues to drop. In June 2009, we launched our Individual Genome Sequencing Service, the first physician-intermediated personal genome sequencing service for consumers. Built around physician-patient consultation, the service requires a physician's order to initiate the process, with genome sequencing performed using our CLIA-certified, CAP-accredited laboratory. We have established collaborations with partners to perform the secondary data analysis of a personal genome (such as calculation of disease risk, ancestry, and information on traits of interest). Some of our partners, as well as other companies in the direct-to-consumer market, use our genotyping technology and products to perform personal genotyping services.

Our Principal Technologies

Our unique technology platforms enable the scale of experimentation necessary for genome-wide discovery, target selection, and validation studies (see Figure 1 below). More than 2,500 customer-authored scientific publications have been published to date using these technologies, representing the efforts of a large and dynamic Illumina user community. Through rapid innovation, we believe we are changing the economics of genetic research, enabling projects once considered unapproachable to now be within reach of more investigators.

Table of Contents

Figure 1: Illumina Platform Overview:



Sequencing Technology

DNA sequencing is the process of determining the order of nucleotide bases (A, C, G, or T) in a DNA sample. Our HiSeq 2000, HiSeq 1000, Genome Analyzer IIx, and HiScanSQ systems represent a family of systems that we believe are setting the standard for productivity, cost-effectiveness, and accuracy among next-generation sequencing technologies. They are used by customers to perform whole-genome, de novo, and targeted re-sequencing of genomes, and to analyze specific gene regions and genes. In January 2011, we announced the MiSeq Personal Sequencing System, which will expand our family of sequencing systems to include a low-cost personal sequencing system that will provide individual researchers a sequencing platform that can go from purified DNA to analyzed data in as few as eight hours or can generate in excess of 1 gigabase (Gb) per run in slightly over a day.

Whole-genome sequencing determines an organism's complete DNA sequence. In de novo sequencing, the goal is to sequence a representative sample from a species never before sequenced. In targeted re-sequencing, a sequence of nucleotide bases is compared to a standard or reference sequence from a previously sequenced species to identify changes that reflect genetic variation. Understanding the similarities and differences in DNA sequence between and within species furthers our understanding of the function of the structures encoded in the DNA.

Our DNA sequencing technology is based on our proprietary reversible terminator-based sequencing chemistry, referred to as sequencing by synthesis (SBS) biochemistry. In SBS, single stranded DNA is extended from a priming site, one base at a time, using reversible terminator nucleotides. These are DNA bases that can be added to a growing second strand, but which initially cannot be further extended. This means that at each cycle of the chemistry, only one base can be added. Each base that is added includes a fluorescent label that is specific to the particular base (A, C, G, or T). Following incorporation, the emitted light can be imaged to determine its color and thus determine the base. Once this is done, an additional step removes both the fluorescence and the blocking group that had prevented further extension of the second

strand. This allows another base to be added, and the cycle can then be repeated. Our technology is capable of generating over 600 billion bases of DNA sequence from a single experiment with a single sample preparation. Key aspects of the SBS chemistry are the subject of significant intellectual property owned by us.

In our DNA sequencing systems, we apply the SBS biochemistry on microscopic clusters of DNA. Each cluster starts as a single DNA molecule fragment, typically a few hundred bases long, attached to the inside surface of a flow cell. We then use a proprietary amplification biochemistry to create copies of each starting molecule. As the copies are made, they are covalently linked to the surface, so they cannot diffuse away. After a number of cycles of amplification, each cluster might have approximately 1,000 copies of the original starting molecule, but still be only about a micron (one-millionth of a meter) in diameter. By making so many copies, the fluorescent signal from each cluster is significantly increased. Because the clusters are so small, hundreds of millions of clusters can be independently formed inside a single flow cell. This large number of clusters can then be sequenced simultaneously by alternate cycles of SBS biochemistry and fluorescent imaging. Sequence reads are analyzed using specially developed data analysis software.

With the ability to generate over 600 Gb of DNA sequence per run, our SBS sequencing technology provides researchers with the broadest range of applications and the opportunity to sequence even large mammalian genomes in days rather than weeks or years. Since the launch of our first Genome Analyzer in 2007, our systems have reduced the cost of sequencing by more than a factor of 100.

BeadArray Technology

Our BeadArray technology combines microscopic beads and a substrate in a proprietary manufacturing process to produce arrays that can perform many assays simultaneously, enabling large-scale analysis of genetic variation and biological function in a unique high-throughput, cost effective, and flexible manner. The arrays manufactured using BeadArray technology are imaged by our iScan and HiScanSQ systems for a broad range of DNA and RNA analysis applications including SNP discovery, SNP genotyping, CNV analysis, gene expression analysis, and methylation analysis.

Our proprietary BeadArray technology consists of microscopic silica beads, each bead covered with hundreds of thousands of copies of oligonucleotides, or oligos, that act as the capture sequences in one of our assays. We deploy our BeadArray technology on BeadChips; silicon wafers the size of a microscope slide, with varying numbers of sample sites per slide. BeadChips are chemically etched to create tens of millions of wells for each sample site.

We create unique bead pools, or sensors, for different DNA and RNA analysis applications by affixing thousands to millions of copies of a specific type of oligonucleotide molecule to each of the billions of microscopic beads in a batch. We make different batches of beads, with the beads in a given batch coated with one particular type of molecule. The particular molecules on a bead define that bead's function as a sensor. To form an array, a pool of coated beads is brought into contact with the array surface where they are randomly drawn into the wells, one bead per well. Because the beads assemble randomly into the wells, we perform a final procedure called "decoding" to determine which bead type occupies which well in the array. We employ several proprietary methods for decoding, which is a process that requires only a few steps to identify all the beads in the array. One beneficial by-product of the decoding process is a functional validation of each bead in the array. This quality control test characterizes the performance of each bead and can identify and eliminate use of any empty wells. We ensure that each bead type on the array is sufficiently represented by including multiple copies of each bead type. Multiple bead type copies improve the reliability and accuracy of the resulting data by allowing statistical processing of the results of identical beads.

An experiment is performed by preparing a sample, such as DNA, and introducing it to the array. The molecules in the sample bind to their matching molecules on the coated beads. The molecules in either the sample or on the bead are labeled with fluorescent dye either before or after the binding, which can be detected by shining a laser on the BeadChip. This allows the detection of the molecules resulting in a quantitative analysis of the sample.

Using our BeadArray technology, we achieve high-throughput analysis with a high density of test sites per array, and are able to format arrays in various configurations. We seek to maximize cost effectiveness by reducing consumption of expensive consumables and valuable samples and through the low manufacturing costs associated with our technologies. Our ability to vary the size, shape, and format of the well patterns and to create specific bead pools for different applications provides the flexibility to address multiple markets and market segments. These features enable our BeadArray technology to be applied to high-growth markets of SNP genotyping and CNV analysis, and have allowed us to be a key player in the gene expression market.

VeraCode Technology

Our proprietary VeraCode technology is a detection method for multiplex assays that require high precision, accuracy, and speed. When deployed on our BeadXpress Reader System, VeraCode technology provides a high-throughput solution for biomarker research and validation, pharmaceutical development, industrial and agriculture testing, clinical research, forensics, and molecular diagnostic assay development.

The VeraCode technology platform leverages the power of digital holographic codes to provide a detection method for multiplex assays. VeraCode enables low-cost multiplexing from 1 to 384-plex in a single well. The VeraCode technology consists of cylindrical glass beads (measuring 240 microns in length by 28 microns in diameter) inscribed with a unique digital holographic code to designate and track the specific analyte or genotype of interest throughout the multiplex reaction. When excited by a laser, each VeraCode bead emits a unique code image, allowing for quick and specific detection by the BeadXpress Reader System.

Depending on the desired multiplex levels, assays are created by pooling microbeads with code diversities from one to several hundred. Unlike traditional microarrays, the VeraCode microbeads are used in solution, which takes advantage of solution-phase kinetics for more rapid hybridization times, dramatically reducing the time to achieve results.

In December 2009, we began offering VeraCode Universal Capture and Carboxyl Beads as General Purpose Reagents (GPRs). These royalty-free VeraCode GPR Beads provide customers with a flexible, high-quality, cost-effective multiplexing platform to develop their own custom multiplex assays for genotyping, CNV, gene expression, methylation, and protein analysis studies.

Eco Real-Time PCR Technology

In April 2010, we purchased Helixis, Inc. and its novel real-time PCR technology, and in July 2010 introduced the Eco Real-Time PCR System to the market. Real-Time PCR (also known as quantitative PCR or qPCR) is used to amplify and simultaneously quantify a targeted DNA molecule, with applications in gene expression, viral quantification, array data validation, pathogen detection, and genotyping. The procedure follows the same steps as PCR, whereby thermal cycling (alternately heating and cooling the DNA sample from 20 to 40 times) causes the DNA to self-replicate, resulting in the doubling of DNA product with each cycle. Real-time PCR uses various fluorescent detection chemistries to enable the monitoring of the PCR reaction as it progresses. Data are collected at each cycle rather than at the end of the reaction, providing higher precision, increased sensitivity, increased dynamic range, and higher resolution.

The Eco System combines a proprietary thermal system, four-color multiplex capabilities, and a fine-tuned optical system to deliver accurate qPCR results. Its unique design provides superior thermal uniformity, supporting high-quality PCR performance for demanding applications such as high resolution melt (HRM) curve analysis used for SNP genotyping, DNA fingerprinting, species identification, HLA compatibility typing, allelic prevalence, and DNA methylation analysis. Measuring just over one cubic foot in size, we believe the Eco System's overall performance rivals larger, more expensive systems and provides us with a highly differentiated entry into this market.

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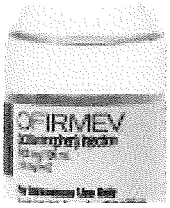

Cadence shares fall 23 percent on $75 million stock sale

Adventrx shares drop 25 percent on stock sale

Also of interest

Layoffs looming as Illumina restructures

Local companies dominate the global genetic sequencing market

Illumina beats Wall Street expectations for first

Illumina was among the country's fastest growing technology companies in 2010, according to a new ranking published by Forbes magazine on Thursday.

The San Diego genetic testing company, which ranked 4th, made the annual list for the fourth time in the last five years.

The top spot on the new list went to First Solar, a semiconductor company in Tempe, Ariz., followed by Neutral Tandem, a Chicago telecommunications firm, and Riverbend Technology, a data processing services provider in West Sacramento.

Forbes said it screened more than 5,000 companies for the list, looking for those with at least $25 million in sales and 10-percent sales growth in 2010. The final 25 were ranked on their sales growth rates over the last five years.

Illumina's growth rate over that period was 76 percent, according to Forbes.

The company had sales of $902.7 million in 2010, a 35% jump over the previous year, according to its latest quarterly financial report.

Illumina is a leading global maker of genetic sequencing machines and other genetic testing products and services. The DNA mapping market has growing rapidly in recent years as the cost of the technology plunged and more scientists and doctors used genomics for research and patient care.

Illumina's position in the latest Forbes list was one notch higher than its fifth-place ranking in 2009 but short of the No. 1 ranking it nabbed in 2008 and 2006.

Click here to see the full Forbes list for 2010.

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Technology

America's 25 Fastest-Growing Tech Companies

John J. Ray, 02.16.11, 06:00 PM EST

2010 Forbes Fast Tech List

Rank	Company Name	Business	Closing Price (2/2/2011)	Est. Long-Term EPS Growth (%)	LTM Sales ($Mil)	5-Year Sales Growth (%)
1	**First Solar**	Semiconductors/ Related Devices	$164.40	24	$2,595	182
2	**Neutral Tandem**	Telephone Communications Not Radiotelephone	15.53	12	181	100
3	**Riverbed Technology**	Data Processing And Preparation	35.65	27	552	80
4	**Illumina**	Analytical Instruments	71.31	27	822	76
5	**Cavium Networks**	Semiconductors/ Related Devices	42.29	20	207	56
6	**ViroPharma**	Pharmaceutical Preparations	16.58	10	405	55
7	**Rackspace Hosting**	Internet Software/ Services	35.68	24	735	51
8	**Salesforce.com**	Internet Software/ Services	135.08	27	1,554	50
9	**Celgene**	Pharmaceutical Preparations	53.17	25	3,620	46
10	**SolarWinds**	Prepackaged Software	18.86	18	144	43
11	**Cognizant Technology Solutions**	Computer Programming Services	76.16	20	4,185	43
12	**Equinix**	Information Retrieval Services	90.44	21	1,118	42
13	**LivePerson**	Internet Software/ Services	11.26	26	105	41
14	**Cubist Pharmaceuticals**	Pharmaceutical Preparations	22.24	11	633	41

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16	**Sourcefire**	Security Systems Services	25.46	27	128	40
16	**Apple**	Computer Hardware/ Software	344.32	21	76,283	35
17	**Google**	Internet Software/ Services	612.00	18	29,321	34
18	**Gilead Sciences**	Biological Prod's Not Diagnostic	39.46	15	7,949	31
19	**Red Hat**	Prepackaged Software	42.58	19	860	31
20	**Fortinet**	Security Systems Services	39.01	18	325	31
21	**Luminex**	Hardware, Software and Supplies for Medical Testing	17.34	28	139	30
22	**CommVault Systems**	Prepackaged Software	33.08	18	299	27
23	**Quality Systems**	Prepackaged Software	80.29	18	335	27
24	**NCI**	Computer Integrated Systems Design	21.15	15	535	24
25	**Dolby Laboratories**	Motion Picture Audio Technology	60.26	16	923	23

Prices as of 2/2/11
5 Year sales growth, annualized.
Estimated long Term EPS Growth: Annualized, projected over next three to five years.

Page: < Previous | 1 | 2

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Fast Tech 2009

The 25 Fastest-Growing Technology Companies In America

Paul M. Murdock and John J. Ray 01.29.09, 6:00 PM ET

Buried beneath the downer headlines about massive layoffs and struggling businesses, there is some good news. A select group of tech companies--the 25 Fastest-Growing Technology Stocks in America--is thriving despite the tough economy.

Thirteen companies are making their Fast Tech debuts this year, including Apple, which earned almost $5 billion on $33 billion in sales in its latest 12 months.

The fastest-growing company, based on five-year annualized sales growth, is top-ranked Illumina, which more than doubled its revenues each year for the past five years. Illumina was on our 2007 list, but missed the mark last year because it lost money in 2008. Second-ranked Google has finished first or second in its four years on the Fast Tech 25.

Last year's list of the 25 fastest-growing tech stocks weathered Wall Street's storm somewhat better than the overall market. The class of 2008 Fast Tech stocks fell 30% over the past 12 months, while the Nasdaq 100 Technology Sector Index and the S&P 500 each suffered losses of 39%. This marks the sixth consecutive year--since we first published the Fast Tech list in 2003--that each new group of Fast Tech companies outperformed the market in the subsequent 12 months.

Two of last year's entries, DRS Technologies and LifeCell, were taken over before the end of our one-year performance-measuring period. Both acquisitions came at premiums relative to their January 2008 prices.

Only one 2008 Fast Tech company, Genentech, finished the full 12-month stretch with its stock in positive territory, a 19% gain. The $11 billion (revenues) biotech returns to this year's list with eight other returnees, including Cognizant Technology Solutions, the only company to qualify every year since 2003. More than half of this year's Fast Tech companies are newcomers for 2009. Of the nine repeat performers from last year, five are software developers.

To make the list, companies must have latest 12-month revenues of $25 million or more, annualized sales gains of at least 10% over the past five years and be profitable over the past 12 months. In addition, we require a Thomson IBES long-term consensus profit forecast of at least 10%, annualized. We also exclude companies with significant legal problems or with possible accounting or corporate governance issues, based on scoring data from Audit Integrity of Los Angeles.

Last year, we introduced the Fast 15, a group of companies that may not have met all the stringent requirements of our main list, but appeared to be on track to break into the top ranks at some future date. This year, we tightened our screening criteria for this second group of stocks; these companies must now meet all the criteria of the Fast 25, except we screen them on the basis of three-year sales growth rather than five-year.

On top of our 2009 Fast 15 is OSI Pharmaceuticals,a biotech company specializing in drugs for cancer, diabetes and obesity. Over the last year, the company has registered earnings of $121 million on $365 million in net revenue. On average, OSI has more than doubled its revenues in each of the past three years.

Seeking Alpha $^{\alpha}$

Illumina Dominating the Sequencing Market

by: Dave Westenberg

March 4, 2009 | about: ILMN

While the impact of investor fear on promising biotech developmental stage companies that are moving the entire industry toward the personalized medicine paradigm is unknown, what should be known is that one of those essential road towards that paradigm is paved with cash.

The future of personalized medicine depends on understanding human genome. Over the next decade it will be critical to sequence every piece of organic matter in order to better understand the map of life. Sequencing is profitable and one company dominates the sequencing market: Illumina (ILMN).

While biotech companies' actual sales are more resistant to macroeconomic conditions, the current investment climate calls for cash flow positive picks. The company's Q3 acquisition of Avantome put the company in the red for Q3, but without the acquisition costs, the company still made $.15 EPS. Last quarter, ILMN made $.22 EPS. The company's cash exceeds its debt, and the company can remain strong for the foreseeable future. In a challenging funding environment, the company's cash flow positive standing puts them in position to be acquirers of struggling companies and discounted IP. In the Q4 2008 conference call, management said they would be "opportunistic." With a brilliantly timed secondary offering, the company was able to raise 300 million when the stock price was in the high 80s, right before the huge October and November market slump.

ILMN has shown consistent top growth every quarter. Sequentially they have growth for the last 30 plus quarters. While the basic law of large numbers suggests that the delta will fall, 30 plus percent top line growth still justifies a large multiple. This 30 percent YOY top line growth is on the low end of estimates.

ILMN's product line continues to grow and the company has no shortage of buyers globally. Management believes the demand for sequencing and geno-typing as "insatiable" (quoted from Q3 conference call). Most users and analysts believe that ILMN's products (GA, iScan, and the Beadexpress) are best-in-class and have a strong leg up over its closes competitor Affymetrix (AFFX). In the Q4 call, CEO Flatley said that market share is "60 percent in sequencing and genotyping is 60 percent." Although growing market share in instruments maybe tough when ILMN already has much of the market, consumables will be key going forward.

ILMN's substantial instrument sales in prior quarters put them in a position to grow consumable products. While the typical model of companies is to sell the razor for nothing and charge a premium for the razor blades, ILMN has historically been able to sell both at good margins (consumable still are the higher margin product.) Going forward, they expect instrument sales to plateau and margins in instruments to decline, but consumables to raise considerably more than offsetting instruments. Throughput has also grown considerable. As the instruments continue to get faster more consumables will be used per installed base. The iScan system now produces over $700,000 consumable revenue per installed base.

With its market share and technological advantages, Illumina has the sequencing market for at least near term. Predictable consumable revenue, strong margins going forward, lack of a strong competitor means this company should be a sure bet in the short term. Longer term, Illumina looks promising too as long as it can acquire or produce a diagnostics business. With a strong cash position and progress with the Bead-Express, diagnostics maybe around the corner. In the mean time, I'll take dominating the billion dollar plus sequencing market for a good biotech pick.

Disclosure: Author holds a long position in ILMN

ILLUM-0929

Forbes.com

FastTech

Illumina: Shining In Dreary Times

Madalina Iacob 01.29.09, 6:00 PM ET

In a dreary market for life science companies marked by layoffs and drastic research cutbacks, San Diego's Illumina looks positively brilliant. The company, which makes tools that scientists use to analyze the genes of humans, animals and plants, should rack up a 55% increase in revenues in 2008. Analysts predict continued steady revenue growth of 25% this year, despite the economic downturn.

Illumina has grown from just $10 million in revenues in 2002 to an estimated $567 million in 2008. Along the way it has captured as much as 70% market share in certain fields of genetic analysis, says Tycho Peterson, an analyst at J.P. Morgan. Net income is projected to hit $79 million in 2008, up from $51 million the previous year, according to Deutsche Bank Securities.

Though Illumina's stock price, at a recent $28.45, is 40% off last year's high, it's rebounded from the $19 range it traded in December, and the company boasts a $3.5 billion market capitalization.

Illumina's strong performance helped it land the No. 1 spot on Forbes' 2009 list of the 25 fastest-growing tech companies. Illumina grabbed the top spot on Forbes' 2007 fast tech list but dropped off the list in 2008.

A group of scientists and physicians created Illumina in 1998 to pursue what was then a new technology to characterize the genome of humans, bacteria and animals. Its biggest competitor has been Affymetrix. The two companies settled a heated patent dispute early last year. In 2007, Illumina bought Solexa, a Hayward, Calif., gene analysis company, for $600 million in stock.

Illumina Chief Executive Jay Flatley knows that his company cannot relax for a moment. "The challenge in sequencing is the competition, because such a big market attracts smaller start-ups," Flatley says. "We will continue to innovate and make sure we develop technology faster than the competition."

The company has generated some dedicated customers. Edward Rubin, director at the U.S. Department of Energy Joint Genome Institute in Walnut Creek, Calif., has 12 Illumina gene-analysis machines at his lab. "What the company offers us now is the state of the art," says Rubin. The institute uses the Illumina-Solexa sequencer to examine genetic information in plants and microbes in order to further biofuels research.

"They do a phenomenal job at coming out with great products," says Ross Muken, analyst at Deutche Bank Securities.

Illumina sells its genetic analysis products to both the high-end sequencing market--large genomic centers and labs like the Trust Beijing Genome Institute, the Sanger Institute in the U.K. and the National Institutes of Health--as well as to small labs like the Bovine SNP Consortium, which uses Illumina's products to diagnose specific diseases in cows, says Muken.

"Their genotyping products are spectacular," says Dr. Stephen Scherer, director of the Centre for Applied Genomics at the Hospital for Sick Children in Toronto. The Center uses a new Illumina product, the Human 660W-Quad BeadChip, launched last November, to target regions in the human genome that may play a role in common diseases, like autism, diabetes or heart disease.

"This experiment was not possible before because of technical challenges, but with the new 660W it is. Throughout 2009 we will see a lot of data," Scherer said.

Despite its terrific growth, technical obsolescence remains a concern. "Illumina might get leap-frogged by a novel technology," says Alastair Mackay of Garp Research and Securities. The market for genetic analysis is giant, estimated at $2.6 billion in

2008 and projected to grow to $3.6 billion by 2011. Illumina aims to lower the price of its products drastically so that one day everyone might benefit from DNA sequencing.

"One thing people don't realize is how important this technology is to the consumer market. This will become commonplace to the consumer in five, 10 years," says Illumina's Flatley. "That's what gives us confidence. It's an enormous market."

See Also:

Illumina Helps Shed Light On Cancer

Illumina's Capital Idea

Google's Genetic Start-Up

YAHOO! FINANCE

Illumina Names Dr. Daniel S. Grosu Chief Medical Officer

As New Medical Point Person for Regulators, Grosu to Provide Medical Perspective to Project Teams, Work Closely with Illumina Clinical Services Lab

Business Wire Mon, Oct 31, 2011 6:00 AM EDT

SAN DIEGO--(BUSINESS WIRE)-- Illumina, Inc. (NASDAQ:ILMN - News) today announced that it has appointed Dr. Daniel S. Grosu, M.D., as Vice President and Chief Medical Officer. In this newly created position, Dr. Grosu will play a key role in building Illumina's diagnostic capabilities through collaborations with regulatory agencies, internal product development teams, and Illumina's CLIA-certified clinical laboratory.

"Dr. Grosu brings the experience, credentials, and intellectual rigor required to move Illumina's cutting-edge technology into the clinic," said Illumina's Gregory Heath, Senior Vice President and General Manager, Diagnostics. "As Chief Medical Officer, he will assist in aggressively driving our business towards this enormous new market opportunity."

"During the next few years, we will see tremendous advances in medicine driven by technological breakthroughs in genomics and related systems biology areas," said Dr. Grosu. "These developments will bring us fully into the long-awaited era of personalized medicine, and Illumina is ideally positioned to be both a key enabler and a key player in this historic process. I am delighted to join Illumina at such an exciting time for our industry."

Prior to joining Illumina, Dr. Grosu was Group Director, Clinical Science, Clinical and Medical Affairs at Ortho-Clinical Diagnostics. He was also previously the Director and Global Clinical Leader, Global Clinical Development, Diagnostic Imaging at Bayer Healthcare Pharmaceuticals. Prior to that, Dr. Grosu was at Siemens Medical Solutions. He holds bachelor's and master's degrees from Wheaton College in Wheaton, Ill., a medical degree from Missouri's Saint Louis University, and a master's degree in business administration from the University of Oxford.

About Dr. Grosu's Compensation

Illumina will grant an option to purchase 60,000 shares of Illumina's common stock and 6,700 restricted stock units (RSUs) to Dr. Grosu as part of his inducement to join the company. An RSU represents a conditional right to receive one share of our common stock at a specified future date. The options and RSUs were approved by Illumina's compensation committee pursuant to NASDAQ Marketplace Rule 5635(c)(4) and will be granted under Illumina's New Hire Stock and Incentive Plan, which was approved by Illumina's Board of Directors on January 29, 2008. The option will have the following terms: an exercise price equal to the closing fair market value of Illumina's common stock on the grant date, a ten-year term, and vesting over four years with 25 percent of the option vesting one year from the grant date and 1/48th of the option vesting monthly thereafter. The RSUs will vest over four years with 25 percent of the RSUs vesting on each of the first four anniversaries of the grant date. The grant date for the option and RSUs to Dr. Grosu will be his start date with Illumina, which is expected to be October 31, 2011.

About Illumina

Illumina (http://www.illumina.com) is a leading developer, manufacturer, and marketer of life science tools and integrated systems for the analysis of genetic variation and function. We provide innovative sequencing and array-based solutions for genotyping, copy number variation analysis, methylation studies, gene expression profiling, and low-multiplex analysis of DNA, RNA, and protein. We also provide tools and services that are fueling advances in consumer genomics and diagnostics. Our technology and products accelerate genetic analysis research and its application, paving the way for

molecular medicine and ultimately transforming healthcare.

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illumina

Illumina Receives FDA 510(k) Clearance for Its BeadXpress(R) Multiplex Analysis System

Provides Clinically Validated Platform for the Next Generation of Molecular Diagnostic Tests

SAN DIEGO, May 04, 2010 (BUSINESS WIRE) --Illumina, Inc. (NASDAQ:ILMN) today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) market clearance for the company's BeadXpress system for multiplex genetic analysis. According to the FDA's indications of use, the BeadXpress system - consisting of Illumina's BeadXpress Reader and VeraScan software - is an in-vitro diagnostic device intended for the simultaneous detection of multiple analytes in a DNA sample utilizing VeraCode holographic microbead technology. The system is FDA cleared for in vitro diagnostic use only with FDA cleared VeraCode tests.

"This approval represents a significant and exciting transitional step for Illumina into the diagnostics field, where the potential is great for molecular medicine to make a real difference in the way disease is detected and ultimately prevented and treated," said Jay Flatley, president and CEO. "It demonstrates Illumina's ability to meet stringent regulatory requirements in designing and manufacturing an FDA-cleared in-vitro diagnostic device. This will serve as an important foundation for our future plans in the diagnostics area. Ultimately, our goal is to become a leader in translational medicine, focusing on complex diseases that benefit from high performance analysis, including genotyping, copy number, gene expression, methylation and protein analysis."

Illumina introduced the BeadXpress system in 2007 with Research Use Only kits for custom genotyping, gene expression, methylation and protein analysis. Since then it has been adopted by research, agricultural, industrial and pharmaceutical institutions worldwide. Utilizing uniquely inscribed digital microbeads, VeraCode technology provides high-quality data, broad multiplexing capability and assay flexibility. Illumina submitted the system for FDA review in September 2009.

"510(k) clearance opens up a wide range of new possibilities for our many clinical research and commercial partners, who can now pursue diagnostic development on our proven, high-performance BeadXpress platform," said Gregory Heath, Ph.D., senior vice president and general manager, Diagnostics. One of those partners is EraGen Biosciences, Inc., which concluded a licensing agreement with Illumina in 2009 to transfer their assays onto the BeadXpress System. "This clearance is a significant step forward in progressing our partnership in the clinical marketplace," said Irene Hrusovsky, M.D., president and CEO of EraGen Biosciences.

For more information, please visit http://www.illumina.com.

About Illumina

Illumina (http://www.illumina.com) is the leading developer, manufacturer, and marketer of integrated systems for the analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations, and biotechnology companies. Our tools provide researchers around the world with the performance, throughput, cost effectiveness, and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information from advances in genomics and proteomics. We believe this information will enable researchers to correlate

genetic variation and biological function, which will enhance drug discovery and clinical research, allow diseases to be detected earlier, and permit better choices of drugs for individual patients.

Forward-Looking Statements

This release contains forward-looking statements that involve risks and uncertainties. Important factors that could cause actual results to differ materially from those in any forward-looking statements include challenges inherent in new product development and manufacturing and the other factors detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We undertake no obligation, and do not intend, to update any forward-looking statements after the date of this release.

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Why Illumina's Future Remains Bright

by Gene Marcial | February 17, 2012 9:15 am

Even as the allure of **Illumina** (NASDAQ:ILMN[1]) has somewhat dimmed from its rejection of **Roche**'s (PINK:RHHBY[2]) takeover bid[3], it still is a stock to watch — and buy, as profit-taking picks up speed.

Illumina develops important research tools for large-scale analysis of genetic variation and function, where Roche wants to expand, and dominate.

Illumina's stock has continued to cool down after its torrid advance following Roche's unsolicited $44.50 offer on Feb. 7, 2012, and we should expect more selling by traders who had jumped in when the stock was zooming up on the news. The stock had skyrocketed to as high as $55 in late January — way before the formal bid was announced on Feb. 7. It has since fallen to $53, and should drop even more as Wall Street pulls its buy recommendation on the stock.

That's the time the savvy pros are expected to buy or come back to the stock. That's because they believe Illumina is worth much more than Roche's bid, which Illumina described as "grossly inadequate" and "dramatically undervalues" the company and, therefore, is not in the best interest of its shareholders.

Predictably, many Street analysts pulled their recommendation on the stock to a hold or underperform from a buy. But Illumina's management and board are undeterred.

"We feel strongly about this," said Jay Flatley, president and CEO of Illumina, who told analysts at a conference call on Feb. 7 that the company, "based on its track record and market leadership is securely positioned to capitalize on tremendous market opportunities in the years ahead."

Illumina has the "promise and potential," argued Flatley, to experience "extraordinary growth as genetic information becomes broadly applied beyond molecular biology research and into molecular diagnostics, reproductive health and cancer management."

As for the stock, some pros believe the obvious — the lower it gets, the more attractive it becomes. The stock traded as high as $79.40 per share on July 5, 2011. When it collapsed to a 52-week low of $25 on Dec. 13, 2011, it was clear to many industry watchers that Illumina had been thrown into the bargain bin. And so the likes of Roche paid heed to the stock.

Some big investors and some analysts are convinced Roche will come back with a higher bid, before somebody else in Big Pharma comes along to gobble up Illumina.

"Roche is intent in pursuing its takeover bid through private negotiations and more likely than not will submit a higher bid," said the head of an investment management company that already owns shares but declined to be named. Roche in December 2011 had offered $40 per share to acquire Illumina, which the latter also rejected.

"We believe Roche will have to raise its offer price," said Jeffrey Loo, analyst at S&P Capital IQ, as he sees "notable synergies as clinical applications developed through genetic sequencing is in its infancy, but is expected to grow significantly within several years."

Even if Illumina stays independent, many analysts believe Illumina is worth much more than Roche's $44.50 bid. The unsolicited takeover bid validates Illumina's valuation, according to some on Wall Street. Analyzing and understanding genetic variation and function "are critical to the development of personalized medicine, a key goal of genomics," Loo said. He noted that genetic variation accounts for many of the physical differences among humans, such as hair, color, height and eye color.

Such variations, he said, have important medical consequences, including a predisposition to disease and different response to drugs. The value of Illumina's tools is in assisting researchers process billions of tests necessary to convert raw genetic data into medically valuable information to improve drugs and therapies — and potentially cure diseases.

Quintin J. Lai, analyst at investment firm Robert W. Baird, who rates the stock as "outperform," has a 12-month price target of $60 per share.

"Our price target continues to be based in part on Roche's hostile bid for the company, which we believe gives Illumina a scarcity value that potentially attracts additional, possibly compelling, bids," Lai said. He noted that Roche has been an acquisitive company over the years.

Illumina has long been rumored as a target of Roche and other conglomerates, Lai said, "which could create a situation where additional players will drive the stock higher." He is optimistic that Illumina will be a long-term strong-growth company. Lai expects Illumina's earning to jump to $1.72 per share in 2013, up from an estimated $1.47 in 2012, and $1.30 in 2011.

Investors who seek to participate in the growth of genetic research in helping find a cure for a variety of diseases should look into Illumina's rejection of Roche's bid not as a bummer but an opportunity to get in on a better deal — and larger participation in the advance of medicine.

As of this writing, Gene Marcial did not hold a position in any of the aforementioned securities.

Links in this item:

1. ILMN: http://studio-5.financialcontent.com/investplace/quote?Symbol=ILMN
2. RHHBY: http://studio-5.financialcontent.com/investplace/quote?Symbol=RHHBY
3. takeover bid: http://www.investorplace.com/2012/01/roche-hostile-bid-illumina-rhhby-ilmn-gene-sequencing/

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illumina

Illumina's Board Unanimously Rejects Roche's Unsolicited Tender Offer as Inadequate

Urges Stockholders Not to Tender Their Shares

Files 14D-9 with SEC Detailing Reasons for Board's Recommendation

Hosts Conference Call for Investors at 5:00 PM ET

SAN DIEGO--(BUSINESS WIRE)--Feb. 7, 2012-- Illumina, Inc. (NASDAQ:ILMN), a leading developer, manufacturer, and marketer of life science tools and integrated systems for the analysis of genetic variation and function, today announced that its Board of Directors thoroughly reviewed Roche's unsolicited tender offer with the assistance of its financial and legal advisors and unanimously determined that the $44.50 per share cash offer is grossly inadequate in multiple respects, dramatically undervalues Illumina and is contrary to the best interests of Illumina's stockholders. Accordingly, the Board recommends that stockholders not tender any of their shares to Roche. The Company filed today a Schedule 14D-9 with the Securities and Exchange Commission ("SEC") detailing the reasons for its rejection. The letter sent today by Illumina to the Chairman of Roche also appears below.

"It is the Board's unanimous belief that Roche's offer dramatically undervalues Illumina and fails to reflect the value of the Company's unique leadership position and future growth prospects," said Jay Flatley, President & Chief Executive Officer. "Illumina has established itself as the innovation and market leader in tools for genetic analysis, with a proven track record of profitability and outperformance, resulting in significant value creation. Our industry is nascent, with the promise and potential to experience extraordinary growth in the years ahead as genetic information becomes broadly applied beyond molecular biology research, and into medical diagnostics, reproductive health and cancer management. As the growth of this industry accelerates, Illumina is singularly positioned to expand its market leadership, and to deliver value to our stockholders that is far superior to Roche's offer."

The specific reasons Illumina's Board recommends stockholders reject Roche's offer, which are detailed in its 14D-9 filing, include:

1) The Offer is Grossly Inadequate and Dramatically Undervalues Illumina's Industry-Leading Position and Growth Opportunities

The Board believes that the Offer is grossly inadequate and dramatically undervalues Illumina because it does not reflect the underlying value of Illumina's assets, operations and prospects, including its industry-leading position and growth opportunities.

Illumina is the leader in developing and commercializing tools and services for genetic analysis with an unrivaled breadth and depth of technological platforms. The Board believes that Illumina has a robust and compelling product portfolio in the life sciences tools industry, with over 2,300 peer-reviewed sequencing-related publications and more than 8,000 peer-reviewed publications using Illumina technology. These publications underscore strong third-party validation of Illumina's market-leading portfolio of nine platforms spanning next-generation sequencing, microarrays and related technologies, along with the associated consumables and informatics. This suite of powerful technologies has created one of the strongest brands in the life sciences tool sector. As evidence of this strength, today,

Illumina enjoys a 60% share of the next-generation sequencing market, a rapidly growing segment in the life science tools industry. Globally, the Board believes that approximately 90% of the world's sequencing output is produced on Illumina instruments. Illumina's history and track record of commercially effective innovation – combining game-changing technology developments with rapid product introductions – is unparalleled.

The industry as a whole and Illumina in particular have substantial growth opportunities. The Board believes that Illumina is singularly positioned in a nascent industry, which has the promise and potential to experience extraordinary growth in the years ahead as genetic information becomes broadly applied beyond molecular biology research and into medical diagnostics. The Board also believes that Illumina is positioned to continue to benefit significantly from positive trends in basic and translational research, as well as clinical and consumer demand for genomic information. Illumina is focused on capturing and realizing the significant, additional growth opportunities for sequencing in other markets, including molecular diagnostics, reproductive health, cancer management and industrial-end markets such as agricultural biotechnology, veterinary medicine and forensics. The Board believes that Illumina has developed a breadth and depth of platforms, capabilities and expertise that is poised to address the ever-expanding user base among these new markets. The Board is particularly optimistic about how platforms, such as HiSeq 2500 and MiSeq, and Illumina's ongoing proprietary discovery and development efforts, will further diversify Illumina's customer base and product applications and drive its entry into the clinical molecular diagnostics market.

Illumina's future prospects are underpinned by a robust pipeline of new products and services. The Board has a high degree of confidence in management's ability to deliver significant growth in its business. This confidence is supported by Illumina routinely achieving or exceeding its goals over many years and through many business cycles. The future prospects are also underpinned by a robust line of new products and services, which the Board believes will create powerful new tools in the armaments of researchers and healthcare providers. Moreover, the Board believes that no other company in the sector has as compelling a track record as Illumina in consistently and continuously providing new breakthrough technologies to enable faster, more accurate, reliable and affordable genetic analysis instrumentation, consumables and services.

Illumina has a long and proven track record of performance. The Board believes that the standalone value to stockholders reflected in Illumina's current business plan is far superior to the value offered to Illumina's stockholders in the Offer. In this regard, the Board considered Illumina's long and proven track record of delivering and creating value for its stockholders. Illumina has routinely delivered compelling results, achieving annual increases in revenue and EPS at compounded growth rates of approximately 42% and 26%, respectively, since 2006. Illumina has created significant value for its stockholders over the last five years (prior to Roche's announcement of its unsolicited offer), generating an 84% return compared to a 9% decline in the S&P 500. Thus, the Board believes that Illumina's business plan as an independent entity will deliver substantially greater value to its stockholders than would the Offer.

2) The Timing of the Offer is Blatantly Opportunistic and Does Not Reflect Illumina's Strong Platform of New Products and Pipeline

The Board believes that the timing of the Offer is opportunistic and disadvantageous to Illumina's stockholders because, among other things:

Roche timed its Offer opportunistically to capitalize on recent Share price dislocation. Over the past two years, Illumina delivered seven successive quarters of revenue growth, with its Share price reaching an all-time high of $79.40 as recently as July 2011. Roche first approached Illumina in

November 2011, just weeks after Illumina announced third quarter 2011 results reflecting a softness in research funding, which the Board believes to be temporary, and when its Shares were trading near a two-year low due to a short-term dislocation in the stock price. As research funding stabilizes through 2012 and the application of sequencing continues to broaden, the Board believes that Illumina is poised to continue to deliver strong growth rates in Illumina's existing markets. In addition, the Board believes that Illumina's ongoing technology development efforts will give Illumina significant potential to accelerate growth further in the years ahead.

Roche timed its Offer opportunistically to capture for itself the substantial growth opportunities inherent in Illumina's strong platform of new products and pipeline. As Illumina continues to develop what it believes to be a significant pipeline of platforms and solutions for genetic analysis, the Board believes that Illumina will maintain and build on its record of achieving strong and diverse customer adoption. For example, Illumina's MiSeq platform has the potential to deliver the power of Illumina's sequencing technology to new users in a user-friendly package, while the recently announced HiSeq 2500 continues to enhance performance for users demanding the capability to sequence a human genome in a day. Illumina's BaseSpace informatics solution lowers the information technology hurdles, further enabling increased adoption of sequencing technologies. Illumina's product portfolio also includes microarray, PCR and mid-level multiplex analysis platforms and innovative reagent and software solutions that can be used by customers across the entire genetic analysis workflow. Illumina's FastTrack service offering also provides an expanding customer base across the pharmaceuticals, biotechnology, clinical and consumer markets with access to genetic analysis technology. In addition, Illumina is developing proprietary clinical content for the eventual development of diagnostics in the oncology field, including in ovarian, gastric and colorectal cancers, as well as autoimmune diseases, genetic diseases and maternal fetal medicine. Finally, the leadership of Illumina's platforms and its growth potential is further demonstrated by numerous partnerships with leading companies in the molecular diagnostics space, such as Sequenom, Foundation Medicine and others. The Board believes these proprietary diagnostics represent a sizeable long-term growth opportunity for Illumina.

The Board believes that Illumina is on the verge of benefitting from its continuous significant investment in novel platforms and has a promising pipeline that will drive sustainable future growth and value in the near, medium and long term. To date, the Board believes that Illumina has delivered significant innovation, growth and, consequently, stockholder value. However, the Board also believes that Illumina is well-positioned to further benefit substantially from compelling market opportunities in genetic analysis and diagnostics given Illumina's technology platforms, product pipeline, management team and proven culture of innovation.

3) The Offer Fails to Capture Illumina's Value as an Enabler of Personalized Healthcare

The Board believes that the Offer fails to recognize Illumina's central role in enabling a forward-looking vision of personalized medicine and the value Illumina creates for various stakeholders involved in the delivery of healthcare globally. Genetic information and its clinical application are gaining increasing importance, proving central to the pharmaceutical discovery and development process. Likewise, genetic information is being employed in the discovery and development of novel biomarkers, companion diagnostics and clinical molecular diagnostics solutions. When coupled, these therapeutics and in-vitro diagnostics enable the delivery of personalized medicine, benefiting patients and healthcare providers, as well as the pharmaceutical, biotechnology and in-vitro diagnostics industries, among other stakeholders. The Board believes that Illumina's technologies, products and services are catalysts and critical to driving the growing use of genetic information across healthcare.

4) Roche's Tactics Seek to Disadvantage Illumina's Stockholders

The Board believes that Roche's urgency in launching the Offer reflects its tactic to act upon the short-term dislocation in Illumina's stock price. Purchaser's $44.50 per Share proposal is $34.90 below Illumina's 52-week high of $79.40. Thus, when the closing stock price was $37.69 on January 24, 2012, the Board believes that Roche acted to take advantage of Illumina's depressed stock price levels in its attempt to transfer the significant future value of Illumina from its stockholders to Roche and its stockholders.

5) The Offer Values Illumina at a Price Below Recent Trading Levels

The market price of Illumina's stock has remained above the Offer price of $44.50 per Share since the public announcement of the Offer on January 25, 2012. The closing price per Share on the NASDAQ Global Select Market on February 6, 2012, the last trading day prior to the date of this Statement, was $51.97, which is 17% greater than the Offer price of $44.50 per Share.

6) The Offer's Conditions Create Significant Uncertainty and Risk

The Board believes that the numerous conditions set forth in the Offer create significant uncertainty and risk as to whether the Offer can be completed and the timing for completion. As described in "Item 2. Identity and Background of Filing Person – Tender Offer" above and in Annex A attached hereto, the Offer is subject to a litany of conditions, including, among others, the following conditions: (1) the Minimum Tender Condition, (2) the Rights Condition, (3) the Section 203 Condition, (4) conditions relating to the absence of any agreement of, or transaction by, Illumina that impairs Purchaser's or Roche's ability to acquire Illumina or otherwise diminishes the expected value to Roche of the acquisition of Illumina, (5) conditions relating to antitrust considerations in the United States and foreign jurisdictions, (6) conditions relating to the absence of litigation or other adverse actions, (7) conditions related to Exon-Florio, (8) conditions relating to the absence of material adverse effects on Roche and its subsidiaries, taken as a whole, or Illumina and its subsidiaries, taken as a whole, (9) conditions relating to the performance of market indices, (10) conditions relating to the absence of changes to the constituent documents of Illumina or any of its subsidiaries, (11) conditions relating to the absence of adverse effects on Illumina's contracts and (12) conditions relating to certain changes in ownership of Illumina's securities. The Board believes that the effect of these, and other numerous conditions, is that Illumina's stockholders cannot be assured that Purchaser will be required to consummate the Offer. In addition, the Schedule TO provides that the conditions to the Offer are for the sole benefit of Roche, Purchaser and their affiliates and may be asserted by Purchaser or Roche in Purchaser's sole discretion regardless of the circumstances (including any action or omission by Roche or Purchaser) giving rise to such conditions.

7) Illumina Has Received Inadequacy Opinions from Its Financial Advisors

The Board considered the fact that, on February 7, 2012, each of Goldman, Sachs & Co. and BofA Merrill Lynch rendered an oral opinion to the Board, subsequently confirmed in writing, that, as of the date of such opinion and based upon and subject to the factors and assumptions set forth in its written opinion, the consideration proposed to be paid to the holders of Shares (other than Purchaser and its affiliates) pursuant to the Offer was inadequate from a financial point of view to such holders. The full texts of the written opinions of Goldman, Sachs & Co. and BofA Merrill Lynch, each dated February 7, 2012, which set forth the assumptions made, procedures followed, matters considered and limitations on the review undertaken in connection with such opinion, are attached as Annexes B and C to Illumina's 14D-9, respectively. Each of Goldman, Sachs & Co. and BofA Merrill Lynch provided its opinion for the information and assistance of the Board in connection with its consideration of the

Offer. The opinions of Goldman, Sachs & Co. and BofA Merrill Lynch are not recommendations as to whether or not any holder of Shares should tender such Shares in connection with the Offer or any other matter.

The full text of Illumina's 14D-9 filing is available on the SEC's website, www.sec.gov and in the "Investor Relations" section of the Company's website at www.illumina.com. "Purchaser" refers to CKH Acquisition Corporation, an indirect wholly owned subsidiary of Roche that, together with Roche, is making the unsolicited tender offer.

Following is a copy of the letter Illumina sent today to Roche's Chairman:

Dr. Franz B. Humer
Chairman
Roche Holding Ltd.
CH-4070 Basel
Switzerland

Dear Franz:

Our Board of Directors, along with our financial and legal advisors, met on January 15 and again on January 17 to review and consider both Illumina's strategic plan and Roche's January 3 proposal to acquire Illumina for $40 per share in cash. We met again on February 2 to review Roche's unsolicited tender offer to acquire Illumina for $44.50 per share in cash commenced on January 27, and again on February 7 to complete our review and finalize our recommendation.

After careful consideration, including a thorough review of the terms and conditions of Roche's tender offer, our Board of Directors unanimously determined that Roche's offer is grossly inadequate in multiple respects, dramatically undervalues Illumina, and is not in the best interests of Illumina's stockholders. Our Board strongly believes that Illumina's business plan as an independent entity will deliver value to our stockholders that is far superior to Roche's offer.

Illumina has established itself as the innovation and market leader in tools for genetic analysis, with a proven track record of profitability and outperformance, resulting in significant value creation for our stockholders. Our industry is nascent, with the promise and potential to experience extraordinary growth in the years ahead as genetic information becomes broadly applied beyond molecular biology research, and into medical diagnostics, reproductive health and cancer management. As the growth of this industry accelerates, Illumina is singularly positioned not only to maintain but expand its market leadership, translating into tremendous opportunities for our stockholders, customers, healthcare providers and patients, and other key stakeholders.

Today, we enjoy a 60% share of the global next-generation sequencing market, and we also believe that approximately 90% of the world's sequencing output is produced on Illumina instruments. Our market-leading services offering continues to benefit significantly from positive trends in basic and translational research, as well as clinical and consumer demand for genomic information. As research funding stabilizes through 2012 and the application of sequencing continues to broaden, Illumina is poised to continue to deliver strong growth rates in our existing businesses. In addition, our Board believes that Illumina's ongoing technology and market development efforts will give us enormous potential to accelerate growth further in the years ahead.

ILLUM-0942

As you know, the technologies developed by Illumina have been fundamental to the advances

achieved over the past decade in understanding the human genome, as well as that of hundreds of other species. Illumina has delivered to the market the most compelling commercial product portfolio in the life science tools industry, with over 2,300 peer-reviewed sequencing-related publications and more than 8,000 peer-reviewed publications using Illumina technology. These publications underscore strong third party validation of our market-leading portfolio of nine platforms spanning next-generation sequencing, microarrays and related technologies along with the associated consumables and informatics. Illumina's brand and franchise, uniformly recognized among researchers and customers alike, reflect a clear track record of delivering breakthrough systems, accompanied by industry-leading reliability and service.

Our history and track record of commercially effective innovation – combining game-changing technology developments with rapid product introductions – is unparalleled, and our current product portfolio, robust as it is, does not begin to fully reflect the value-creation potential of our research and development pipeline and the numerous ways in which we continue to push the envelope of genetic analysis scale and accessibility. Illumina is focused on capturing and realizing the significant, additional growth opportunities for sequencing in other markets, including molecular diagnostics, cancer management and industrial end markets such as agricultural biotechnology, veterinary medicine and forensics. We are particularly optimistic about how platforms like HiSeq 2500 and MiSeq, and our ongoing proprietary discovery and development efforts, will further diversify our customer base and product applications and drive our entry into the clinical molecular diagnostics market. Our continued investment in research and development promises to yield significant ongoing technology and product innovation with superior performance, increased utility and reliability, and greater ease of use, speed and affordability.

In addition, Illumina's management team has routinely exceeded shareholder expectations and delivered compelling results, achieving annual increases in revenue and EPS at compounded growth rates of approximately 42% and 26%, respectively, since 2006. Our management team has a track record of solid execution, and of effectively seizing and defining new market opportunities by making sound, high-value investments in promising technologies.

In closing, our Board has noted your decision to opportunistically time your offer to a temporary dislocation in our stock price. Our Board is confident in Illumina's strong prospects for continued and substantially greater value creation in the months and years ahead.

Against this backdrop – for all of these reasons and more – your proposal fails to compensate our stockholders for the intrinsic and scarcity value associated with Illumina's unmatched leadership position.

The Board of Directors of Illumina has taken, and will continue to take, its fiduciary responsibility to stockholders extremely seriously. Our Board and Illumina management are fully committed to building, fostering and protecting Illumina's value and to acting in the best interests of all our stockholders. At this juncture, we believe the only course of action consistent with those principles is to vigorously resist Roche's blatantly opportunistic attempt to acquire Illumina at a grossly inadequate price. Furthermore, we continue to believe that our highly qualified, independent directors are better positioned to act in our stockholders' interests than directors selected and compensated by you to advance your own strategic objectives at the expense of our stockholders.

ILLUM-0943

Sincerely,

William H. Rastetter, Ph.D.
Chairman

Jay T. Flatley
President & CEO

cc: Board of Directors of Illumina

Goldman, Sachs & Co. and BofA Merrill Lynch are acting as financial advisors and Dewey & LeBoeuf LLP is acting as legal counsel to Illumina.

Conference Call & Webcast Details

Illumina will host a conference call to discuss the Board of Directors' recommendation and the Company's 4Q11 earnings results, beginning at 2:00 pm Pacific Time (5:00 pm Eastern Time) today, Tuesday, February 7, 2012. Interested parties may listen to the call by dialing 888-455-2265 (passcode: 8701498), or if outside North America, by dialing 719-457-2637 (passcode: 8701498). A slide presentation and live audio webcast will be available in the Investor Relations section of Illumina's web site under the "Company" tab at www.illumina.com.

A replay of the conference call will be available from 5:00 pm Pacific Time (8:00 pm Eastern Time) on February 7, 2012 through February 14, 2012 by dialing 888-203-1112 (passcode: 8701498), or if outside North America, by dialing 719-457-0820 (passcode: 8701498).

About Illumina

Illumina (www.illumina.com) is a leading developer, manufacturer, and marketer of life science tools and integrated systems for the analysis of genetic variation and function. We provide innovative sequencing and array-based solutions for genotyping, copy number variation analysis, methylation studies, gene expression profiling, and low-multiplex analysis of DNA, RNA and protein. We also provide tools and services that are fueling advances in consumer genomics and diagnostics. Our technology and products accelerate genetic analysis research and its application, paving the way for molecular medicine and ultimately transforming healthcare.

FORWARD-LOOKING STATEMENTS

This communication may contain statements that are forward-looking. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. Among the important factors that could cause actual results to differ materially from those in any forward-looking statements are (i) our ability to develop and commercialize further our sequencing, BeadArray™, VeraCode®, Eco™, and consumables technologies and to deploy new sequencing, genotyping, gene expression, and diagnostics products and applications for our technology platforms, (ii) our ability to manufacture robust instrumentation and consumables, (iii) significant uncertainty concerning government and academic research funding worldwide as governments in the United States and Europe, in particular, focus on reducing fiscal deficits while at the same time confronting slowing economic growth, (iv) business disruptions associated with the tender offer commenced by CKH Acquisition Corporation, a wholly owned subsidiary of Roche Holding Ltd, and (v) other factors detailed in our filings with the U.S. Securities and Exchange Commission ("SEC"), including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. Illumina undertakes no

obligation, and does not intend, to update these forward-looking statements.

ADDITIONAL INFORMATION AND WHERE TO FIND IT

This communication does not constitute an offer to buy or a solicitation of an offer to sell any securities. In response to the tender offer commenced by CKH Acquisition Corporation, a wholly owned subsidiary of Roche Holding Ltd, Illumina has filed a solicitation/recommendation statement on Schedule 14D-9 with the SEC. INVESTORS AND SECURITY HOLDERS OF ILLUMINA ARE URGED TO READ THE SOLICITATION/RECOMMENDATION STATEMENT AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY (WHEN THEY BECOME AVAILABLE) BECAUSE THEY CONTAIN IMPORTANT INFORMATION. Investors and security holders will be able to obtain free copies of these documents (when they become available) and other documents filed with the SEC by Illumina through the web site maintained by the SEC at http://www.sec.gov. Investors and security holders also will be able to obtain free copies of these documents, and other documents filed with the SEC by Illumina, from Illumina by directing a request to Illumina, Inc., Attn: Investor Relations, Kevin Williams, MD, kwilliams@illumina.com.

In addition, Illumina will file a proxy statement and a WHITE proxy card with the SEC. The definitive proxy statement will be mailed to security holders of Illumina. INVESTORS AND SECURITY HOLDERS OF ILLUMINA ARE URGED TO READ THE PROXY STATEMENT AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY (WHEN THEY BECOME AVAILABLE) BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and security holders will be able to obtain free copies of these documents (when they become available) and other documents filed with the SEC by Illumina through the web site maintained by the SEC at http://www.sec.gov. Investors and security holders also will be able to obtain free copies of the proxy statement, and other documents filed with the SEC by Illumina, from Illumina by directing a request to Illumina, Inc., Attn: Investor Relations, Kevin Williams, MD, kwilliams@illumina.com.

CERTAIN INFORMATION REGARDING PARTICIPANTS IN THE SOLICITATION

Illumina and certain of its directors and executive officers may be deemed to be participants in the solicitation of proxies in connection with Illumina's 2012 Annual Meeting of Stockholders under the rules of the SEC. Security holders may obtain information regarding the names, affiliations and direct and indirect interests (by security holdings or otherwise) of Illumina's directors and executive officers in (i) Illumina's Annual Report on Form 10-K for the year ended January 2, 2011, which was filed with the SEC on February 28, 2011, and (ii) Illumina's proxy statement for its 2011 Annual Meeting of Stockholders, which was filed with the SEC on March 24, 2011. To the extent that Illumina's directors' and executive officers' holdings of Illumina's securities have changed from the amounts printed in the proxy statement for the 2011 Annual Meeting of Stockholders, such changes have been or will be reflected on Statements of Changes in Beneficial Ownership on Form 4 filed with the SEC. These documents can be obtained free of charge from the sources indicated above. Additional information regarding the interests of these participants in any proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will also be included in any proxy statement and other relevant materials to be filed with the SEC when they become available.

Source: Illumina, Inc.

ILLUM-0945

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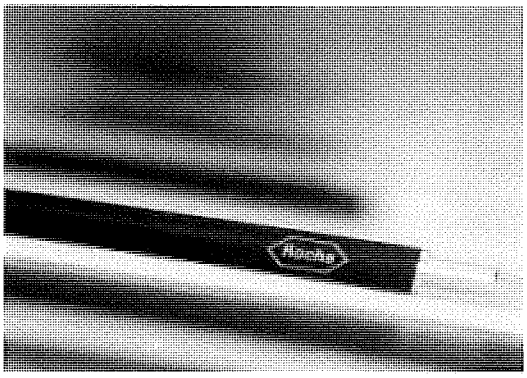
Roche sees alternatives if Illumina bid fails

Tue, Mar 6 2012



By Paul Arnold

ZURICH (Reuters) - Swiss drugmaker Roche (ROG.VX: Quote, Profile, Research, Stock Buzz) put pressure on U.S. gene decoder Illumina (ILMN.O: Quote, Profile, Research, Stock Buzz) to consider its hostile $5.7 billion bid, saying it sees other alternatives if the takeover fails.

"Roche and Illumina both stand to benefit from a rapid merger. However, this is a sector where we have other options should the transaction fail over price," Roche Chairman Franz Humer told the company's annual shareholder meeting on Tuesday.

"We continue to believe that our offer to Illumina's shareholders is attractive and fair. It remains our preference to enter into a negotiated transaction with Illumina and to commence discussions to that end."

Illumina has adopted a so-called poison pill defense strategy for Roche's unsolicited bid, and has advised shareholders not to tender their shares on the grounds the price was too low.

The San Diego-based company makes machines that decode a person's entire genome and would give Roche a leading position in the market for gene sequencing, which can help better identify which patients benefit from a given drug.

Humer said other companies were making quantum leaps in gene sequencing, noting Roche itself was working on such new technology.

Other players in the gene sequencing space include Ion Torrent, a unit of Life Technologies (LIFE.O: Quote, Profile, Research, Stock Buzz), as well as small operators like privately held Oxford Nanopore Technologies, which last month unveiled a palm-sized DNA sequencer.

But analysts said Illumina was clearly the market leader and Roche was unlikely to abandon its bid. Rather, Humer's comments were seen as a move to unnerve Illumina, whose stock price would tumble if Roche ditched its offer.

"There are alternatives, but not of Illumina's quality," said Karl-Heinz Koch of Helvea.

Martin Voegtli of Kepler Capital Markets agreed, adding: "I don't expect Roche will walk away from Illumina."

"If the shareholders notice that they can't get much more, the pressure will increase to examine a combination of the Roche and Illumina businesses."

Roche has been forging ahead in developing targeted therapies and Illumina's technology would help it to progress further in this field as gene sequencing is central to such "personalized" medicine, particularly in cancer.

The Swiss group extended its offer for Illumina last week, showing its willingness to play a waiting game, a strategy that has paid off with takeover targets in the past, although analysts believe it will probably ultimately have to raise its bid to win control.

Roche took seven months to buy U.S. diagnostic test-maker Ventana for $3.4 billion in 2008, when chief executive Severin Schwan was head of its diagnostics unit. It first made an unsolicited, low-end bid before increasing its original offer by 19 percent - a pattern analysts see being repeated with Illumina.

Roche shares were up 0.2 percent at 1200 GMT, outperforming a 0.3 percent softer sector index.

(Reporting by Paul Arnold; writing by Emma Thomasson; Editing by Dan Lalor and Ben Hirschler)

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Profile:

Illumina Inc (ILMN.OQ)

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ILMN.OQ on NASDAQ Stock Exchange Global Select Market	Price Change (% chg)	Prev Close	Day's High	Volume	52-wk High
50.47 USD 3:57pm EST	$0.12 (+0.24%)	$50.35	$50.88	127,110	$79.40
		Open	Day's Low	Avg. Vol	52-wk Low
		$50.42	$50.33	1,858,183	$25.57

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FULL DESCRIPTION

Illumina, Inc. (Illumina), incorporated in April 1998, is a developer and manufacturer of life science tools and integrated systems for the analysis of genetic variation and function. The Company provides a line of genetic analysis solutions, with products and services that serve a range of interconnected markets, including sequencing, genotyping, gene expression, and molecular diagnostics. The Company is organized in two business segments: Life Sciences and Diagnostics. Its Life Sciences business unit includes all products and services related to the research market, namely the product lines based on its sequencing, BeadArray, VeraCode, and real-time PCR technologies. Its Diagnostics business unit focuses on molecular diagnostics. Its customers include genomic research centers, academic institutions, government laboratories, and clinical research organizations, as well as pharmaceutical, biotechnology, agrigenomics, and consumer genomics companies. The Company sells its products to a number of customers outside the United States, including customers in other areas of North America, Europe, and the Asia-Pacific region. In January 2011, the Company acquired Epicentre Technologies Corporation, a provider of nucleic acid sample preparation reagents and specialty enzymes for sequencing and microarray applications. In April 2010, the Company purchased Helixis, Inc. In July 2010, the Company introduced the Eco Real-Time PCR System.

In its deoxyribonucleic acid (DNA) sequencing systems, the Company applies the SBS biochemistry on microscopic clusters of DNA. Each cluster starts as a single DNA molecule fragment, typically a hundred bases long, attached to the inside surface of a flow cell. The Company then uses amplification biochemistry to create copies of each starting molecule. Its BeadArray technology combines microscopic beads and a substrate in a manufacturing process to produce arrays that can perform many assays simultaneously, enabling large-scale analysis of genetic variation and biological function. Its BeadArray technology consists of microscopic silica beads, each bead covered with hundreds of thousands of copies of oligonucleotides (oligos). The VeraCode technology platform leverages the power of digital holographic codes to provide a detection method for multiplex assays. VeraCode enables multiplexing from 1-384-plex in a single well. The VeraCode technology consists of cylindrical glass beads (measuring 240 microns in length by 28 microns in diameter) inscribed with a digital holographic code to designate and track the specific analyte or genotype of interest throughout the multiplex reaction. Real-Time PCR (PCR) is used to amplify and simultaneously quantify a targeted DNA molecule, with applications in gene expression, viral quantification, array data validation, pathogen detection, and genotyping.

Sequencing/Array Combination Platforms

The HiScanSQ combines its SBS sequencing technology and iScan microarray analysis instrumentation into one system, with a modular design that can evolve with changing research needs. This flexible system allows researchers to use its sequencing and array technologies interactively to bring increased power to their experiments.

Array Platforms

The iScan supports its Infinium, GoldenGate, DASL, gene expression, and methylation assays. Its BeadXpress Reader is designed for both small and high-throughput laboratories conducting molecular testing with

COMPANY ADDRESS

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multiplexed-based assays deployed on our VeraCode bead technology. It supports a range of applications, including DNA, ribonucleic acid (RNA), and protein-based assays.

Consumables

Its InfiniumHD Whole-Genome BeadChips represent its technologically advanced multi-sample DNA analysis microarrays, enabling the interrogation of up to 2.5 million markers per sample, depending on the BeadChip. In addition to the Omni family, the HumanOmni2.5 and HumanOmni1S BeadChips, provide common and rare variants identified by the 1000 Genomes Project for performing genome-wide association studies (GWAS) projects. This product line also includes agriculturally relevant genome panels, such as the BovineHD and MaizeSNP50 BeadChips. The Company offers iSelect Custom Genotyping BeadChips. Its GoldenGate Universal-32 Sample BeadChip provides a flexible customized solution for mid-plex genotyping assays performed on the iScan System or HiScan, while the VeraCode GoldenGate genotyping arrays are well-suited for low-plex genotyping on the BeadXpress Reader.

Real-time PCR Platforms

The Eco Real-Time PCR System provides qPCR results. Its user interface provides experimental design and setup, enabling the system to perform qPCR on 48 samples in less than 40 minutes.

FastTrack Services

The Company offers genotyping services to academic institutions, biotechnology, and pharmaceutical customers. The in-house molecular geneticists help customers perform GWAS projects, linkage analysis, and fine mapping studies. The Company employs a range of its products, including standard and custom GoldenGate, standard Infinium and Infinium HD, and iSelect Infinium assays.

Service Partnership Programs

The Company has developed partnered programs, such as its Certified Service Providers (CSPro) and Illumina Genome Network (IGN) to create a world-wide network of Illumina technology-enabled service offerings. There are over 50 Illumina CSPro-certified organizations worldwide providing sequencing, genotyping, and gene expression services using its technologies and products. The genome sequencing service network comprises CSPro-certified academic and commercial organizations possessing 10 or more HiSeq 2000 or Genome Analyzer systems.

Individual Genome Sequencing

Illumina's Individual Genome Sequencing Service provides personal genome sequencing for consumers. It is performed in its CLIA-certified, CAP-accredited laboratory using its next-generation sequencing technology. The service is built around physician-patient consultation, with a physician's order required to initiate the process. The offering includes sequencing of an individual's DNA to 30-times depth, providing information on SNP variation and other structural characteristics of the genome, such as insertions, deletions, and rearrangements. The Company is collaborating with a number of partners to provide secondary data analysis, such as calculation of disease risk, ancestry, and information on traits of interest. The service requires individuals to follow its physician-mediated process, which involves pre-service consultation, patient consent, and a seven-day period, during which the patient may withdraw consent. The final genome data is returned to the physician, who in turn delivers it to the consumer.

The Company competes with Affymetrix, Inc., Agilent Technologies, Inc., Beckman Coulter, Inc., Complete Genomics, Inc., Helicos BioSciences Corporation, General Electric Company, Life Technologies Corporation, Luminex Corporation, Pacific Biosciences of California, Inc., QIAGEN N.V., Roche Diagnostics Corp. and Sequenom, Inc.

» Full Overview of ILMN.OQ

OFFICERS & DIRECTORS

Name	Compensatio
William Rastetter	
Jay Flatley	
Marc Stapley	
David Walt	
Mostafa Ronaghi	

» More Officers & Directors

ILLUMINA INC NEWS

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06 Mar 2012

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Illumina outlook drags down genetic tools sector

Fri, Oct 7 2011

By Kavyanjali Kaushik

(Reuters) - Shares of Illumina Inc (ILMN.O: Quote, Profile, Research, Stock Buzz) fell 35 percent and dragged down its peers on Friday, a day after the maker of genetic analysis tools forecast a weak third quarter on uncertainty related to research funding in the United States and Europe.

Declining sales in the wake of weakening global markets and a lack of clarity on government funding levels have pushed down the stocks of Illumina and its peers by about a fifth over the past three months.

"The life science tool sector saw a softening in academic spending market as early as the second quarter and most of the companies realized that academics right now are in the state of uncertainty," Robert W. Baird & Co analyst Quintin Lai told Reuters.

Companies such as Illumina, Affymetrix Inc (AFFX.O: Quote, Profile, Research, Stock Buzz) and Life Technologies (LIFE.O: Quote, Profile, Research, Stock Buzz) get 20-40 percent of their revenue from U.S. government-backed research and could be hurt by a budget squeeze.

Illumina shares took the most beating as the company was more at exposure than the others, Lai said.

"What was built into the stock price was that Illumina was not going to have any hiccup and that Life Technologies and Affymetrix are going to be suffering the headwinds," Lai said.

"Now, when you see results like Illumina's pre-release last night, the stock got hit really big today."

San Diego, California-based Illumina, which currently serves life-sciences research, applied markets and the molecular diagnostics market, said it expects these conditions to continue through at least the fourth quarter and suspended its full-year outlook.

Illumina said it expects to post revenue of about $235 million for the third quarter, compared with Wall Street expectations of $278 million.

Citigroup said while there has been ongoing concern over a weakening environment for the tools sector, the magnitude of Illumina's miss was a surprise and cut its price target on the stock to $32 from $44.

Three other brokerages also cut their price targets on Illumina's stock.

Illumina's shares were at $27.80 in late morning trade on Nasdaq after falling to a nearly two-year low of $25.71. Shares of Bruker BioSciences Corp (BRKR.O: Quote, Profile, Research, Stock Buzz) were down 4 percent at $13.15, while those of bigger rival Thermo Fisher Scientific Inc (TMO.N: Quote, Profile, Research, Stock Buzz) were down 6 percent at $50.36.

Affymetrix's stock was down 6 percent at $5.35 and Life Technologies shares lost 7 percent of their value to trade at $36.50.

(Reporting by Kavyanjali Kaushik in Bangalore; Editing by Sayantani Ghosh and Sriraj Kalluvila)

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EXHIBIT G

OF

DECLARATION OF KAREN POSSEMATO

illumina

Illumina Acquires Epicentre Biotechnologies, Leading Provider of Nucleic Acid Sample Preparation Reagents and Specialty Enzymes

Combination Enhances Illumina's Sample Preparation and Enzyme Portfolio

SAN DIEGO, Jan 11, 2011 (BUSINESS WIRE) -- Illumina, Inc. (NASDAQ:ILMN) today announced that it has acquired Epicentre Biotechnologies, a leading provider of nucleic acid sample preparation reagents and specialty enzymes used in sequencing and microarray applications. A key component of the acquisition is direct access to Epicentre's proprietary Nextera(TM) technology for next-generation sequencing library preparation, which greatly simplifies genetic analysis workflows and reduces time from sample preparation to answer.

"As next-generation sequencing continues to improve in throughput and cost, there's a critical need for sample prep to evolve as well, to lower costs, handle higher sample volumes and reduce both hands-on and overall processing time," said Jay Flatley, President and CEO of Illumina. "Epicentre's Nextera technology provides a step-change improvement in library prep that will translate into greater ease of use, lower costs, and faster turnaround times for sequencing applications. In addition to Nextera, Epicentre is a leading supplier of specialty enzymes and kits that are beneficial to Illumina's technologies."

The rapid adoption of Nextera sequencing sample prep kits by existing Illumina sequencing customers is indicative of the cost effectiveness, ease of use, and efficiency of Nextera technology. With this patented technology, researchers can prepare sequencer-ready libraries from genomic DNA with less than 15 minutes of hands-on time - a significant timesaving compared to alternate methods. In addition, Nextera technology requires 10-100 times less starting DNA, which enables applications with limited starting material such as tumor biopsies, degraded DNA, or purified RNA. These unique features of Nextera sequencing library prep kits are all critical to advancing the evolution of next-generation sequencing.

The combined company will be uniquely positioned to offer an end-to-end solution for next-generation sequencing, microarray, and real time PCR applications. Epicentre's unique capabilities in enzyme engineering and sample preparation reagent development will complement Illumina's core platform expertise to comprehensively address the needs of researchers across their entire genetic analysis workflow.

About Illumina

Illumina (www.illumina.com) is a leading developer, manufacturer, and marketer of life science tools and integrated systems for large-scale analysis of genetic variation and function. We provide innovative sequencing and array-based solutions for genotyping, copy number variation analysis, methylation studies, gene expression profiling, and low-multiplex analysis of DNA, RNA, and protein. We also provide tools and services that are fueling advances in consumer genomics and diagnostics. Our technology and products accelerate genetic analysis research and its application, paving the way for molecular medicine and ultimately transforming healthcare.

Forward-Looking Statements

This release contains forward-looking statements that involve risks and uncertainties. Important factors that could cause actual results to differ materially from those in any forward-looking statements include challenges inherent in integrating Epicentre with our existing operations and the other factors that are detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We do not intend to update any forward-looking statements after the date of this release.

SOURCE: Illumina, Inc.

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EXHIBIT II

OF

OPPOSER/PETITIONER'S MOTION FOR

SUMMARY JUDGMENT AND

MEMORANDUM IN SUPPORT THEREOF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc.,	)	
	)	Opp. No. 91194218 (SN 77768176) (Parent)
Opposer/Petitioner,	)	
	)	Opp. No. 91194219 (SN 77775316)
v.	)	
	)	Can. No. 92053479 (RN 3887164)
Meridian Bioscience, Inc.,	)	
	)	Can. No. 92053482 (RN 3868081)
Applicant/Registrant.	)	

DECLARATION OF GREGORY F. HEATH

I, Gregory F. Heath, Ph.D., declare as follows:

1. I am a Senior Vice President of Illumina, Inc. ("Illumina") and, since March 2008, I have been the General Manager of Illumina's Diagnostics Business Unit. In my current role with the company, I am responsible for managing Illumina's emerging diagnostics business.

2. Illumina is a global company that develops, manufactures and markets genetic analysis tools and integrated systems for the analysis of genetic variation and function, and provides services related to the same. More specifically, Illumina develops and sells innovative array- and sequencing-based solutions for DNA, RNA, and protein analysis which serve as tools for disease research and diagnosis, drug development and for the development of molecular tests in the clinic. Illumina products and services serve life-sciences research, applied markets and the molecular diagnostics market.

3. Illumina began development of products and services for the molecular diagnostic

CF

market in 2008, with the creation of a Diagnostics Business Unit within its company. In March 2008, I was hired to serve as the General Manager of Illumina's Diagnostics Business Unit. After internal development of diagnostic products, Illumina publicly announced its intention to enter the market for molecular diagnostics in April 2010. Around May 2010, Illumina announced the launch of an *in vitro* diagnostic device intended for the simultaneous detection of multiple analytes in a DNA sample, utilizing its VeraCode® holographic microbead technology. Illumina's genotyping assay for Factor V and Factor II was granted 510(k) market clearance by the U.S. Food and Drug Administration (FDA) for *in vitro* diagnostic use. Factor V and Factor II are blood proteins involved in a person's ability to form normal clots. Unlike earlier tests for detecting the clotting activity of the Factor V and II molecules, Illumina's test is a more sensitive molecular test for detecting DNA sequences that encode mutations for Factor V and II. About the same time, the FDA also granted market clearance for Illumina's BeadXpress® instrument for *in vitro* diagnostic use with the Factor V and Factor II test. Illumina is currently developing the next generation of molecular tests, systems, and services that will facilitate earlier diagnosis, selection of appropriate therapies, and monitoring of disease progression. Marketed and sold under the ILLUMINADX mark, Illumina's technologies enable sophisticated analysis of pathogens and subtle changes in patients' genes and chromosomes, allowing clinical laboratories and physicians to personalize disease management for improved healthcare. In addition to molecular diagnostics, molecular cytogenetics and cancer discovery initiatives, the Illumina Clinical Services Laboratory currently offers physician-ordered genome sequencing services. True and correct copies of press releases issued by Illumina relating to its efforts in the diagnostics field are attached hereto as Exhibit 1.

4. Illumina uses its ILLUMINADX mark in connection with its products and

services that target the diagnostics market. Representative examples of the use of the ILLUMINADX mark are attached hereto as Exhibit 2.

5. Illumina began seeking regulatory approval for products designed for diagnostics in early 2008. True and correct copies of press releases and articles discussing Illumina's successful efforts to obtain regulatory approval for products design for diagnostics are attached hereto as Exhibit 3.

6. In the life sciences industry, the research and diagnostics markets are inextricably linked. Illumina now serves both markets as do many other companies such as Beckmann Coulter, Becton Dickinson, Gen-Probe, Luminex, Roche, and Siemens. True and correct copies of webpages of several companies selling both research and diagnostics products are attached hereto as Exhibit 4. The transition from research markets to diagnostic markets is also discussed in various review articles also attached hereto as Exhibit 4.

7. Both Illumina and Meridian Bioscience, Inc. advertise their products and services in the same trade magazines and promote their products and services to the same set of consumers at the same trade shows. True and correct copies of advertisements and trade show exhibitor lists are attached hereto as Exhibit 5.

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 10th day of April 2012

Gregory F. Heath, Ph.D.

EXHIBIT 1

OF

DECLARATION OF GREGORY F. HEATH

illumina

Illumina Announces Corporate Reorganization

SAN DIEGO, Jan 04, 2008 (BUSINESS WIRE) -- Illumina, Inc. (NASDAQ:ILMN) today announced that it has reorganized its operating structure to further leverage the synergies between its sequencing and genotyping businesses. Under the new structure, a newly created Life Sciences Business Unit will include all products and services related to the research market namely the BeadArray, BeadXpress and Sequencing product lines. The Company has also created a Diagnostics Business Unit to put more focus on the emerging opportunity in molecular diagnostics. The Diagnostics Business Unit will develop diagnostic content for the BeadXpress system, and ultimately for Illumina's Sequencing products.

"Over the last few years we have experienced incredible growth. This new organizational structure provides the foundation to continue scaling our global operations and more effectively leverage our technology assets to capitalize on future opportunities. A specific result will be the acceleration of the integration of our sequencing and genotyping technologies. Additionally, it will enable us to put more focus on developing our diagnostics business," said Jay Flatley, President and Chief Executive Officer of Illumina.

The timing of this reorganization was driven by several management changes. John Stuelpnagel, Senior Vice President, Chief Operating Officer and General Manager, Arrays has decided to move to part-time status as of April 1, 2008. Dr. Stuelpnagel is expected to have a continuing role with the company working on key projects as an Illumina Fellow. Additionally, he will step down from Illumina's Board of Directors as of that date.

"John has spent the last ten years founding, building and leading Illumina into a pre-eminent life sciences company. Although we are disappointed that John has decided to step down from his full time role, we expect to continue to benefit from his broad experience, leadership and vision," said Flatley.

John West, Senior Vice President and General Manager, Sequencing has announced his resignation effective February 1, 2008. "As the former CEO of Solexa, John has been instrumental in building the next generation sequencing market and facilitating the integration of Solexa into Illumina. We thank John for his outstanding contributions to Solexa and Illumina and wish him well in his future endeavors," Flatley said.

Effective immediately, Christian Henry, Senior Vice President and Chief Financial Officer will take on the role of Acting General Manager of the Sequencing business. In addition to his other duties, Mr. Henry's primary goal will be to effectively manage the integration of the Sequencing business into the new combined Life Sciences Business Unit. The integration is expected to be completed before the end of the second quarter.

The Company is pleased to announce that it has hired a Senior Vice President and General Manager, Life Sciences who will be responsible for managing the newly created Life Sciences Business Unit. We expect this individual to fully complete the transition from his current role to Illumina by April 1, 2008.

Illumina is also pleased to announce that it has hired a Senior Vice President and General Manager, Diagnostics. Expected to start in early March 2008, this senior executive brings a wealth of diagnostic experience to Illumina. "His leadership will help mold our diagnostic strategy and operations to leverage the key assets of the company," explained Flatley.

As a result of our rapid growth, the company has initiated searches for a Senior Vice President Product Development and a Senior Vice President of Operations. These new positions will report to the General Manager, Life Sciences. We expect to integrate all product development activities from the array and sequencing businesses under the Senior Vice President Product Development. Similarly, all manufacturing and materials activities will be integrated under the Senior Vice President Operations. We will continue to operate in all our existing development and manufacturing locations, namely San Diego, Hayward and Little Chesterford, UK.

"To keep pace with our rapid growth, Illumina's infrastructure has matured significantly over the last several years. Our new organizational structure is a required evolution on the path toward our goal of becoming the global leader in genetic analysis. I look forward to an exciting 2008 for Illumina," continued Flatley.

About Illumina

Illumina is a leading developer, manufacturer and marketer of next-generation life science tools and integrated systems for the analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations and biotechnology companies. Our tools provide researchers around the world with the performance, throughput, cost effectiveness and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information from advances in genomics and proteomics. We believe this information will enable researchers to correlate genetic variation and biological function, which will enhance drug discovery and clinical research, allow diseases to be detected earlier and permit better choices of drugs for individual patients.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: this release may contain forward-looking statements that involve risks and uncertainties. Among the important factors that could cause actual results to differ materially from those in any forward-looking statements are the costs and outcome of Illumina's litigation with Affymetrix and our ability (i) to integrate effectively our recent acquisition of Solexa, Inc., (ii) to develop and commercialize further our BeadArray(TM), VeraCode(TM) and Solexa(R) technologies and to deploy new gene expression and genotyping products and applications for our technology platforms, (iii) to manufacture robust micro arrays and Oligator(R) oligonucleotides, (iv) to integrate and scale our VeraCode technology, (v) to scale further oligo synthesis output and technology to satisfy market demand derived from our collaboration with Invitrogen, together with other factors detailed in our filings with the Securities and Exchange Commission including our recent filings on Forms 10-K and 10-Q or in information disclosed in public conference calls, the date and time of which are released beforehand. We disclaim any intent or obligation to update these forward-looking statements beyond the date of this release.

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Illumina Appoints Joel McComb as Senior Vice President and General Manager of Life Sciences and Gregory F. Heath as Senior Vice President and General Manager of Diagnostics

SAN DIEGO--(BUSINESS WIRE)--March 17, 2008--Illumina, Inc. (NASDAQ:ILMN) today announced the appointment of Joel McComb as Senior Vice President and General Manager of the Company's Life Sciences Business Unit and Gregory F. Heath, Ph.D., as Senior Vice President and General Manager of the Company's Diagnostics Business Unit.

Joel McComb joins Illumina from GE Healthcare where he held a number of executive positions including his most recent position as President of the Interventional Medicine Business. Prior to this role, Joel was President of Life Sciences Discovery Systems, a $600 million division of GE Healthcare. This business unit was formed after GE acquired Amersham Biosciences, and markets molecular biology, genomics, proteomic, and cellular imaging products. In this role Joel had responsibility for product development, manufacturing, service, global sales and marketing, information systems, quality, business development, and program management. Prior to his work at GE Healthcare, Joel was President and Chief Executive Officer of Innovadyne Technologies. He was responsible for the strategy and implementation of all operations, beginning with the startup of Innovadyne through its subsequent sale as a profitable business to Gilson, Inc. From 1995 to 2001 Joel held various positions at Beckman Coulter, including roles as General Manager of the Primary Care Diagnostic Division and Director of Corporate Business Development. Joel earned a Bachelor of Science degree in genetics from the University of California, Davis and a MBA degree from the Golden Gate University in San Francisco, CA.

In his new position as Illumina's General Manager of Life Sciences, Joel is responsible for managing all products and services related to the research market, namely the BeadArray(TM), BeadXpress(R), and Sequencing product lines.

Gregory F. Heath brings with him more than 20 years of Diagnostics experience, including launching the world's first FDA-approved microarray for diagnostic use. He joins Illumina from Roche Molecular Systems where he held a number of senior executive positions, including Head of Clinical Genomics, Senior Vice President of Global Product Marketing, Senior Vice President of Global Marketing and Business Development, and most recently, Senior Vice President of Global Business. In this last role, Greg was responsible for new product development and global marketing activities for the Infectious Disease, Blood Screening, Genetics, and Oncology portfolios. From 2000 to 2003, Greg was Head of Business Development and Licensing for the Diagnostics Division of F. Hoffman La Roche in Basel and led the Strategic Planning, Business Development and Licensing activities of the Molecular Diagnostics, Centralized Diagnostics, Applied Science, Near Patient Testing, and Diabetes Care business areas. Prior to this, Greg held numerous roles in Marketing and Business Development with Roche Diagnostic's U.S. affiliate. Greg earned a Bachelor of Science degree in psychology from Illinois State University and a Master of Arts degree in experimental psychology from Hollins College (Roanoke, VA). He graduated with a Ph.D. in Experimental Psychology from Virginia Commonwealth University and completed his post-doctoral work in behavioral pharmacology at Michigan State University.

In his new position as General Manager of Diagnostics, Greg is responsible for managing Illumina's emerging diagnostics business, specifically overseeing the development of diagnostic content for the BeadXpress system, and ultimately for Illumina's Sequencing products.

"With our newly-created Life Sciences and Diagnostics Business Units we are ideally positioned to take

advantage of our rapidly growing market opportunities," said Jay Flatley, President and Chief Executive Officer of Illumina. "Joel will focus on the integration of our sequencing, genotyping, and gene expression businesses. Greg's substantial experience in the diagnostics industry will help us further develop our diagnostic strategy and operations to leverage the key assets of the company."

About Mr. McComb's and Dr. Heath's Compensation

The Company granted options to purchase 200,000 and 150,000 shares of Illumina's common stock to Mr. McComb and Dr. Heath, respectively, as part of their inducement to join the company. The options were granted by the Company's compensation committee pursuant to NASDAQ Marketplace Rule 4350(i)(1)(A)(iv) and under Illumina's New Hire Stock and Incentive Plan, which was approved by Illumina's Board of Directors on January 29, 2008. These options have the following terms: an exercise price equal to the closing fair market value of Illumina's common stock on the grant date, a ten-year term and vesting over five years with 20 percent of each option vesting one year from the grant date and 1/60th of each option vesting monthly thereafter. The grant date for these options is March 17, 2008.

About Illumina

Illumina (www.illumina.com) is a leading developer, manufacturer, and marketer of next-generation life-science tools and integrated systems for the large-scale analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations, and biotechnology companies. Our tools provide researchers around the world with the performance, throughput, cost effectiveness, and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information from advances in genomics and proteomics. We believe this information will enable researchers to correlate genetic variation and biological function, which will enhance drug discovery and clinical research, allow diseases to be detected earlier, and permit better choices of drugs for individual patients.

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Illumina Announces Appointments Of Elizabeth Brady As Vice President, Global Supply Chain, And Emily Winn-Deen As Vice President, Diagnostics Development

Business Wire

04/30/10 - 06:00 AM EDT

Illumina, Inc. (NASDAQ:ILMN) today announced the appointments of Elizabeth Brady as vice president, Global Supply Chain, and Emily S. Winn-Deen, Ph.D., as vice president, Diagnostics Development.

Ms. Brady will be responsible for Illumina's global sourcing, planning, logistics and distribution operations, reporting to William Bonnar, senior vice president, Operations. "Elizabeth has an outstanding background as a senior leader with extensive global experience in supply chain management spanning the electronics and healthcare industries," said Mr. Bonnar. "At Illumina, she will play a critical role in building a world-class supply chain operation that will be a key element in realizing our growth objectives."

Prior to joining Illumina, Ms. Brady served as vice president, Global Supply Chain, Cardiac Rhythm Management Division of Boston Scientific Corporation, where she built a supply chain organization that helped successfully launch new products, reduce obsolete inventory, implement life cycle management and reduce planning cycle time. Previously, she served as vice president, Supply Chain, at Tellabs Operations, Inc., a maker of telecom infrastructure equipment. She also held supply chain leadership positions in the U.S. and Ireland with 3Com Corporation. Ms. Brady holds a B.S. in Business Analysis and Business Economics from Indiana University, Bloomington.

Dr. Winn-Deen will be responsible for the development of diagnostics products at Illumina, reporting to Gregory Heath, Ph.D., senior vice president and general manager, Diagnostics. "Emily brings an impressive track record of more than 20 years of successful leadership in the life sciences and diagnostics fields, much of it focused on novel biomarkers and product development for emerging markets," said Dr. Heath. "As head of development, she will play a crucial role in building Illumina's diagnostics capability and paving the way for our future leadership in this critical area."

Prior to joining Illumina, Dr. Winn-Deen served as president of Rx Dx Advisors, a consulting practice focused on evaluating market trends and new technology, corporate partnering, business and product development, and regulatory compliance. Previously, at Cepheid, she held vice president positions in Genetics and Oncology R&D, and in Strategic Development and Business Planning. She has served in senior R&D positions at a range of diagnostics and pharmaceutical companies, including Roche Molecular Systems, Applera Corporation, Oncor and Bayer Diagnostics. Dr. Winn-Deen holds a B.A. in chemistry from Lehigh University and a Ph.D. in chemistry from Boston University.

About Ms. Brady's and Dr. Winn-Deen's Compensation

Illumina granted an option to purchase 120,000 shares of Illumina's common stock to Ms. Brady and an option to purchase 112,000 shares of Illumina's common stock to Dr. Winn-Deen, as part of their inducement to join the company. The options were granted by Illumina's Compensation Committee pursuant to NASDAQ Marketplace Rule 5635(c)(4) and under Illumina's New Hire Stock and Incentive Plan, which was approved by Illumina's Board of Directors on January 29, 2008. These options have the following terms: an exercise price equal to the closing fair market value of Illumina's common stock on the grant date, a ten-year term, and vesting over four years with 25 percent of the option vesting one year from the grant date and 1/48th of the option vesting monthly thereafter. The grant date for the option to Ms. Brady is May 3, 2010. The grant date for the option to Dr. Winn-Deen is April 26, 2010.

For more information about careers at Illumina, please visit www.illumina.com/careers.

About Illumina

Illumina (http://www.illumina.com) is a leading developer, manufacturer, and marketer of life-science tools and integrated systems for the large-scale analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations, and biotechnology companies. Our tools provide researchers around the world with the performance, throughput, cost effectiveness, and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information from advances in genomics and proteomics. We believe this information will enable researchers to correlate genetic variation and biological function, which will enhance drug discovery and clinical research, allow diseases to be detected earlier, and permit better choices of drugs for individual patients.

Forward-Looking Statements

This release may contain forward-looking statements that involve risks and uncertainties. Important factors that could cause actual results to differ materially from those in any forward-looking statements are detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We do not intend to update any forward-looking statements after the date of this release.

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genomeweb

Decode, Illumina to Co-develop, Sell Molecular Diagnostics

May 15, 2006

Decode, Illumina to Co-develop, Sell Molecular Diagnostics

By a GenomeWeb staff reporter

NEW YORK, May 15 (GenomeWeb News) - Decode Genetics and Illumina plan to co-develop and commercialize DNA-based diagnostics in several major disease areas, the firms said today.

According to the firms, the partnership will use Illumina's platform for high-multiplex SNP-genotyping to develop diagnostics for gene variants that Decode has shown to be risk factors for various diseases.

Under the terms of the agreement, Illumina will gain access to disease-related biomarkers, which will be jointly validated as diagnostic panels. Illumina will market and sell these on its forthcoming BeadXpress platform, the partners said.

Illumina will also install its SNP-genotyping platform at Decode's labs in Iceland.

Initially, the companies will focus on the gene encoding leukotriene A4 hydrolase, which has been linked to heart attack; the gene encoding transcription factor 7-like 2, which is linked to type II diabetes; and the gene encoding BARD1, which is linked to breast cancer.

The companies will share development costs and split the profits from sales of the diagnostics tests.

At Goldman Sachs Confab, Illumina Predicts Future Growth in AgBio, Diagnostic Sectors

June 17, 2008
By Justin Petrone

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Around 30 percent of Illumina's revenues currently come from sales to commercial customers, but the company expects that portion to shift in five years to 40 percent of its revenue, due in part to growth in the agricultural biotechnology and molecular diagnostics segments.

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Scientists and policy-makers don't always see eye-to-eye.
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Celebrities are lending their fame to science, one blogger says.
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The microbiome may be a driver of evolution.
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Physicians, Patients Talk Genetic/MDx Tests
The LA Times reports on a new study that examines genetic and molecular diagnostic test spending in the US.
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Papers of Note

People on the Move

ILLUM-0607

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Monday,

Illumina Starts Validating Ovarian, Gastric Cancer Genes from Discovery Project; Adds Colorectal Cancer

January 18, 2011

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By Julia Karow

This article was originally published January 13.

As part of its Cancer Discovery Initiative, Illumina is validating genes discovered by sequencing ovarian and gastric cancer samples in larger sample sets and expects to have results for ovarian cancer in the latter half of the year, according to a company executive. It has also embarked on a third cancer type, colorectal cancer.

The aim of the initiative, which Illumina launched two years ago (*IS 1/20/2009*), is to use sequencing to discover biomarkers for early disease detection and to predict response to therapy or relapse. Eventually, the firm wants to develop new diagnostics on the BeadXpress platform. According to its website, Illumina is partnering with "leading cancer research institutions" for the project.

The company chose to tackle ovarian and gastric cancer first, where survival rates are poor if the disease is detected late. Also, for ovarian cancer, most diagnoses are currently made at a late stage. The aim is to discover biomarkers for early detection and to predict resistance to platinum therapy. Last fall, Illumina reported that it had completed sequencing the genomes, methylomes, and transcriptomes of 25 tumor/normal ovarian cancer samples (*IS 11/2/2011*), and had found about 40 "significant genes," half of which had not previously been implicated in the disease. It had also completed sequencing 25 tumor/normal gastric cancer samples.

At the JP Morgan Healthcare Conference in San Francisco last week, Illumina CEO Jay Flatley said that the company is currently validating the ovarian cancer genes — along with some additional related genes — by targeted sequencing in 300 samples. The project is expected to be completed mid-year, and in the second half of the year, "we'll determine what's come out of this cancer discovery activity," Flatley said.

For gastric cancer, he said, company researchers have discovered three "very important genes," and are beginning to validate those in a set of 250 samples.

The company has also selected colorectal cancer as a third cancer type to investigate. Half of colorectal cancers that are treated with surgery alone relapse, according to the firm's website, and therapies selected by stage of diagnosis are not well associated with the likelihood of response. The goal, thus, is to discover biomarkers for disease prognosis and relapse. "Sequencing on those cancer samples is just now beginning," Flatley said. He did not mention the number of samples to be analyzed.

In this issue of In Sequence

Illumina's Low-Cost MiSeq Promises to Speed up Next-Gen Sequencing

Two Sequencing-Based Prenatal Tests Make Strides Toward the Clinic

Illumina Passes Terabase Milestone for HiSeq; Customers to Reach 600 Gb per Run this Spring

Acquisition of Epicentre Gives Illumina Exclusive Access to Nextera Sample-Prep Method

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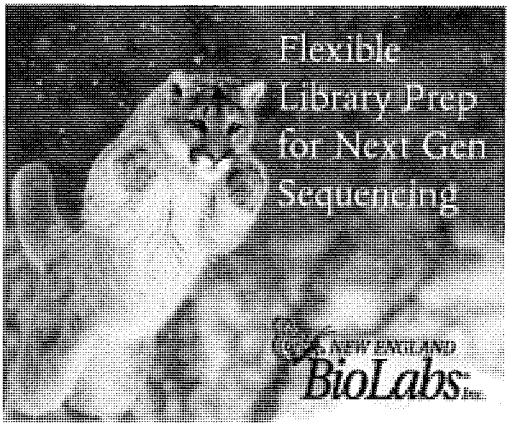

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People on the Move

David Botstein, **Eric Lander**, and **Craig Venter** will share the 2012 Dan David Prize, and will split the $1 million prize the award carries.
The three winners have been recognized for their contributions to the Human Genome Project and an array of genomics research efforts, from developing microarrays and DNA sequencing technologies to computational genomics and SNP mapping, and launching labs, companies, and institutes that have driven cutting-edge genomics.
Botstein currently is a director of the **Lewis-Sigler Institute for Integrative Genomics** at **Princeton University**. Venter is founder, chairman, and president of the **J. Craig Venter Institute**, as well as the **Institute for Genomic Research**, and **Celera Genomics**. Lander is founding director of the **Broad Institute of Harvard and MIT** and director of its

ILLUM-0608

According to the website, if validation pans out, Illumina plans to offer diagnostic services for ovarian cancer in its CLIA lab. Ultimately, it wants to run prospective trials on these markers and gain regulatory clearance for diagnostics developed on its BeadXpress platform, which received 510(k) clearance from the US Food and Drug Administration last year.

Have topics you'd like to see covered in *In Sequence*? Email the editor at jkarow [at] genomeweb [.] com.

Related Stories

Clinical Genome Sequencing Requires Better Standards for Accuracy, Completeness, NHGRI Team Says
August 24, 2011 / Clinical Sequencing News

Illumina, Helicos Platforms Offer Distinct Advantages for Ancient DNA Sequencing, Danish Group Says
August 23, 2011 / In Sequence

Illumina and University of Oxford to Sequence 500 Human Genomes to Inform Diagnosis, Treatment
August 3, 2011 / Clinical Sequencing News

Illumina Books Orders for More than 135 MiSeqs, Starts Early-Access Shipments
August 2, 2011 / In Sequence

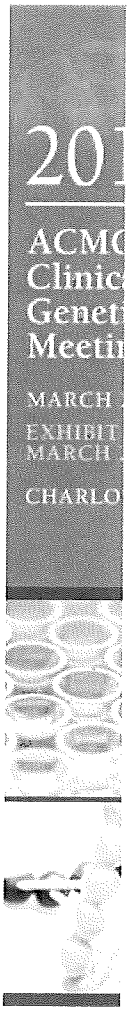
New Products
July 19, 2011 / In Sequence

Genome Biology Program.

Jorge Garces has joined **GenMark Diagnostics** as senior vice president of R&D, the company said recently. Garces most recently served as CEO and president of **Enigma Diagnostics**' US business. Prior to that, he was VP of R&D and site operations manager at **Hologic**. He has also held positions at **Third Wave Technologies**, **Genzyme Genetics**, and **Athena Diagnostics**.

Combimatrix this week said it has named two San Diego area executives, **Richard Ding** and **Joseph Limber**, to seats on its board of directors, and that former President and CEO **Amit Kumar**, as well as **Rigdon Currie** and **John Abeles**, will not be candidates for reelection at its next stockholders meeting.
Ding is CEO of **BioTheranostics**, a molecular diagnostics test developer and lab, and formerly was VP of strategy and business development at **BioMerieux**. Limber is president and CEO of **Prometheus Laboratories**, a pharmaceutical and diagnostics company focused on personalized medicine. He also previously was president and CEO of **Aclara BioSciences**, subsequently named **Monogram Biosciences**.

Upcoming Events



Real-Tim
Technica

Tech Gui

Science

Investigators from the Wellcome Trust Sanger Institute, the University of Cambridge, and elsewhere used exome sequencing to reveal the compound inheritance patterns behind an autosomal recessive condition called thrombocytopenia with absent radii, or TAR, syndrome. By underscoring the potential importance of non-coding, regulatory regions in the genome, the work may also inform studies of other conditions.

Business

Affymetrix said that it has released eBioscience from certain obligations under the terms of their proposed merger as the Santa Clara, Calif.-based array firm continues in its efforts to salvage the $330 million deal. Affy said in a Form 10-K filed with the SEC that it is in discussions with financing sources and eBioscience about restructuring a financing agreement that could support the deal, but no agreement has been reached.

Funding

Research councils from 22 participating countries are providing roughly $13.5 million in funding to support the BIOMARKAPD program, a multinational collaboration aimed at improving and harmonizing methods for using molecular biomarkers for neurodegenerative disorders, such as Alzheimer's and Parkinson's disease. The consortium, led by the Karolinska Institute, will also support projects to identify new markers.

Genome Technology Magazine

Using a MeDIP-seq approach to study an unsequenced species, the University of Birmingham's Kevin Chipman and his colleagues identified a potential link between environmental pollutants, epigenetic changes, and cancer in a fish called the common dab. In addition to finding epigenetic changes in the tumors themselves, Chipman and his team saw changes to the methylation profiles of DNA in surrounding tissue as well, which suggest a few ways that tumor-associated changes could occur.

Do you think biologists p threat?

- Yes. The what peopl potentially c organisms.
- Yes. The regulated o anyway.
- Maybe. F working in I potentially c
- No. The anything da getting out
- No. Som biologists a important w

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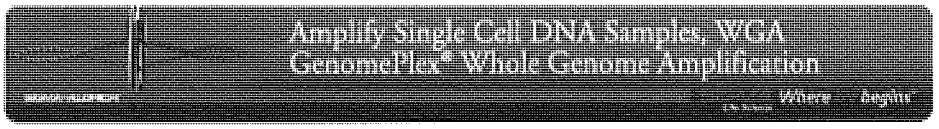

Matt Dublin on
New algorithms

Log in or Register

SEARCH

Wednesday, May 11, 2011

Illumina Aims to Have FDA-Cleared Dx, CLIA Lab In '09; CEO Says Arrays Have Dx Future

November 18, 2008
By Justin Petrone

The firm's first assay will run on its digital microbead-based BeadXpress reader, but the CLIA lab will offer both sequencing and array-based services, a sign that Illumina believes these two platforms mey play a larger role in its diagnostics offering in the future.

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FDA Clears Affymetrix Gene Expression Reagents for IVD Use
May 10, 2011 / BioArray News

1. **GenomeWeb Daily News**
UPDATE: Report Suggests Big Payoff from Human Genome Project

2. **In Sequence**
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3. **GenomeWeb Daily News**
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4. **GenomeWeb Daily News**
CardioDx Raises $60M in Private Financing

5. **BioArray News**
Affymetrix to Launch Next-Gen Cytogenetics Array in Q3, Plans FDA Submission

In this issue of BioArray News

Illumina Aims to Have FDA-Cleared Dx, CLIA Lab In '09; CEO Says Arrays Have Dx Future

Illumina, OGT Betting Their New Chips Will Tap 'Huge' Cyto-Testing Market

Some Genomics Customers 'Surprised,' 'Concerned' About Affy's Impending Buy

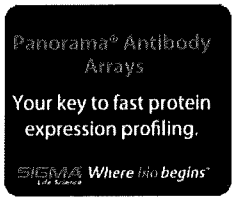
Microarray-Related NIH Grants in Fiscal Year 2008, Sep. 16 — Nov. 3, Part II of II

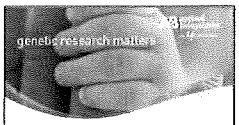
Young Investigator Profile

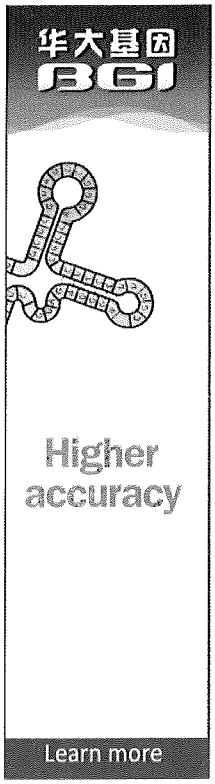
Blog

Papers of Note

Influence of Mammalian TE Distribution on Gene Transcription
Zhang et al., PLoS Computational Biology
A trio of researchers at the British Columbia Cancer Agency and the University of British Columbia show that in both human and mouse, the "distributions of transposable elements reveal hazardous zones in mammalian introns." The researchers also report "several factors that likely contribute to whether a particular TE can influence gene transcription," they write, adding that "TEs in extremely close proximity — less than 20 bp — to exons show a strong bias to be near splice-donor sites."







Tech Guide Archives

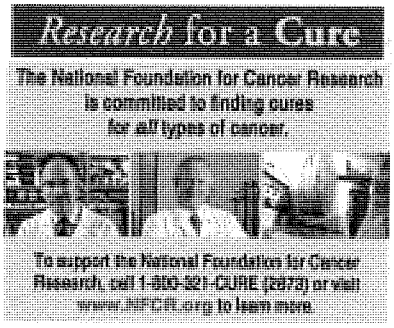
Real-Time PCR Technical Guide, Volume One

ILLUM-0224

'Functional Complotype' and Susceptibility to Alternative Pathway-Driven Disease
Heurich, Martínez-Barricarte et al., PNAS
A team led by investigators at Cardiff University shows that "combining disease 'risk' variants in add-back assays yielded six-fold higher hemolytic activity compared with 'protective' variants" in their investigations of age-related macular degeneration. The team says its results "introduce the concept of a functional complotype — combination of polymorphisms — defining complement activity in an individual, thereby influencing susceptibility to AP [alternative pathway]-driven disease."

People on the Move

Upcoming Events



Do you change your grant application strategy when funding success rates fall?

- Yes. I focus on one particularly promising project for which to submit a proposal.
- Yes. I make it my mission to submit as many proposals as possible.
- No. I've always made sure to submit several proposals for every single round.
- No. I've always only submitted however many proposals my research agenda has afforded.

Vote
View Results

Science

A study published online in *PLoS ONE* this week underscores the genetic variation that can exist amongst individuals sharing the same self-reported ancestry — findings that the authors say have implications for understanding and applying genetic information in a personalized medicine context.

Business

PerkinElmer reported after the close of the market on Thursday a 14 percent jump in first quarter revenues year over year, as well as the acquisition of Geospiza. The deal supports the recent launch of its next-generation sequencing service and fits its shift toward a business model with greater emphasis on recurring revenues.

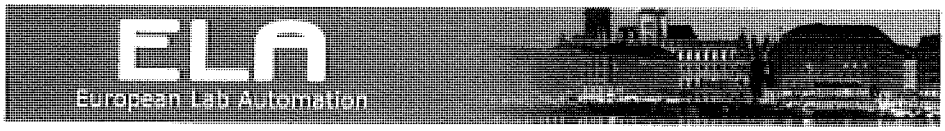
Funding

The European Cooperation in Science and Technology (COST) organization will receive €30 million ($44.5 million) in new funding from the European Commission. COST's Biomedicine and Molecular Biosciences programs support networks in all areas of genomics, proteomics, and metabolomics research.

Genome Technology Magazine

In this month's Q&A, *Genome Technology* speaks with the Whitehead Institute's Yaniv Erlich. Erlich recently published a study showing that blood-based DNA samples from discordant monozygotic twins might not always show distinct genotypes, and *GT* spoke with him to find out more.

Drupal



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ILLUM-0225

Drupal.behaviors.print = function(context) {window.print();window.close();}>

genomeweb

Illumina, Solexa, MDS, Molecular Devices, Thermo Fisher, FDA, Cepheid, Applied Biosystems, Luminex, US Air Force, CombiMatrix

March 21, 2007

Illumina, Solexa, MDS, Molecular Devices, Thermo Fisher, FDA, Cepheid, Applied Biosystems, Luminex, US Air Force, CombiMatrix

Accounting Rules Prevent Illumina from Recognizing Revenue on Some Solexa Sequencers

Accounting rules will prevent Illumina from booking most of the revenue from the sale of at least 13 Genome Analyzers that Solexa shipped to early-access customers, Illumina President and CEO Jay Flatley said at an investor conference last week.

A few weeks before it was acquired by Illumina in late January, Solexa said it had begun invoicing early-access customers in the fourth quarter, and that it expected to begin recording revenue from these placements in the current quarter.

"Due to the wonders of acquisition accounting, much of the revenue that occurred [before the merger was completed], even though it was not recognized as revenue for Solexa ... will not be recognizable by us," said Flatley, who spoke at the Cowen and Company 27th Health Care Conference in Boston. "So that revenue will disappear, it will not be recognized either by Solexa or by Illumina."

The rule will affect all 13 units that Solexa shipped in 2006, as well as any additional systems shipped between Jan. 1 and Jan. 26, the date Illumina completed the acquisition, a company spokeswoman told *BioCommerce Week* sister publication *In Sequence*.

Also at the conference, Flatley said although the integration of Solexa is "going quite well," R&D has not been consolidated yet. "We think it will take a little bit longer for us to put together all of

the key R&D teams," Flatley said.

Illumina had been conducting internal research in the area of sequencing, he added, which will be combined with Solexa's R&D groups.

He also reiterated that as of early February, the company had received 40 orders for the instrument, including the 13 systems it had shipped to early-access customers by the end of 2006.

Illumina Launches BeadXpress Platform

Illumina this week launched its BeadXpress system, the platform at the base of its molecular diagnostics strategy.

The BeadXpress is based on the VeraCode digital microbead technology the firm gained through its $17.5 million acquisition of CyVera in April 2005.

Illumina CFO Christian Henry said at the Lehman Brothers Global Healthcare Conference in Miami this week that the firm has already made its first shipments of the BeadXpress system.

According to Illumina, the BeadXpress system allows researchers to assay tens to hundreds of analytes in a single sample at one time. In addition to molecular diagnostics, Illumina anticipates the system will be used for biomarker research and validation, pharmaceutical development, industrial testing, and agricultural research.

"What this platform does is it enables us to move all the way down into lower and mid-multiplex ranges, which we really believe are going to be critical in the molecular diagnostics space," said Henry. "We're believers that microarrays are not the right approach to molecular diagnostics, in that they're not flexible enough, the reaction times are too long, and they're too expensive."

The firm expects 2007 revenue of between $295 million and $315 million, said Henry.

MDS Acquires 92 Percent of Molecular Devices' Shares

Molecular Devices' shareholders this week tendered 92 percent of the firm's shares in the acquisition offer from MDS.

In January, the companies had agreed to a deal under which MDS would buy Molecular Devices for $615 million in cash, or $35.50 a share for all of Molecular Devices' common stock (see *BioCommerce Week 1/31/2007*).

MDS said it would make an additional offering for the remaining 8 percent of shares outstanding. That offering is at the same price of $35.50 per share and will expire on March 23.

Upon completion of the acquisition, Molecular Devices and MDS' Sciex unit will be combined into a business unit called MDS Analytical Technologies. The new unit will be led by MDS Sciex President Andy Boorn.

According to MDS, Molecular Devices and MDS Sciex combined brought in 2006 revenue of $432 million.

Thermo Fisher Expands Asset Management Services in Europe

Thermo Fisher Scientific said last week that it has expanded its asset management services capabilities in Europe.

In addition to a new management team, new services are being launched to help customers in the pharmaceutical, chemical, petrochemical, and biotechnology sectors optimize the management of their laboratory assets.

"By establishing a full presence in Europe, existing and new customers will benefit from local support and solutions tailored to their individual needs," Thermo Fisher said in a statement.

The European Asset Management Services, based in the UK, will focus on companies there, in Germany, France, Spain, Italy, the Netherlands, and Scandinavia.

FDA Clears Cepheid's Meningitis Molecular Dx

The US Food and Drug Administration last week cleared for marketing a Cepheid test designed to help physicians detect viral meningitis within two and a half hours.

The test is Cepheid's third molecular diagnostic assay to receive 510(k) clearance since the beginning of 2006.

Cepheid's Xpert EV test is an automated diagnostic that uses reverse transcription PCR on cerebrospinal fluid samples to determine if a patient has enterovirus, which causes 90 percent of meningitis cases. The test is run on the company's GeneXpert diagnostic system, one of two RT-PCR platforms developed by Cepheid. The other is its SmartCycler.

According to a statement released by the FDA last week, in a multi-site study the test was 96-percent accurate in detecting viral meningitis, and 97-percent accurate in patients who did not have the enterovirus.

Bacterial meningitis is far more lethal than the viral form of the disease, and requires swift diagnosis. Because symptoms of the two diseases are so similar, doctors currently treat viral patients empirically with antibiotics for the bacterial form.

Being able to swiftly determine which pathogen a patient has should allow doctors to make more

accurate therapeutic decisions and avoid unnecessary antibiotic treatments, the FDA said.

Two Banks Upgrade ABI's Stock

Two investment banks last week upgraded their ratings on Applied Biosystems' stock.

Am Tech/JSA Research upgraded ABI's stock to "buy" from "neutral," while Matrix Research raised its rating for ABI to "buy" from "hold."

ABI's shares rose 4.1 percent over the past week to close at $29.73 on Tuesday.

Investment Bank Starts Coverage of Luminex

Investment bank Thomas Weisel Partners this week initiated coverage of Luminex with an "overweight" rating.

The rating follows an upgrade in December from investment firm Soleil Securities on Luminex's stock from "hold" to "buy."

Luminex's shares closed at $14.75 on Tuesday.

US Air Force Extends CombiMatrix Contract to Develop Influenza Dx

CombiMatrix last week said that the US Air Force has extended a contract to continue developing an influenza genotyping system.

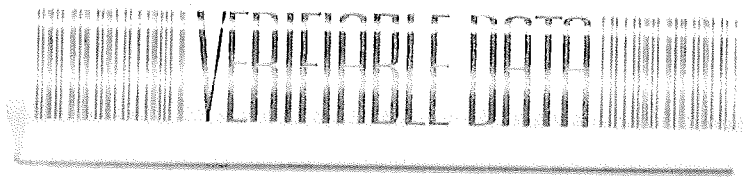
Under the $890,000 deal, CBMX will develop a field-deployable system designed to identify all influenza strains, including H5N1 avian flu, and other respiratory pathogens.

The original program started in 2005 when the USAF's Institute of Occupational Health paid CBMX $340,000 for a one-year deal to begin developing an array to identify the infections.

Last year's agreement enabled the company to retain the right to sell the resulting assays to other customers.

CBMX CEO Amit Kumar said it is important to be able to track mutations in bird flu, and added that CBMX's system can "determine when any other strain of influenza A is gaining an upper hand in a population, and can identify other infectious diseases that cause flu-like symptoms.

The company said the first effort will be to update the array with new information from influenza A sequencing that is related to human disease.



The difference
between
good data
and great data
is in the code.

veracode™
BY ILLUMINA®

ILLUM-0466

illumina®

VeraCode™ technology. A digital revolution.

Illumina's unique VeraCode digital holographic code technology delivers unparalleled data quality for a multitude of bioassay formats. Precision and verifiability—that's the promise contained in every VeraCode microbead.

Unique code technology

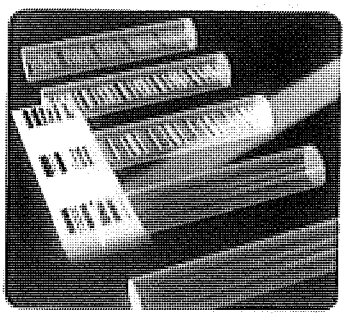
VeraCode's breakthough technology is based on the use of cylindrical glass microbeads that:

- Measure 240µm in length x 28µm in diameter
- Contain a unique holographic code
- Are highly stable
- Provide information, such as target of interest in multiplex assays
- Enable tracking of critical identifiers
- Can easily carry high-density codes (24-bit), for virtually unlimited bead types

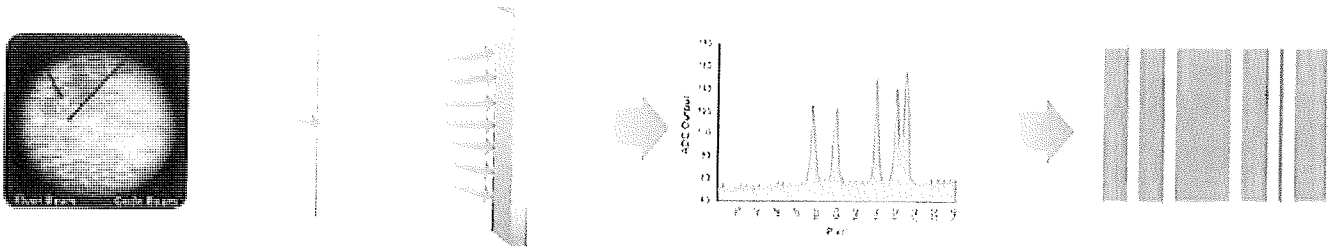
Making the code

The VeraCode digital code uses a patented holographic inscribing and detection process:

- The center of each bead supports a nanometer-scale, permanent change to index of refraction when exposed to ultraviolet light
- This index change forms a hologram that is imprinted via a local structural change of the glass matrix
- Successive writing of holograms into one microbead produces a specific pattern, or holographic code



Each Illumina VeraCode bead contains a code that identifies the bead type. This information is combined with the assay readout for downstream analysis.



Code Detection

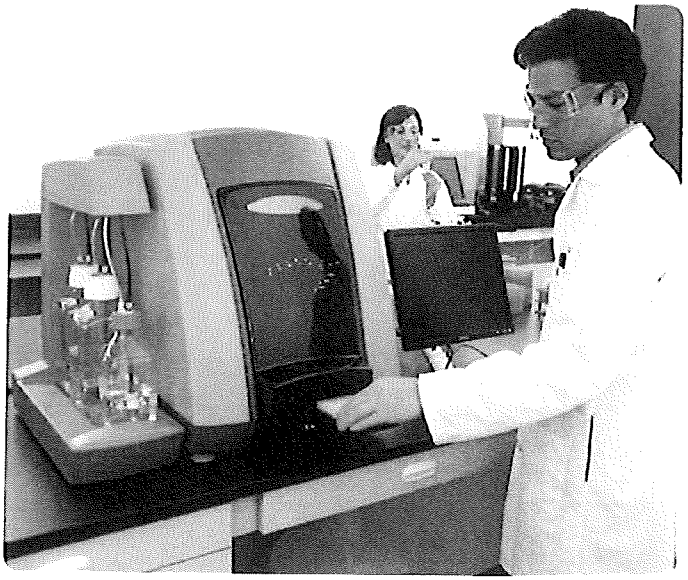
The holographic code image in each microbead diffracts an incident laser beam into multiple components. These components make up the optical "signature" of the bead code, which can be read using a CCD camera contained within the BeadXpress™ Reader.

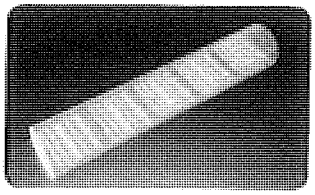
100% verifiability means true precision.

Imagine the possibilities

This versatile technology is the solution for applications that benefit from robust, multiplex-based testing methods. Apply the code to fit your research needs. The possibilities are limitless, but include:

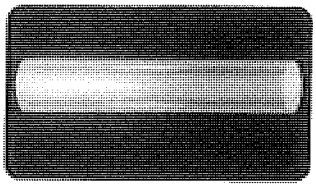
- Biomarker research and validation
- Pharmaceutical development
- Industrial testing
- Agriculture
- Clinical research
- Molecular diagnostic assay development





Why the code?

The unique digital holographic code contained within each VeraCode microbead enables customizable tracking of multiplex assay markers and critical identifiers such as sample ID, laboratory ID, and reagent kits. Up to 24 bits of information inscribed in each code allows for an unprecedented level of error checking, improving the robustness of the optical readout process and providing a level of reliability that sets a new standard in multiplex testing.



Why the glass?

The high-purity silica glass used to make VeraCode microbeads has physical properties that make it an ideal substrate for attachment of biomolecules. The beads' surface chemistry enables easy development of a wide variety of nucleic acid and protein-based assays. The glass purity also minimizes any fluorescent background, so there is no interference with readout, providing a highly stable platform for reliable and reproducible results.

ILLUM-0468

veracode
BY ILLUMINA

A breakthrough in multiplex range and assay flexibility.

VeraCode is the technology solution that grows with your needs and remains relevant during dynamic changes in your research pursuits.

Flexible multiplexing range

Whether you need a single-plex antibody detection assay or a 384-plex genotyping assay, VeraCode is the only technology to offer true multiplexing and assay versatility on one platform, providing researchers with a single powerful solution capable of meeting all of their assay needs.

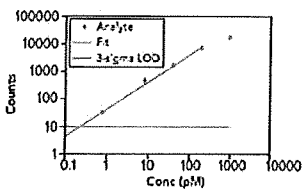
- 1- to 384-plex-per-sample range is ideal for the development of focused research assays
- Multiplexing levels are achieved by simply pooling uniquely coded beads
- VeraCode microbeads use non-overlapping bead codes providing highly specific detection and unequalled precision

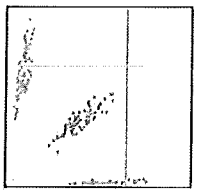
Unparalleled assay flexibility

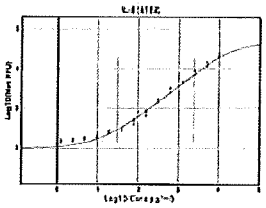
The glass surface of the VeraCode microbeads provides a single, flexible platform for the development of numerous types of solution-based bioassays with the power of microarrays. Existing applications for VeraCode include, but are not limited to:

- Genotyping
- Gene expression
- Protein-based assays

Unmatched versatility in both multiplexing levels and assay applications







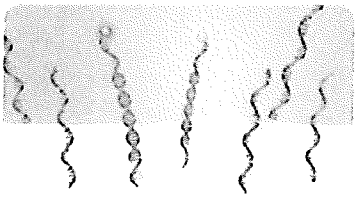
Perform multiple assay applications—such as SNP genotyping, gene expression, and protein-based assays—all on a single platform.

Multiplexed assay applications

GoldenGate® Genotyping

Illumina has adapted the proven power and flexibility of its GoldenGate Assay for use with the VeraCode technology. The GoldenGate protocol enables:

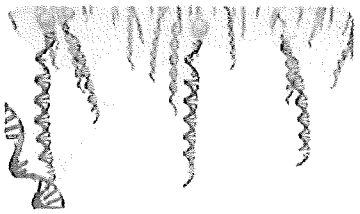
- Simultaneous genotyping of 96 to 384 SNPs for each sample in a 96-well microplate
- A high degree of multiplexing throughout successive extension and amplification steps
- Minimization of time, volume, and material requirements
- Call rates, reproducibility, and heritability rates >99.9%



Universal Capture Beads

Design your own customized nucleic acid-based assays using VeraCode Universal Capture Bead sets. Each set features a unique oligonucleotide capture sequence and allows easy selection of multiplexing level by simply pooling different tubes of uniquely coded beads.

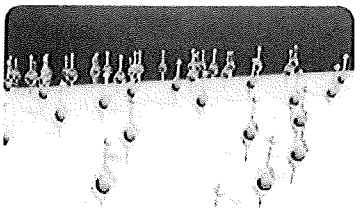
- Unique oligonucleotide bead types offer one-of-a-kind code identifiers
- High-density capture oligonucleotides immobilized on the microbeads provide a flexible and open platform for assay development
- Pre-screened capture sequences avoid cross-reactivity within genome

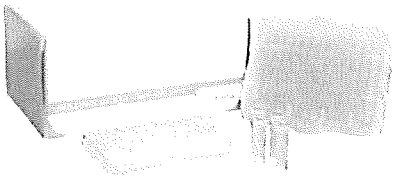


Carboxyl Beads

The VeraCode Carboxyl Bead sets provide a powerful and open base for the development of protein-based assays by enabling the immobilization of specific capture antibodies on a coded carboxyl bead surface, thereby offering a limitless range of assay possibilities.

- Custom multiplex levels are achieved by pooling different tubes of uniquely coded carboxyl microbeads
- Superior low-end precision delivers highly sensitive assays
- Proven sensitivity and specificity demonstrated in a 10-plex cytokine assay





Assay bead kits are conveniently packaged for specific applications.

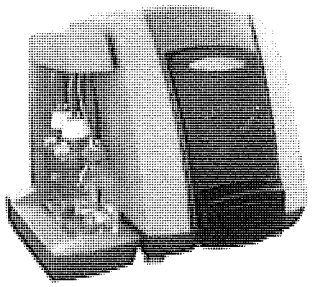
veracode BY ILLUMINA

Extraordinary accuracy and reliability.

The BeadXpress Reader

Assays developed for the VeraCode microbeads are analyzed with Illumina's patented BeadXpress Reader, a high-throughput, two-color laser detection system designed to be compatible with standard laboratory automation. The key features of the BeadXpress System include:

- A fluidic system and reagent carrier that enable the scanning of multiple plates per day without the need to refill system buffers
- An open-platform, two-color laser detection bioassay system that supports the development of single-color assays such as Allele Specific Primer Extension (ASPE), as well as two-color assays such as Illumina's GoldenGate Assay
- Rapid sample throughput rates of 120 samples/hr. at 10-plex and 80 samples/hr. at 96-plex
- Analysis of standard 8-well strips or 96-well plates



The Illumina BeadXpress Reader employs a dual-color laser detection system to identify and analyze each VeraCode bead.

beadxpress™

Robust performance

VeraCode microbeads provide a highly stable platform. Because assays developed with VeraCode microbeads typically include 25 to 30 replicates of each bead type, the data generated is particularly robust. Using the BeadXpress System, VeraCode microbeads are:

- Optically sampled up to a dozen times each, providing about 300 independent data points for each analyte
- Randomly arrayed in the groove cell to minimize scanner errors
- Inscribed with up to 24 bits of information; the initial bits in a code sequence are used for error checking, thereby greatly improving the reliability of the readout and results

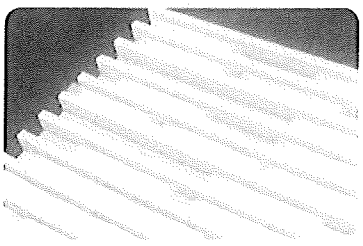
Powerful and friendly analysis software

Powerful VersaScan Software provides user-friendly customization of scanning protocols and is compatible with Illumina's proven BeadStudio Data Analysis Software.

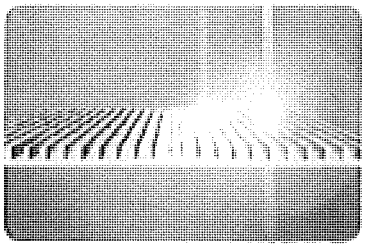
- Enables acquisition and viewing of intensity data, report generation, and data extraction for application-specific data analysis modules
- Generates *.csv and *.idat files for data export to Illumina BeadStudio or third-party data analysis programs

Get into the groove.

One of the patented technologies developed to enable the rapid and accurate readout of the VeraCode microbeads is the transparent groove plate. The groove plate forms the bottom of a fluidic cell that has 8 chambers, one for each well in a column of a standard 96-well plate. Through a unique combination of fluid flow, gravity, and capillary force, the VeraCode microbeads enter the groove plate cell and align closely within the grooves.



Once aligned, the entire cell is read by the optical system for fluorescent measurement and code classification. This approach creates a spatially random array of particles at a high packing density that enables rapid and accurate detection of the unique bead codes and the assay-specific fluorescence results.



Service that's always 100% Illumina.

With your purchase, Illumina will ensure that your BeadXpress system is properly installed and qualified, and will provide ongoing maintenance and service. Illumina also offers:

- Unlimited support by phone from Technical Support Scientists
- Extended warranty plans to meet the specific needs of your laboratory
- Customized training packages with our skilled Field Applications Scientists

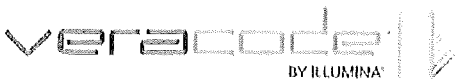
VeraCode® technology.

The difference between good data and great data is in the code.

The revolutionary VeraCode system, with its unique digital holographic code technology, offers:

- Unmatched data precision and verifiability
- Robust performance and customizable tracking
- A flexible single platform for numerous bioassay formats, including genotyping, gene expression, and protein-based assays
- An ideal solution for low- to mid-plex levels: 1 to 384 targets/samples in a single well
- Rapid and accurate high-throughput, 2-color laser detection system
- User-friendly analysis software

Visit www.illumina.com or call 800.809.4566 to see how the VeraCode difference can revolutionize your research.



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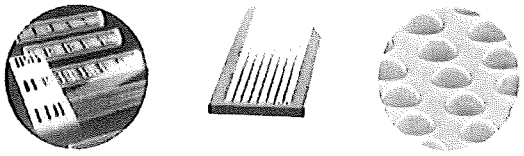
Tools for Cancer Genomics



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Cancer Genomics From Every Angle.

Cancer is complex. It's a heterogeneous disease that cannot be analyzed from a single vantage point. Distinct types of cancer can arise from unique tissue types. Within each tissue type, subgroups can exist that behave differently. Understanding the molecular mechanisms that drive a normal cell to become a cancerous cell requires analyses to be done from multiple molecular angles. Studying this multi-step disease process requires the profiling of each cancer's unique signature, acquired through pathogenesis and involving a series of inherited and somatic changes.

A systematic understanding of the molecular changes that lead to each type of cancer will transform the way it is diagnosed and treated in the future. We are working alongside the community of researchers using our products to help them find these answers faster than was ever thought possible. Illumina gives them this power

Illumina provides genomic-scale tools for the study of:

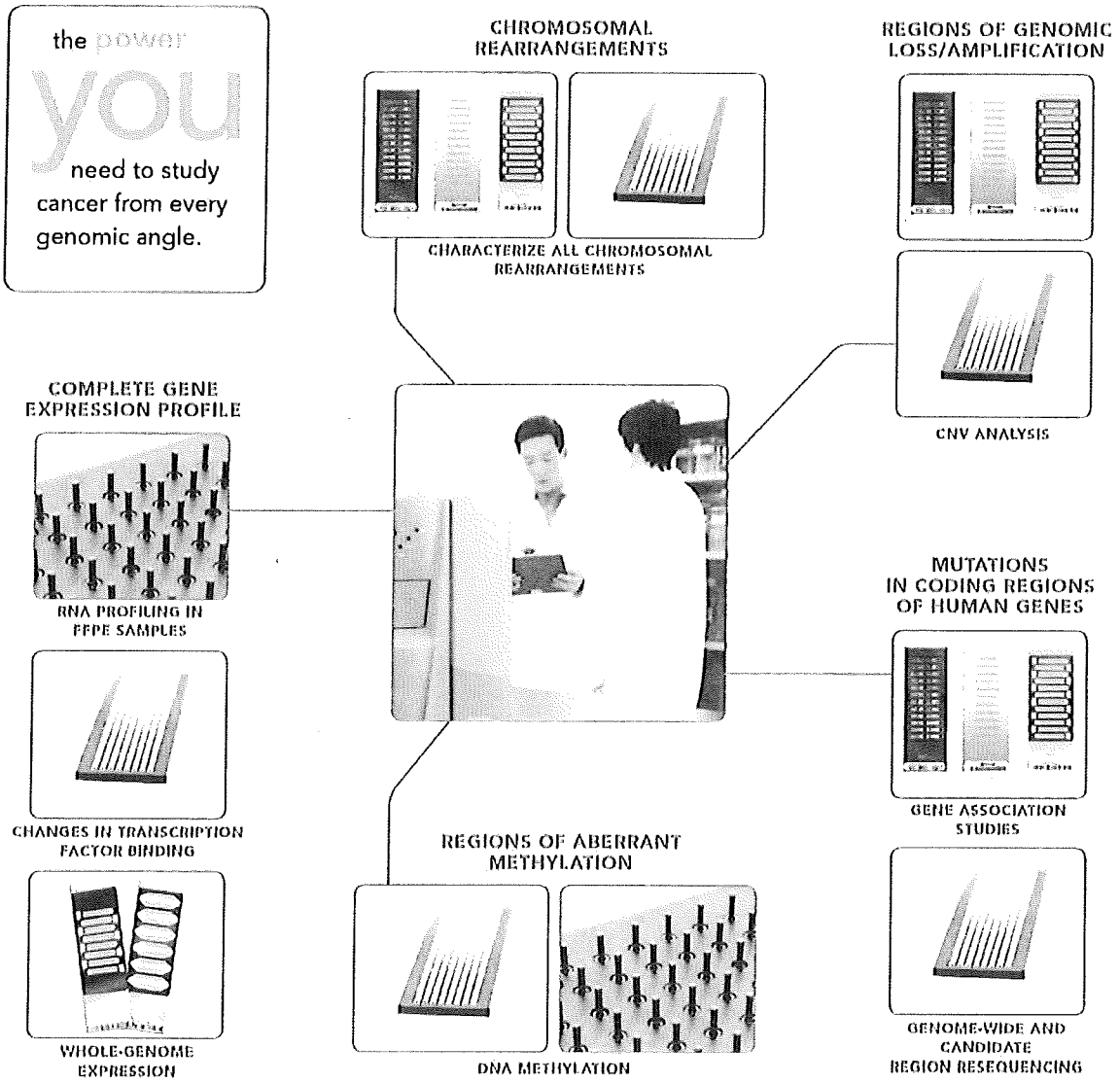
- Genomic loss and amplification – of specific regions in the genome, including those that contain cancer-associated genes
- Chromosomal rearrangements – that may impact key genes or pathways and impact tumorigenesis
- Epigenetic changes – such as aberrant DNA methylation, histone binding changes
- Genetic changes in coding and non-coding regions of genes – understood through genome-wide sequencing or SNP genotyping approaches
- Gene expression profiling – of tissues through the pathogenesis from normal to cancerous

Cancer Genomics and Illumina.
The Industry's Most Comprehensive Toolbox.

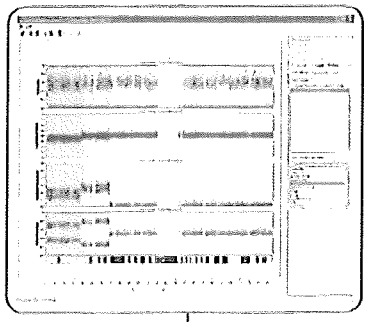
Illumina provides the technologies, tools and support to find the answers that will help to move your cancer research program forward. All of our technologies deliver high data quality, reproducibility, multi-sample formats and superior value. Whether you need RNA or DNA-based applications, genome-wide or focused content panels, standard or custom approaches, we have the power you need to study cancer from every genomic angle.

Illumina tools allow you to:

- Categorize and understand important pathways and profiles
- Discover and validate therapeutic targets
- Develop targeted therapies and combinations of therapies
- Understand markers that can enable early risk detection
- Gene expression profiling – of tissues through the pathogenesis from normal to cancerous



Genomic Tools from Illumina.
Finding Answers in Cancer Research.

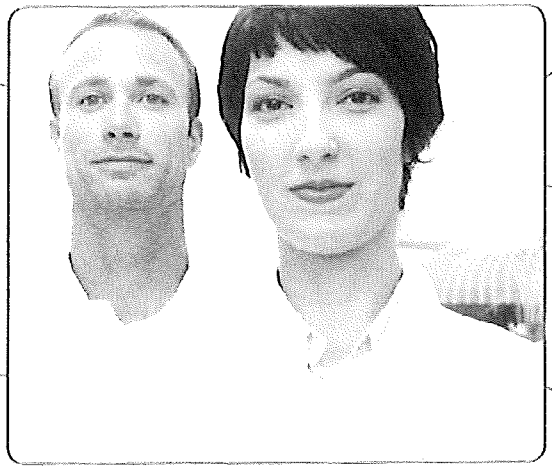


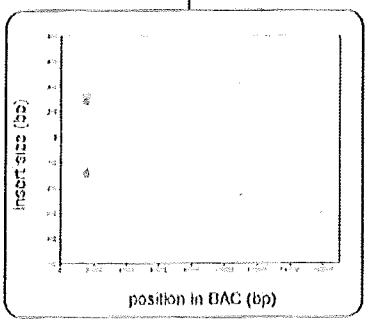
Genomic Loss and Amplification

Illumina offers a comprehensive set of tools for the study of genomic loss and amplification including copy number variation (CNV) screening products and genome-wide CNV detection and discovery tools. Our CNV tool kit provides industry-leading resolution down to only a few kilobases. Illumina's CNV products support DNA copy number analysis in a wide variety of sample types and include the most comprehensive copy number variant coverage available.

Measure Genomic Loss and Amplification Highlights

- Industry-leading SNP and CNV data quality in one experiment
- High resolution and low noise
- Streamlined paired sample analysis
- Unique CNV content



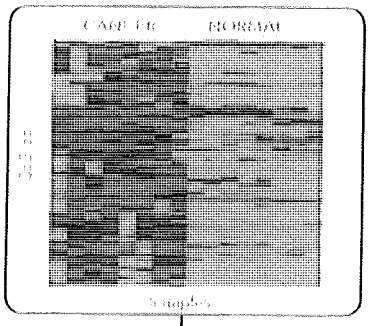


Chromosomal Rearrangements

Illumina's tools for the study of chromosomal rearrangements such as inversions or translocations provide the power and value necessary to look at chromosomal rearrangements on a genome-wide basis. Innovative tools give cancer researchers the power to establish breakpoint maps to better understand "hot spot" regions for this type of DNA change. While other technologies such as FISH or shotgun sequencing have low resolution and are cost-prohibitive on a genome-wide basis, Illumina technology delivers industry-leading resolution at fraction of the cost.

Detect Genomic Loss and Amplification Highlights

- Easily detect insertions, deletions, inversions, and translocations at the single base pair level
- Breakpoint mapping tools for discovery and screening
- Economical and more scalable alternatives to FISH or shotgun sequencing approaches

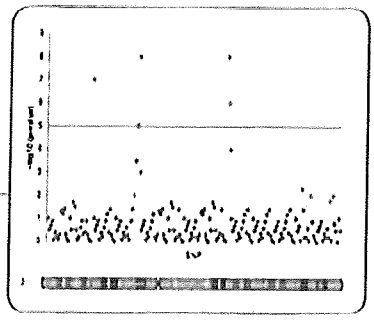


Characterize Epigenetic Changes

Illumina's tools for studying aberrant DNA methylation and protein-DNA interaction across the genome deliver unprecedented scale and resolution. Whole-genome CpG methylation discovery, CpG biomarker screening, and ChIP applications offer the industry's complete set of epigenetic tools to help understand the effects of aberrant DNA methylation – either hyper- or hypomethylation – histone modification and other DNA-protein interactions both in basic cancer research and in clinical applications.

Epigenetic Highlights

- Single CpG resolution and robust performance for standard and custom CpG biomarker panels
- High resolution and signal-to-noise ratios for histone binding studies
- Multi-sample formats allow for easy expansion of experimental scale

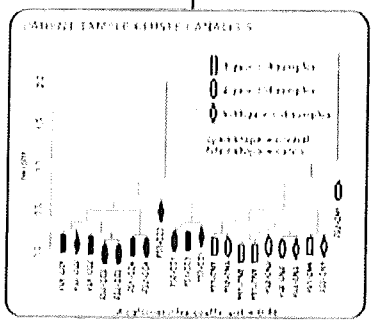


Study Genetic Changes in Genes

Illumina's genotyping products are rapidly becoming the gold standard for genome-wide association and other SNP genotyping studies. Solexa sequencing technology offers cancer researchers an economical and rapid way to sequence entire genomes. Whole genomes, targeted regions, or entire genes can be interrogated at a fraction of the cost and time available with other technologies. This value and speed has helped many researchers find the answers they needed faster than they ever thought possible.

Genetic Changes Highlights

- Genome-wide sequence at 1/100th of the cost of traditional methods
- High-quality data with individually-scored base calls provides high confidence in the discovery and profiling of polymorphisms
- Industry-leading genomic coverage and power for standard and custom genotyping panels
- Minimal starting material required, as little as 50ng for sequencing applications



Profile Gene Expression

Understanding tumor expression profiles at different stages of disease initiation and progression is crucial for understanding human cancer. RNA profiling has already proven to be important in understanding cancer sub-types. Performing whole-genome and targeted analysis of tumor samples economically, with high data quality and with scalable/reliable methods will be important to better leveraging this information in cancer research.

Gene Expression Profiling Highlights

- Generate concordant data sets with whole-genome arrays and digital gene expression data
- Analyze entire genomes, economically and with high data quality
- Study intact or degraded (FFPE) samples
- Generate reliable RNA profiles with as little as 50ng of total RNA
- Detect and characterize changes in low-abundance transcripts

Powerful Technologies. Complimentary Platforms.

Illumina's BeadArray™, Solexa® and VeraCode™ technology platforms give you the ability to design studies that look at cancer from every genomic angle. On their own, each platform offers power, versatility, and value for genetic analysis applications. Combined, they give you unprecedented power to expand experimental scale and understand disease.

	BeadArray Technology	Solexa Sequencing Technology	VeraCode Technology
Measure Genomic Loss and Amplification			
CNV Screening	●		
CNV Discovery		●	
Detect Chromosomal Rearrangements			
Breakpoint Mapping		●	
Insertions, Deletions and Translocations		●	
Characterize Epigenetic Changes			
DNA Methylation Biomarker Panels	●		
DNA Methylation Discovery		●	
ChIP-Seq Applications (DNA-Protein Binding)		●	
Changes in Transcription Factor Binding		●	
Study Genetic Changes in Genes			
Whole-Genome Genotyping	●		
Focused Genotyping Panels	●		●
SNP Discovery		●	
Resequencing		●	
Profile Gene Expression			
Whole-genome Expression	●		
Focused Gene Expression	●		
Digital Gene Expression (Whole-Genome and Focused)		●	
RNA Profiling of FFPE Samples	●		

you&i

Let's find the answers together.

Together we're the Illumina Community. A growing and dynamic community of researchers, Illumina employees, and physicians working side-by-side to find answers that can help us all understand, cure, and ultimately prevent disease.

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Explore Your Genome with Illumina

Genomes, health, and ancestry

An individual genome is a blueprint for life. This blueprint is a DNA sequence of three billion bases inherited from each parent. It contains the information that specifies how we develop, how our body works, and how we react to drugs or toxins in our environment. The sequence contains all the changes (e.g. mutations or genetic variants) accumulated through human evolution, some of which we inherit from our ancestors. Capturing our personal whole-genome sequence provides us with access to our own individual blueprints. It includes a catalog of all our genes plus the genetic variants that make us different from each other.

Our genome sequence can help us to understand our ancestry. *Homo sapiens* originated in Africa and subgroups later migrated across the globe. The species gradually evolved, accumulating genetic changes that resulted in people being better adapted to survive in their new environments. By comparing the genomes of different and related individuals today we can reconstruct our own evolutionary tree and trace our ancestry back to our common roots, however diverse our origins.

A genome sequence will be of increasing importance in healthcare in the future. Most diseases have a genetic component, and the clues to these risk factors are in our individual genetic blueprints. While scientists have only scratched the surface in the quest to understand the medically important variants, they are making steady progress. The accumulating knowledge of medical genetics is driving a future in which you will be able to update the interpretation of your genome with the latest information as soon as it becomes available. Sequencing your genome is an investment that will grow in value, drawing on the cumulative discoveries of scientists around the world.

You can be among the first to have your genome sequenced --- with Illumina. Technology and the resulting discoveries are advancing rapidly. The secrets of the genome are being unlocked step by step. The current foundation of knowledge will allow you to understand aspects of your genome today, and that understanding will only deepen as the discoveries continue, positioning you to be on the cutting edge for many years to come. Today's investment, tomorrow's answers ...

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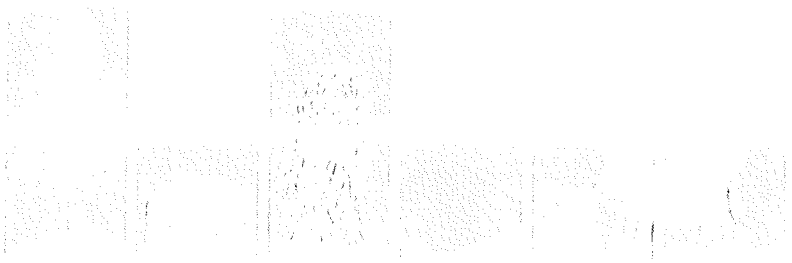
Explore Your Genome with Illumina

you can

discover more
validate seamlessly
screen quickly



Agriculture research powered by Illumina.

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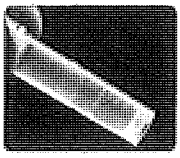

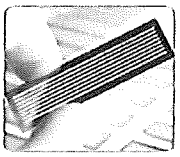

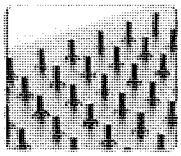

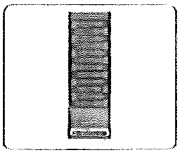

- Identify mutations in coding regions.
- Measure structural variation.
- Detect chromosomal rearrangements.

- Characterize epigenetic changes.
- Profile gene expression.

- Detect chromosomal rearrangements.
- Identify mutations in coding regions.
- Measure structural variation.

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GENE EXPRESSION

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Targeted Sequencing

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- Superior assay to identify copy-neutral events and resolve mosaicism

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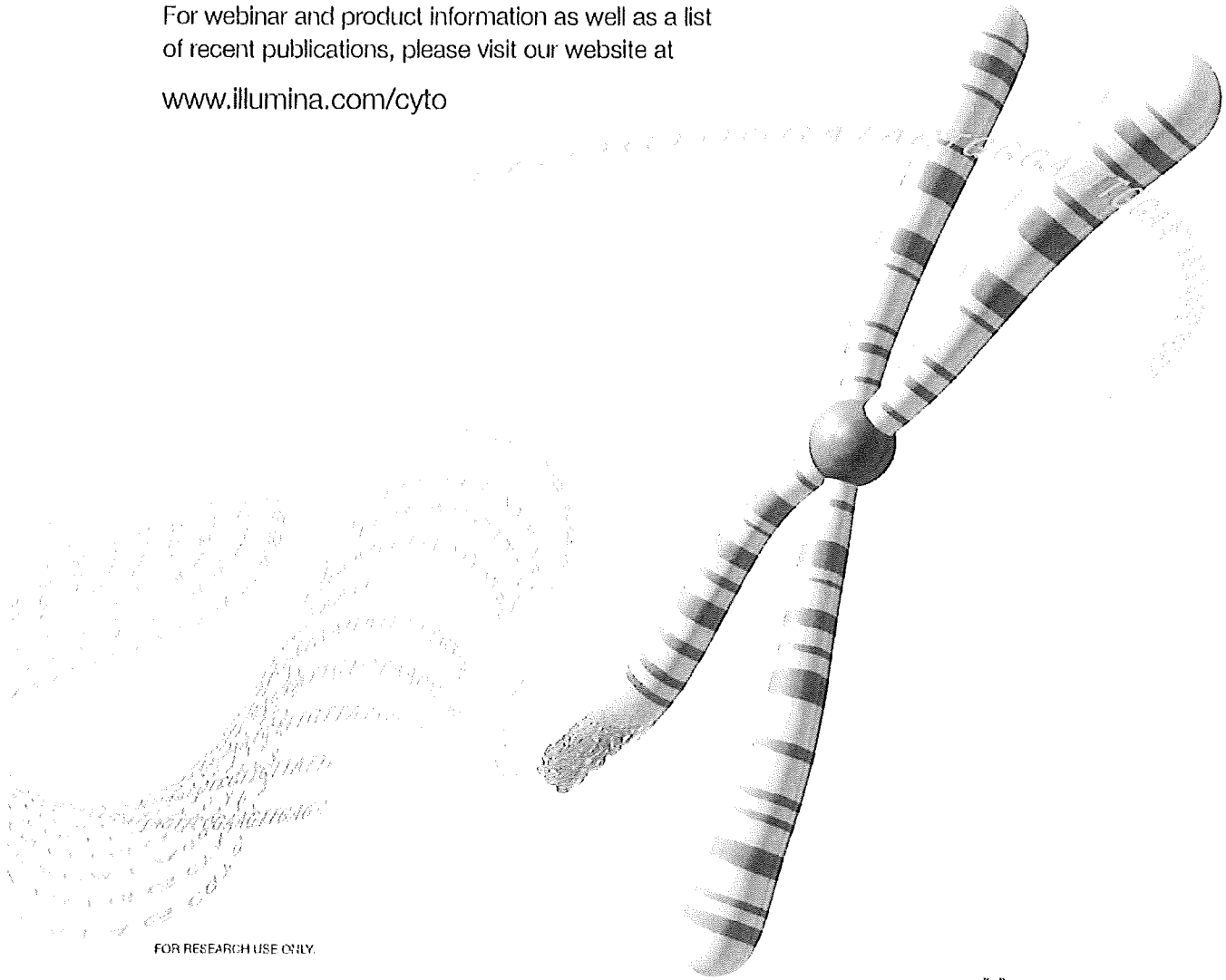

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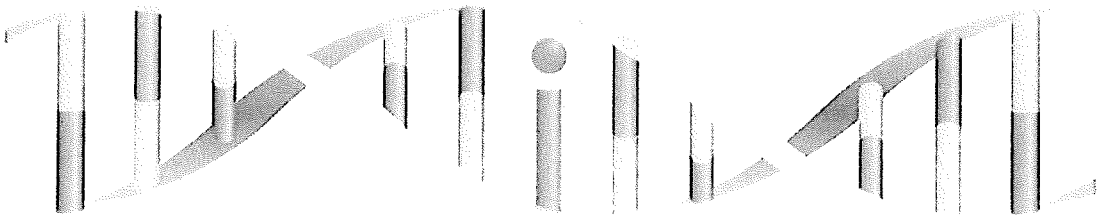

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The most comprehensive set of DNA analysis tools available.

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- **CNV analysis** — Obtain the most comprehensive access to known and novel CNV regions.
- **DNA sequencing** — Sequence virtually anything at a fraction of the cost and time.
- **DNA methylation** — Get single CpG site resolution with high-multiplex standard or custom methylation panels.
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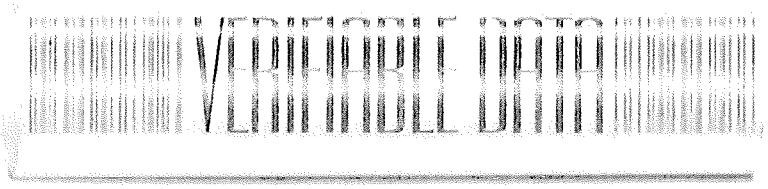

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Introducing VeraCode® technology by Illumina.

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you&i

Let's find the answers together.

Illumina provides the technologies, tools and support to find the answers that will help move your cancer research program forward.

Whether you need to understand important pathways and profiles, discover and validate therapeutic targets or profile the gene expression or epigenetic changes of cancerous tissues, we want to partner with you.

Working alongside you, we strive to make it as easy as possible to find the answers—from discovery to profiling to routine testing.

Visit Us At Booth #2209

- Attend an expert session presented by Illumina scientists
- Pick up a list of cancer publications using Illumina technology
- Sign up for a tour of Illumina's headquarter facility
- Get a bracelet representing your support of your favorite cancer cause

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ILLUM-0543

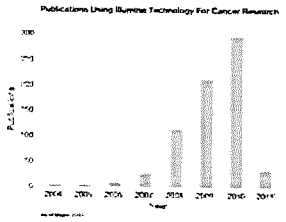
You&ICancerAd.indd 1 2/19/2008 5:30:04 PM

Empowering cancer research.

Sequencing. Microarrays. Real-time PCR. Technology is fueling a new era of cancer discovery and validation.

The growing Illumina community is a part of this revolution. Taking advantage of simplified workflows and streamlined platforms. Advancing research. Increasing our understanding. Publishing results.

The Illumina community is discovering more. Publishing more.



2008

- First publication describing whole-genome sequencing on human cancer[1]
- Accurate human whole-genome sequencing using reversible terminator chemistry[2]

2009

- The power of second-generation transcriptome sequencing used to identify rearrangements in coding genes[3]
- Whole-genome sequencing of the largest collection of samples (24) for a single cancer type, documenting large sample-to-sample variability[4]

2010

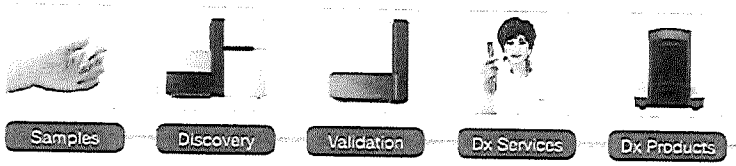
- Next-generation sequencing technology provides new insights into the mechanisms of cancer progression and a greater understanding of diagnosis and treatment options[5-7]
- Use of next-generation sequencing to inform a patient's treatment[8]

2011

- Discovery of causative gene mutations for a rare skin cancer condition[9]

Accelerating translational medicine

Technology enhances understanding. Drives discovery.

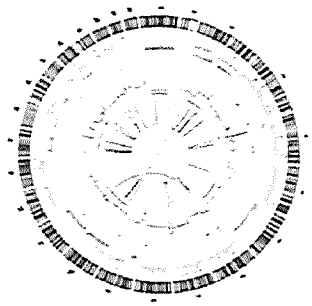


Illumina's cancer discovery initiative.

Our belief in the power of Illumina technology is so strong that we work side by side with researchers to obtain samples for our cancer discovery work. Using whole-genome sequencing, we are exploring how biomarker discovery can lead to early detection, resistance to therapy, and prognosis in ovarian, gastric, and colorectal cancer. Discovering now analyzing subtle changes in genes and chromosomes will change diagnostics forever. Ultimately leading to novel diagnostic services and products as shown in the continuum above.

Illumina's clinical services lab.

Innovative. Comprehensive. The first choice for doctor-ordered Individual Genome Sequencing services. The first to generate a complete human sequence in a clinical laboratory. Fully CLIA-certified and CAP-accredited for high-complexity molecular testing.

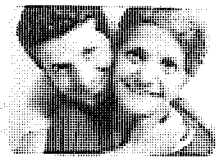


While taking a genome-wide approach to cancer, researchers can use a circus plot to visualize the [illegible] that are common to cancer. The plot shows variations found in a melanoma cell line, marking each chromosome on the outside ring, then showing validated inputs, density of substitutions, coding substitutions, copy number variants, loss of heterozygosity, to reveal the intrachromosomal and interchromosomal structural variants in the middle of the plot.

Transforming diagnostics.

New technologies. New discoveries. New hope. With innovation, insight, and commitment, the Illumina community is leading the way toward a brighter future in cancer diagnostics, therapy, and personalized treatment.

- New developments provide hope for earlier detection and better prognoses
- Novel biomarkers may lead to future treatments tailored to an individual's genetic disposition
- Individual Genome Sequencing services provide genetic information that will facilitate clinical decision making in cancer and medicine



Learn more about Illumina at

Illumina

ILLUM-0300

Comprehensive cancer research portfolio

	Next-Gen Sequencing	Next-Gen Genotyping	Sequencing + Arrays	Multiplexed Analysis	Real-Time PCR
Find Structural Variation					
CNV Screening	■	•	•		•
CNV Discovery	■	•	•		
Detect Chromosomal Rearrangements					
Breakpoint Mapping	■		■		
Insertions, Deletions, and Translocations	■	•	•	•	•
Characterize Epigenetic Changes					
DNA Methylation Biomarker Trends		•	•	•	•
DNA Methylation Discovery	■		■		
CNP-Sequencing (DNA-Protein Binding)	•		•		
Changes in Transcription Factor and Histone Binding	•		•		
Identify Variants in Gene Regions					
Whole-Genome Genotyping	■	•	•		
Custom/Focused Genotyping	•	•	•	•	•
SNP Discovery	■		■		
Whole-Genome Resequencing	■		■		
Exome Resequencing	■		■		
Custom Targeted Resequencing	■		■		
Custom Amplicon Resequencing	■		■		
Profile Gene Expression					
Whole-Genome Expression	•	•	•		
Focused Gene Expression					•
MicroRNA and Small RNA Profiling	•		•		•
MicroRNA and Small RNA Discovery	•		•		

• Illumina-supported intact vendor
• Illumina-supported intact and vendor-supported [illegible]
• Customer-supported intact and vendor-supported [illegible]

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References
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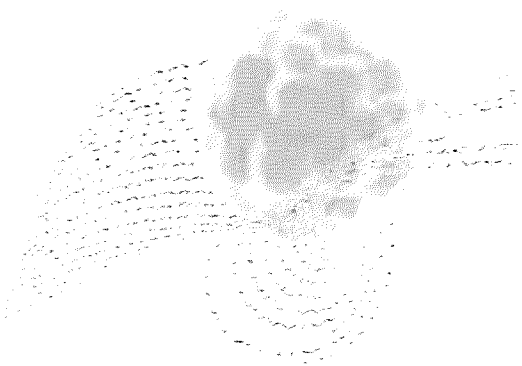
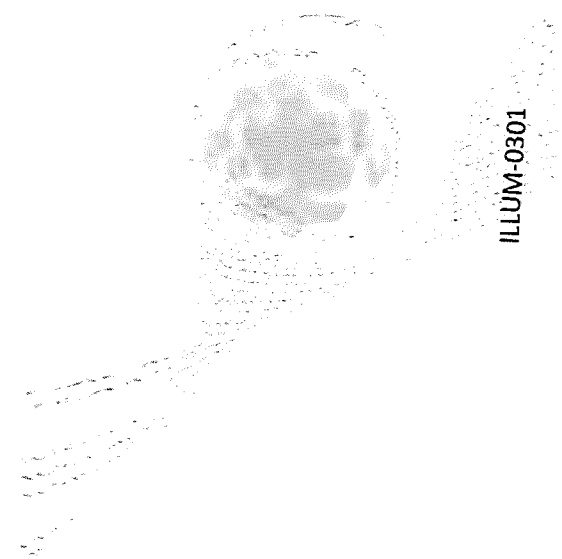
Illumina

Cancer Genomics

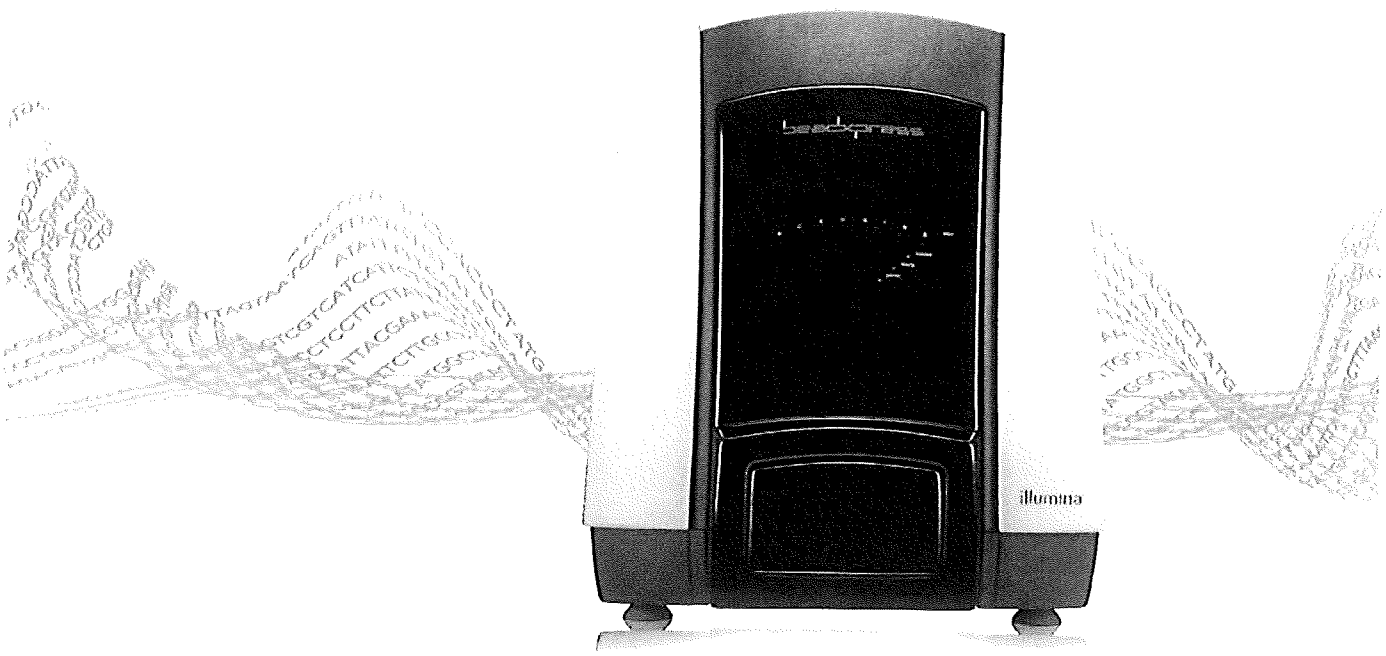
Transforming our understanding of cancer





ILLUM-0301

Illumina



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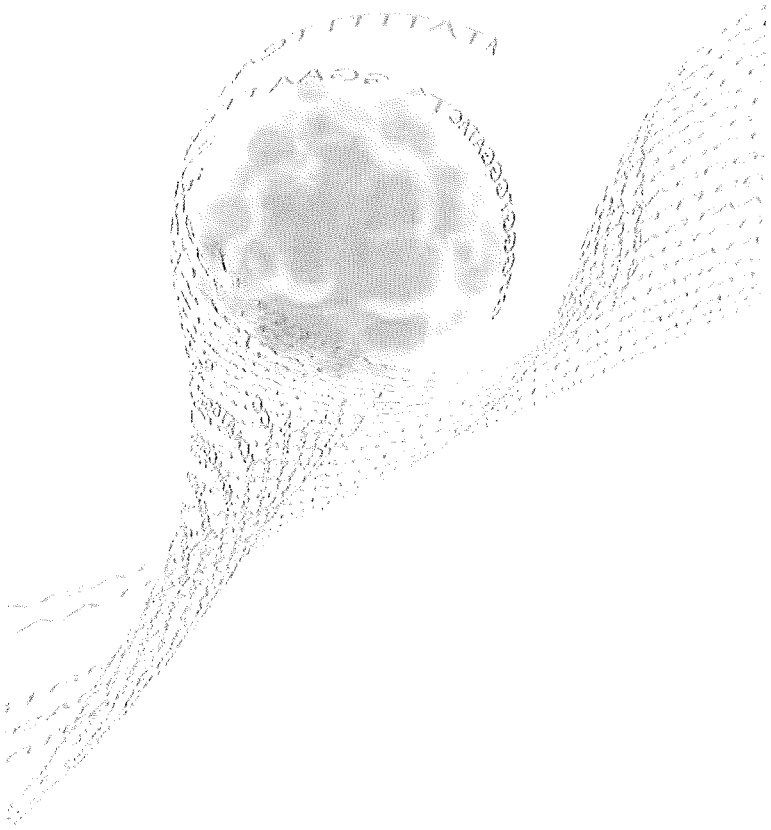
ILLUM-0302

Illumina

Transforming our understanding of cancer.



Illumina Diagnostics Asset Review- ADME

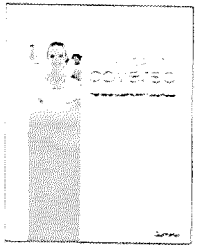
Sales Tools

Lead Generation Activities

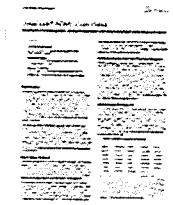
Sales Support

Sales Tools

Veracode ADME Brochure



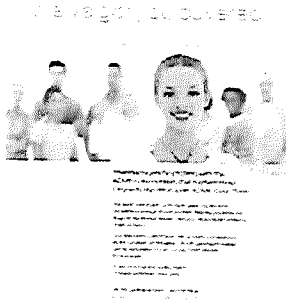
Veracode ADME Data Sheets



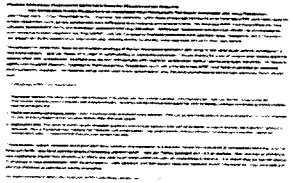
Advertising

Print

Veracode ADME Print Ad

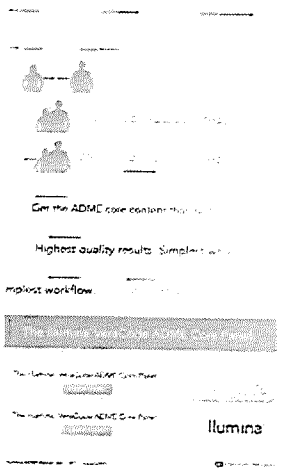


Press Releases

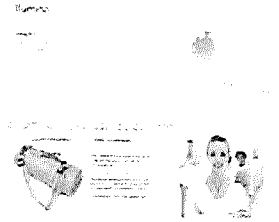


Web

Veracode ADME Web Banners

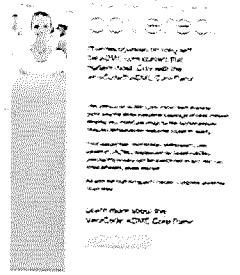


Direct Mail



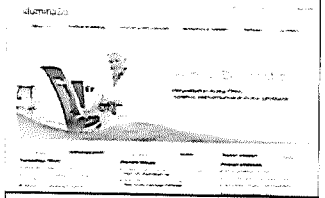
eMarketing

E-mail Blast

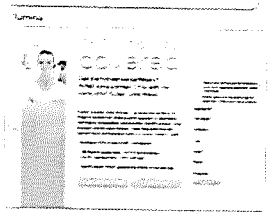


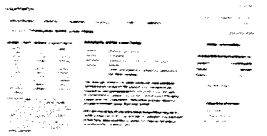
Web Page

Home Page



Landing Page





Tradeshows

None

ILLUM-0304

Illumina Diagnostics Asset Review- Cytogenetics

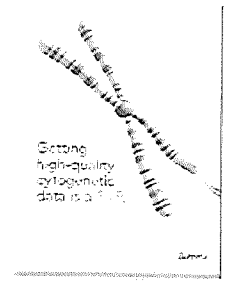
Sales Tools

Lead Generation Activities

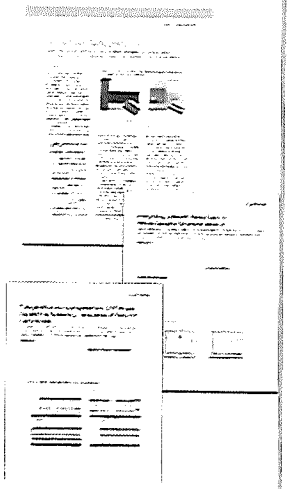
Sales Support

Sales Tools

Cytogenetics Brochure



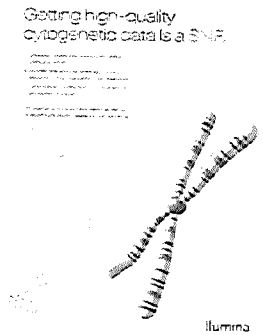
Cytogenetics Data Sheets



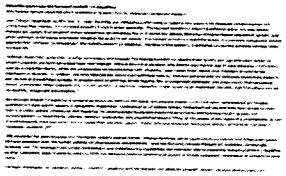
Advertising

Print

Cytogenetics Print Ad

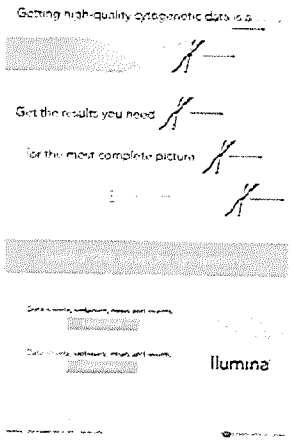


Press Releases



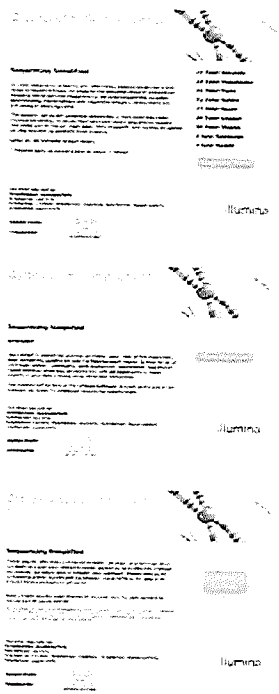
Web

Cytogenetics Web Banners



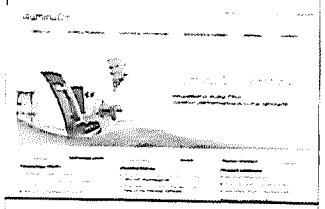
eMarketing

Seminar Series eMail Blasts

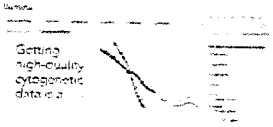


Web Page

Home Page



Landing Page



Tradeshows

None

ILLUM-0305

Illumina Diagnostics Asset Review- BeadXpress Reader and Veracode Technology

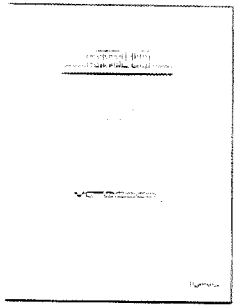
Sales Tools

Lead Generation Activities

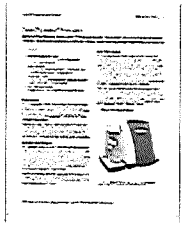
Sales Support

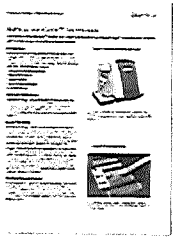
Sales Tools

Old Veracode Brochure



BeadXpress Reader and Veracode Data Sheets

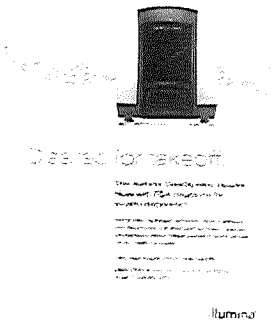




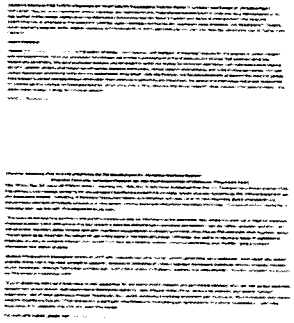
Advertising

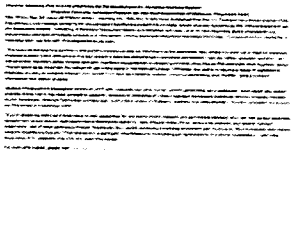
Print

BeadXpress Print Ad



Press Releases





Online

None

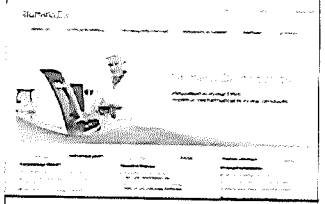
eMarketing

eMail Blasts

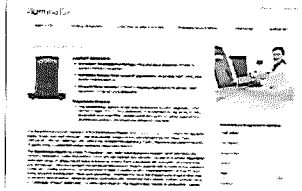
None

Web Page

Home Page



Landing Page



Tradeshows

None

ILLUM-0306

Illumina Diagnostics Asset Review- High Level DX Campaign

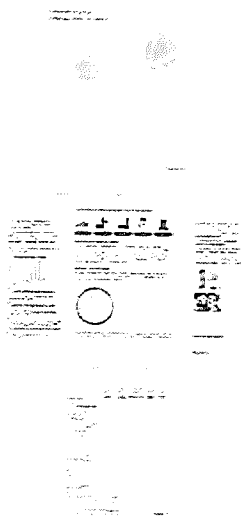
Sales Tools

Lead Generation Activities

Sales Support

Sales Tools

Cancer DX Brochure



CancerDX Flyer

Advertising

Print

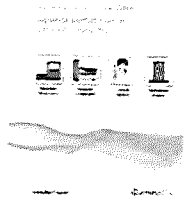
None

Press Releases

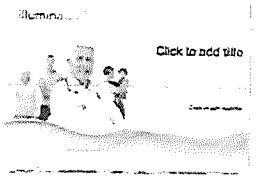
None

Printed Materials

DX Notebook

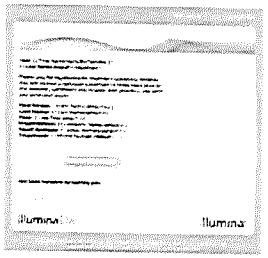


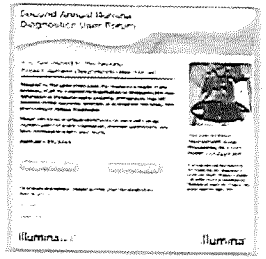
PPT Slide Deck

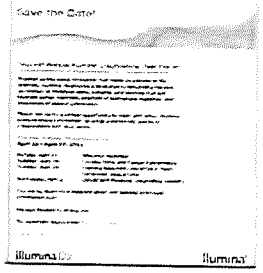


eMarketing

Marketo User Group eMail Blasts

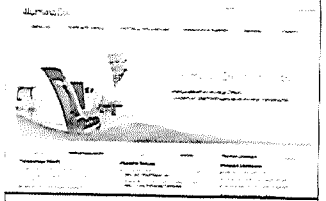






Web Page

Home Page



Landing Page

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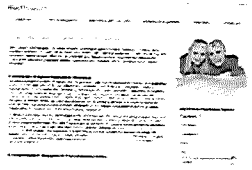
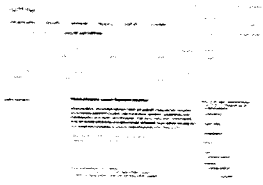
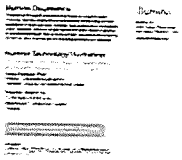


Illumina.com

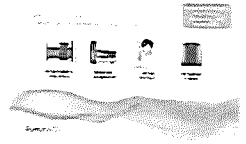


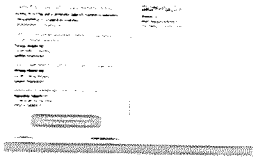
Tradeshows

ACMG 2011



ACMG 2010





ILLUM-0307

EXHIBIT 2

(Part I of II)

OF

DECLARATION OF GREGORY F. HEATH

Illumina Diagnostics

Innovation is in our DNA.
Superior performance is in our products.

Technology Technology (RUO)

BeadXpress Technology

- VeraCode Technology Overview Video

Latest News Events

Latest News

- Illumina Receives FDA 510(k) Clearance for VeraCode(R) Genotyping Test for Factor V (Leiden) and Factor II (Prothrombin)
- Illumina Receives FDA 510(k) Clearance for Its BeadXpress(R) Multiplex Analysis System
- Illumina Introduces VeraCode(R) ADME Core Panel for Pharmaceutical Research

Product Literature Publica

Product Literature

- VeraCode Brochure (PDF)
- VeraCode Technology Spotlight (PDF
- BeadXPress Reader Data Sheet (PDF

Product Literature (RUO)

- ADME Brochure (PDF)
- ADME Data Sheet (PDF)
- Cyto Brochure (PDF)

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ILLUM-0615

About IlluminaDx

Powered by the same innovation that made us a leader in life sciences, IlluminaDx is dedicated to developing the next generation of molecular tests, systems, and services that will facilitate earlier diagnosis, selection of appropriate therapies, and monitoring of disease progression. Our technologies enable sophisticated analysis of pathogens and subtle changes in patients' genes and chromosomes, allowing clinical laboratories and physicians to personalize disease management for improved healthcare.

Our Vision

Our vision is to become a leader in translational medicine, focusing on complex diseases that benefit from high-performance analysis, including genotyping, copy number, gene expression, methylation, and protein analysis. We leverage the strength of our technologies in four major areas:

- Molecular Diagnostics
- Molecular Cytogenetics
- Cancer Discovery Initiative
- CLIA Laboratory Services

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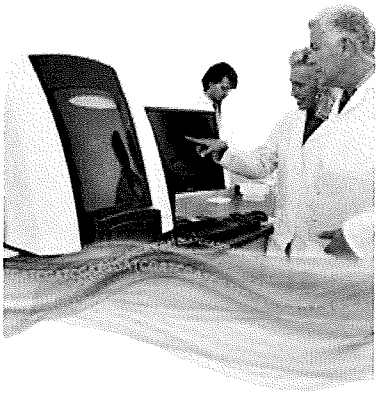
Molecular Diagnostics



IlluminaDx is committed to the rapidly growing field of molecular diagnostics. Leveraging our extensive knowledge of science and cutting-edge technology, we are relentless in the creation of innovative products to enhance the quality of life for mankind. IlluminaDx is developing various multiplexed, accurate, and cost-effective nucleic acid tests (NATs) that will be used to diagnose and manage human diseases. Our plans will initially focus on human infectious diseases and cytogenetics. We will ultimately extend into oncology to support cancer therapy management through diagnostic, prognostic, staging, and therapeutic monitoring.

The BeadXpress system is the first 510(k)-cleared IlluminaDx *in vitro* diagnostic (IVD) device. It is intended for the simultaneous detection of multiple analytes in a DNA sample using VeraCode holographic microbead technology. The BeadXpress system consists of the BeadXpress Reader and VeraScan software. It is cleared for use only with FDA-cleared VeraCode tests.

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Applications / **Cytogenetics**

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Highlights

Intelligent Content
BeadChips target most relevant regions and provide genome-wide coverage

Unsurpassed Flexibility
Reliable detection of deletions, duplications, inversions, rearrangements, and amplifications

High Resolution
BeadChips with down to 1.2kb marker spacing, and single-base resolution sequencing

Easy Workflows
Fast, simple, and proven sample preparation protocols, automated processing, and visual data readout

Software Support
Analysis and visualization programs able to integrate with other analysis tools

Literature

- Cytogenetics Brochure (PDF)
- Molecular Cytogenetics Data Sheet (PDF)
- Interpreting Infinium Assay Data for Whole-Genome Structural Variation (PDF)
- Cytogenetics into Cytogenomics Application Note (PDF)
- Infinium HD BeadChips Data Sheet (PDF)
- More

Featured Research Papers

- SNP array mapping of chromosome 20p deletions: genotypes, phenotypes, and copy number variation.
- Genomic analysis using high-density single nucleotide polymorphism-based oligonucleotide arrays and multiplex ligation-dependent probe amplification provides a comprehensive analysis of INI1/SMARCB1 in malignant rhabdoid tumors.
- A new diagnostic workflow for patients with mental retardation and/or multiple congenital abnormalities: test arrays first.
- Preclinical validation of a microarray method for full molecular karyotyping of blastomeres in a 24-h protocol
- More...

News & Events

- Japanese Society for Gene Diagnosis and Therapy Conference (JSGDT)
- American Society of Human Genetics (ASHG)
- Association for Molecular Pathology (AMP)
- More

Epigenetic Analysis
Gene Expression Analysis
Protein Analysis
Real-Time PCR
Agrigenomics
Cytogenetics
Cancer Genomics

iScan
BeadXpress
Eco Real-Time PCR System
Software
BaseSpace

Service Partnerships
Illumina Financial Solutions
Illumina Connect

Webinars

FAQs
DesignStudio
Assay Design Tool
Product Files
Eco Real-Time PCR Support
Customer Service
Training

Newsroom
Investor Relations
Privacy
Legal
California Transparency in Supply Chain

Innovative technologies
At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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Applications / **Cytogenetics**

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Type of Institute:
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Products

Study chromosomal abnormalities such as amplifications, deletions, rearrangements, copy number changes, and copy-neutral loss of heterozygosity (LOH) with Illumina's efficient and easy-to-run Infinium HD BeadChips or the Genome Analyzer IIx high-throughput sequencing system. Achieve substantially higher resolution than G-banding, FISH, and CGH with either or both platforms, and expand the scope and depth of your cytogenetic analysis.

Infinium HD BeadChips: Complete Genome-Wide Coverage in Multi-Sample Array Formats

Illumina's revolutionary Infinium HD technology allows for unconstrainted design of SNP orintensity-only markers, enabling dense, uniform coverage across the genome and the ability to target high-value genomic regions. From 300,000 markers on the HumanCytoSNP-12 BeadChip to more than 1.1 million markers per sample on the HumanOmni1-Quad BeadChip, Infinium HD BeadChips support high-resolution copy number and LOH analysis with median marker spacing down to 1kb.

Epigenetic Analysis
Gene Expression Analysis
Protein Analysis
Real-Time PCR
Agrigenomics
Cytogenetics
Cancer Genomics

iScan
BeadXpress
Eco Real-Time PCR System
Software
BaseSpace

Partnerships
Illumina Financial Solutions
Illumina Connect

FAQs
DesignStudio
Assay Design Tool
Product Files
Eco Real-Time PCR Support
Customer Service
Training

Investor Relations
Privacy
Legal
California Transparency in Supply Chain

Innovative technologies
At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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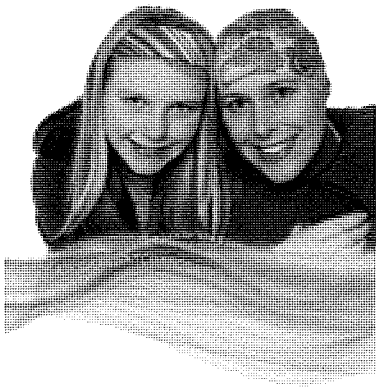
Illumina Cancer Discovery Initiative



Each cancer manifestation can have different underlying genetic factors, making it challenging to develop a standardized approach to treatment. Recent technological advances in DNA sequencing and microarray-based analysis offer the potential for new discoveries that may lead to individualized treatments tailored to a persons' genetic disposition and, possibly, earlier detection for a brighter prognosis.

A Revolution in Cancer Biomarker Discovery

Illumina's Cancer Discovery Initiative aims to produce cutting-edge diagnostics through the application of our core technologies on oncology discovery, validation, and, eventually, diagnostic product development. To accomplish this, Illumina is partnering with cancer research institutions throughout the multi-stage initiative. As an entry point for the Cancer Discovery Initiative, we are targeting ovarian cancer, the leading cause of death from gynecological cancer and fifth leading cause of cancer mortality in women. While early-stage ovarian cancer diagnosis is difficult, it is a critical factor for survival. Five-year survival rates diminish drastically as the disease progresses and 60% of cases relapse after 24 months due to Platinum therapy resistance.

To begin the process, samples were obtained for 25 tumor and 25 normal paired specimens. Each pair was sequenced to compare the whole genomes, methylomes, and transcriptomes in order to identify disease-associated markers. This effort accounted for for 50% of the total cancer genomes sequenced at this time. In the next stage, identified markers will be validated using Illumina's BeadArray technology and targeted resequencing. If these markers prove successful, services to screen for possible cancer biomarkers may be initially offered in Illumina's CLIA laboratory. Ultimately, the goal is to use this content to develop novel diagnostics on Illumina's BeadXpress platform and obtain regulatory clearance.

A Comprehensive Approach to Understanding Cancer

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Cancer Targets

Research efforts like these can take years to translate into a diagnostic test. For more information on our progress with ovarian cancer biomarker discovery and our product portfolio for cancer research, download the following literature:

- Illumina Cancer Discovery Initiative (PDF)
- Cancer Genomics Brochure (PDF)

Following the ovarian cancer initiative, we will begin to seek biomarkers for early detection in gastric cancer, followed by the search for colorectal cancer biomarkers indicative of response to adjuvant chemotherapy.

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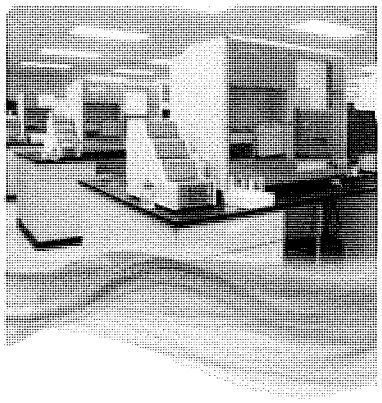
ILLUM-0622

Illumina Clinical Services Laboratory



Since 2002, Illumina has been providing high-quality DNA analysis services to the scientific community, including many of the top researchers from world-renowned institutions. This wealth of experience is now available to you through the CLIA-certified, CAP-accredited Illumina Clinical Services Laboratory.

What is CLIA?

CLIA stands for Clinical Laboratory Improvement Amendments. Essentially, CLIA is an important laboratory certification by the Centers for Medicare & Medicaid Services (CMS) for companies performing diagnostic testing. In total, CLIA covers approximately 200,000 laboratory entities. The objective of the CLIA program is to ensure quality laboratory testing.

To read more about CLIA, visit the Centers for Medicare and Medicaid Services.

What is CAP?

The goal of the College of American Pathologists (CAP) laboratory accreditation program is to advance the quality of pathology and laboratory services through education, standard setting, and ensuring that laboratories meet or exceeds regulatory requirements. An accredited laboratory is one that is inspected by a not-for-profit accrediting organization that has been approved by the CMS.

The Illumina Clinical Services Laboratory currently offers physician-ordered genome sequencing services. The laboratory is staffed with certified Clinical Laboratory Scientists and uses the latest Illumina technology. In 2009, the laboratory was the first to generate a complete human genome sequence in a clinical laboratory setting.

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Tests & Reagents

Illumina offers innovative tools for multiplex analysis of nucleic acid and protein based assays available as general purpose reagents (GPRs). Our GPRs are manufactured in our GMP- and ISO 9001-certified facilities to ensure that our customers receive the highest quality reagents.

Illumina has developed a comprehensive line of products that address the scale of experimentation and the breadth of functional analysis required to achieve the goals of molecular research. Our research portfolio enables multiplex analysis of nucleic acid sequences from whole genome sequencing to multiplexed arrays to real time PCR.

General Purpose Reagents (GPRs)

- Universal Capture Beads
- VeraCode Carboxyl Beads
- VeraCode Read Buffer

Clinical Research (RUO)

- Research Application Portfolio
- Cytogenetics Research
- Pharmacogenetics ADME Research

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General Purpose Reagents

Innovations in genomics research are resulting in a regular stream of potential biomarkers requiring further validation before they can be translated into an actionable diagnostic test. For assay developers, access to flexible, high-quality, cost-effective multiplexing platforms to deploy this new genomic and proteomic content is critical for success.

To meet this increasing demand, Illumina offers general purpose reagents (GPRs) for use in CLIA high-complexity laboratories and companies developing diagnostic tests. These GPRs offer a truly open platform, enabling laboratories to efficiently and cost-effectively use new content to develop multiplex assays based on their preferred multiplex and methodology.

Learn more with VeraCode Beads, GPR (PDF).

General Purpose Reagents currently available

- VeraCode Universal Capture Beads
- VeraCode Carboxyl Beads
- BeadXpress System Read Buffer

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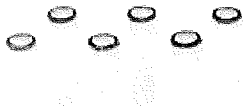
ILLUM-0625

VeraCode GPR Universal Capture Beads



Technology: VeraCode

Species: Any

Contents: Each VeraCode GPR Universal Capture Bead Set is sufficient for 6 x 96 samples

VeraCode General Purpose Reagent (GPR) Universal Capture Beads provide a versatile substrate for assay development, offering a truly open platform that enables laboratories to develop multiplex assays based on their preferred multiplex and methodology. These highly stable glass microbeads are pre-immobilized at high density with a unique 23-mer capture oligonucleotide sequence. Each Universal Capture Bead is inscribed with a unique code that is used downstream to designate and track the specific analyte or genotype of interest in the multiplex reaction. VeraCode Universal Capture Beads are available in two formats, 48 individual bead types and two sets of 48-plex pre-pooled bead types, enabling laboratories and manufacturers of molecular tests to custom develop up to 144 distinct analytes in a single well.

The purchase price of the GPR Universal Capture Beads gives the customers the right to use them in diagnostic services and test kits without the need for additional royalties to Illumina. By offering these without any additional royalty, customers are provided the convenience and flexibility needed so they can concentrate on evolving their menu.

Order Information

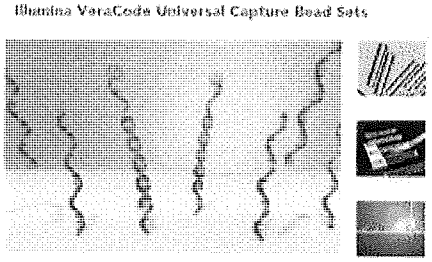
Bead Codes:

VC GPR Pre-Pool 48-Plex Uni, Code

GET A QUOTE

Flexible design and convenient workflow

Designing a multiplexed genotyping assay with VeraCode GPR Universal Capture Bead Sets is made easy with VeraCode Assay Designer Software, an integrated design tool for single and multiplexed allele-specific primer extension (ASPE) assay designs. SNP and small insertion and deletion genotyping assay designs are scored for melting temperature, GC content, cross-reactivity within a multiplex and folding. Users can quickly create custom multiplex plates of pooled universal capture bead types using the convenient VeraCode bead kitting system which eliminates vortexing, pipetting, and centrifugation.



Oligonucleotide capture probes are covalently linked to cylindrical silica microbeads for SNP genotyping assays. The insets (right) show photographs of actual microbeads taken using a light microscope (top) and rendered images of laser scanning (middle, bottom).

- View the VeraCode Assay Designer Video
- VeraCode Beads, GPR Data Sheet
- Assay Designer Data Sheet
- Partners

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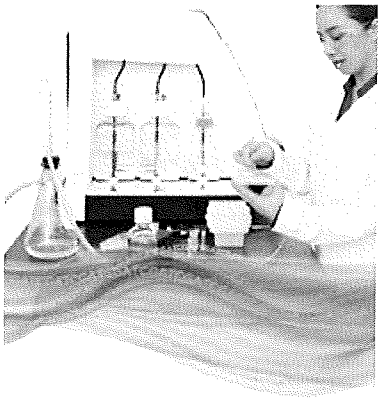
VeraCode GPR Carboxyl Beads

Technology: VeraCode

Species: Any

Contents: Each VeraCode GPR Carboxyl Bead Set includes sufficient beads for 576 samples/code



VeraCode General Purpose Reagent (GPR) Carboxyl Beads provide a versatile substrate for assay development, offering a truly open platform that enables laboratories to develop multiplex assays based on their preferred multiplex and methodology. These highly stable glass microbeads are each inscribed with a unique code used downstream to designate and track the specific analyte or genotype of interest in the multiplex reaction. Laboratories can develop custom assays by covalently attaching proteins, peptides, nucleic acid sequences, and other ligands to this highly stable and flexible substrate. Forty-eight unique Carboxyl Bead types are currently available. Beads can be easily pooled in varying combinations to achieve the desired level of multiplexing using the VeraCode Bead Kitting system, which reduces pipetting and opportunity for error. Carboxyl beads demonstrate low non-specific binding in multiplex assays.

The purchase price of the GPR Carboxyl Beads gives the customers the right to use them in diagnostic services and test kits without the need for additional royalties to Illumina. By offering these without any additional royalty, customers are provided the convenience and flexibility needed so they can concentrate on evolving their menu.

Order Information

Bead Codes:

Set A (8193, 8195, 8196, 8197, 819

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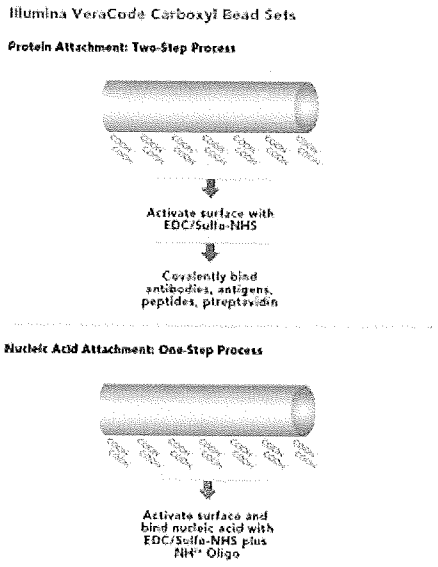

VeraCode Carboxyl Bead Sets enable the attachment of protein and nucleic acid molecules to cylindrical glass beads. The beads harbor unique codes for each bead type for downstream tracking and identification.

- VeraCode Beads, GPR Data Sheet
- Cytokine Multiplex Assay White Paper
- Partners

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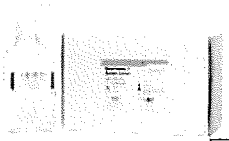
ILLUM-0627

Products / **BeadXpress System Read Buffer**

The BeadXpress System Read Buffer transports VeraCode beads from the 96-well sample plate into the read cell of the BeadXpress Reader and, subsequently, flushes the beads to waste once measurements have been taken. The Buffer is required for running any assay or calibration on the BeadXpress Reader System.

Catalog IDs: VC-400-1001

QUESTIONS



BX System Read Buffer (10X

Catalog #: VC-400-1001

Quantity: 1

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Innovative technologies
At Illumina, our goal is to apply innovative technologies and revolutionary assays to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. These studies will help make the realization of personalized medicine possible. With such rapid advances in technology taking place, it is mission critical to have solutions that are not only innovative, but flexible, scalable, and complete with industry-leading support and service. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and prioritizing the needs of its customers, we strive to meet this challenge. Illumina's innovative, array-based solutions for DNA, RNA, and protein analysis serve as tools for disease research, drug development, and the development of molecular tests in the clinic.

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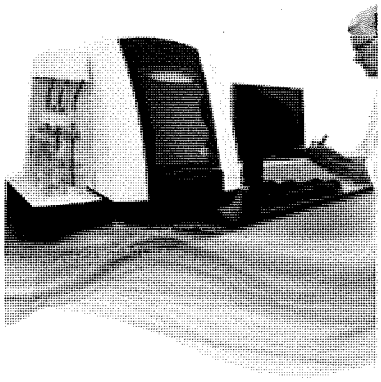
Systems & Applications

Illumina offers a broad portfolio of innovative platforms for analyzing DNA, RNA, and protein-based analytes. These systems support applications for basic and translational life science research and the development of diagnostic tests on the BeadXpress System.



In Vitro Diagnostics (IVD)

The BeadXpress system, comprised of the BeadXpress Reader and VeraScan software, is an FDA 510(k)-cleared *in vitro* diagnostic (IVD) device intended for the simultaneous detection of multiple analytes in a DNA sample using VeraCode microbead technology. The BeadXpress system is cleared for diagnostic use only with FDA cleared VeraCode tests.

- BeadXpress Reader

Clinical Research (RUO)

For the highest microarray multiplexing capabilities and next-generation sequencing with industry-leading output and accuracy, Illumina offers several RUO systems.

- Sequencing
- iScan

Applications (RUO)

Illumina systems enable a wide range of translational research and biomarker discovery applications for whole-genome or focused genotyping and profiling of RNA expression, structural variation, protein levels, and epigenetic markers.

- Gene Expression Analysis
- Genotyping & CNV Analysis
- Sequencing Applications
- Protein Analysis
- Gene Regulation & Epigenetic Analysis

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Resources & Support

When you purchase Illumina technology, you receive more than an instrument or an assay. You get world-class resources and continuous support. We provide you with the largest, best-trained, most experienced microarray and next-generation sequencing support team. A global team over 100 strong dedicated to supporting your lab's needs. Personalized installation and training. Rapid response times. Innovative online e-learning. Bioinformatics expertise. Global service—24 hours a day, 7 days a week.

- Training Programs
- Support
- Research Articles

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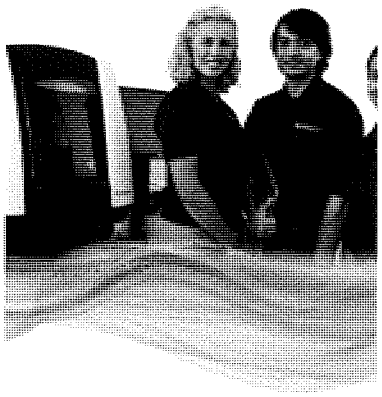
Services



If you have limited time and resources, you can still take advantage of Illumina technology. Put Illumina's team of experts to work for you through our collaborative lab services teams. You'll receive personalized service, industry-leading data quality, and guaranteed turnaround time.

- Illumina CLIA Lab
- Service Providers

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Illumina Cancer Discovery Initiative

Each cancer manifestation can have different underlying genetic factors, making it challenging to develop a standardized approach to treatment. Recent technological advances in DNA sequencing and microarray-based analysis offer the potential for new discoveries that may lead to individualized treatments tailored to a persons' genetic disposition and, possibly, earlier detection for a brighter prognosis.

A Revolution in Cancer Biomarker Discovery

Illumina's Cancer Discovery Initiative aims to produce cutting-edge diagnostics through the application of our core technologies on oncology discovery, validation, and, eventually, diagnostic product development. To accomplish this, Illumina is partnering with cancer research institutions throughout the multi-stage initiative. As an entry point for the Cancer Discovery Initiative, we are targeting ovarian cancer, the leading cause of death from gynecological cancer and fifth leading cause of cancer mortality in women. While early-stage ovarian cancer diagnosis is difficult, it is a critical factor for survival. Five-year survival rates diminish drastically as the disease progresses and 60% of cases relapse after 24 months due to Platinum therapy resistance.

To begin the process, samples were obtained for 25 tumor and 25 normal paired specimens. Each pair was sequenced to compare the whole genomes, methylomes, and transcriptomes in order to identify disease-associated markers. This effort accounted for for 50% of the total cancer genomes sequenced at this time. In the next stage, identified markers will be validated using Illumina's BeadArray technology and targeted resequencing. If these markers prove successful, services to screen for possible cancer biomarkers may be initially offered in Illumina's CLIA laboratory. Ultimately, the goal is to use this content to develop novel diagnostics on Illumina's BeadXpress platform and obtain regulatory clearance.

A Comprehensive Approach to Understanding Cancer

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Cancer Targets

Research efforts like these can take years to translate into a diagnostic test. For more information on our progress with ovarian cancer biomarker discovery and our product portfolio for cancer research, download the following literature:

- Illumina Cancer Discovery Initiative (PDF)
- Cancer Genomics Brochure (PDF)

Following the ovarian cancer initiative, we will begin to seek biomarkers for early detection in gastric cancer, followed by the search for colorectal cancer biomarkers indicative of response to adjuvant chemotherapy.

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ILLUM-0632

illumina Dx™

The Illumina® Cancer Discovery Initiative

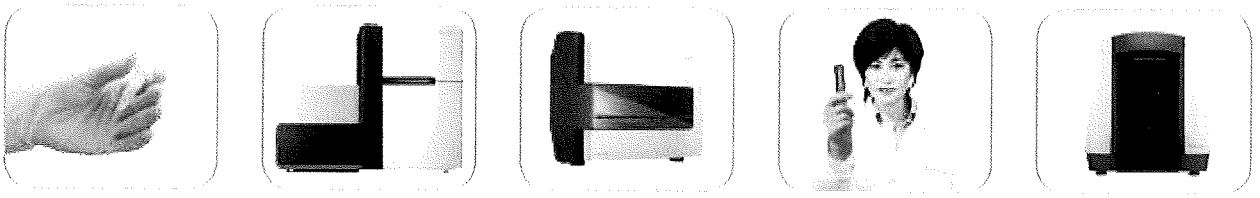
Cancer is one of the leading causes of death worldwide. Increasing health care costs and the escalating prevalence of disease among aging populations have spurred the need for innovative diagnostic approaches. As with many complex diseases, the variation of genetic associations poses a challenge for a standardized treatment approach, as each manifestation can have different, multiple underlying genetic factors. Recent technological advancements in DNA sequencing and microarray-based genetic analysis offer the potential for new discoveries, leading to a revolution in cancer therapy. These developments provide hope for earlier disease detection and future treatments tailored to an individual's genetic disposition for a brighter prognosis.

What is Illumina Doing?

As a leading provider of integrated solutions that advance the understanding of genetics and health, Illumina is working to develop better, more sensitive, cutting-edge cancer diagnostic tools. Our ground-breaking next-generation sequencing technology is transforming genetic research, enabling scientists to peer into the human genome, epigenome, and transcriptome at a depth and resolution previously not achievable. With such a wealth of genetic information, researchers are able to compare data across multiple individuals and populations to identify genetic disease associations. As the technology advances, it is becoming faster, cheaper, and more accessible, enabling discoveries that can one day translate into powerful cancer diagnostic tools.

Illumina's Cancer Discovery Initiative is focused on applying our core technologies on oncology discovery, validation, and, eventually, product development. We launched this initiative by targeting ovarian, gastric, and colorectal cancers. Why these particular ones? Currently, these cancers are either detected in later stages, resulting in low survival rates and/or pose significant therapeutic challenges. Early detection and prognostic evaluation directly impact a successful patient outcome, making these areas where Illumina technology can make a difference. By working with groups to discover biomarkers for early detection and the likelihood of therapeutic response, we can help drastically improve patient care.

Cancer Discovery Roadmap



Ovarian cancer
Colorectal cancer
Gastric cancer

ILLUM-0633

TGATAACAGTAACAACACTTCTGTTAACGTTAAGATTACTTGATCCAGTGATTGAACGTACCGTAAGGAACGTATCAATTGAGACTAAATATTAACGTACCATTAAGAGGTACCGTGTTCTGTTAACGTTAAGATTACTTGATCCAGTGATTG
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Cancer type	Diagnostic dilemma	Discovery goal
Ovarian	• Most diagnoses occur in later stage • 5-year survival decreases dramatically as disease advances	• Biomarkers for early detection • Biomarkers predicting platinum therapy resistance
Gastric	• Metastasis occurs in 80-90% of individuals with gastric cancer • Six month survival rate is 65% with early stage diagnosis and <15% with advanced stages	• Biomarkers for early detection • Biomarkers predicting platinum therapy resistance
Colorectal	• 50% of cancers treated with surgery alone relapse • Therapies selected by stage of diagnosis not well associated with likelihood of response	• Biomarkers for disease prognosis and relapse

The Cancer Initiative Has Three Goals:

1. *Identify early detection biomarkers for at-risk populations*
2. *Identify markers that predict which patients will respond to therapy*
3. *Identify markers of disease prognosis*

To achieve these goals, Illumina is partnering with leading cancer research institutions to undergo a multi-stage discovery and development process. The first step is to obtain samples for tumor and normal paired specimens. Next, the genomes, methylomes, and transcriptomes from these samples will be sequenced in an effort to identify disease-associated markers followed by validation using Illumina technologies and the ability to offer diagnostic services. Ultimately, we hope to deploy novel diagnostics on Illumina's BeadXpress® platform after prospective trials and regulatory clearance. We began with the ovarian cancer initiative and are progressing rapidly towards offering services for this disease in Illumina's Clinical Laboratory Improvement Amendments (CLIA) laboratory.

Spreading Awareness

Research efforts like these can take years to translate into a diagnostic test. In the meantime, each of us can join the cause against cancer by spreading awareness about the disease. Illumina is working with the Ovarian Cancer National Alliance and the Clearity Foundation to get the word out. Visit these groups at www.ovariancancer.org and www.clearityfoundation.org to learn more.

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Pub. No. 570-2009-001 Current as of 25 March 2011

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TGATAACAGTAACAGACTTCTGTTAACGTTAAGATTACTTGATCGACTGATTCAACGTACCGTAACGTAACGTATGAATTGAGACTAAATATTAACGTACGATTAAGAGCTACGGTCTTCTGTTAACGTTAAGATTACTTGATCGACTGATTC
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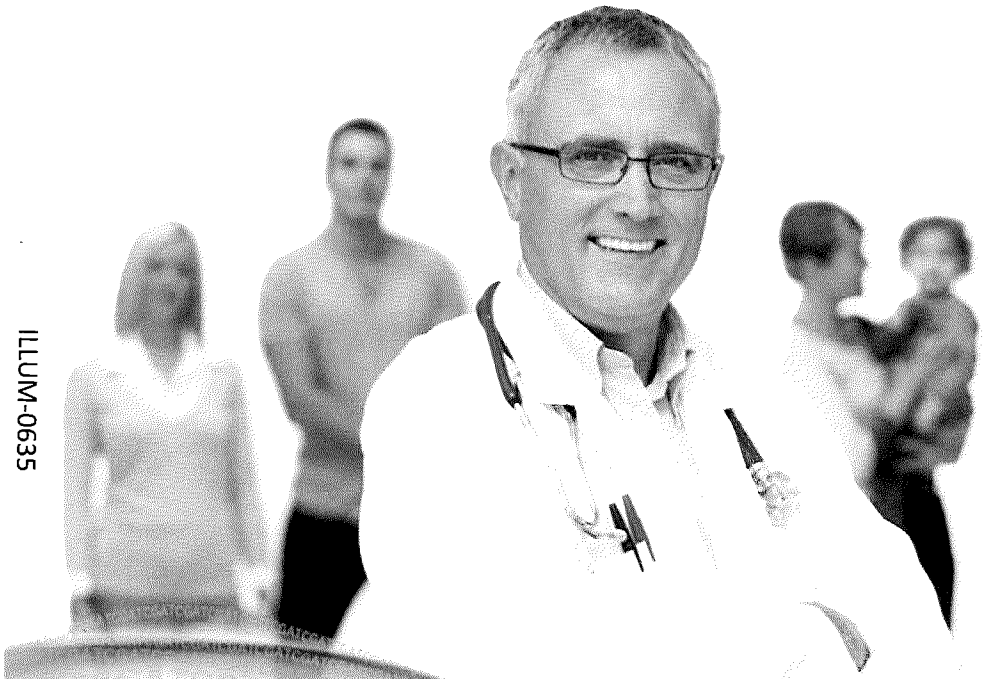

Platform Approach to Cancer Discovery and Diagnostics Development

Emily Winn-Deen, Ph.D.
Vice President
Diagnostics Product Development

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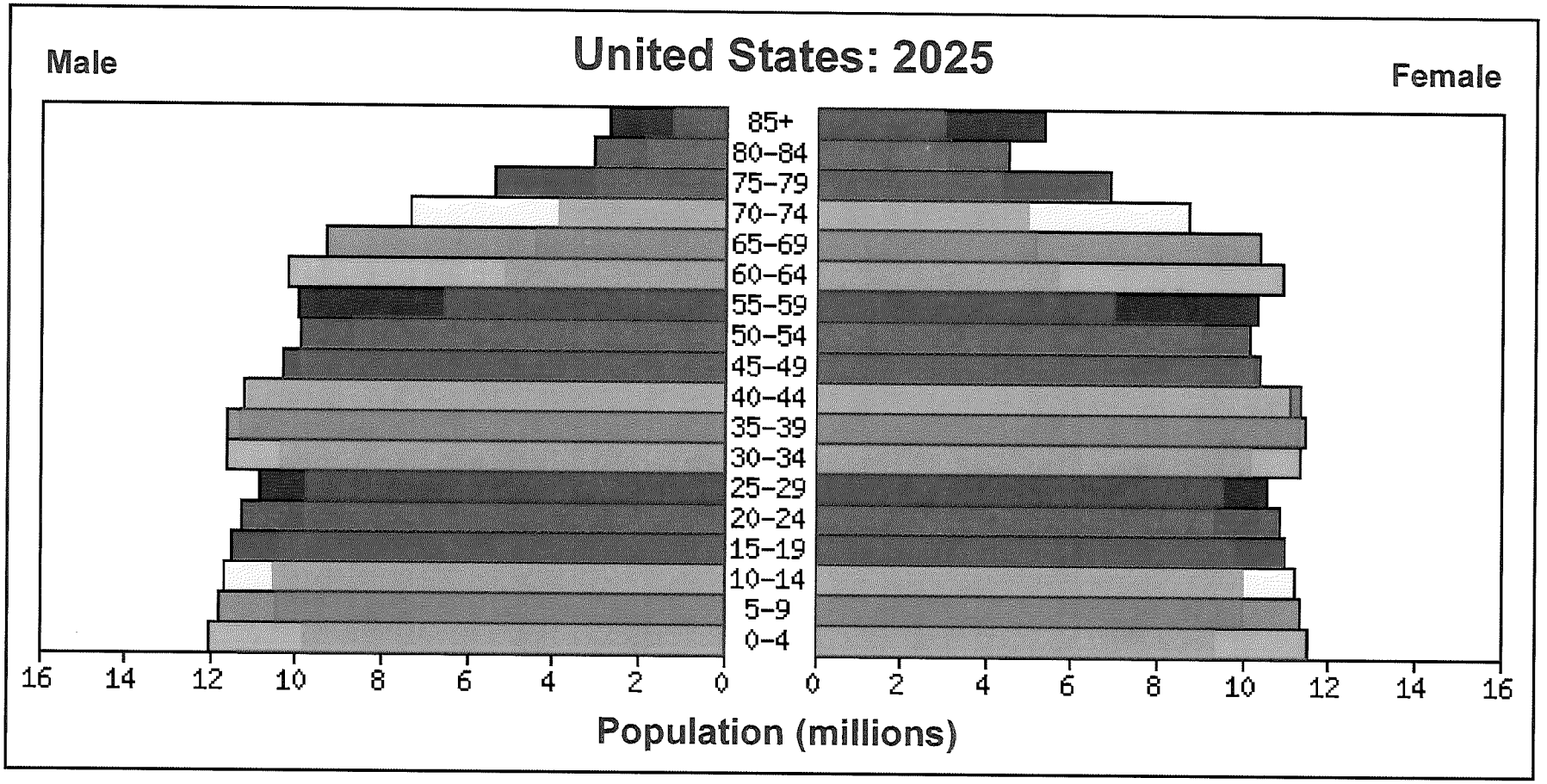
Why Focus on Cancer?
The Population is Aging



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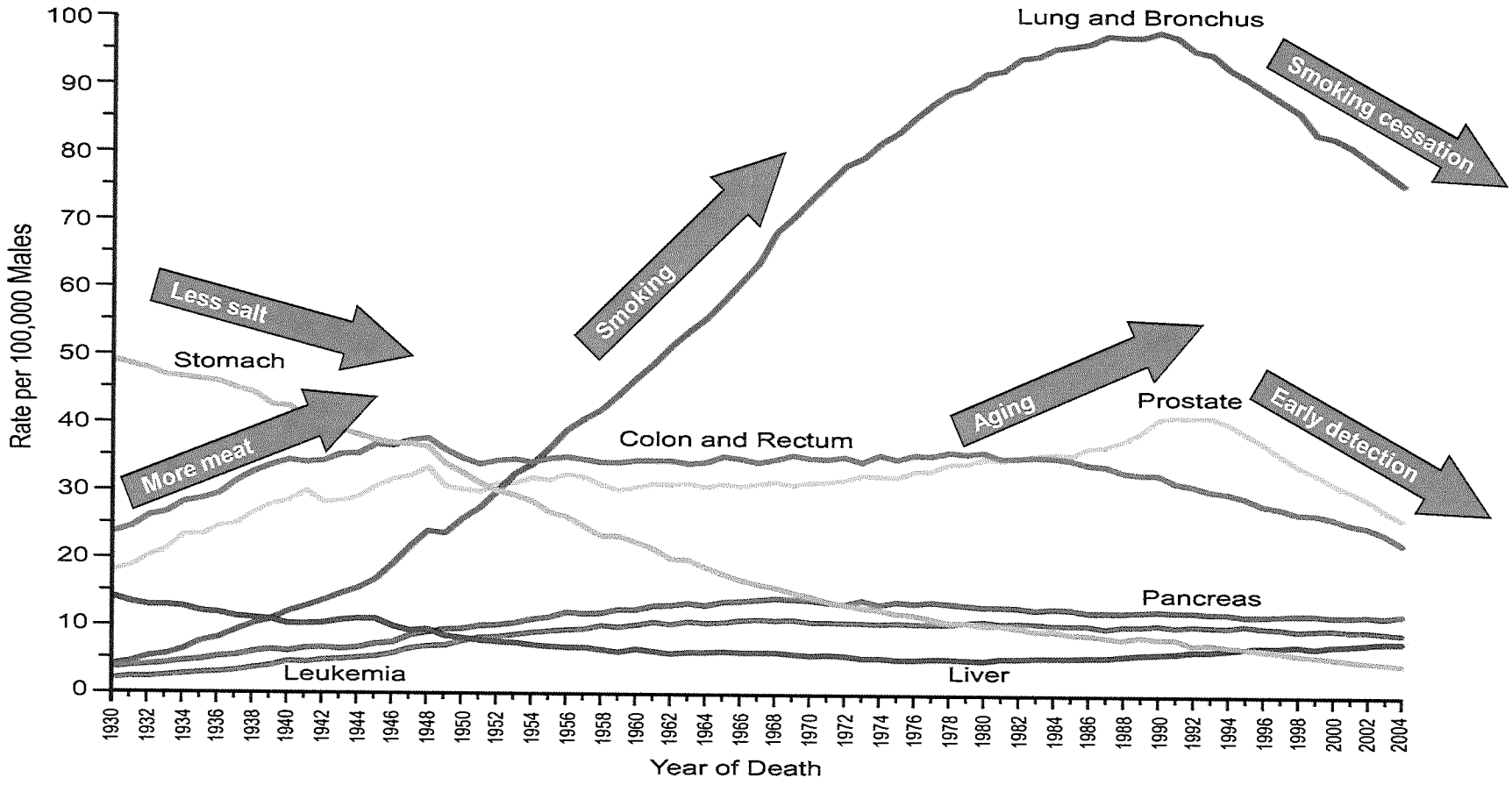
Cancer Continues to be a Major Health Issue

Annual Age-adjusted Cancer Death Rates* Among Males for Selected Cancers, United States, 1930 to 2004



From Jemal, A. et al.
CA Cancer J Clin 2008;58:71-96.

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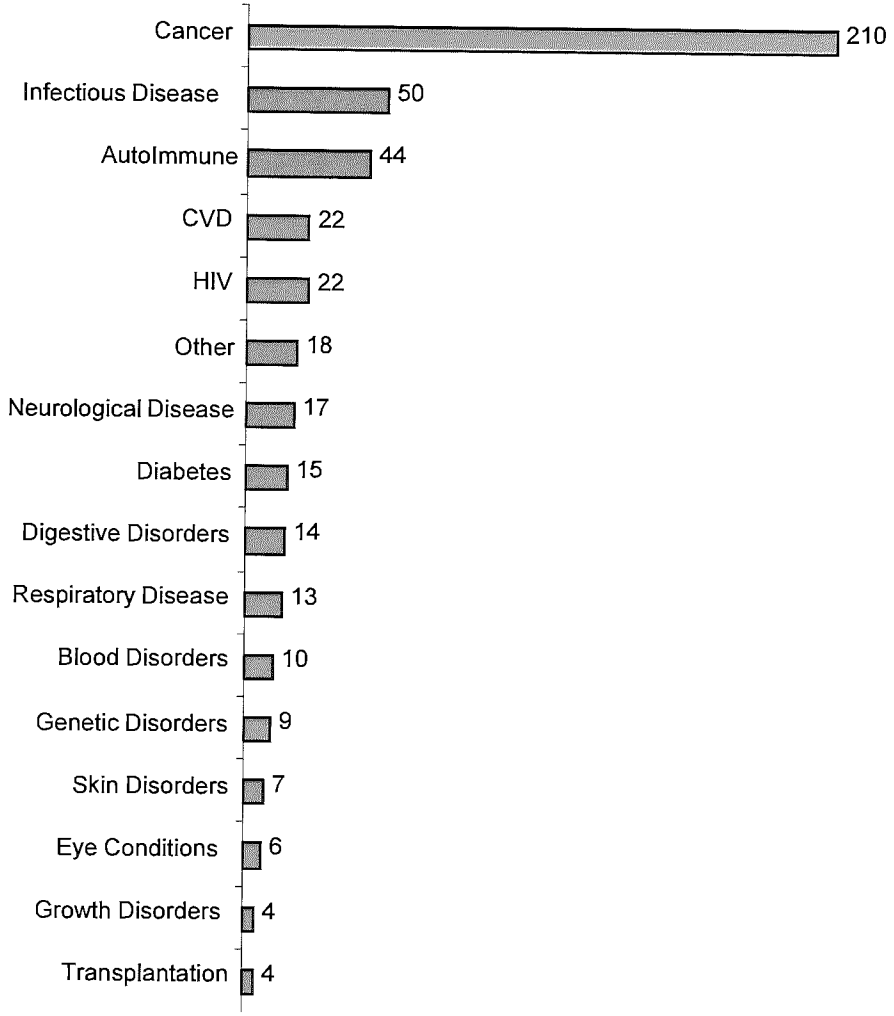
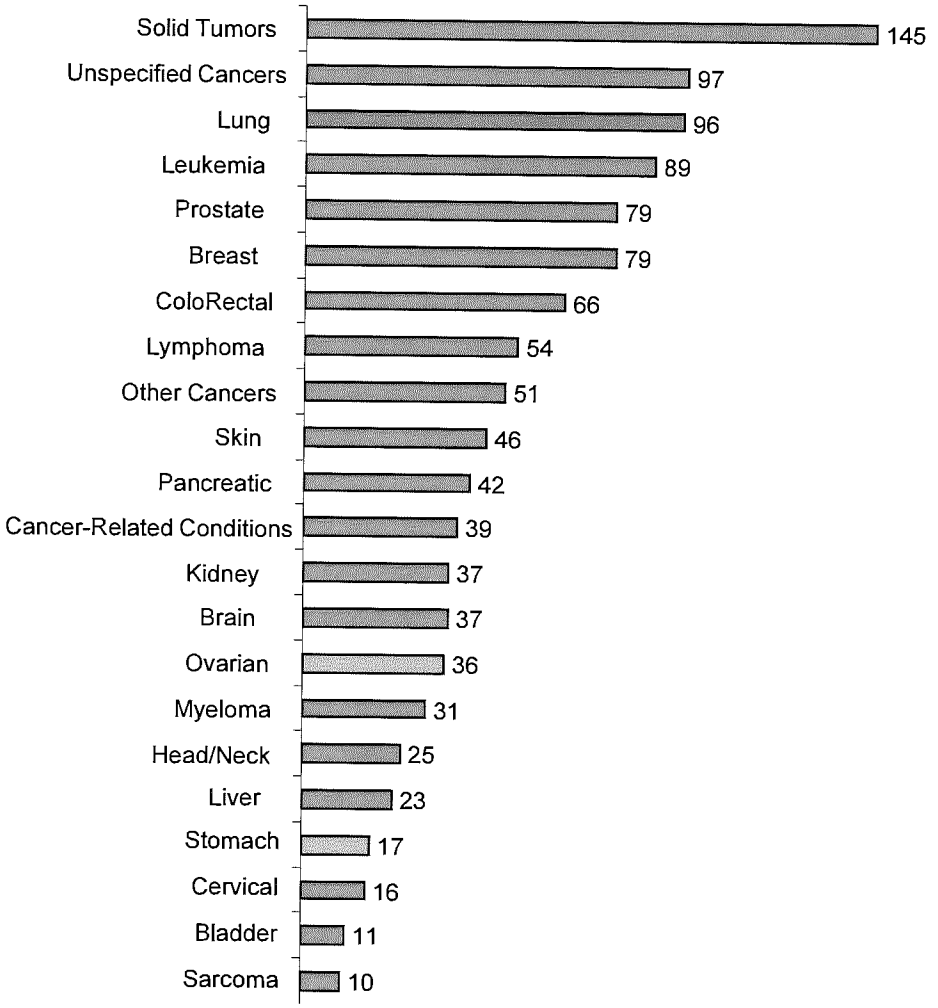
Cancer Therapies Dominate the Biotech Pharma Pipeline



Solid Tumors Lead Cancer Therapies



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Source: PhRMA: 2006 Medicines in Development Biotechnology

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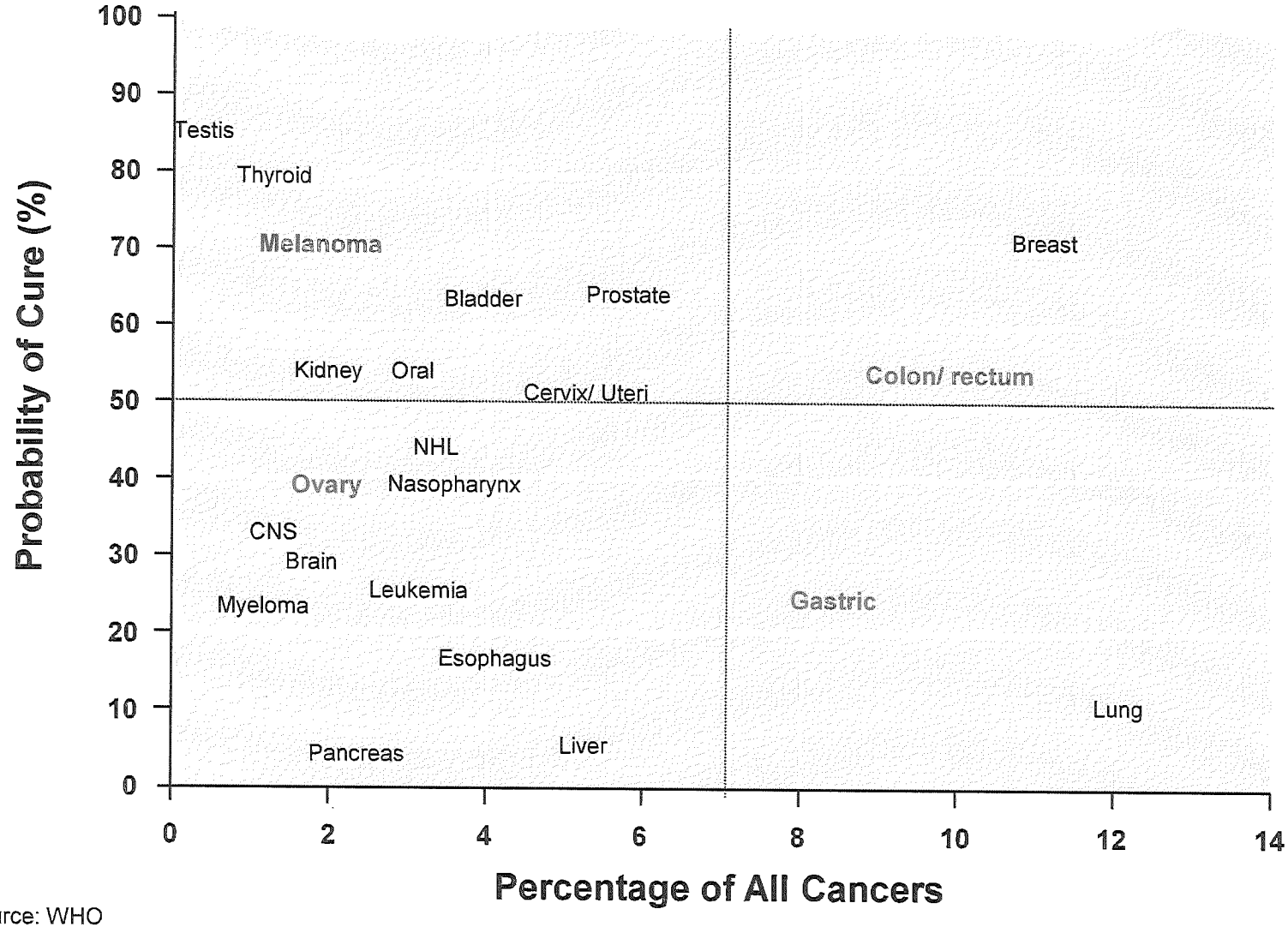
Oncology Discovery

Initial Targets



Source: WHO

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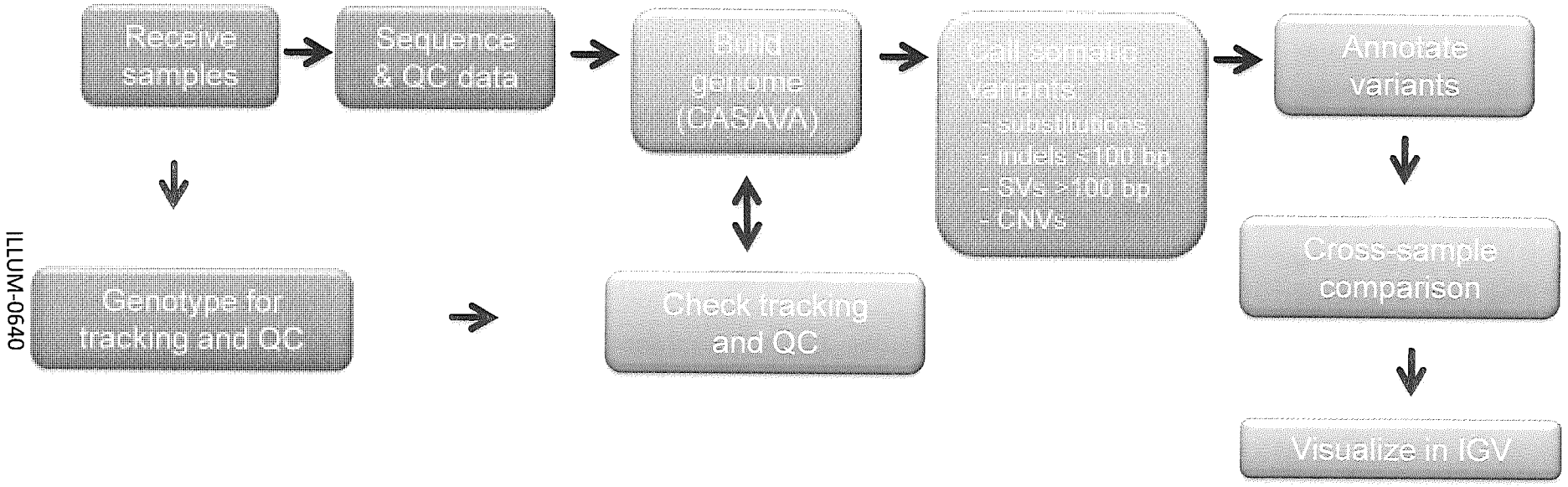
Cancer Sequencing Workflow



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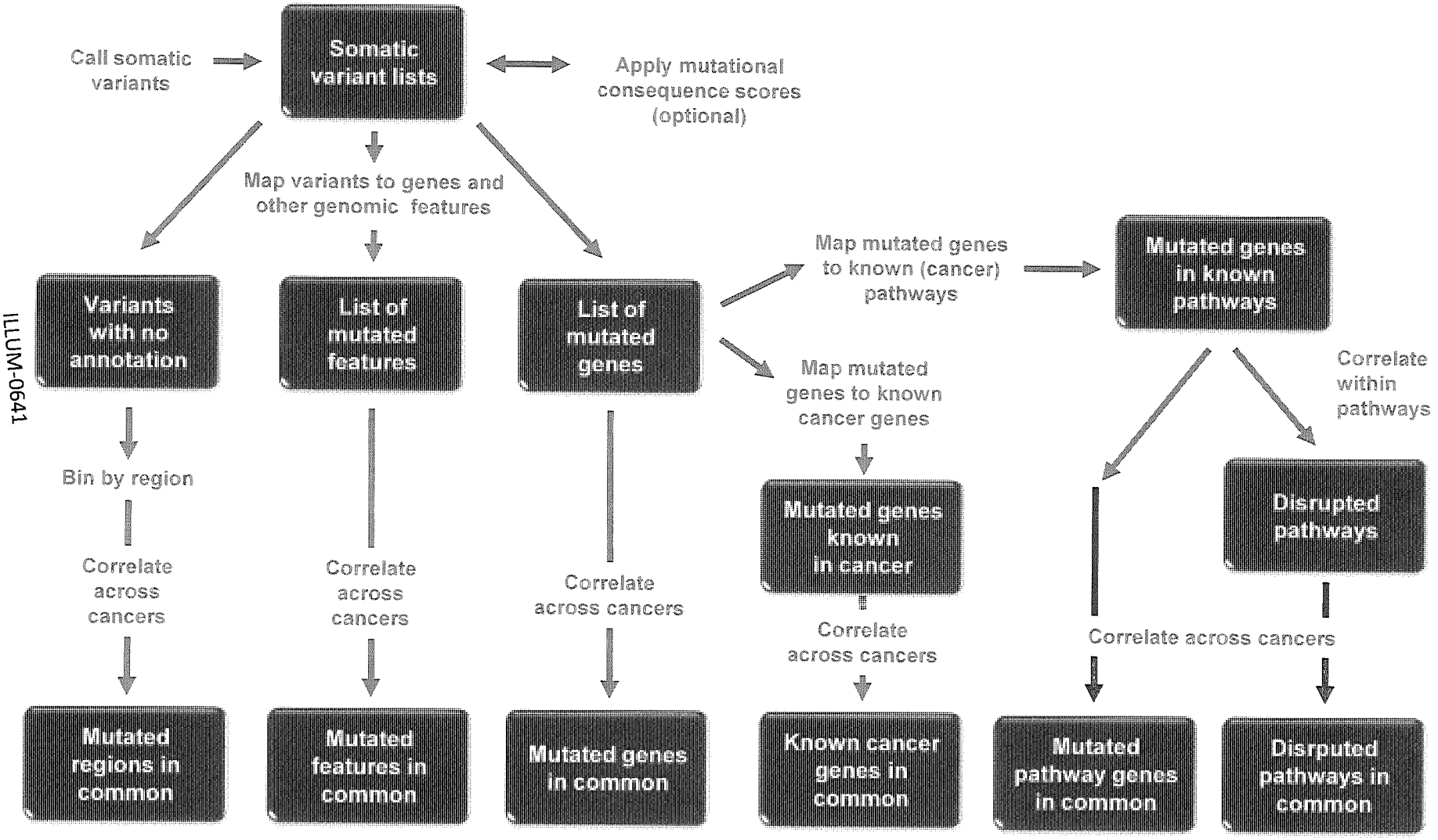
Oncology Discovery

Cancer Specific Analyses



ILLUM-0641

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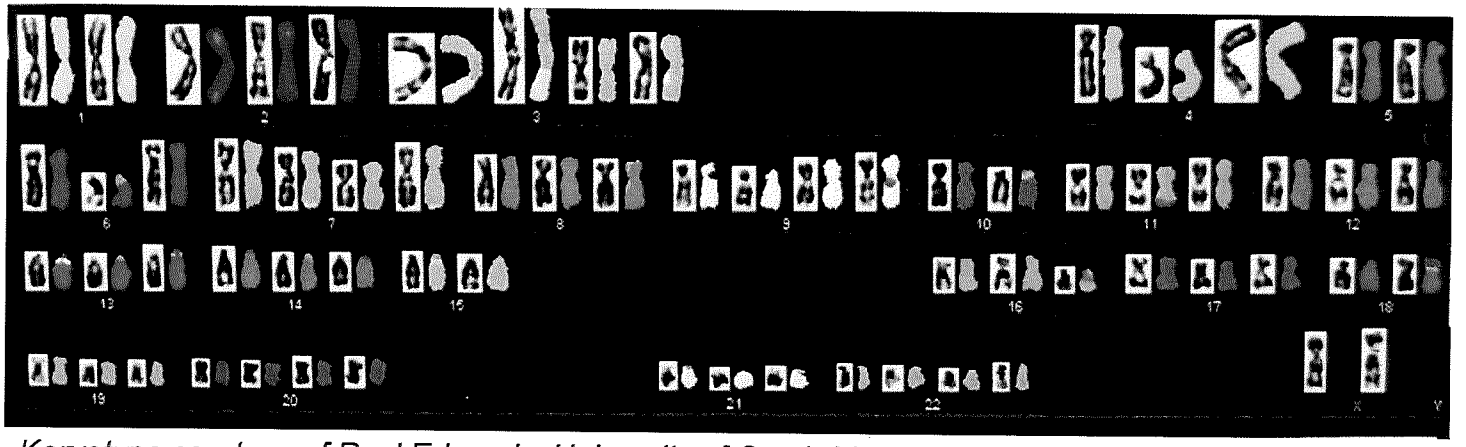
Melanoma: COLO-829

- Collaboration with Mike Stratton's team at the Sanger Center (UK)
- Melanoma cell line COLO-829 and its matched normal (>30x depth)
- Male; metastatic tumour; prior to treatment
- *BRAF*, *CDKN2A* and *PTEN* mutations previously confirmed by exon sequencing
- SKY karyotype indicates pseudotriploidy

ILLUM-0642



Karyotype courtesy of Paul Edwards, University of Cambridge

Variant Detection

- **Run specifications**
  - 2 x 75 base runs, 15 Gb / run. 0.2, 1, 2 & 4 kb libraries
- **Single base substitutions**
  - Paired reads aligned with ELAND (non-gapped)
  - Requires Q100 per allele, e.g. 3 x Q33 bases or equivalent
- **Small indels**
  - Split reads aligned individually or grouped (Pindel, BWA, Grouper)
  - Minimum 3x depth
- **Larger structural variants**
  - Anomalous read pairs from short and long insert libraries
  - >3 S.D. (deletions) or >5 S.D. (insertions)
  - Minimum 10 reads
- **Copy number changes**
  - Read depth (BWA+) in 10 kb windows

ILLUM-0643

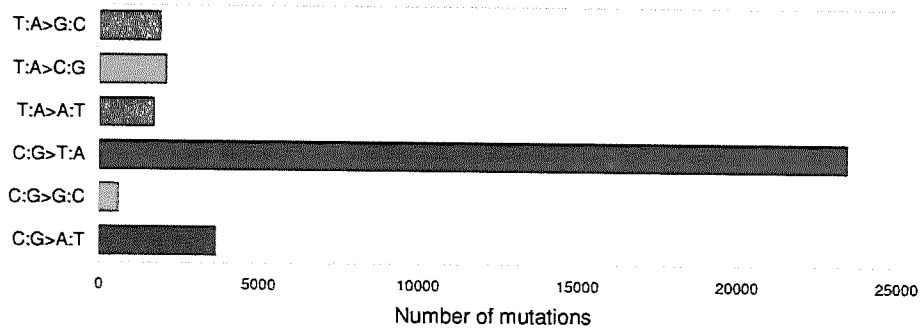
Somatic Substitutions in COLO-829

- **Subtraction process**
  - High stringency calibrated tumour calls (germline + somatic)
  - Subtract if evidence of variant in normal; & dbSNP
- **33,345 somatic substitutions** (gain of an allele) in total
  - 1 per 100 kb
  - 32,325 single base
  - 510 double base (adjacent)
- **96.6% specificity**
  - 454/470 novel somatic calls confirmed by new PCR-capillary sequencing
  - 16 may be artefacts of either method
- **88% (98%) sensitivity**
  - 42/48 previous somatic variants called automatically
  - (98%) or 47/48 automatic + manual (five seen only manually as the evidence was below automatic threshold)
  - 1/48 disputed call

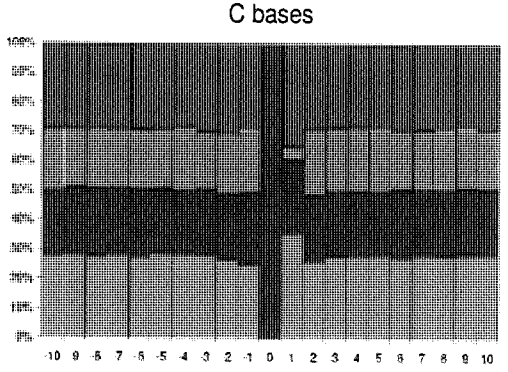
ILLUM-0644

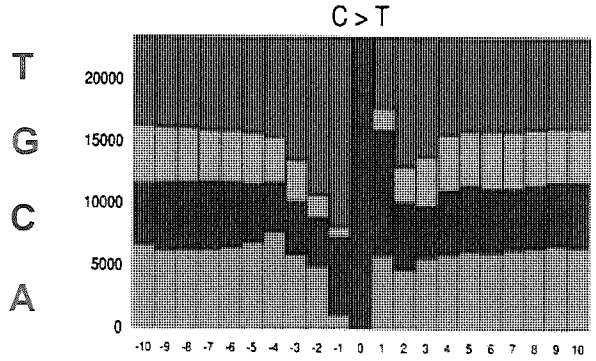
Somatic Mutational Signature of UV Exposure

- 69.9% of all somatic substitutions are C→T or G→A



- 92% of somatic C→T are in a YC pyrimidine dimer (vs. 53% by chance)





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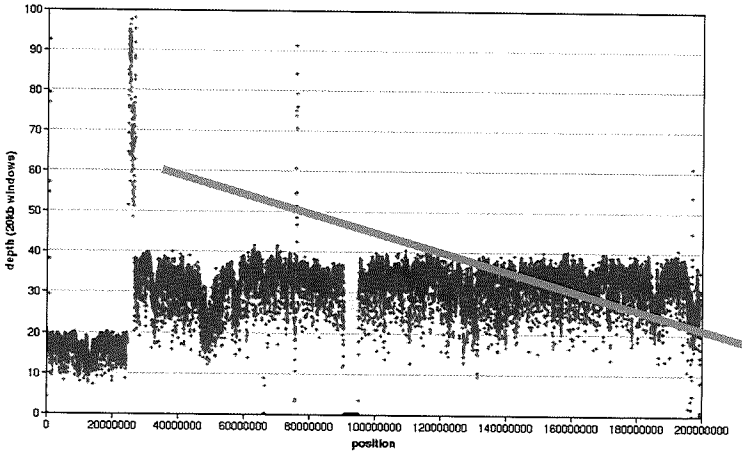
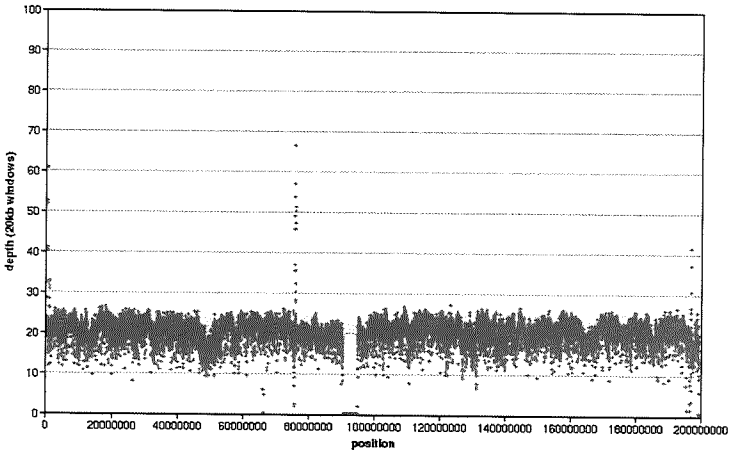
Complex CNV in tumour on chromosome 3

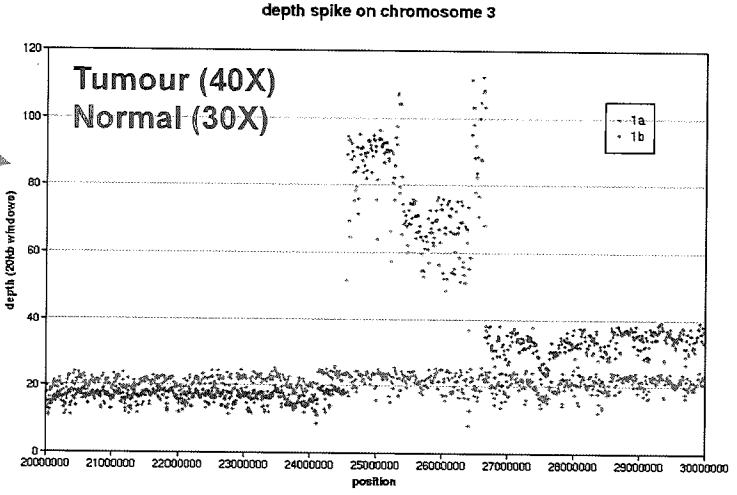
Tumor

ILLUM-0646



Normal





4 genes in this region:
RARB, TOP2B, NGL1,KS

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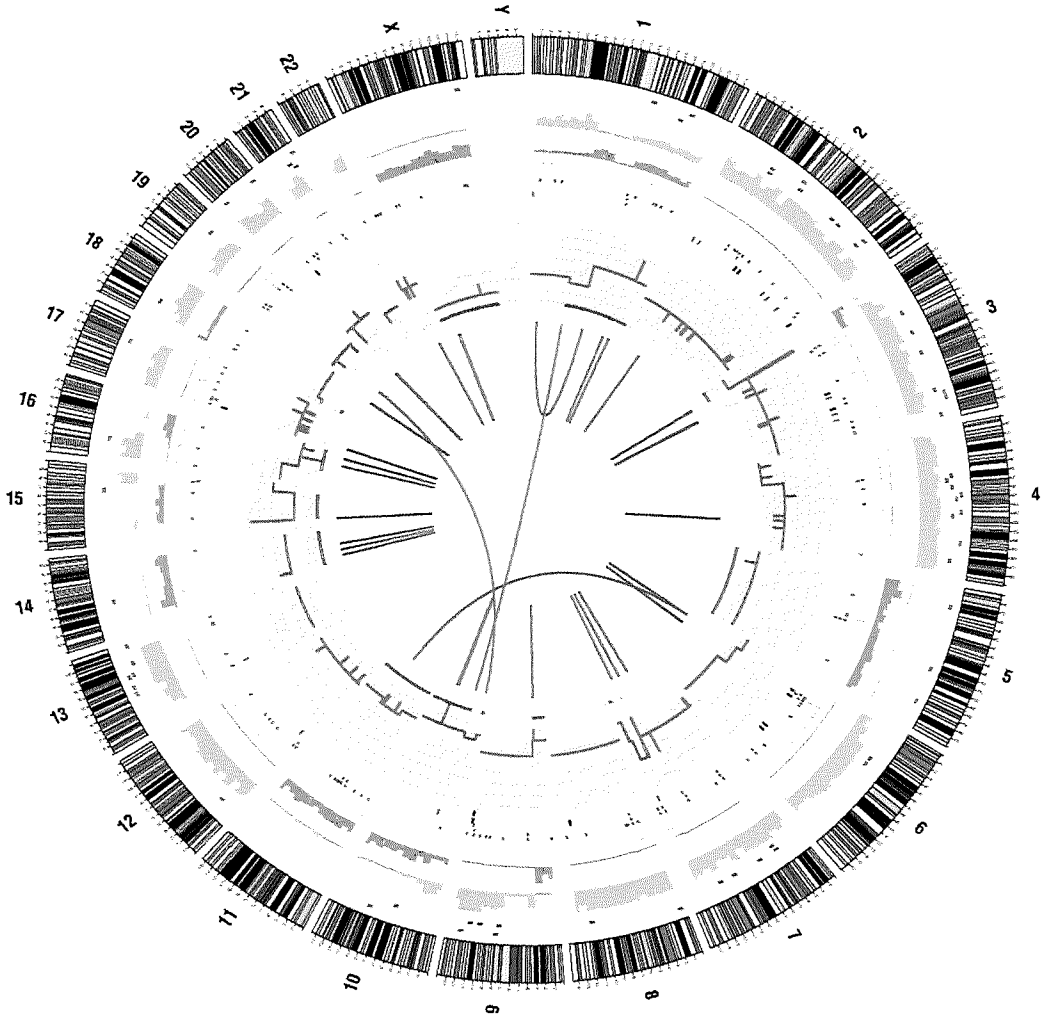
Catalogue of COLO-829 Somatic Variants



Ideograms / val indels / sn_{10M} / cdsn / cn /loh / sv

- 33,345 Single base substitutions
  - 286 coding
- 1018 small indels
  - 14 coding
- 37 Structural rearrangements
  - 34 intrachromosomal:
    - 25 deletions
    - 6 insertions
    - 2 duplications
    - 1 complex
  - 3 interchromosomal
  - 19 breakpoints in genes
- 198 changes in copy number

Oncology Discovery

Ovarian Cancer

Deadly

- 204,449 New cases annually; 124,860 deaths

Incurable

- Less than 40% are cured

Difficult Dx

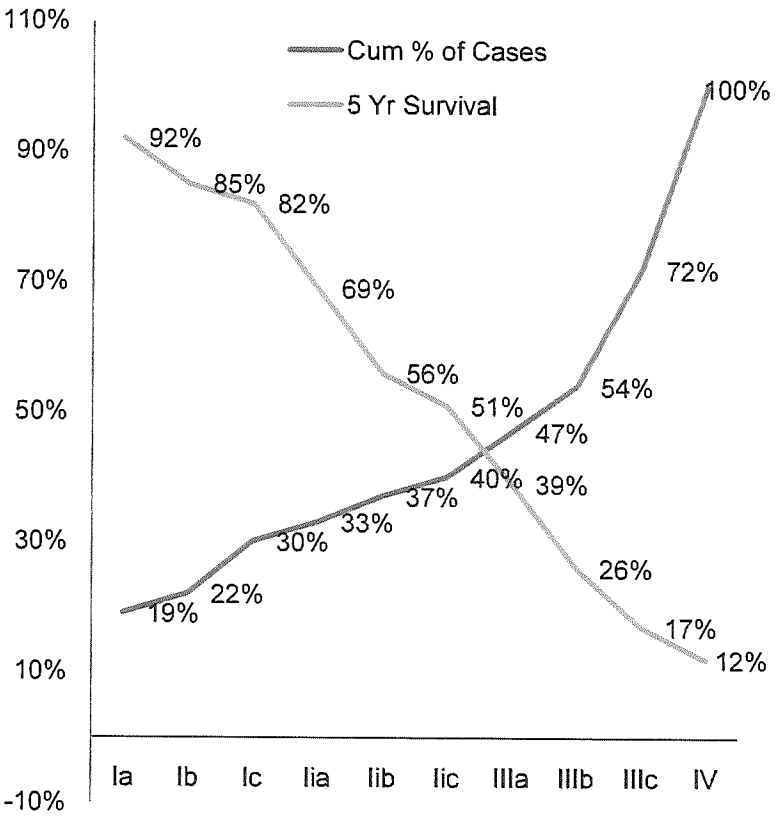
- Patients present with a suspicious/palpable mass

Early Dx is Key

- Five year survival is good if diagnosed early, but most patients are diagnosed late stage

Illumina Solution

- Develop a diagnostic assay which will diagnose ovarian cancer at an early stage



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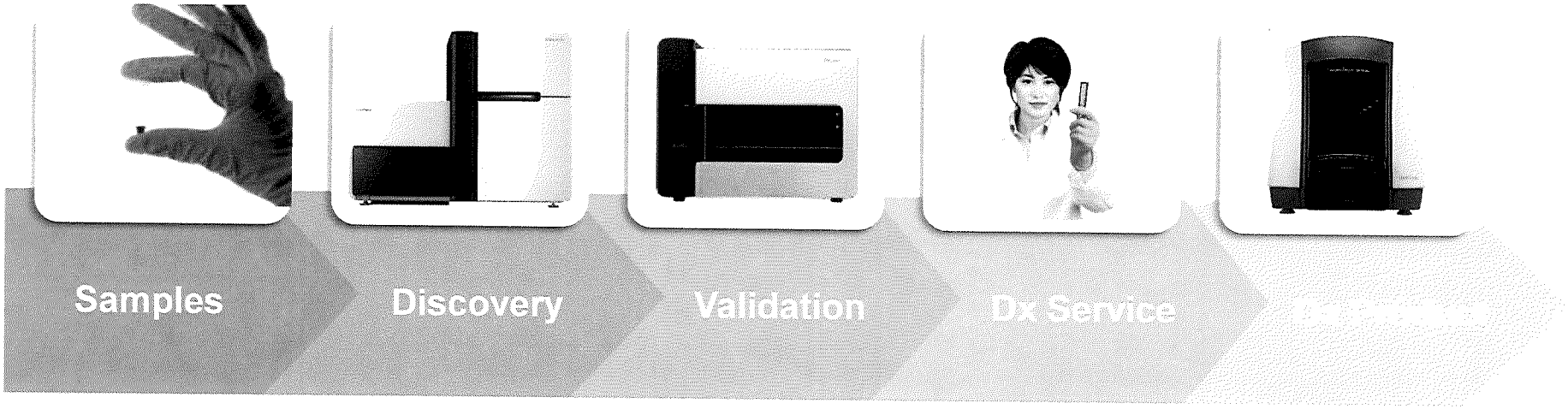
Ovarian Cancer Discovery

- Establish end-to-end workflow for sequencing, analysis, interpretation
- Refine analysis tools
- Sequence 25 tumour normal genome pairs (>30x depth)
- Identify genome wide catalogues of somatic mutation
- Search for mutational signatures, novel biomarkers, etc.
- Incorporate RNA and methylation data
- Gain experience in line with ICGC and similar projects

ILLUM-0649

Illumina's Oncology Discovery Initiative



ILLUM-0650

Clinical Partnership

Samples	Discovery	Validation	Dx Service	Clinical Partnership
• Obtain consent • Obtain samples • Prep samples • Build libraries	• 25 Tumor/ Normals • W GS • Methylome • Transcriptome	• 300 + samples • BeadChip analysis	• LDT in CLIA lab	• Prospective trials • CE- IVD • US IVD

Ovarian is here

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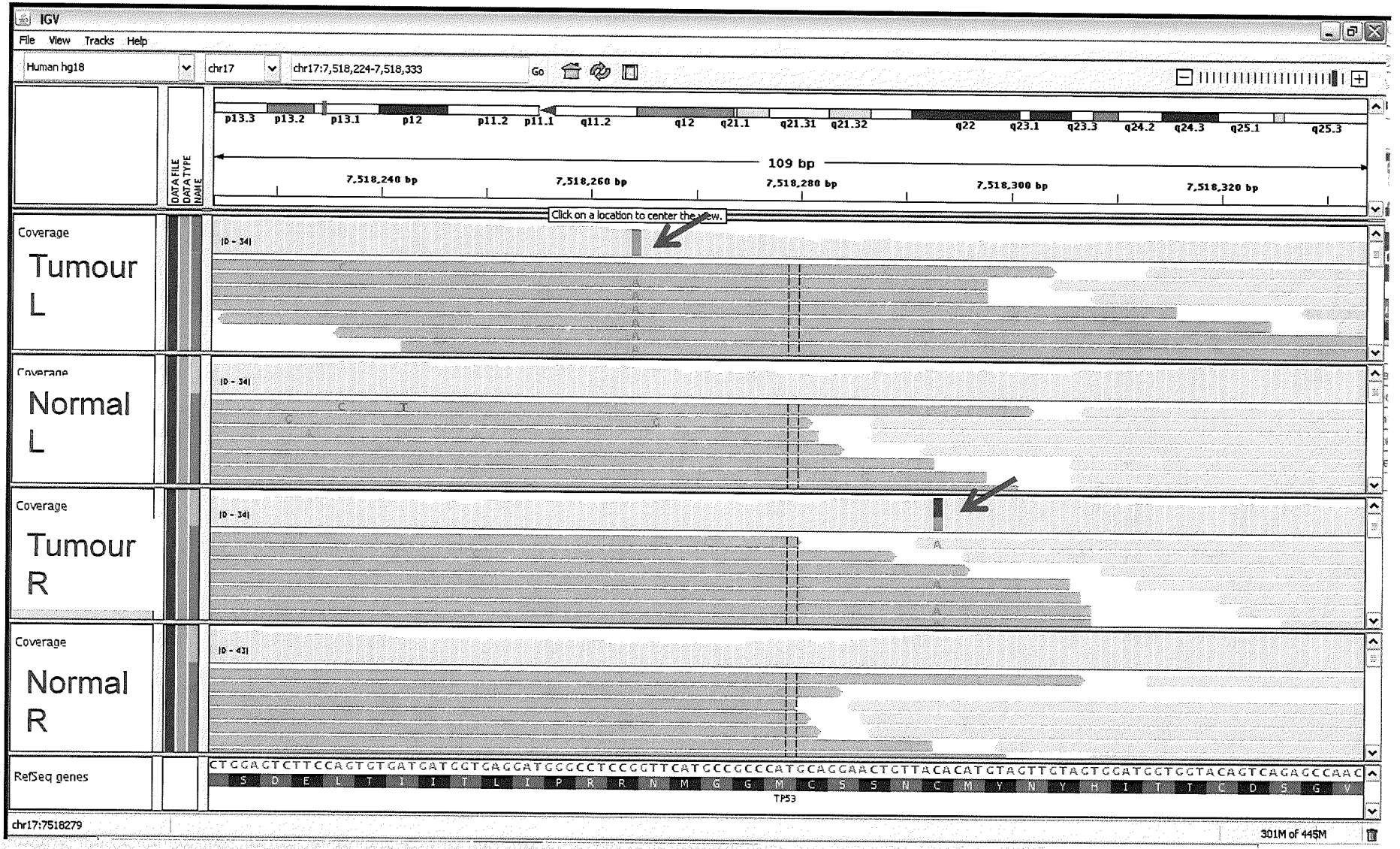
Cancer Genome Summary Statistics

Tumour	Tumour depth	Normal depth	Somatic gains
Melanoma 829	40.7x	32.5x	33,345
Breast 100	31.4x	29.0x	4,838
Ovarian A	40.5x	37.3x	7,147
Ovarian B	32.5x	35.1x	1,099,481
Ovarian C	38.0x	39.1x	4,284
Ovarian D	32.7x	37.2x	1,244
Ovarian E	36.2x	35.4x	3,727
Ovarian F	37.2x	29.7x	11,984
Ovarian G	30.4x	32.0x	3,091
Ovarian H	39.9x	35.0x	5,623
Ovarian I	34.8x	34.2x	8,824
Ovarian J	35.8x	39.9x	4,815

Tumour	Tumour depth	Normal depth	Somatic gains
Ovarian K	32.3x	33.0x	3,255
Ovarian L	32.8x	39.6x	3,093
Ovarian M	37.6x	42.9x	4,480
Ovarian N	38.3x	37.8x	6,698
Ovarian O	36.7x	30.1x	5,485
Ovarian P	35.9x	39.2x	3,489
Ovarian Q	34.7x	35.5x	5,584
Ovarian R	35.7x	33.9x	5,973
Ovarian S	34.5x	33.6x	2,154
Ovarian T	35.2x	33.3x	2,203
Ovarian U	38.1x	35.6x	2,881

ILLUM-0651

IGV visualisation of two variants in *TP53*



illumina Dx

ILLUM-0652

Summary of *TP53* somatic substitutions (SNVs)

- 14/17 high grade serous samples have *TP53* somatic substitution variants (SNVs) – further analysis of remaining samples ongoing
- Review vs. COSMIC:
  - All are in known *TP53* hotspots
  - All are novel observations in ovarian cancer
  - Two seen previously in other cancers
- *TP53* mutations reported in 97% of high grade pelvic serous carcinoma samples in a recent study (Ahmed et al 2010)

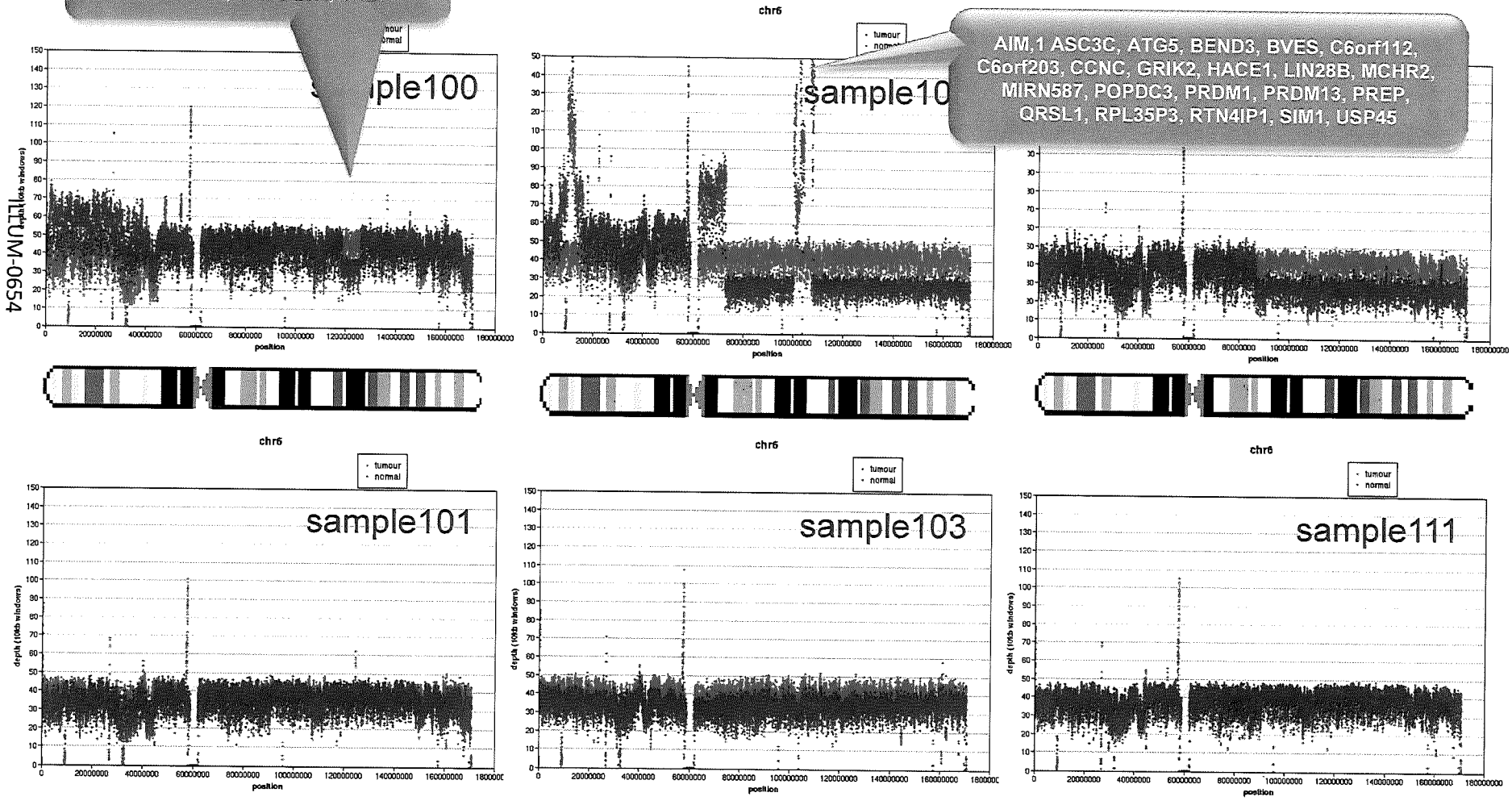
ILLUM-0653

Copy Number: Chr6

C6orf170, FABP7, GJA1, HSF2, NKAIN2 ,PKIB, RLBP1L2, SERINC1, SLC25A5P7, SMPDL3A, TRDN

Tumor
Normal

AIM,1 ASC3C, ATG5, BEND3, BVES, C6orf112, C6orf203, CCNC, GRIK2, HACE1, LIN28B, MCHR2, MIRN587, POPDC3, PRDM1, PRDM13, PREP, QRSL1, RPL35P3, RTN4IP1, SIM1, USP45



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Summary and Future Prospects

- A Genome-Wide Opportunity:
  - Comprehensive variant catalogues
  - >95% specificity and ~90% sensitivity of somatic substitutions
- System developments enable large-scale studies:
  - Chemistry, software improvements (>99.9% raw data accuracy)
  - HiSeq2000 platform (>300 Gb per run: two 30x genomes per instrument per week)
- Implications for individual genome sequencing:
  - Understanding disease mechanism, biomarker discovery
  - Sequencing individual cancer genomes for personalised treatment

ILLUM-0655

Many Thanks…

…to all our Collaborators…

…and the Illumina teams...

ILLUM-0656

EXHIBIT 2

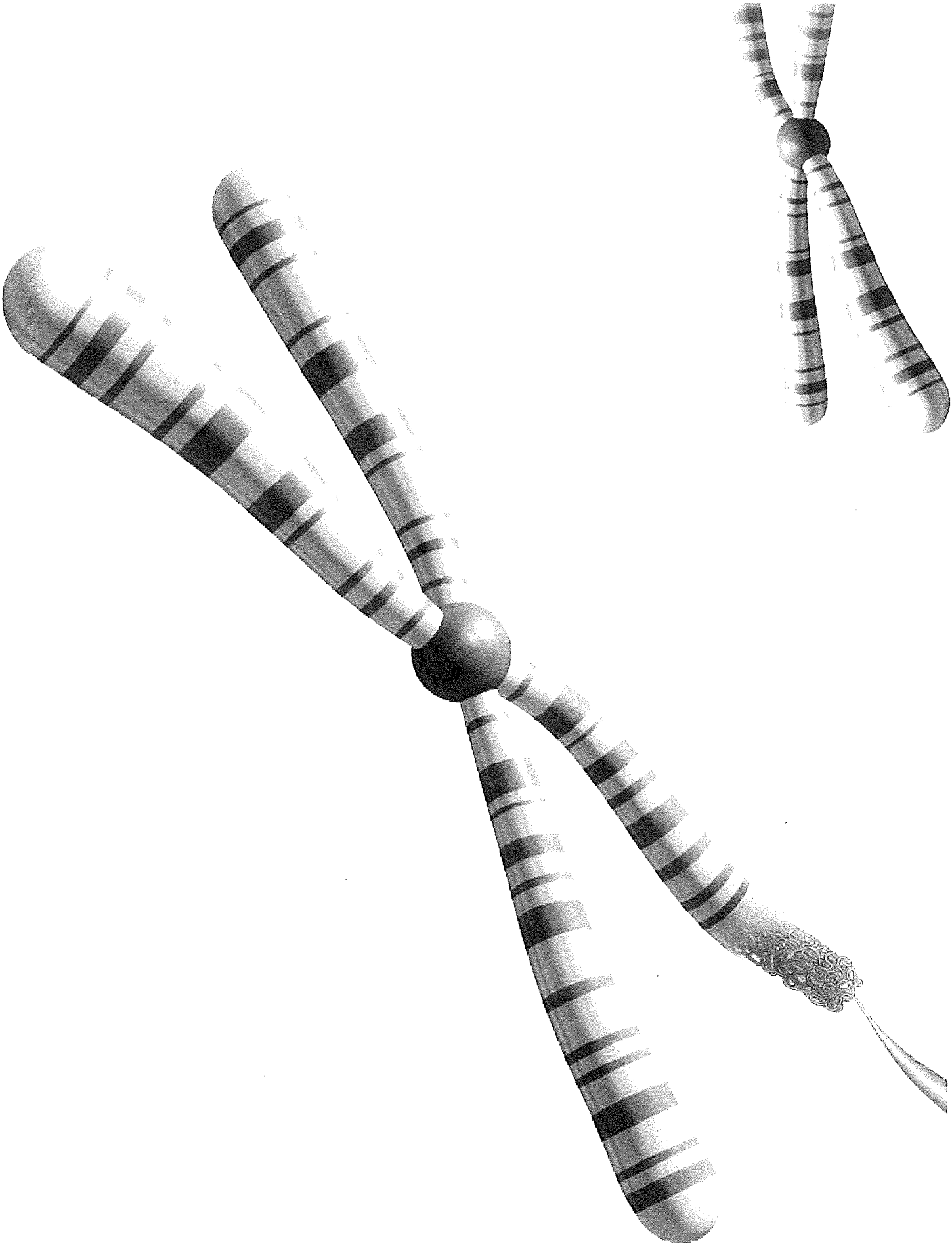
(Part II of II)

OF

DECLARATION OF GREGORY F. HEATH

Getting high-quality cytogenetic data is a SNP.

illumina®



SNP data. Increased insight.

Cytogenetics is at the forefront of the study of cancer and congenital disorders. And we put you at the forefront of cytogenetics.

Illumina SNP array technology combines genotype and intensity information to detect chromosomal abnormalities. This gives you a tool for detection of chromosomal aberrations and the ability to identify abnormalities that other arrays cannot recognize.

See the data from every angle. Get better data quality and reproducibility. Simplify your workflow with automation options.

Get better results faster.
Add SNPs to your data.

› To learn more, visit
www.illumina.com/cyto

More information. Superior detection.

Informative markers. High resolution. With the powerful combination of genotype and intensity information provided by Infinium® HD BeadChips, you can profile both copy number variation and copy-neutral events, and also identify important factors such as mosaicism that can elude standard cytogenetic analysis.

Get complete coverage with meticulously selected SNPs and probes for superior detection of:

- Amplifications and deletions
- Loss of heterozygosity (LOH)
- Uniparental disomy (UPD)
- Mitotic recombination
- Gene conversion events
- Unbalanced translocations

Infinium HD BeadChips are suited to all cytogenetics applications, including studies of developmental disorders and cancer. With unmatched genomic coverage and specific targeting of important known regions, you don't have to choose between focused and broad arrays.

Intelligent Marker Selection

SNP genotyping markers are preferred because they provide greater information and are more robust for finding cytogenetic aberrations. The SNP markers on Infinium HD BeadChips are supplemented with intensity-only non-polymorphic probes to ensure a high-density backbone and enhanced coverage of high-value regions. SNP marker information generates higher signal-to-noise ratios for copy number calculations. This means accurate detection and identification of even minor events.

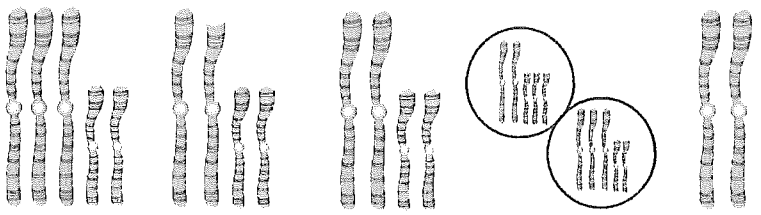
Highly Reproducible Data

All Infinium HD products have high feature redundancy and contain sample-dependent and sample-independent internal controls, so you can have complete confidence in your data. Multi-sample formats supported by high-density arrays minimize array-to-array processing variability, reduce handling errors, and allow more efficient scanning.

Quality-controlled Arrays

Unlike oligo arrays that are synthesized one at a time, Infinium bead pools are shared across months' worth of product, providing unparalleled consistency. During the array manufacture process, features on every BeadChip are positionally verified, and all quality metrics must be passed before shipping.

DETECT A WIDE RANGE OF CHROMOSOMAL ABNORMALITIES



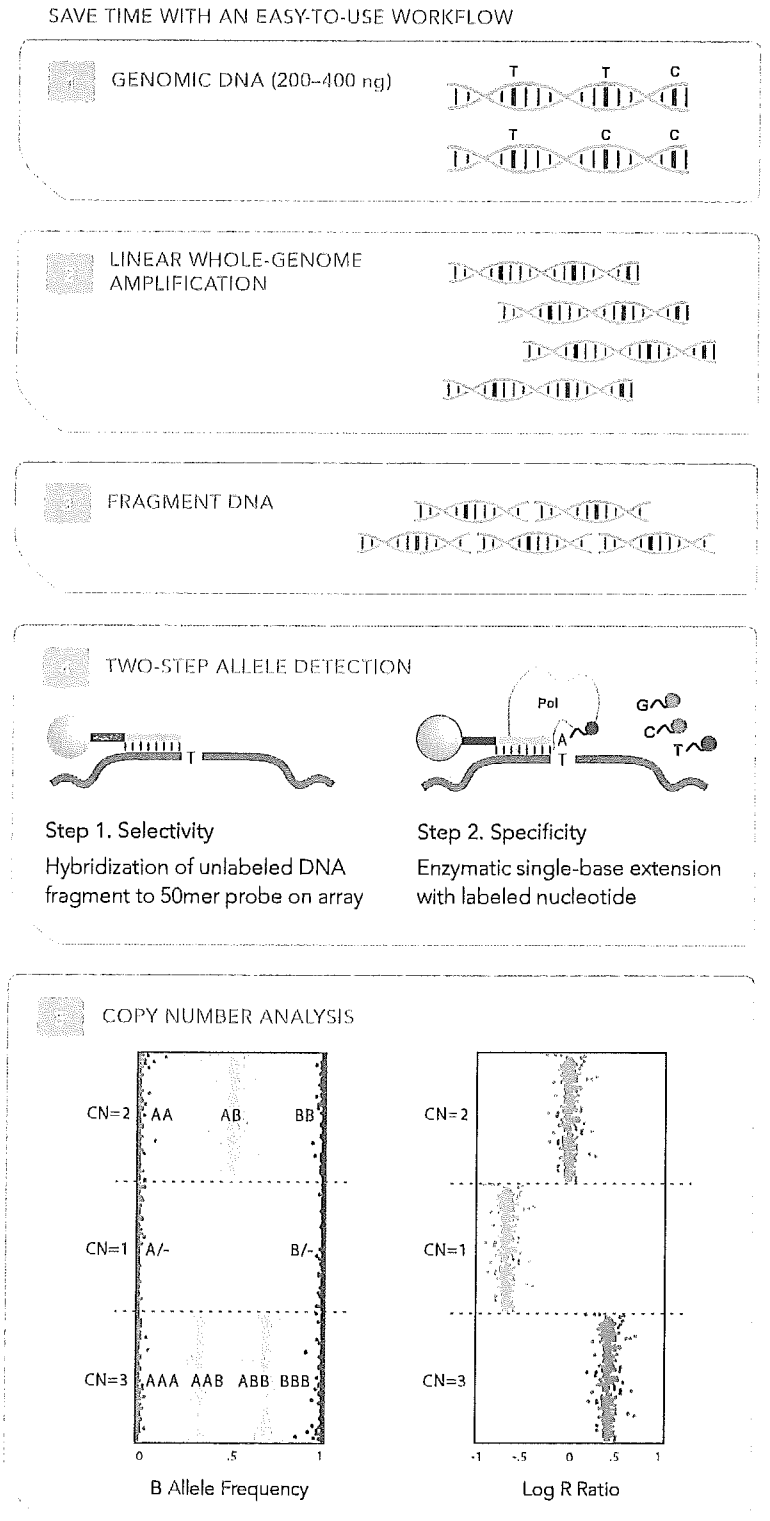
	MEDIAN MARKER SPACING	RESOLUTION	ANEUPLOIDY	UNBALANCED TRANSLOCATION	AMPLIFICATION/ DUPLICATION	MOSAICISM	COPY-NEUTRAL LOH
Infinium HD BeadChips	1.5 kb–6 kb	8 kb–30 kb	✓	✓	✓	✓	✓

ILLUM-0194

Robust assay. Simplified workflow.

Ease of use. Automation options. The Infinium Assay features single-tube sample prep and amplification without PCR or ligation steps. Our streamlined protocol and reagent sets save you time and reduce sample handling errors. And since we use familiar molecular biology techniques, transitioning from your existing technology is easy.

The three-day assay protocol requires less than two hours hands-on time to process four multi-sample BeadChips (less than one hour for automated processing). For high-throughput operation, we offer modular automation options. A customized liquid-handling robot provides assay automation, and the AutoLoader2 allows 24-hour-per-day unattended scanning. Add Illumina LIMS control to maximize accuracy and throughput.



ILLUM-0195

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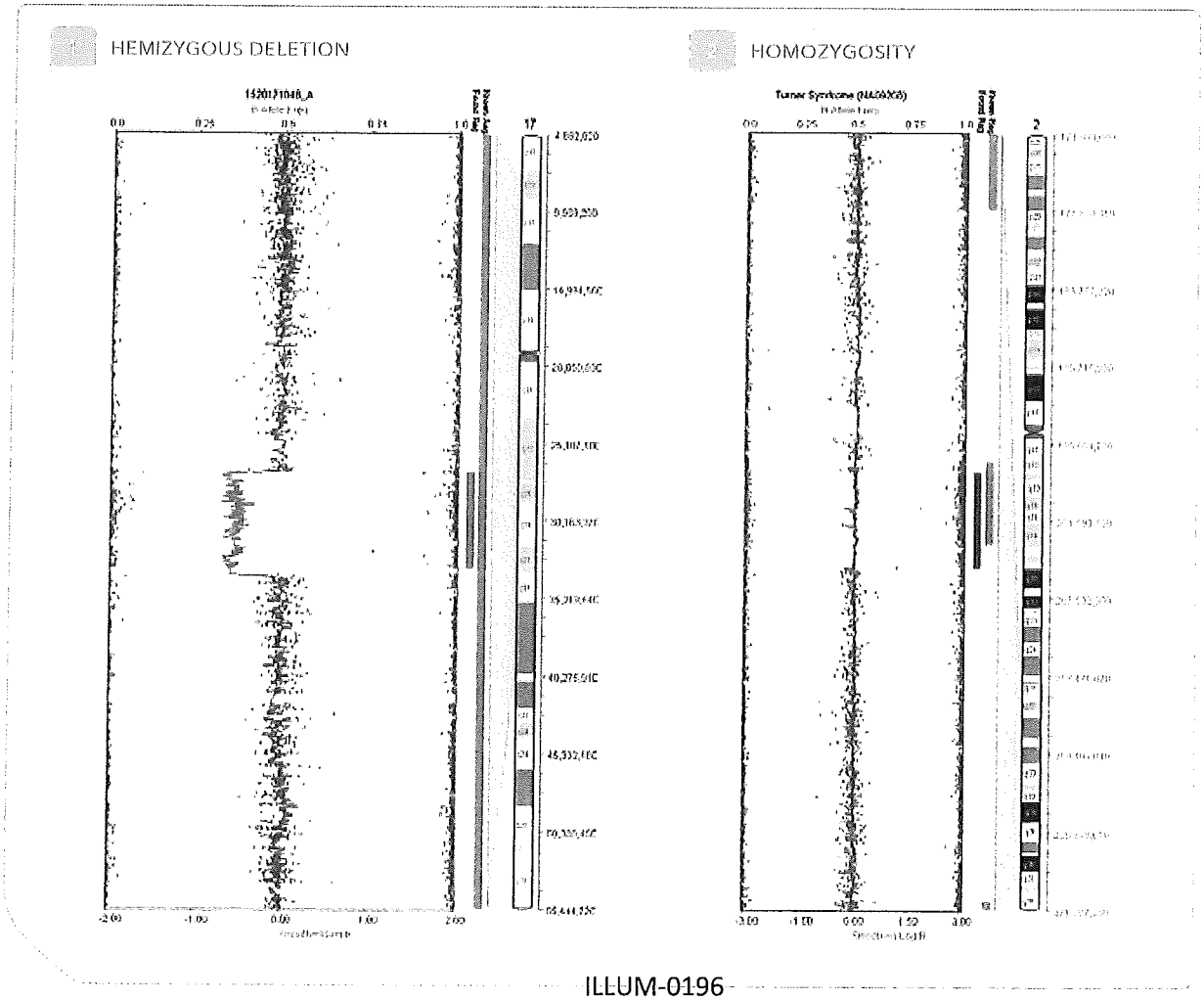
Efficient identification. Intuitive analysis.

Customized views. Convenient software. Developed in collaboration with molecular cytogeneticists, our KaryoStudio software package offers user-friendly, intuitive analysis of Infinium HD data.

Quickly and efficiently identify important structural aberrations, match these to known aberrations, and generate reports based on your findings. Customize analysis by using a standard region list or specific regions and phenotypes for cross-matching. Link out to external resources, such as the Database of Genomic Variants, UCSC genome browser, and DECIPHER. KaryoStudio gives you the right set of features in a streamlined workflow.

For more information about KaryoStudio, including a demonstration video, visit www.illumina.com/karyostudio

RAPIDLY SCAN FOUND REGIONS WITH KARYOSTUDIO



Worldwide coverage. Personalized service.

We partner with you to complete the installation and training process, and this personalized support continues long after your initial training. One call to our Technical Support group puts you in touch with a team of Ph.D. scientists who are experts on Illumina systems, assays, and software. Our dedicated service and support teams give you peace of mind to focus on the biology.

To learn more, visit www.illumina.com/support

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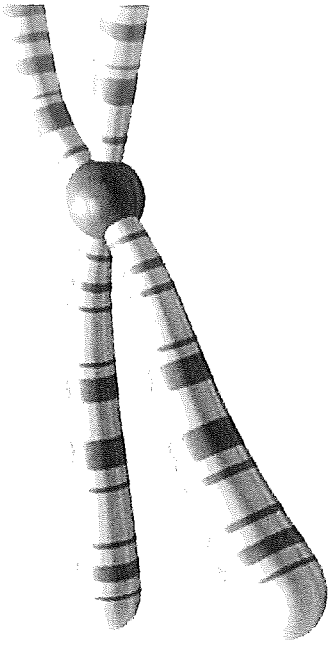

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Pub. No. 372-2009-008 current as of 16 June 2009

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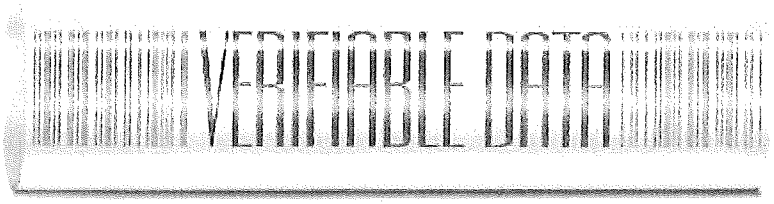


The difference
between
good data
and great data
is in the code.

veracode
BY ILLUMINA

illumina

VeraCode® technology. A digital revolution.

Illumina's unique VeraCode digital holographic code technology delivers unparalleled data quality for a multitude of bioassay formats. Precision and verifiability—that's the promise contained in every VeraCode microbead.

Unique code technology

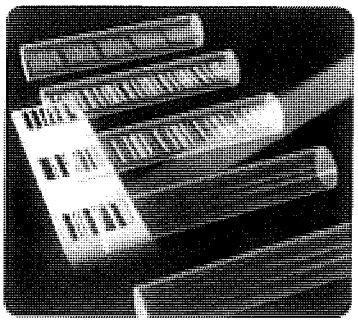
VeraCode's breakthrough technology is based on the use of cylindrical glass microbeads that:

- Measure 240µm in length x 28µm in diameter
- Contain a unique holographic code
- Are highly stable
- Provide information, such as target of interest in multiplex assays
- Enable tracking of critical identifiers
- Can easily carry high-density codes (24-bit), for virtually unlimited bead types

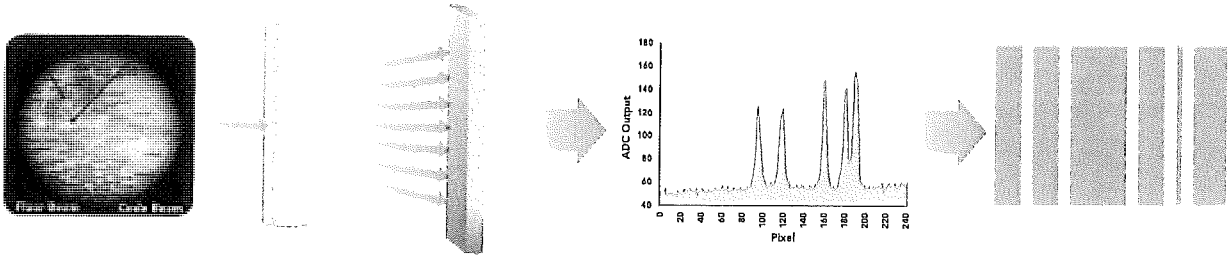
Making the code

The VeraCode digital code uses a patented holographic inscribing and detection process:

- The center of each bead supports a nanometer-scale, permanent change to index of refraction when exposed to ultraviolet light
- This index change forms a hologram that is imprinted via a local structural change of the glass matrix
- Successive writing of holograms into one microbead produces a specific pattern, or holographic code



Each Illumina VeraCode bead contains a code that identifies the bead type. This information is combined with the assay readout for downstream analysis.



Code detection

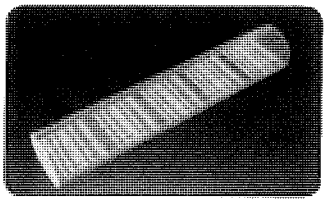
The holographic code image in each microbead diffracts an incident laser beam into multiple components. These components make up the optical "signature" of the bead code, which can be read using a CCD camera contained within the BeadXpress® Reader.

100% verifiability means true precision.

Imagine the possibilities

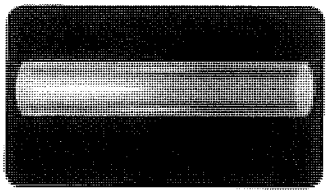
This versatile technology is the solution for applications that benefit from robust, multiplex-based testing methods. With a number of unique product offerings by Illumina, you can apply the code to fit your project needs.

- Biomarker research and validation
- Pharmaceutical development
- Industrial testing
- Agriculture
- Clinical research
- Molecular diagnostic assay development



Why the code?

The unique digital holographic code contained within each VeraCode microbead enables customizable tracking of multiplex assay markers and critical identifiers such as sample ID, laboratory ID, and reagent kits. Up to 24 bits of information inscribed in each code allows for an unprecedented level of error checking, improving the robustness of the optical readout process and providing a level of reliability that sets a new standard in multiplex testing.



Why the glass?

The high-purity silica glass used to make VeraCode microbeads has physical properties that make it an ideal substrate for attachment of biomolecules. The beads' surface chemistry enables easy development of a wide variety of nucleic acid and protein-based assays. The glass purity also minimizes any fluorescent background, so there is no interference with readout, providing a highly stable platform for reliable and reproducible results.

veracode BY ILLUMINA

A breakthrough in multiplex range and assay flexibility.

VeraCode is the technology solution that grows with your needs and remains relevant during dynamic changes in your research pursuits.

Flexible multiplexing range

Whether you need a single-plex antibody detection assay or a 384-plex genotyping assay, VeraCode is the only technology to offer true multiplexing and assay versatility on one platform, providing researchers with a single powerful solution capable of meeting all of their assay needs.

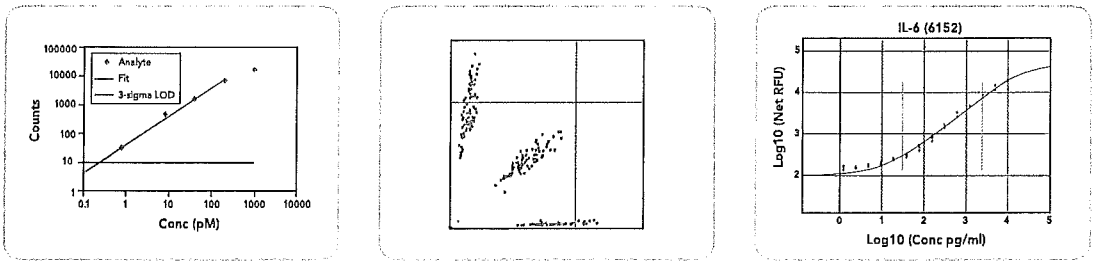
- 1- to 384-plex-per-sample range is ideal for the development of focused research assays
- Multiplexing levels are achieved by simply pooling uniquely coded beads
- VeraCode microbeads use non-overlapping bead codes providing highly specific detection and unequalled precision

Unparalleled assay flexibility

The glass surface of the VeraCode microbeads provides a single, flexible platform for the development of numerous types of solution-based bioassays with the power of microarrays. Existing applications for VeraCode include, but are not limited to:

- Genotyping
- Gene expression
- Protein-based assays

Unmatched versatility in both multiplexing levels and assay applications



Perform multiple assay applications—such as SNP genotyping, gene expression, and protein-based assays—all on a single platform.

Multiplexed assay applications

GoldenGate® genotyping

Illumina has adapted the proven power and flexibility of its GoldenGate Assay for use with the VeraCode technology. The GoldenGate protocol enables:

- Simultaneous genotyping of 96 to 384 SNPs for each sample in a 96-well microplate
- A high degree of multiplexing throughout successive extension and amplification steps
- Minimization of time, volume, and material requirements
- Call rates, reproducibility, and heritability rates >99.9%

Universal capture beads

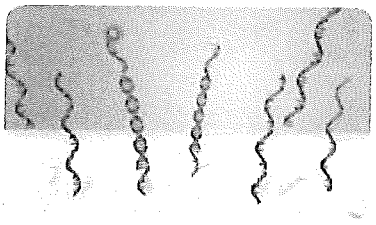
Design your own customized nucleic acid–based assays using VeraCode Universal Capture Bead sets. Each set features a unique oligonucleotide capture sequence and allows easy selection of multiplexing level by simply pooling different tubes of uniquely coded beads.

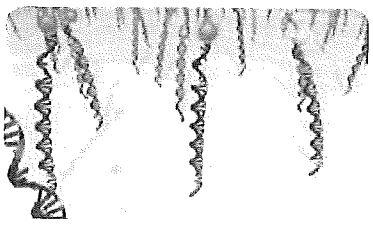
- Unique oligonucleotide bead types offer one-of-a-kind code identifiers
- High-density capture oligonucleotides immobilized on the microbeads provide a flexible and open platform for assay development
- Pre-screened capture sequences avoid cross-reactivity within genome

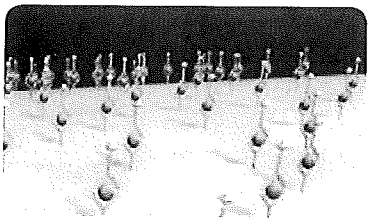
Carboxyl beads

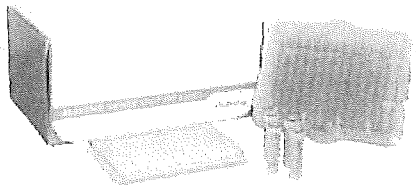
The VeraCode Carboxyl Bead sets provide a powerful and open base for the development of protein-based assays by enabling the immobilization of specific capture antibodies on a coded carboxyl bead surface, thereby offering a limitless range of assay possibilities.

- Custom multiplex levels are achieved by pooling different tubes of uniquely coded carboxyl microbeads
- Superior low-end precision delivers highly sensitive assays
- Proven sensitivity and specificity demonstrated in a 10-plex cytokine assay









Assay bead kits are conveniently packaged for specific applications.

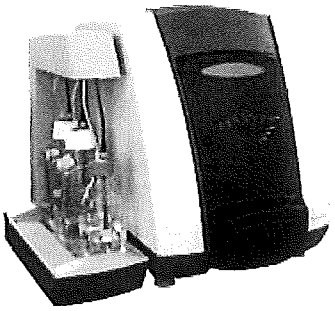
veracode BY ILLUMINA

Extraordinary accuracy and reliability.

The BeadXpress Reader

Assays developed for the VeraCode microbeads are analyzed with Illumina's patented BeadXpress Reader, a high-throughput, two-color laser detection system designed to be compatible with standard laboratory automation. The key features of the BeadXpress system include:

- A fluidic system and reagent carrier that enable the scanning of multiple plates per day without the need to refill system buffers
- An open-platform, two-color laser detection bioassay system that supports the development of single-color assays such as Allele Specific Primer Extension (ASPE), as well as two-color assays such as Illumina's GoldenGate Assay
- Rapid sample throughput rates of 120 samples / hour at 10-plex and 80 samples / hour at 96-plex
- Analysis of standard 8-well strips or 96-well plates



The Illumina BeadXpress Reader employs a dual-color laser detection system to identify and analyze each VeraCode bead.

beadxpress

Robust performance

VeraCode microbeads provide a highly stable platform. Assays developed with VeraCode microbeads typically include 25 to 30 replicates of each bead type so the data generated is particularly robust. Using the BeadXpress system, VeraCode microbeads are:

- Optically sampled up to a dozen times each, providing about 300 independent data points for each analyte
- Randomly arrayed in the groove cell to minimize scanner errors
- Inscribed with up to 24 bits of information; the initial bits in a code sequence are used for error checking, thereby greatly improving the reliability of the readout and results

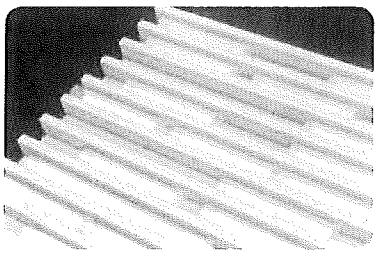
Powerful and friendly analysis software

Powerful VersaScan Software provides user-friendly customization of scanning protocols and is compatible with Illumina's proven BeadStudio Data Analysis Software.

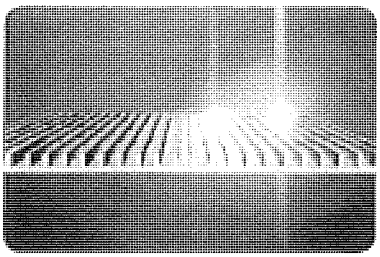
- Enables acquisition and viewing of intensity data, report generation, and data extraction for application-specific data analysis modules
- Generates *.csv and *.idat files for data export to Illumina BeadStudio or third-party data analysis programs

Get into the groove.

One of the patented technologies developed to enable the rapid and accurate readout of the VeraCode microbeads is the transparent groove plate. The groove plate forms the bottom of a fluidic cell that has 8 chambers, one for each well in a column of a standard 96-well plate. Through a unique combination of fluid flow, gravity, and capillary force, the VeraCode microbeads enter the groove plate cell and align closely within the grooves.



Once aligned, the entire cell is read by the optical system for fluorescent measurement and code classification. This approach creates a spatially random array of particles at a high packing density that enables rapid and accurate detection of the unique bead codes and the assay-specific fluorescence results.



Service that's always 100% Illumina.

With your purchase, Illumina will ensure that your BeadXpress system is properly installed and qualified, and will provide ongoing maintenance and service. Illumina also offers:

- Unlimited support by phone from Technical Support Scientists
- A variety of Service Contracts to meet the specific needs of your laboratory
- Customized training packages with our skilled Field Applications Scientists

VeraCode technology.

The difference between good data and great data is in the code.

The revolutionary VeraCode system, with its unique digital holographic code technology, offers:

- Unmatched data precision and verifiability
- Robust performance and customizable tracking
- A flexible single platform for numerous bioassay formats, including genotyping, gene expression, and protein-based assays
- An ideal solution for low- to mid-plex levels: 1 to 384 targets / samples in a single well
- Rapid and accurate high-throughput, two-color laser detection system
- User-friendly analysis software

Learn more at
www.illumina.com/beadXpress

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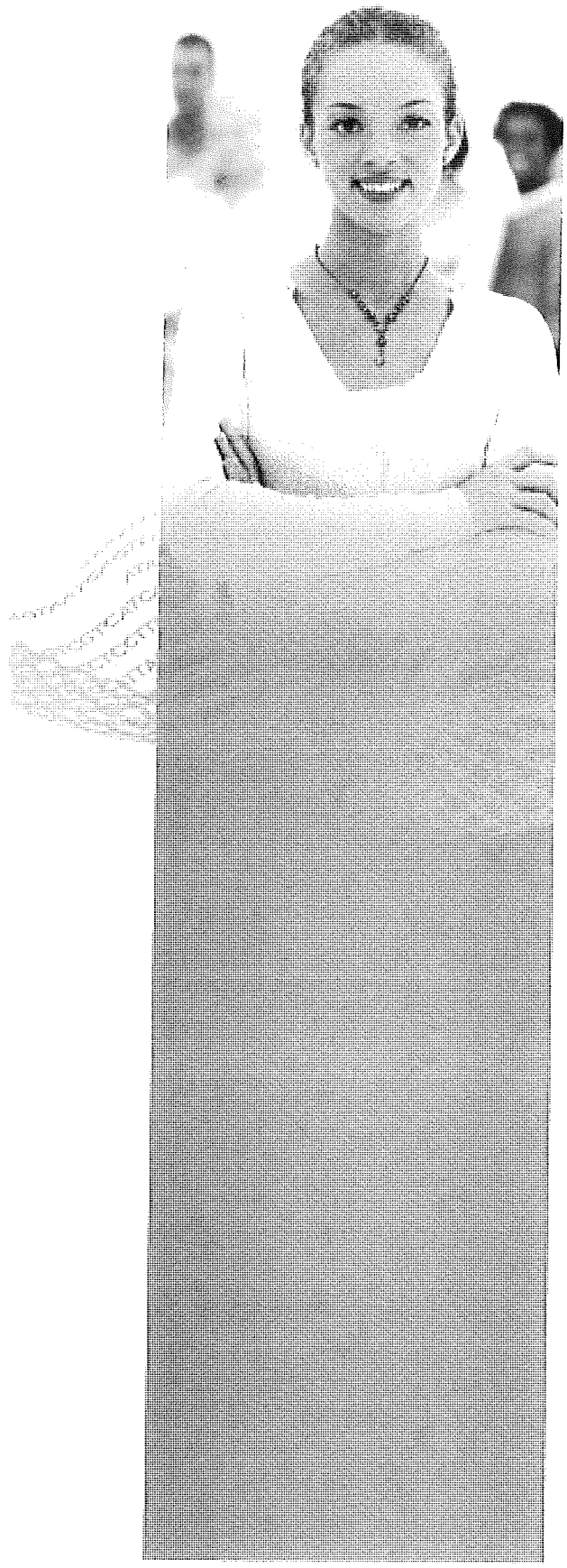


We've got you covered.

The VeraCode® ADME Core Panel.

ILLUM-0218

illumina®

Potential life-saving drug?

Or a blind alley?

That's what you need to find out during pharmacogenetic studies.

Relying on the VeraCode ADME Core Panel and the BeadXpress® Reader will help you assess the genetics behind drug absorption, distribution, metabolism, and excretion (ADME). Investigating associations to drug response, dosing, and safety.

Helping you introduce drugs to market sooner. Bringing personalized medicine closer to reality.

Quickly. Efficiently. Precisely.

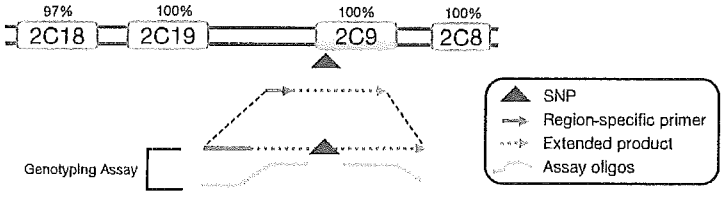
illumina®

Quality counts.

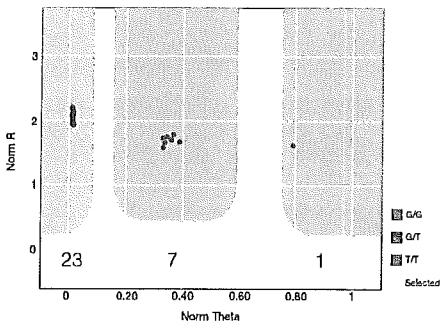
Not only does the VeraCode ADME Core Panel provide more than 95% of key ADME Core content, it also delivers the highest quality data. More than 99.5% concordance. More than 99.5% reproducibility.

Plus, Illumina assay chemistry precisely targets critical ADME content, addressing homologous regions. The information you get will be more precise. The decisions you make more informed.

PRECISELY ADDRESSING HOMOLOGOUS REGIONS



CYP2C9*2 (R144C)



The CYP450 gene family includes a tetrad of closely related genes: CYP2C18, CYP2C19, CYP2C9 and CYP2C8. Using an upfront targeting approach, a specific gene of interest can be pulled out from the genome, avoiding other homologous regions, and can be analyzed precisely with excellent discrimination.

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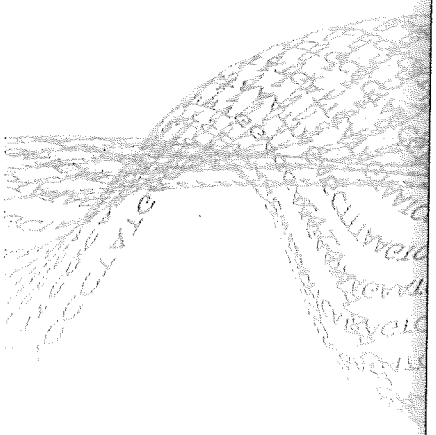
More of what's important.

Make your metabolism studies more efficient. Get drugs to market faster. Improve human health.

The VeraCode ADME Core Panel offers a better path to metabolism studies. The most complete coverage of critical content. Highest quality data. Simplest, fastest workflow. More core.

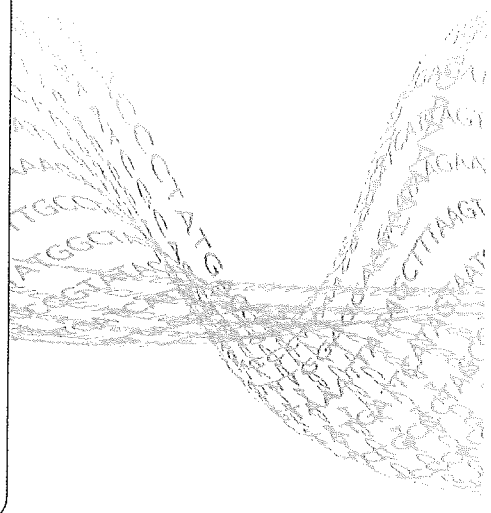


ADME CORE GENES (34 GENES)

ABCB1	CYP2C19	DPYD	SLC22A1	TPMT
ABCC2	CYP2C8	GSTM1	SLC22A2	UGT1A1
ABCG2	CYP2C9	GSTP1	SLC22A6	UGT2B15
CYP1A1	CYP2D6	GSTT1	SLCO1B1	UGT2B17
CYP1A2	CYP2E1	NAT1	SLCO1B3	UGT2B7
CYP2A6	CYP3A4	NAT2	SLCO2B1	VKORC1
CYP2B6	CYP3A5	SLC15A2	SULT1A1	

The essential genes that populate the VeraCode ADME Core Panel include several with well-known associations to model drugs. For example, CYP2D6 has been associated with the metabolism of certain antidepressants, antipsychotics, cancer drugs like Tamoxifen and many others, CYP2C19 has been associated with the metabolism of the anti-platelet Plavix, and CYP2C9 and VKORC1 are most well known for their association to warfarin sensitivity.

For a detailed VeraCode ADME Core SNP list, please contact your account manager or visit www.illumina.com/veracodeADME.



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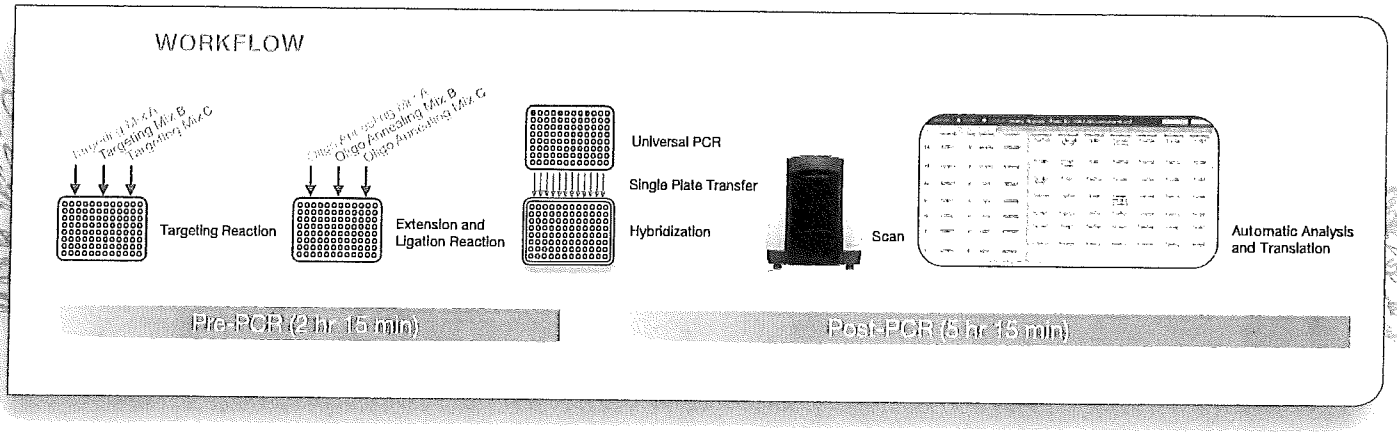
Speed matters.

One day. Why wait longer when you can analyze key ADME content in under 8 hours? The simple workflow, with built-in sample tracking and internal controls, accelerates your studies. The easy-to-use software interface manages a run from setup through data analysis and translation. It even provides useful reports.



Simple workflow.

An initial extension with biotinylated primers specifically targets regions of interest. Products are captured onto paramagnetic particles for allele-specific primer extension and ligation followed by universal PCR. A single plate transfer hybridizes amplified material to VeraCode Beads for scanning on the BeadXpress Reader. Thirty-four genes are assayed within 8 hours with less than 2.5 hours of technical hands-on time. Quickly. Efficiently. Precisely.

Let the coverage begin. Learn more at
www.illumina.com/veracodeADME

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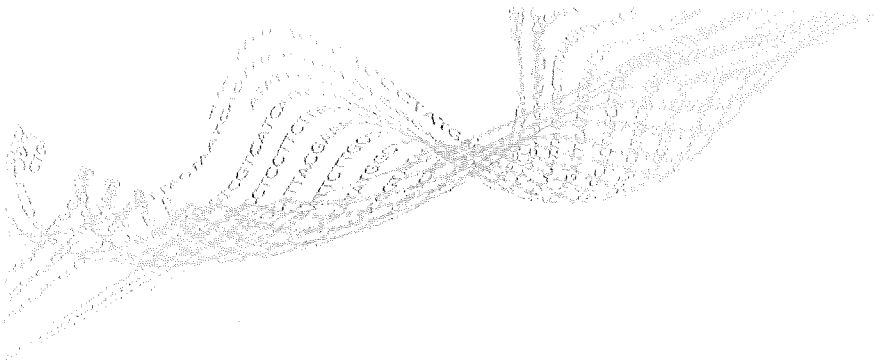

Learn more at www.illumina.com/veracodeADME

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Pub No. 182-2010-001 Current as of 10 March 2010

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BeadXpress® System

Illumina's BeadXpress system is an FDA-cleared in vitro diagnostic* device for the simultaneous detection of multiple analytes in a sample utilizing VeraCode® holographic microbead technology.

Highlights

- **Broadest multiplexing range:** Supports simultaneous detection of multiple analytes, from one to several hundred
- **Assay versatility:** Performs a wide range of applications, including DNA, RNA, and protein-based assays on a single platform
- **Superb data quality:** Enables industry-leading measurement density and sensitivity through the stringency of code detection
- **Dual-color laser system:** Analyzes single as well as true dual-color detection assays

Introduction

Illumina's BeadXpress Reader was specifically developed to analyze bioassay applications using the versatile VeraCode technology. With the broadest multiplexing range in the industry, the BeadXpress Reader is the optimal solution for small and high-throughput laboratories conducting molecular testing applications that benefit from robust, multiplexed-based assays.

VeraCode technology presents a digital revolution for multiplex testing in genotyping, gene expression, and protein-based assays. The unique holographic code embedded in each VeraCode bead type delivers unparalleled data quality by enabling customizable tracking and providing an unprecedented level of data precision and verifiability.

Versatile and Robust

The BeadXpress Reader employs a dual-color laser detection system to identify the unique holographic code embedded in each VeraCode microbead and to detect the signal intensity associated with each bead. Because assays developed with VeraCode microbeads typically include up to 30 replicates of each bead type, the data generated by the BeadXpress Reader is particularly robust. For every sample, each microbead is optically scanned up to a dozen times, providing up to 300 independent data points for each analyte.

In addition to providing outstanding data quality for a broad spectrum of bioassays, the dual-laser BeadXpress Reader enhances the versatility of VeraCode technology by supporting robust single-color detection assays as well as two-color assays.

High Throughput

The BeadXpress Reader draws up eight samples at a time from a standard 96-well plate or 8-well strip and loads them onto the eight-chambered transparent groove plate that forms the bottom of the system's fluidic cell. Illumina's proprietary groove plate design creates a high-density, fixed array of microbeads amenable to rapid and accurate scanning. Through a unique combination of fluid flow, gravity, and capillary force, the VeraCode microbeads efficiently populate the groove plate and align closely within the grooves. Once the beads are aligned, the entire fluidic cell is actuated across the optical system and scanned for fluorescent intensity and code classification.

A two-color, ten-plex VeraCode assay can be scanned at a rate of 120 samples per hour, a 96-plex assay at a rate of 80 samples per hour. During scanning, the BeadXpress Reader acquires fluorescence data and associated code data for each microbead, compiles a virtual representation of the 96-well plate, and exports the data for downstream analysis with Illumina's VeraScan software.

Figure 1: BeadXpress Reader

The Illumina BeadXpress Reader employs a dual-color laser detection system to identify and analyze each VeraCode microbead.

*FDA cleared for in vitro diagnostics with specific VeraCode FDA cleared tests.

Powerful and User-Friendly Analysis

Through a user-friendly graphical interface, VeraScan software allows control of the BeadXpress Reader, enabling users to load assays, perform real-time scans, and view scan data for up to 96 samples per run. The software is ideal for clinical laboratories as it includes administrator control of setting user specific accounts and rights, configuration of default file locations, and security options, including alerts via email. It also offers user-friendly customization of scanning protocols, enables acquisition and viewing of intensity data, report generation, and allows data extraction for application-specific data analysis modules. The software can also export data via *.csv and *.idat files.

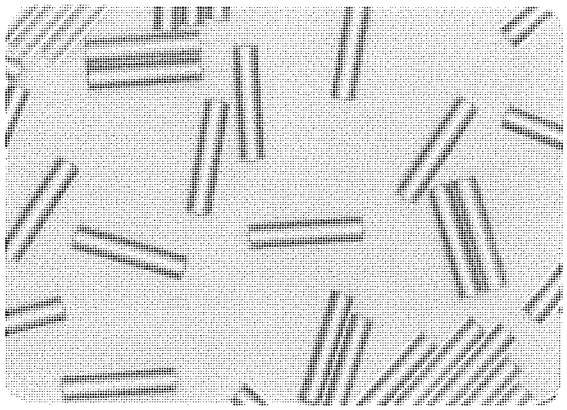
Complete System

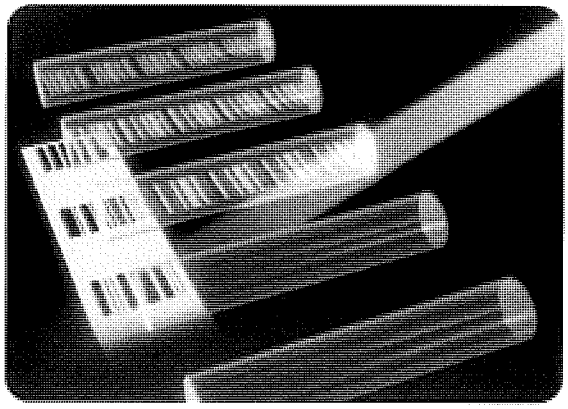
Included in the purchase of a BeadXpress Reader are:

- **1-year limited warranty**
- **PC**
- **VeraScan software**
- **BeadXpress starter kit, which includes a VorTemp incubating plate mixer and the VeraCode bead kitting system**
- **Onsite training by a field applications scientist**

The BeadXpress System

Figure 2: VeraCode MicroBead





VeraCode technology uses cylindrical glass microbeads measuring 240 microns in length by 28 microns in diameter, each inscribed with up to 24 bits of information. Millions of unique bead types can be made by embedding a limited number of unique combinations of overlapping holograms.

Illumina Systems and Software

BeadXpress Reader Specifications

Specifications	Requirements
Environmental Conditions	For indoor use only
	Altitude up to 2400 m
	Temperature range 15°C to 30°C
	Humidity: 20 to 80% RH
Electrical Ratings	90–260 V (AC), 2.0 A, 50/60 Hz, Class I
Physical Conditions	Overall dimensions: 47 cm (W) x 77 cm (D) x 62 cm (H)
	Weight: 57 kg
Laser Classification	Class I laser instrument housing two internal Class 3B lasers (IEC 60825-1, 1.2, 1993)
Laboratory Space	BeadXpress Reader: 47 cm (W) x 77 cm (D) x 72 cm (H)
	PC, keyboard, and monitor: 46 cm (W) x 40 cm (D)
	Sturdy bench that is level within ± 2 degrees
Access to Receiving Dock	BeadXpress Reader shipping crate: 76 cm (W) x 96.5 cm (D) x 86.5 cm (H)
	BeadXpress Reader shipping weight: 160 lbs
	PC box size: standard
	PC, keyboard, and monitor shipping weight: 60 lbs
	Waste container
	Note: Shipping weights include pallets
Power	Dedicated circuit
	BeadXpress Reader (110V): 15 A
	BeadXpress Reader (220V): 12 A
	Note: This includes the power needs for the PC; the BeadXpress Reader itself draws < 2 A
Sinks	Convenient access to a sink for waste disposal

Ordering Information

Catalog No.	Product	Description
VC-101-1000/1001	BeadXpress System	Includes the BeadXpress Reader, reagent carrier, PC, VeraScan software, the BeadXpress starter kit, 1-year limited warranty, installation by a field service engineer, and 1-day onsite VeraCode technology basics training by a field applications scientist.
Extended Warranty Packages		
SV-201-1004	BeadXpress Premium Extended Warranty Plan	The premium warranty plan for the BeadXpress Reader provides the most complete service program from Illumina. This plan includes: • 48-hour guaranteed onsite response from a field service engineer • Two preventive maintenance visits per year • Unlimited field service calls
SV-201-2003	BeadXpress Plus Extended Warranty Plan	The plus warranty plan for the BeadXpress Reader includes: • 3-day guaranteed onsite response from a field service engineer • One preventive maintenance visit per year • Unlimited field service calls
SV-201-2002	BeadXpress Basic Extended Warranty Plan	The basic warranty plan for the BeadXpress Reader includes: • 5-day guaranteed onsite response from a field service engineer • Either one preventive maintenance visit per year or one emergency call per year • No additional field service calls

Illumina, Inc. • 9885 Towne Centre Drive, San Diego, CA 92121 USA • 1.800.809.4566 toll-free • 1.858.202.4566 tel • techsupport@illumina.com • illumina.com

FOR IN VITRO DIAGNOSTICS USE (U.S.A. ONLY)
Illumina's BeadXpress system has been cleared for in vitro diagnostic use in the U.S.A.
It has not been cleared for in vitro diagnostic use in any other country.
***FDA cleared for in vitro diagnostics with specific VeraCode FDA cleared tests.**

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Pub. No. 970-2007-010 Current as of 06 May 2010

illumina*Dx*™

EXHIBIT 3

(Part I of III)

OF

DECLARATION OF GREGORY F. HEATH

Illumina Receives FDA 510(k) Clearance for Its BeadXpress(R) Multiplex Analysis System

Teaser:

Illumina, Inc. (NASDAQ:ILMN) today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) market clearance for the company's BeadXpress system for **multiplex** genetic analysis. According to the FDA's indications of use, the BeadXpress system - consisting of Illumina's BeadXpress **Reader** and VeraScan software - is an in-vitro diagnostic device intended for the simultaneous detection of multiple analytes in a **DNA** sample utilizing VeraCode holographic microbead technology.

Source: Illumina

URL:

http://investor.illumina.com

ILLUM-0657

Top News :

U.S. Stocks Poised For Lower Open On Overseas News; Hot Stocks: ORCL, ZOLL, QSFT,

Illumina Receives FDA 510(k) Clearance for Its BeadXpress® Multiplex Analysis System

Tuesday, May 04, 2010 6:57 AM

(Source: Business Wire)Illumina, Inc. (NASDAQ:ILMN) today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) market clearance for the company's BeadXpress system for multiplex genetic analysis. According to the FDA's indications of use, the BeadXpress system -- consisting of Illumina's BeadXpress Reader and VeraScan software -- is an in-vitro diagnostic device intended for the simultaneous detection of multiple analytes in a DNA sample utilizing VeraCode holographic microbead technology.

"This approval represents a significant and exciting transitional step for Illumina into the diagnostics field, where the potential is great for molecular medicine to make a real difference in the way disease is detected and ultimately prevented and treated," said Jay Flatley, president and CEO. "It demonstrates Illumina's ability to meet stringent regulatory requirements in designing and manufacturing an FDA-cleared in-vitro diagnostic device. This will serve as an important foundation for our future plans in the diagnostics area. Ultimately, our goal is to become a leader in translational medicine, focusing on complex diseases that benefit from high performance analysis, including genotyping, copy number, gene expression, methylation and protein analysis."

Illumina introduced the BeadXpress system in 2007 with Research Use Only kits for custom genotyping, gene expression, methylation and protein analysis. Since then it has been adopted by research, agricultural, industrial and pharmaceutical institutions worldwide. Utilizing uniquely inscribed digital microbeads, VeraCode technology provides high-quality data, broad multiplexing capability and assay flexibility. Illumina submitted the system for FDA review in September 2009.

"510(k) clearance opens up a wide range of new possibilities for our many clinical research and commercial partners, who can now pursue diagnostic development on our proven, high-performance BeadXpress platform," said Gregory Heath, Ph.D., senior vice president and general manager, Diagnostics. One of those partners is EraGen Biosciences, Inc., which concluded a licensing agreement with Illumina in 2009 to transfer their assays onto the BeadXpress System. "This clearance is a significant step forward in progressing our partnership in the clinical marketplace," said Irene Hrusovsky, M.D., president and CEO of EraGen Biosciences.

ILLUM-0658

For more information, please visit http://www.illumina.com.

About Illumina

Illumina (http://www.illumina.com) is the leading developer, manufacturer, and marketer of integrated systems for the analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations, and biotechnology companies. Our tools provide researchers around the world with the performance, throughput, cost effectiveness, and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information from advances in genomics and proteomics. We believe this information will enable researchers to correlate genetic variation and biological function, which will enhance drug discovery and clinical research, allow diseases to be detected earlier, and permit better choices of drugs for individual patients.

Forward-Looking Statements

This release contains forward-looking statements that involve risks and uncertainties. Important factors that could cause actual results to differ materially from those in any forward-looking statements include challenges inherent in new product development and manufacturing and the other factors detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We undertake no obligation, and do not intend, to update any forward-looking statements after the date of this release.

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No Comments

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The sector scan is based on 15-30 minutes delayed data. The Pattern scan is based on EOD data.

Drupal.behaviors.print = function(context) {window.print();window.close();}>

genomeweb

Illumina Sees Clinical Applications for MiSeq; Plans FDA Submission in 2012

August 03, 2011

Illumina Sees Clinical Applications for MiSeq; Plans FDA Submission in 2012

Citing an example of clinical applications for the MiSeq, a company representative said that one customer plans to use the instrument for MRSA testing in a hospital.

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- Following Diagnostic Sequencing Success, MCW Creates Comprehensive Framework to Guide Future Cases
  March 29, 2011 / Clinical Sequencing News

Business Wire
A Berkshire Hathaway Company

May 18, 2010 04:05 PM Eastern Daylight Time

Illumina Receives FDA 510(k) Clearance for VeraCode® Genotyping Test for Factor V (Leiden) and Factor II (Prothrombin)

SAN DIEGO--(BUSINESS WIRE)--Illumina, Inc. (NASDAQ:ILMN) today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) market clearance for the VeraCode® Genotyping Test for Factor V (Leiden) and Factor II (Prothrombin). The VeraCode Genotyping Test is comprised of the company's VeraCode digital microbead technology and proprietary assay chemistry. The BeadXpress® System, which received a separate 510(k) market clearance, is FDA-cleared for *in vitro* diagnostic use only with the VeraCode Genotyping Test for Factor V and Factor II.

About Illumina

Illumina (http://www.illumina.com) is the leading developer, manufacturer, and marketer of integrated systems for the analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations, and biotechnology companies. Our tools provide researchers around the world with the performance, throughput, cost effectiveness, and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information from advances in genomics and proteomics. We believe this information will enable researchers to correlate genetic variation and biological function, which will enhance drug discovery and clinical research, allow diseases to be detected earlier, and permit better choices of drugs for individual patients.

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or
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wgrabill@illumina.com

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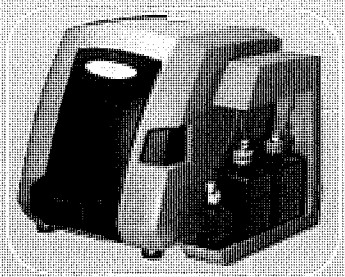
illumina®

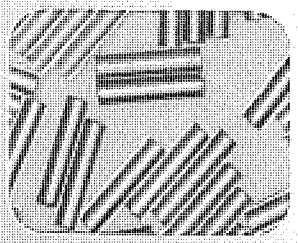
making sense out of life

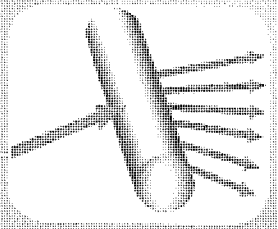
Introduction to Illumina's VeraCode Technology

PRESENTED BY:

David Barker
VP and CSO







ILLUM-0016

Corporate Summary

- Founded: May 1998 - Traditional venture-funded start-up
- IPO: July 2000 – Raised $103M
- Headquarters: 110,000 Sq. Ft., San Diego (Headquarters)
- Illumina-East 15,000 Sq. Ft., Connecticut
- Employees: >450 worldwide

San Diego, CA

Wallingford, CT

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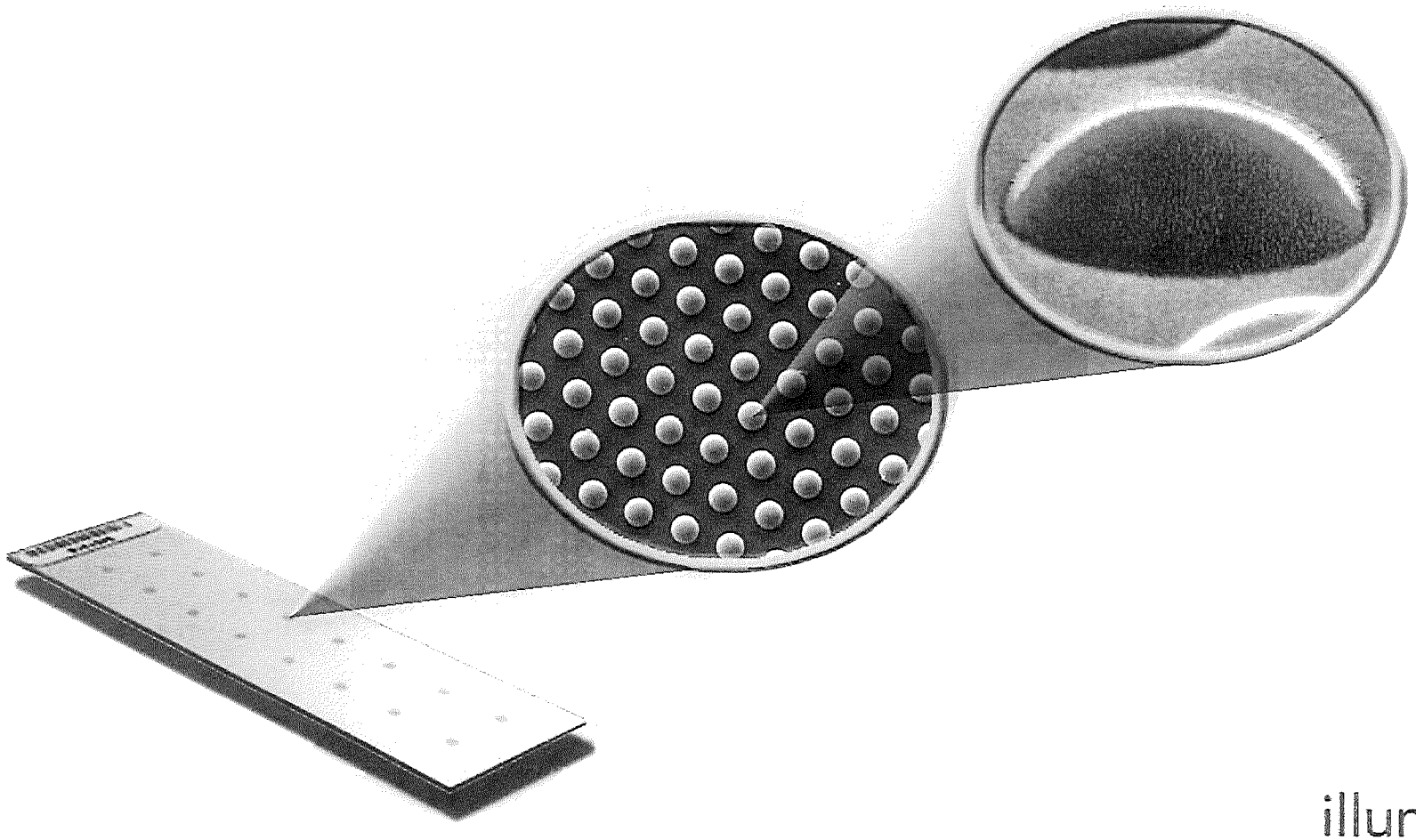
Illumina's Core BeadArray Technology



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BeadStation 500
Powerful & Economical BeadArray™ Platform

- Confocal laser scanning system
- Resolution, 0.8 micron
- Dual line - lasers at 532 & 635nm
- Fully automated operation
- Compact bench top system

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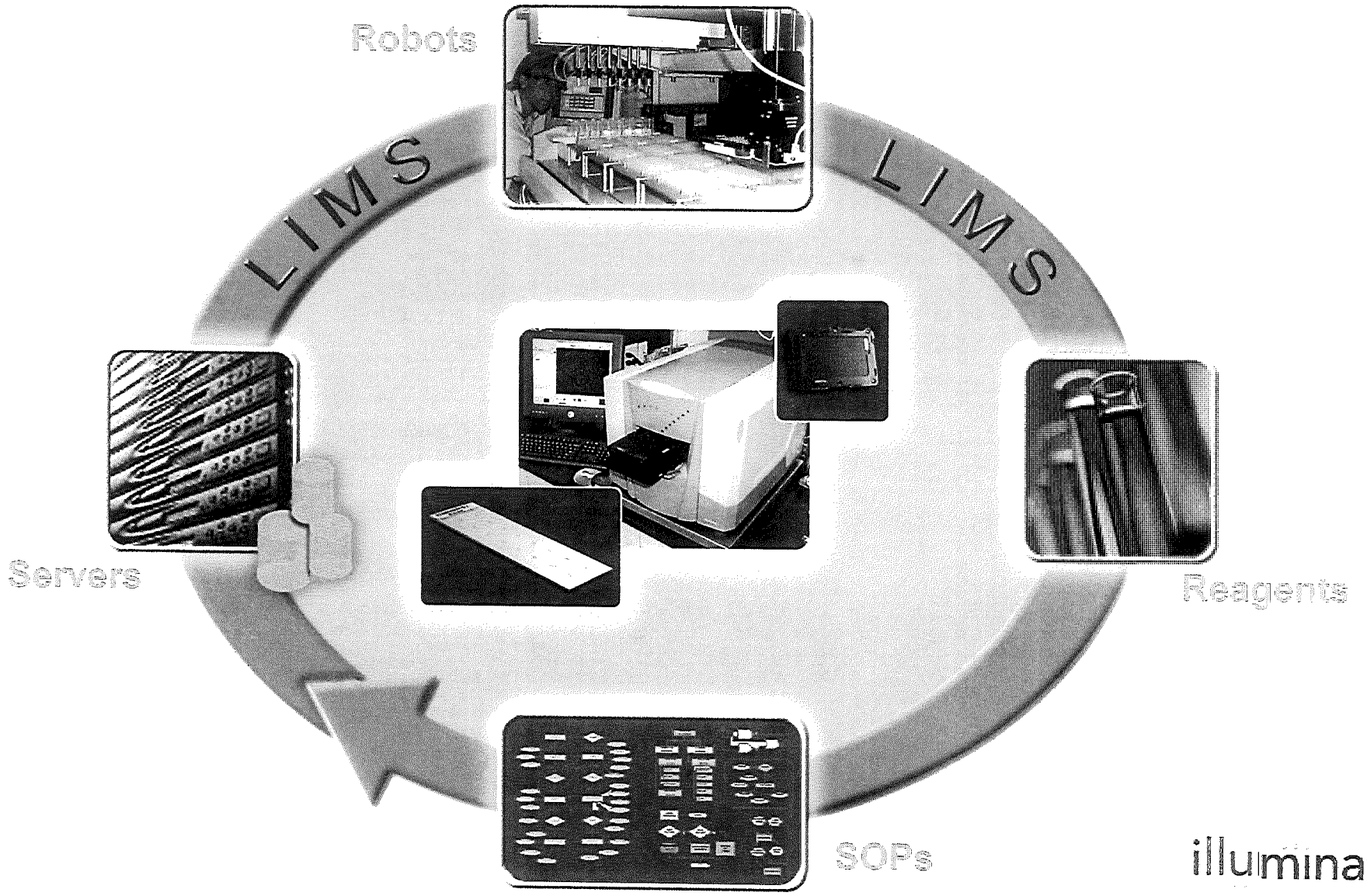
Illumina BeadLab – End-to-End, Turnkey Laboratory



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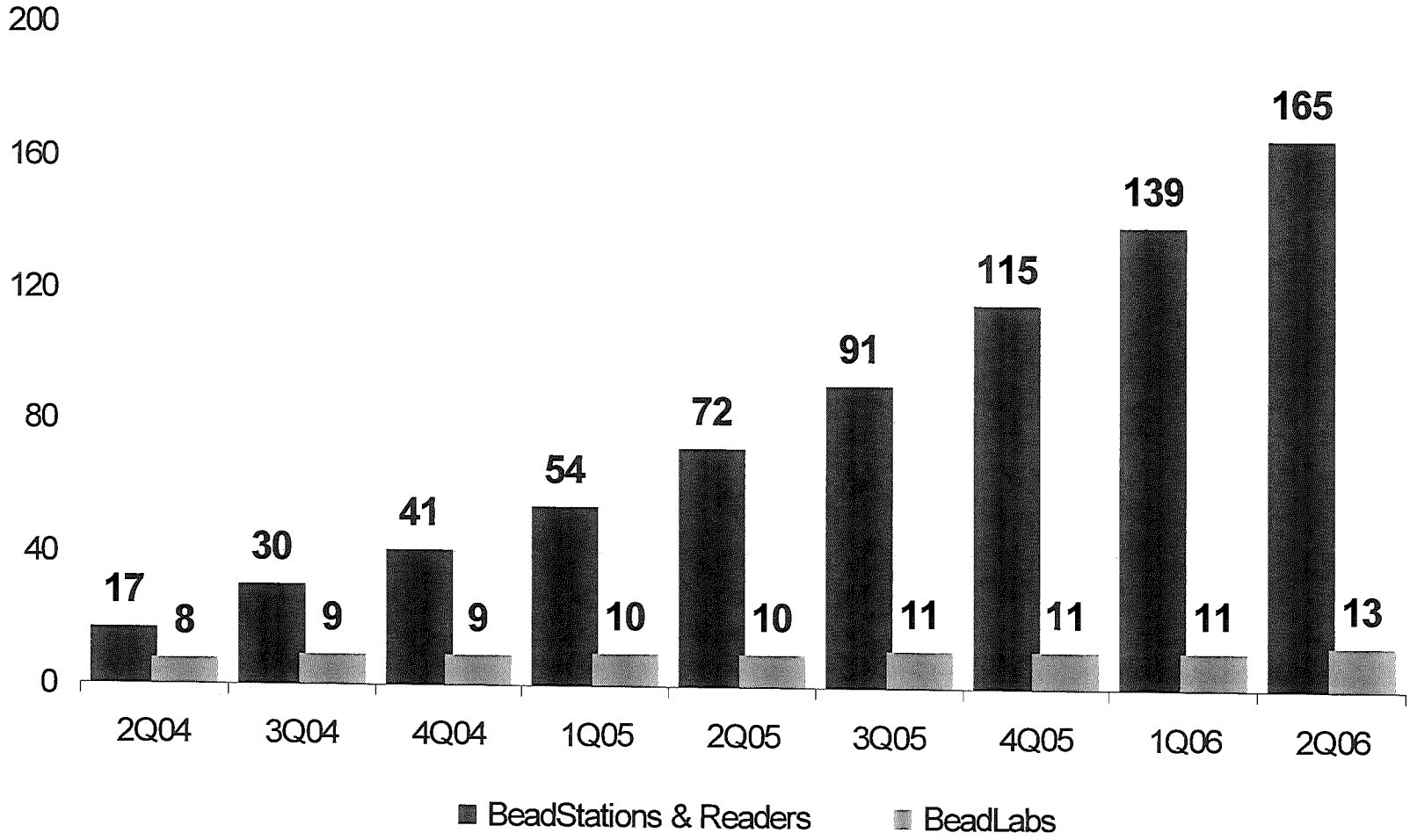
Cumulative BeadLab/BeadStation Shipments



- Shipment of 28 Scanners in 2Q06, including 2 BeadLabs
- Total cumulative shipments of 165 BeadStations & Readers and 13 BeadLabs

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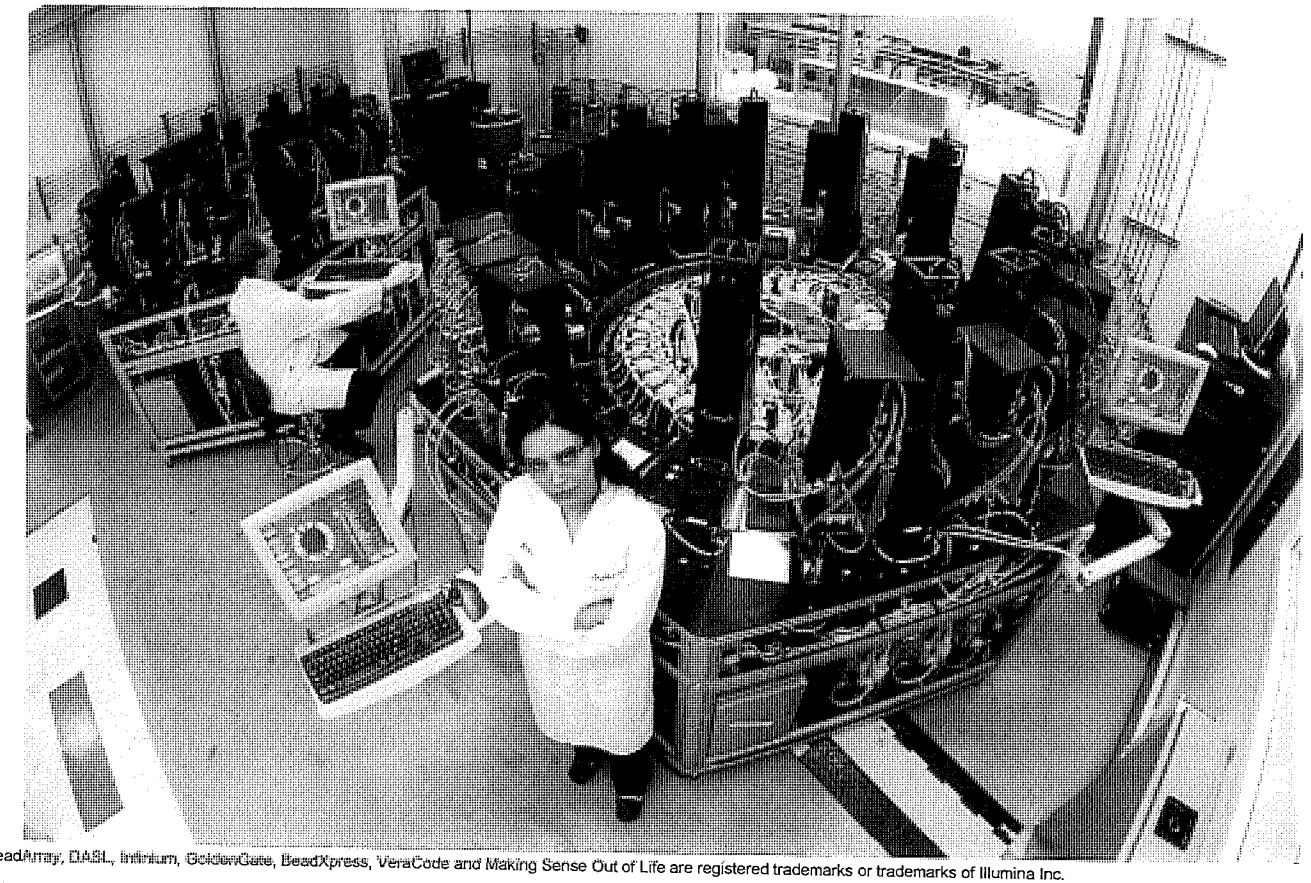
Oligator Synthesis Factory

- Microarrays and assays need lots of oligonucleotides
- New 4th generation synthesizers can supply worldwide oligo needs
  - 13,824 oligos per run; 2 million bases/day
- Invitrogen partnership
  - Leverages IVGN sales and marketing and ILMN manufacturing



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Recent Deal Summary in Healthcare

Customer	Disease(s)	Sample #	Product(s)
Children's Hospital of Philadelphia	All Patients and Parents	30,000	HumanHap550
deCODE	CV, Type 2 Diabetes, Cancer	Confidential	Infinium through BeadXpress
SAIC-Frederick/NCI	Prostate cancer	>2,500	HumanHap300
Max Planck	CNS	Confidential	Human-1 HumanHap300
PARC	CV/statin response	>2,200	Human-1 HumanHap300 Custom Infinium
Cancer Research UK	Colorectal cancer	>4,000	HumanHap300 HumanHapS
CIDR	Type 2 diabetes	>2,500	HumanHap300
Genizon	15-20 common	>16,000	HumanHap300 Custom Infinium
North Shore LIJHS	IBD consortium	>2,000	HumanHap300

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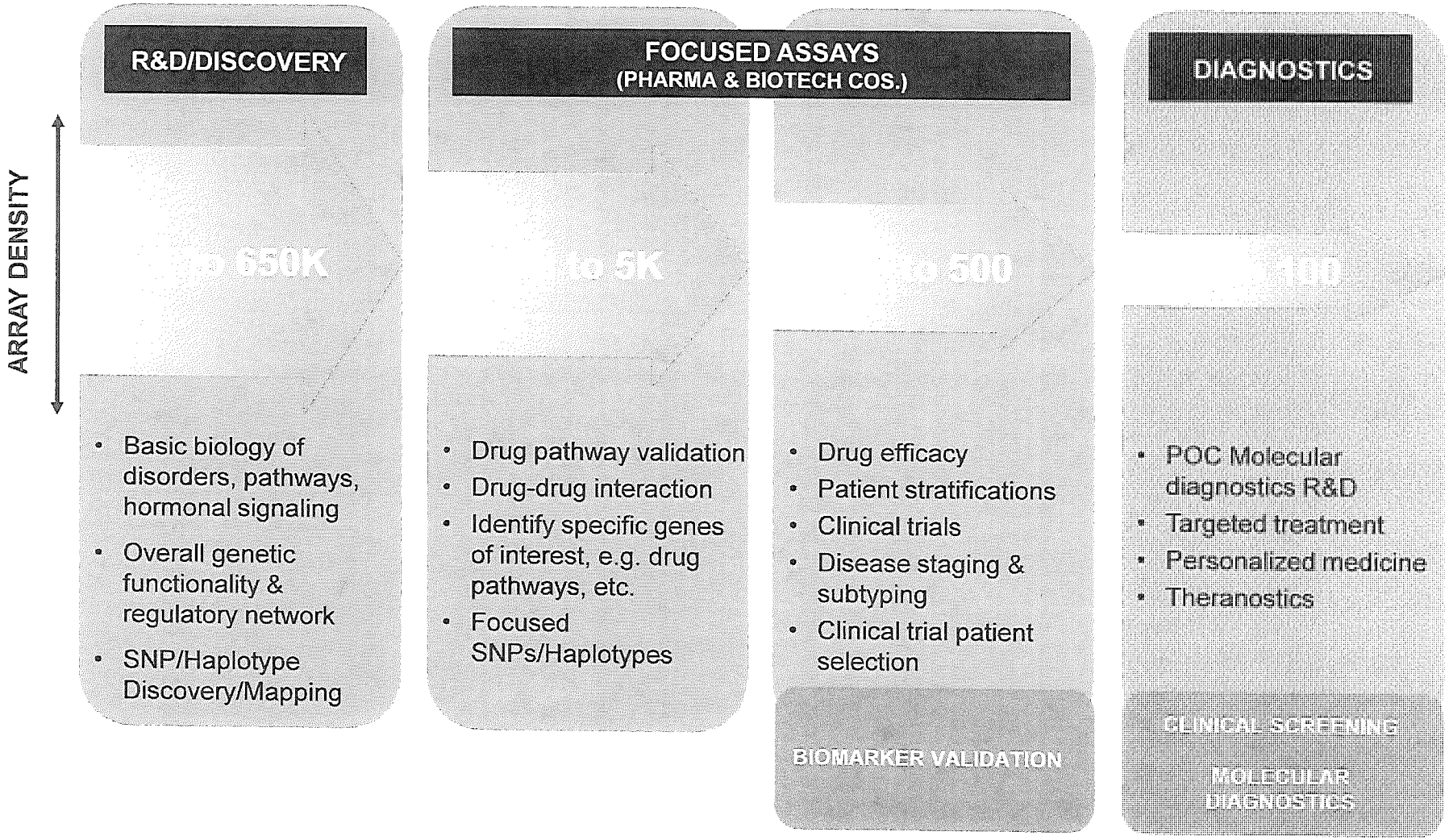
Market Needs



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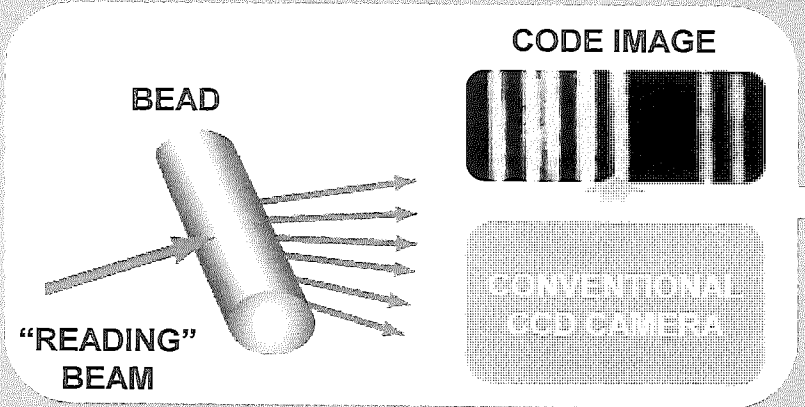
VeraCode Technology

CODE GENERATED BY CREATING EMBEDDED HOLOGRAPHIC DIFFRACTIVE ELEMENTS



BINARY CODE

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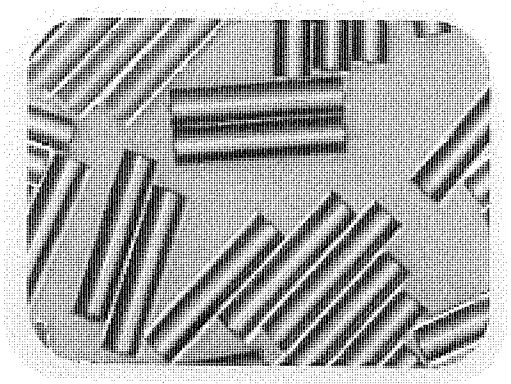

- Glass Surface of Beads Ideal for Bioassays
- High Density Codes Easily Imprinted (24 bit)
- Virtually Unlimited Multiplexing

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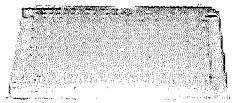
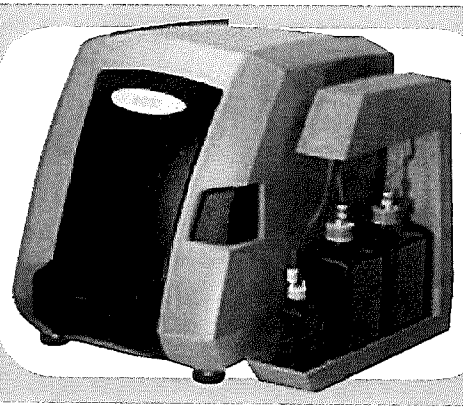
BeadXpress Reader

ASSAY BEAD KIT

SAMPLE PLATE



ASSAY CODE LIBRARY



DATA & LOG FILES

INSTRUMENT SPECIFICATIONS

SAMPLE DELIVERY FORMAT	Standard 96-well plate
MULTIPLEXING PER SINGLE WELL	1 to 384
THROUGHPUT	120 samples/hr at 10-plex 80 samples/hr at 96-plex
DETECTION	Optional 1 or 2 color detection
AUTOMATION	Designed to be compatible with standard laboratory automation LIMS compatible

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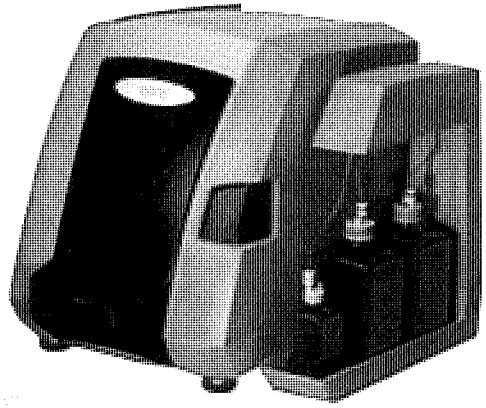
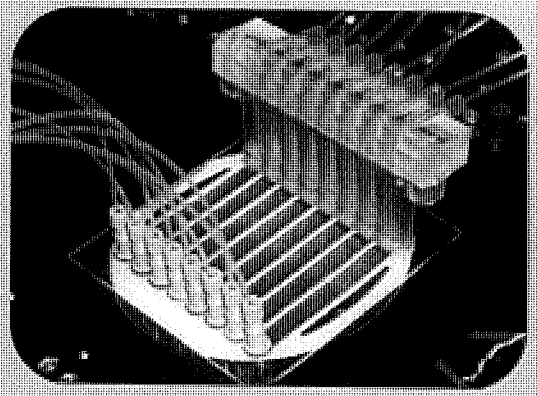
VeraCode Technology

EIGHT WELLS ARE SAMPLED SIMULTANEOUSLY AND MICROBEADS ARE TRANSFERRED INTO A MULTI-SECTORED READER CELL.





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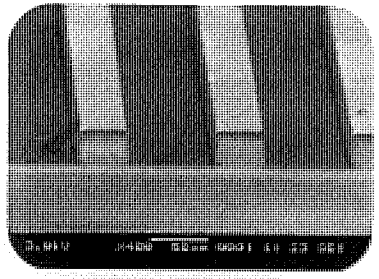
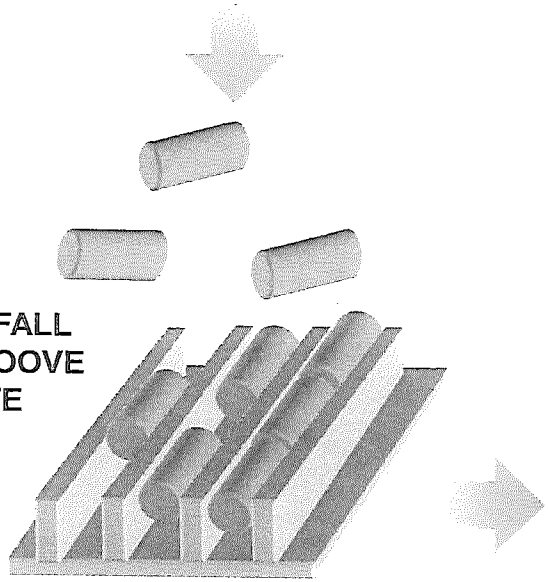
ILLUM-0027

VeraCode Technology

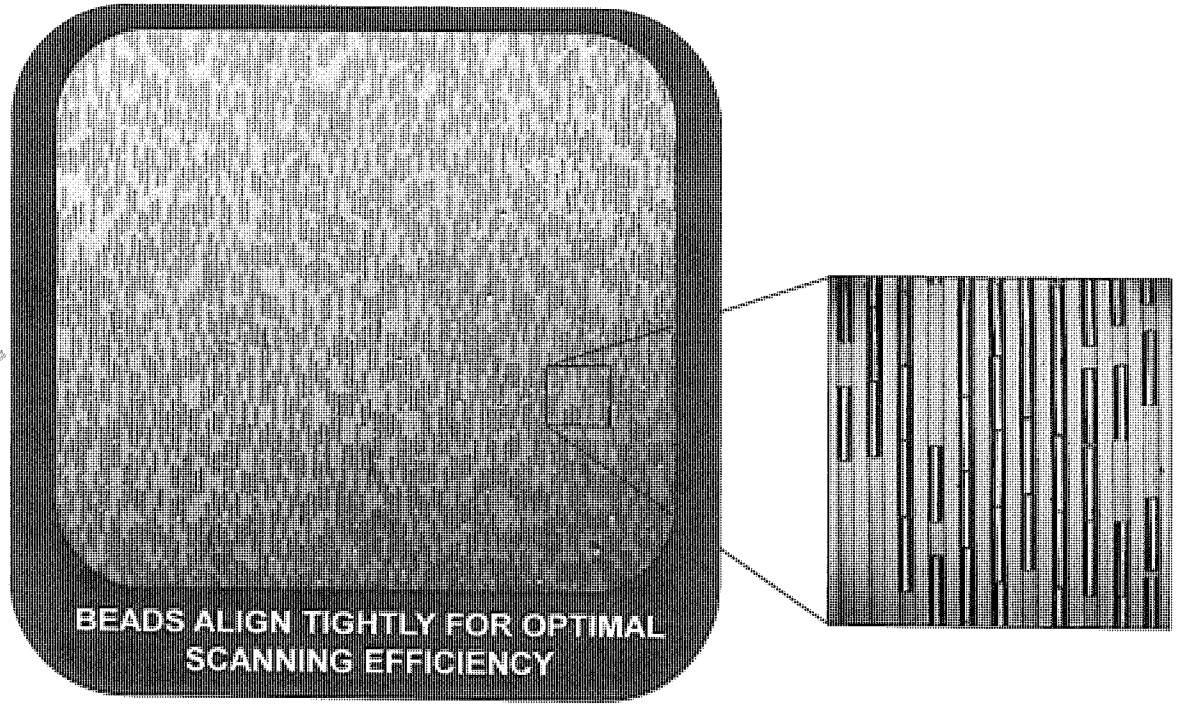
CAPILLARY FORCE ATTRACTS BEADS INTO GROOVES



GROOVE PLATE CROSS-SECTION



BEADS FALL INTO GROOVE PLATE



BEADS ALIGN TIGHTLY FOR OPTIMAL SCANNING EFFICIENCY

ILLUM-0028

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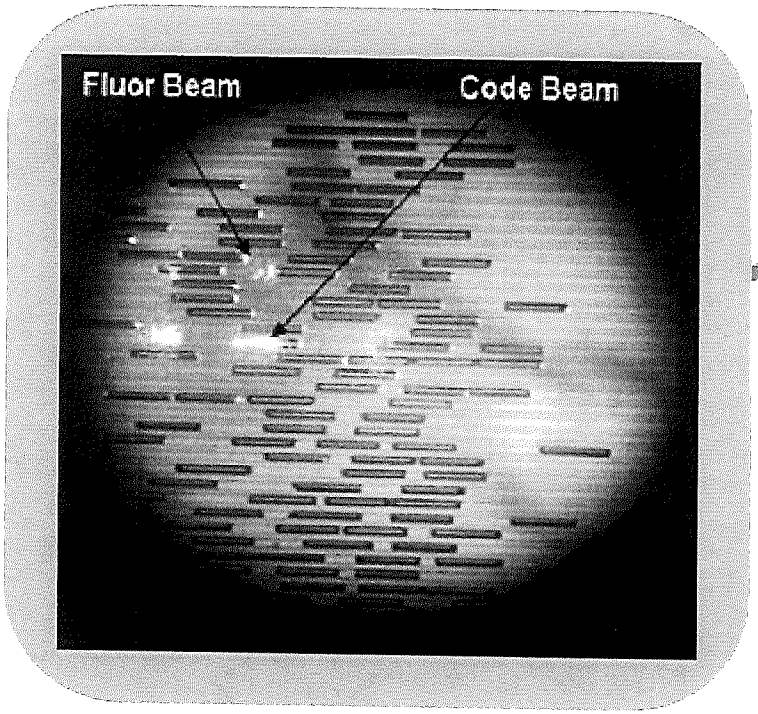
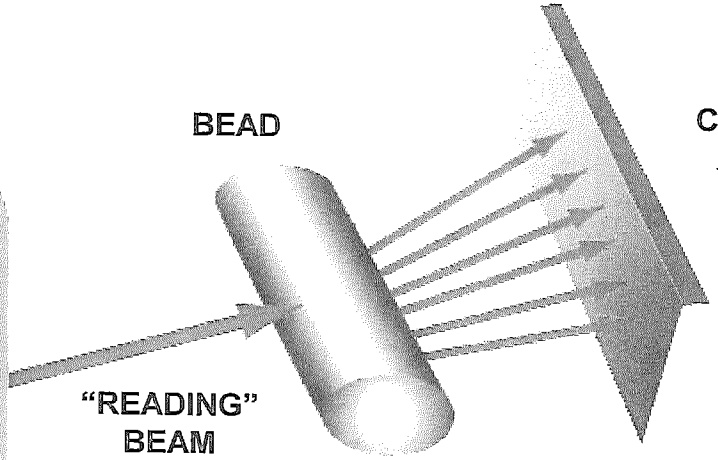
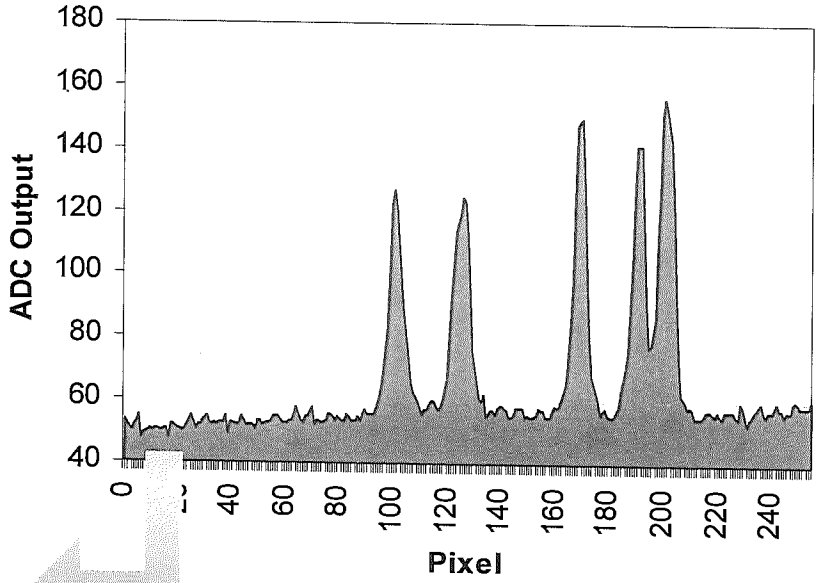
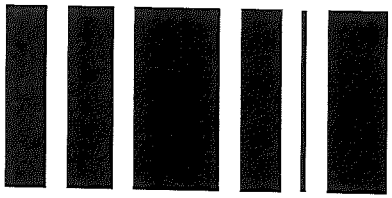
Code Detection









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VeraCode Technology

FOLLOWING READOUT, THE BEADS ARE FLUSHED FROM THE READER CELL USING A SECOND ACTUATION PRESSURE CYCLE.

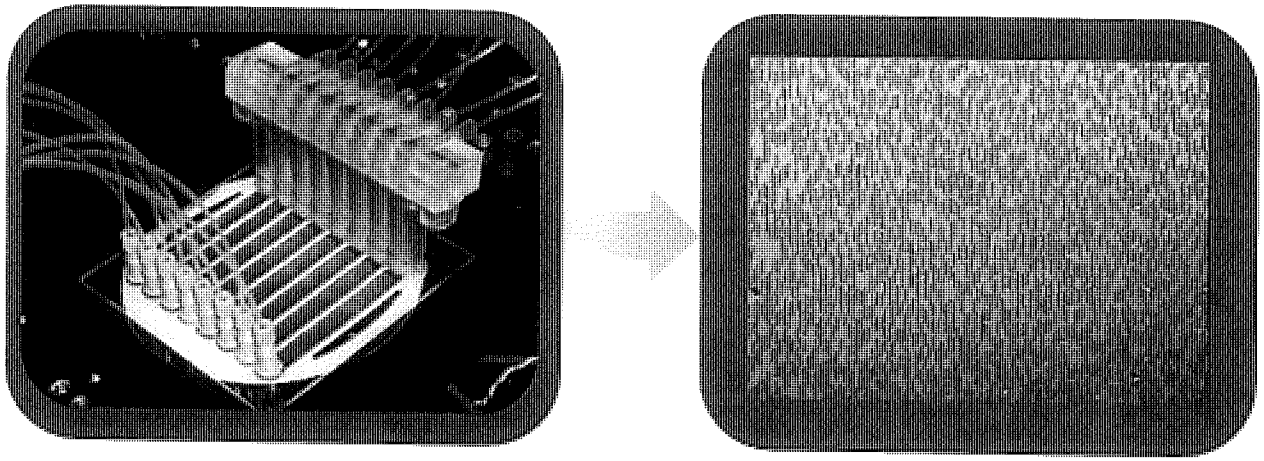

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EXHIBIT 3

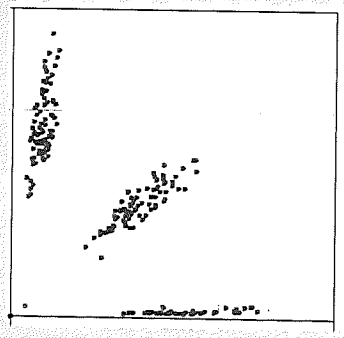
(Part II of III)

OF

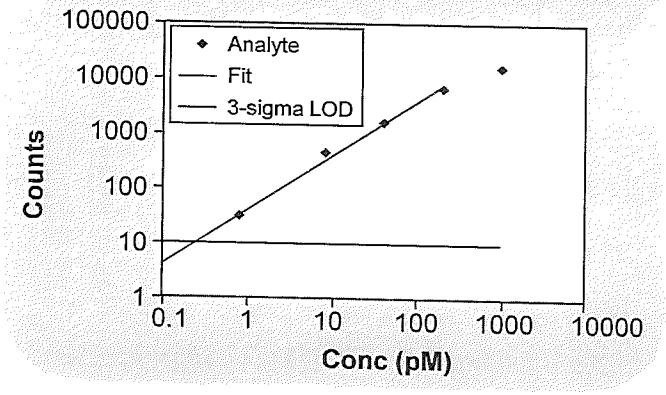
DECLARATION OF GREGORY F. HEATH

A Flexible Platform for Multiple Applications

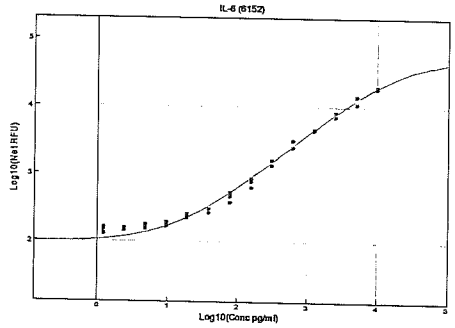
GENOTYPING



GENE EXPRESSION



PROTEIN EXPRESSION



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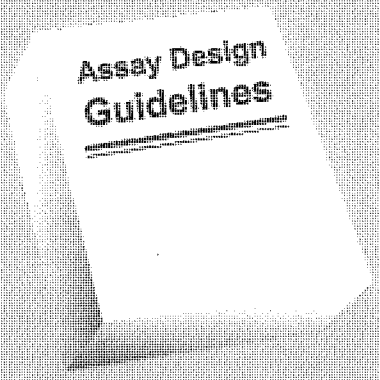
Products in Development

CARBOXYL BEAD SETS (PROTEIN BASED ASSAYS)

IN DEVELOPMENT

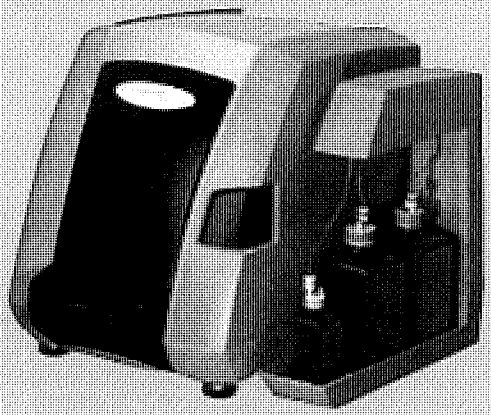
Unique Bead Code Types in Tubes

GUIDELINES



Assay Design Guidelines (RUOI)

CUSTOMER DEVELOPED HOMEBREW



Customer controls level of multiplexing and number of samples

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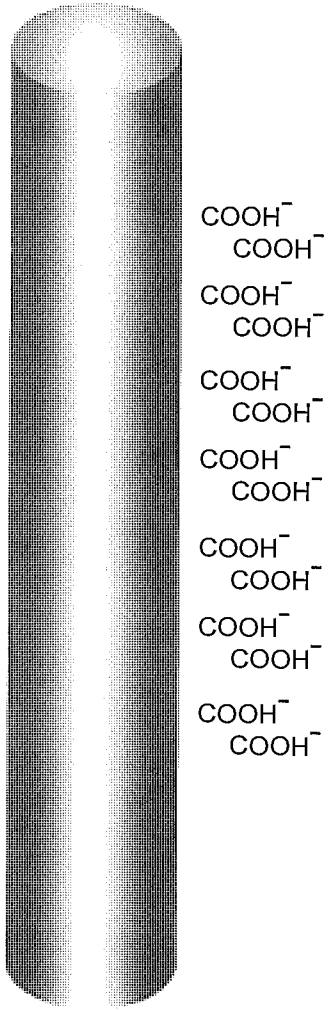
Carboxylated Beads



PROTEIN ATTACHMENT: TWO-STEP PROCESS

Carboxylate Surface → EDC/Sulfo-NHS → Activated Bead → Antibodies, Antigens, Peptides, Streptavidin

- Fast
- Robust
- Inexpensive
- Stable

NUCLEIC ACID ATTACHMENT: ONE-STEP PROCESS

Carboxylate Surface → EDC/Sulfo-NHS plus NH_2-Oligo → Nucleic Acids

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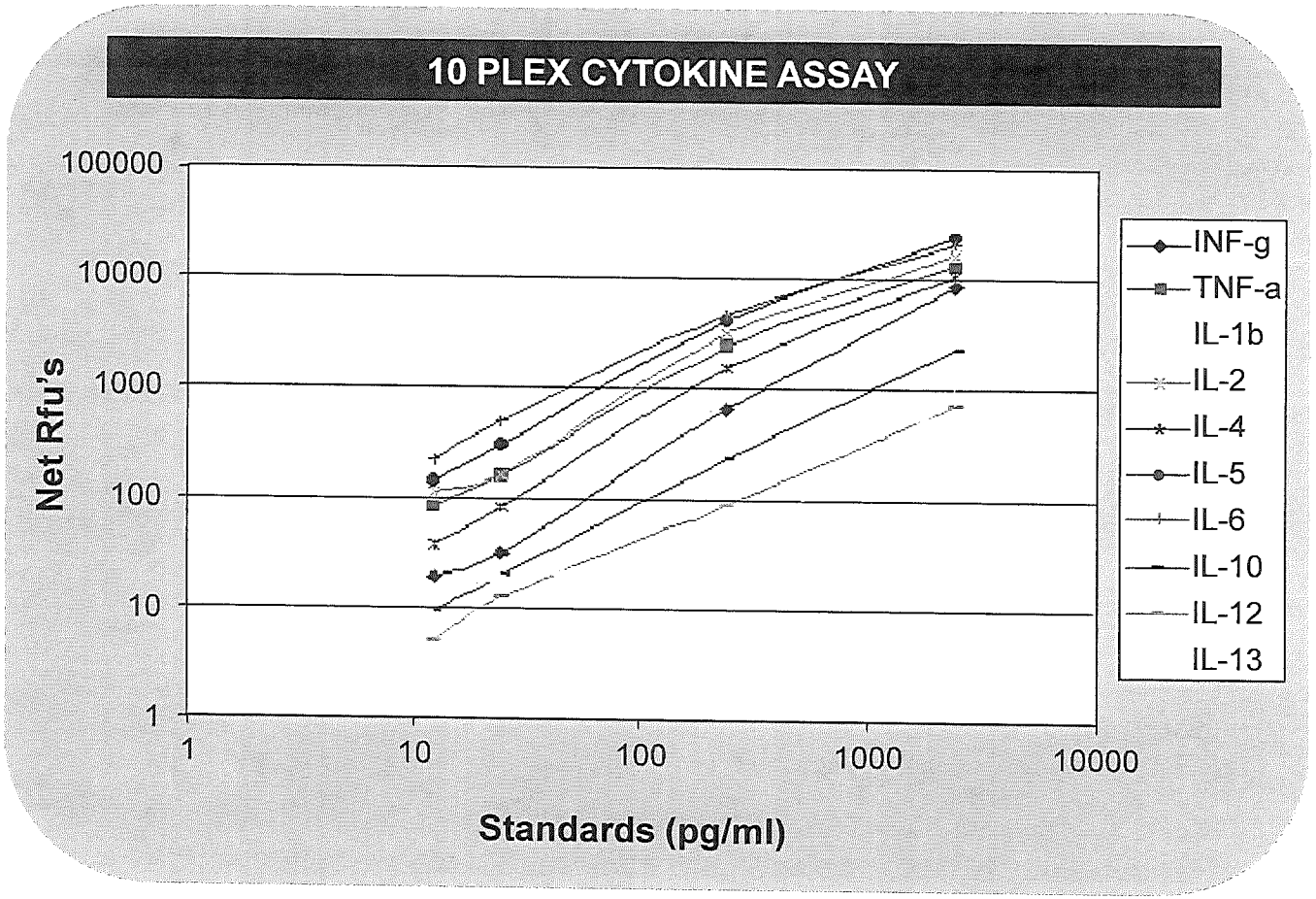
10-plex Cytokine Sensitivity Panel

- Antigen in PBS/1% BSA buffer
- 1 hour reaction time (antigen)
- Sensitivity exceeds 25 pg/mL
- Overall Plate CVs < 10.6%



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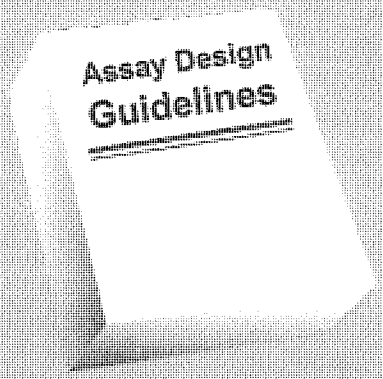
Products in Development

UNIVERSAL CAPTURE BEAD SETS

IN DEVELOPMENT

Unique Bead Code Types in Tubes

GUIDELINES



Assay Design Guidelines (RUO)

CUSTOMER DEVELOPED HOMEBREW

Customer controls level of multiplexing and number of samples

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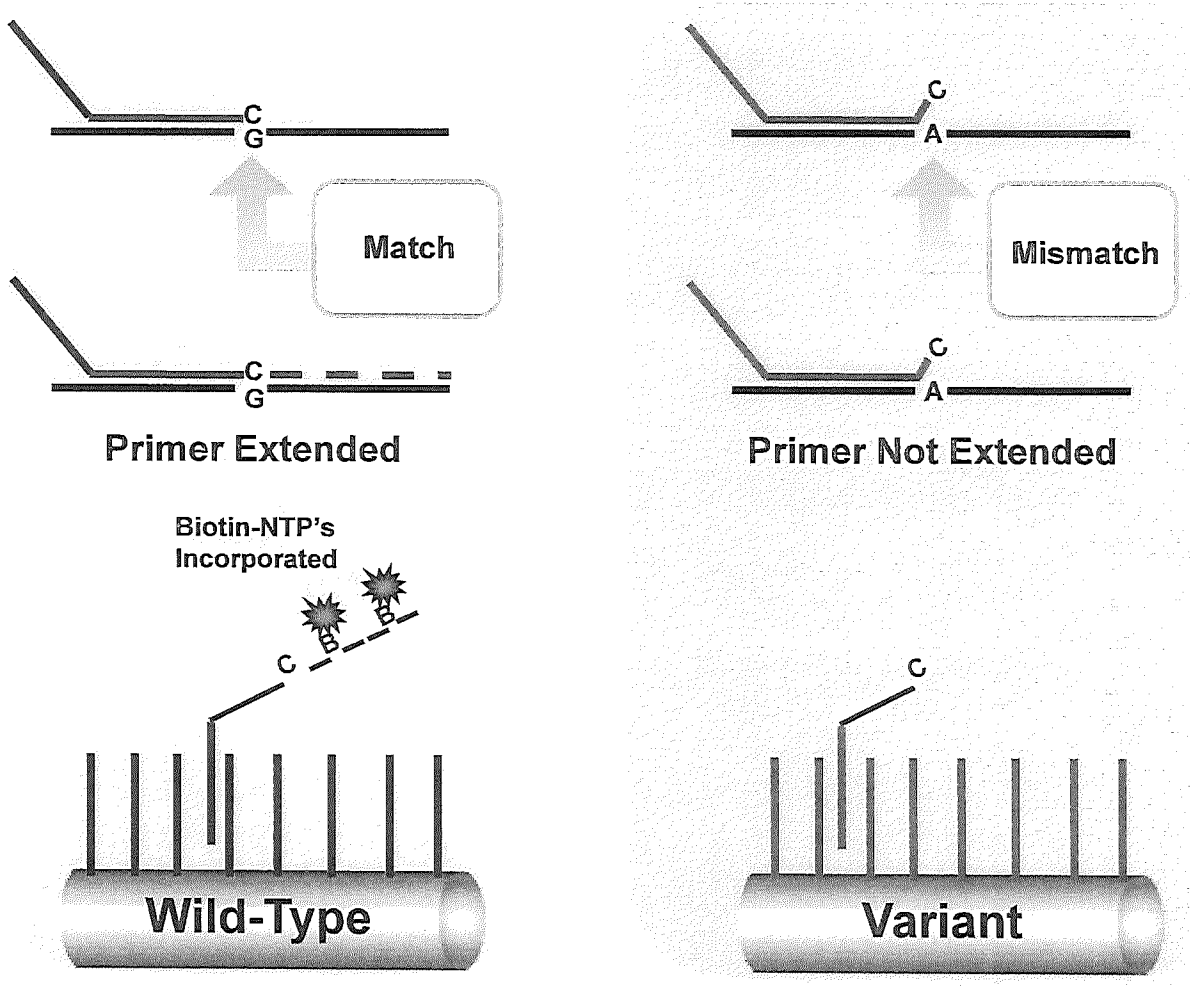
Multiplex Genotyping Example

ALLELE-SPECIFIC PRIMER EXTENSION (ASPE)



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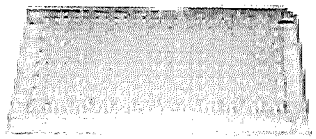
Products in Development

GOLDENGATE GENOTYPING ASSAY (96 & 384-PLEX)

IN DEVELOPMENT



Beads Pooled in 96-well Plates

(96 & 384-plex/well)

OPAs + Reagents

USER MANUAL

GoldenGate Genotyping User Manual (RUO)

GOLDENGATE GENOTYPING

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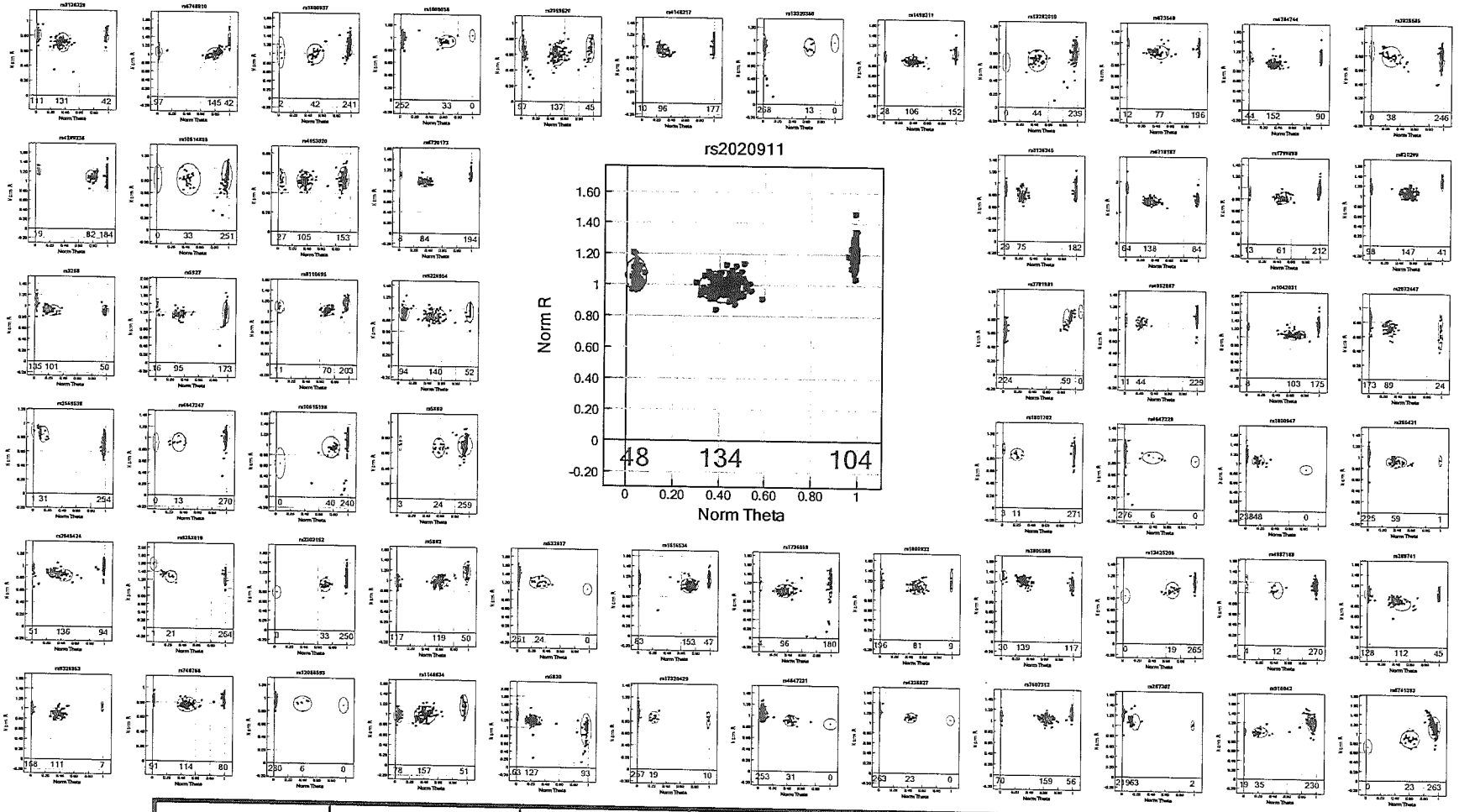
GoldenGate Assay Results



Reaction Multiplex	Samples Tested	Call Rate	Total # of Data Points	Reproducibility	Heritability
96	286	99.2%	41,184	100%	100%

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VeraCode Technology

MULTIPLEXED ASSAY FLEXIBILITY

MOLECULE(S)	ASSAY FORMAT	ASSAY
Nucleic Acid	Multiple Formats: GoldenGate ASPE, SBE, OLA, etc.	Genotyping Gene Expression Infectious Disease
Antibodies	Standard 'Sandwich' Sample Prep	Cytokine, ID CD4/CD8
Antigens	Direct Competitive Confirmatory	Total IgE Infectious Disease
Peptides	Direct Competitive	Specific IgE
Binding Proteins (streptavidin)	Sample Prep	Cell Surface Markers Nucleic Acids

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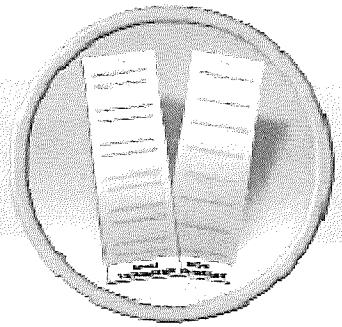
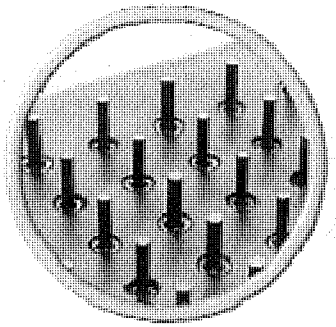
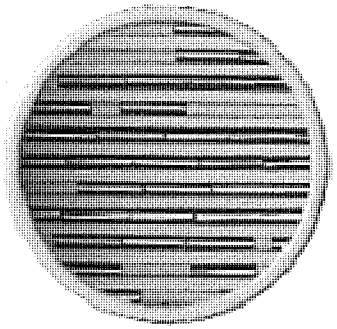
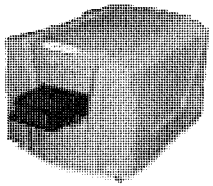
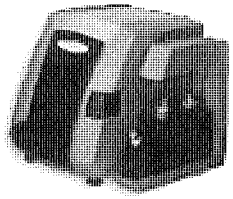
Technology / Platform Synergy

Discovery Research	Focused Research	Molecular Diagnostics
		
• WG genotyping • WG expression • Biomarker discovery • Future WG applications	• Custom genotyping • Focused expression • DASL • Biomarker validation	• Low/mid density GT/GEX • Protein applications • Biomarker screening • Biomarker panels





Decoded Beads **Digitally Coded Beads**

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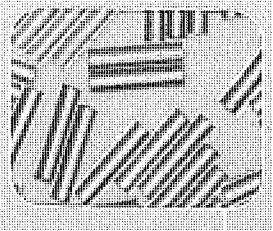
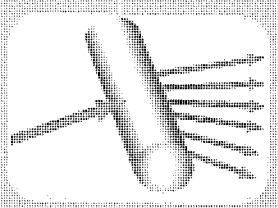
making sense out of life

VeraCode Assay Design

PRESENTED BY:

Jack Quinn
Staff Scientist





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Overview

- Illumina's VeraCode Products
  - Carboxylate Beads
    - Use in Multiplex Protein Assay Development
      - 10 Plex Cytokine Assay
  - Universal Beads
    - Use in Low Plex Genotyping Development
      - 4 Plex Thrombosis Assay
  - GoldenGate Genotyping
    - 96-plex
      - 96 SNPs + 48 controls = 144-plex

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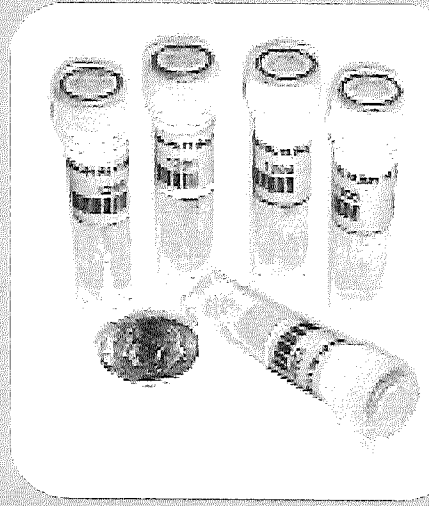
VeraCode Carboxylated Beads

- Protein and Nucleic Acid Use
- Low Non-Specific Binding Characteristics
- Simple & Flexible Immobilization Chemistry
  - Proteins
  - Nucleic Acids
  - Controlled Density



Unique Bead Code Types in Tubes

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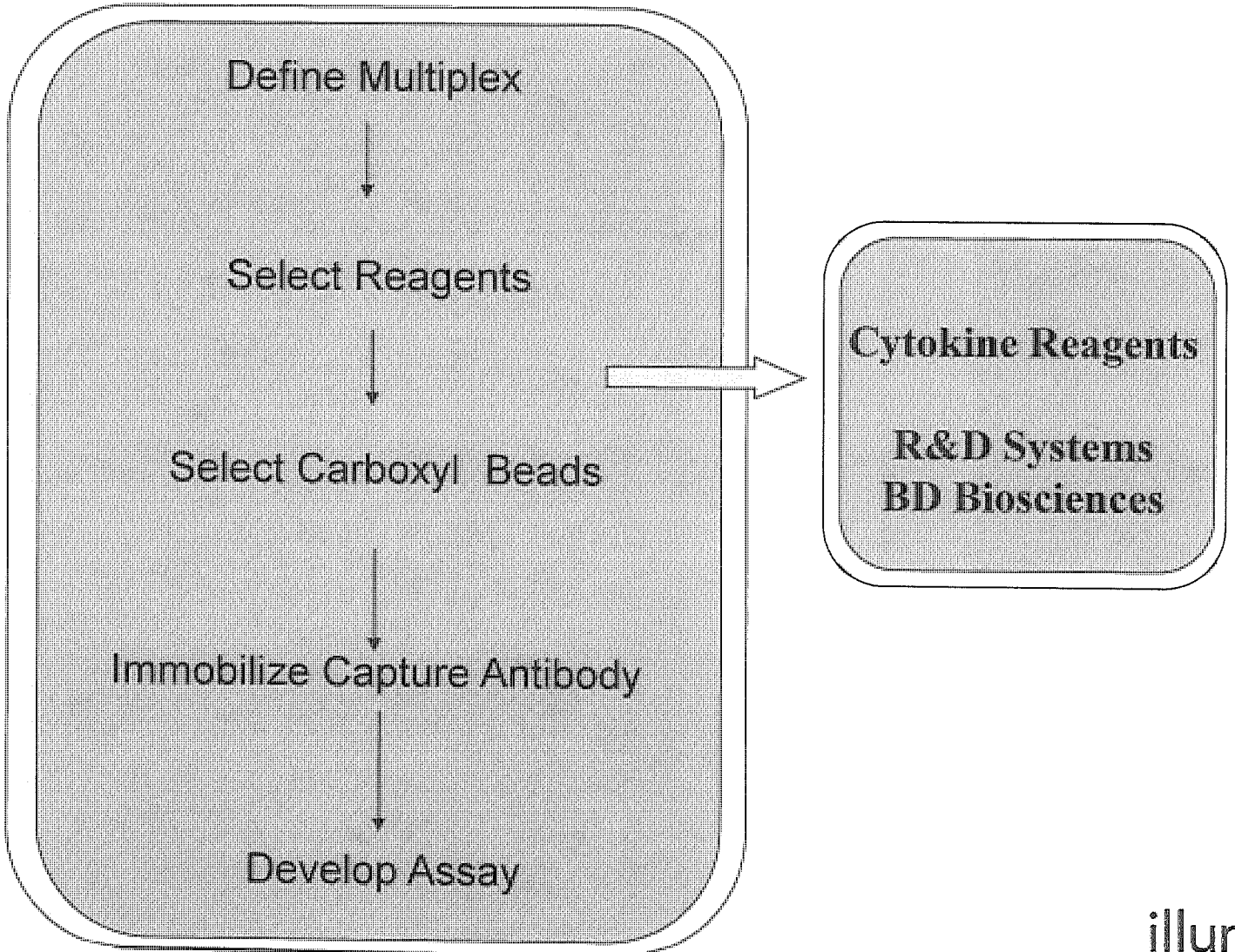
Carboxylate Beads: Assay Design For Proteins



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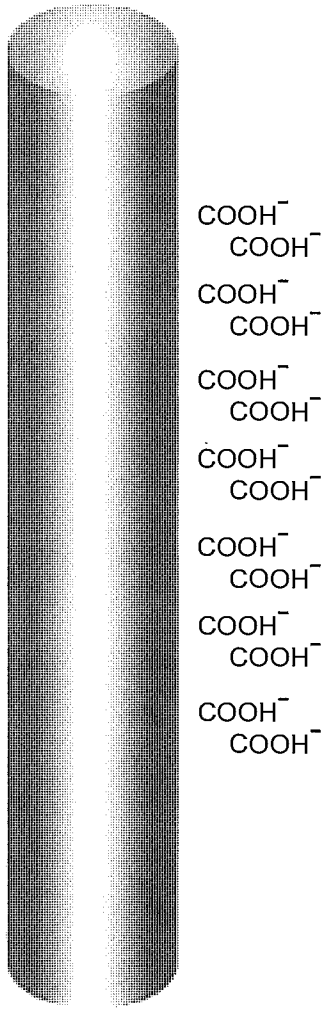
Carboxylate Beads: Chemistry of Attachment



PROTEIN ATTACHMENT: TWO-STEP PROCESS

Activate Surface — EDC/Sulfo-NHS — Covalently Bind

Antibodies
Antigens
Peptides
Streptavidin

- Fast
- Robust
- Inexpensive
- Stable

NUCLEIC ACID ATTACHMENT: ONE-STEP PROCESS

EDC/Sulfo-NHS plus NH₂-Oligo

Nucleic Acids

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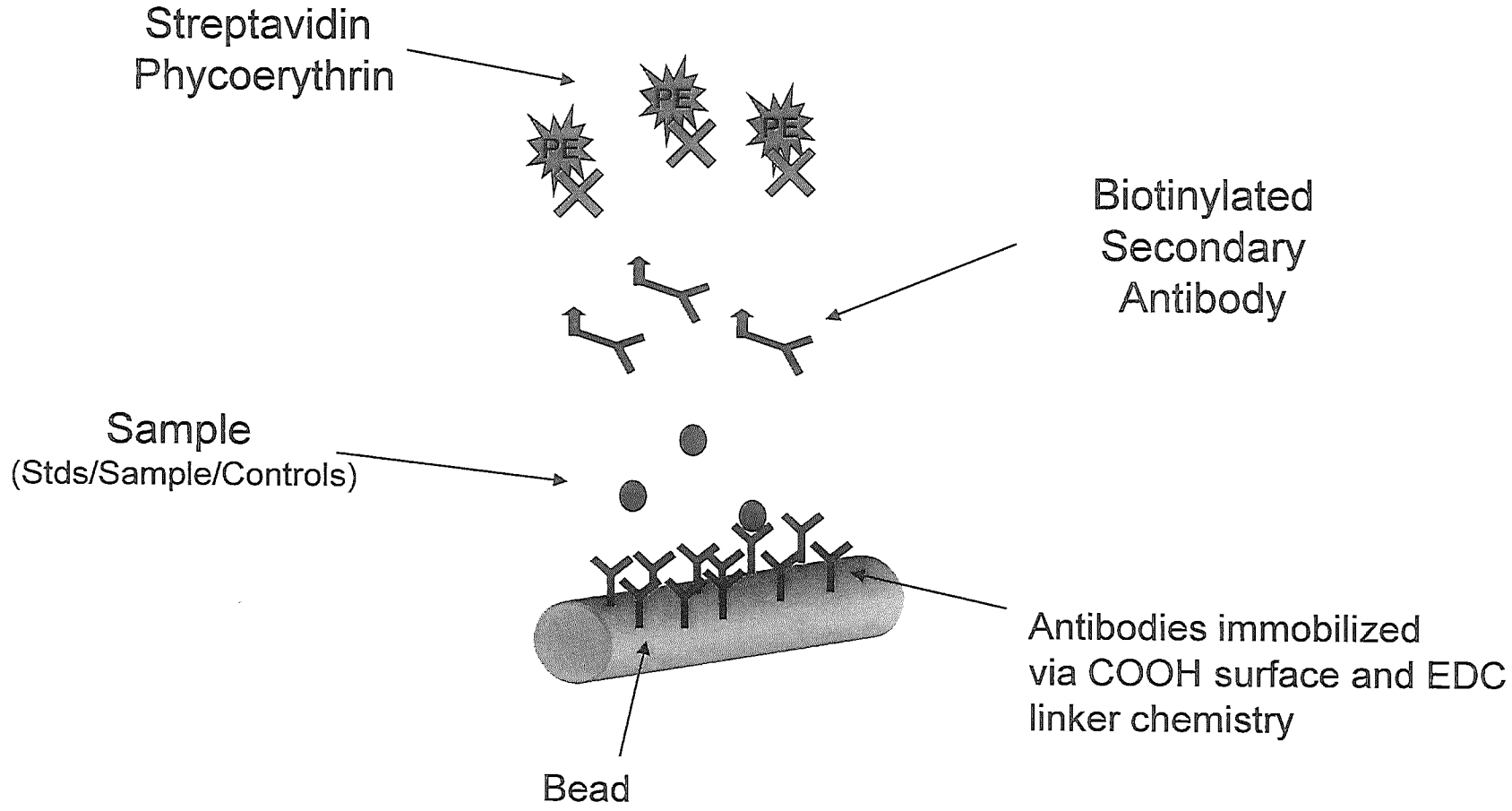
Multiplex Cytokine Assay Format



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Multiplex Cytokine Assay Protocol

Prepare Micro Pla

Put plate in scanner

Kit beads to2 in 96 We Mic

50 ul Label min at RT; Shaking 3x PBST d in 75 uL PBST

Total Hands On Time ~ 15 min/plate
Time to first result ~ 3 hours

(PBST = 1x PBS, 0.05% Tween)

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Precision of Cytokine Assay

6-Plex Assay run over 4 days

8 pt Standard Curve diluted and run each day

3 replicates each level

Operator	Day 1 1	Day 2 1	Day 3 1	Day 4 1
INF-g	5.7	10.2	6.3	8.6
TNF-a	5.6	8.1	7.7	6.9
IL-1b	8.6	6.7	9.5	8.4
IL-4	7.3	7.2	7.1	10.4
IL-5	6.3	4.4	5.7	9
IL-6	6.2	5.7	9.0	7.9
Plate CV	6.6	7.1	7.6	8.5

Expressed as mean % CV

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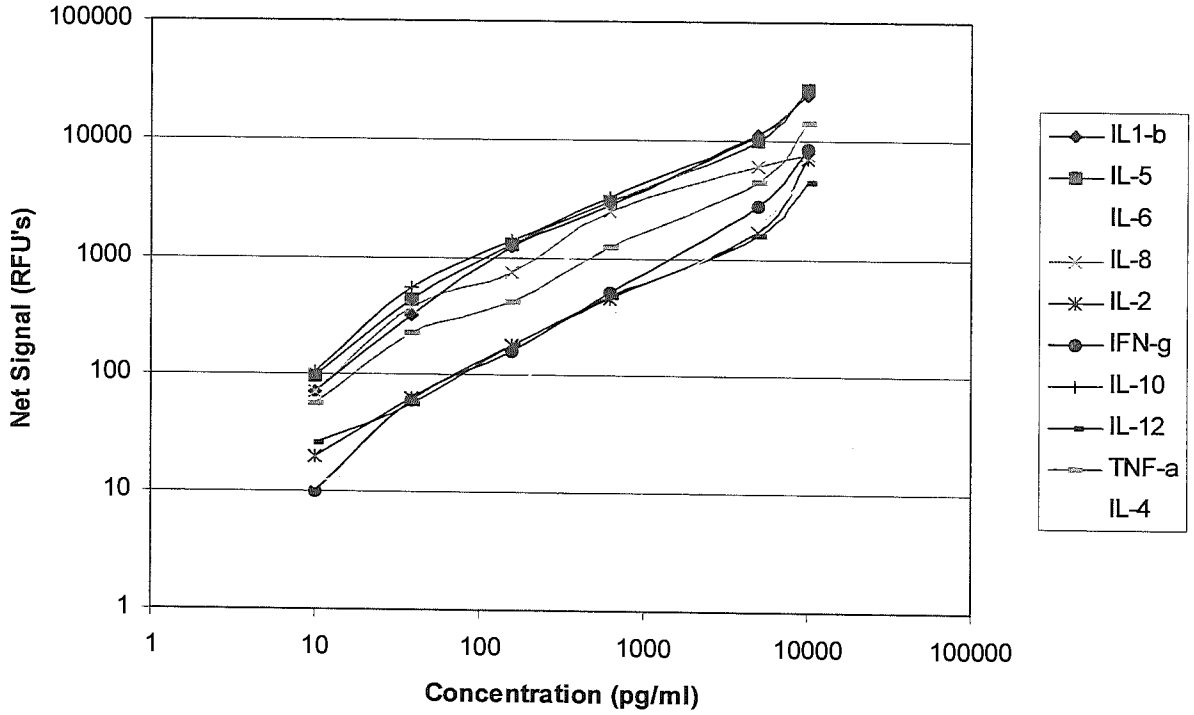
Sensitivity: 10-Plex Dose-Dependent Titration Curves



Cytokine	*Sensitivity (pg/ml)
IL1-b	<10
IL-5	<10
IL-6	<10
IL-8	<10
IL-2	<10
IFN-g	<10
IL-10	<10
IL-12	<10
TNF-a	<10
IL-4	<10

ILLUM-0049

* LOD calculated as Mean Negatives + 3* Stdev Neagatives

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Sensitivity: Low End Precision Drives Sensitivity

Low End Data from Previous 10 plex dose-response curves

Cytokine	Mean Signal Negative	Stdev Negative	Calculated LOD	CV Negative	Mean Signal 10 pg/ml
IL1-b	148	5.0	163	3.4	220
IL-5	154	6.0	171	3.7	254
IL-6	144	6.5	164	4.5	201
IL-8	159	6.1	219	3.8	232
IL-2	143	7.1	164	4.9	163
IFN-g	147	2.9	155	2.0	157
IL-10	143	4.6	157	3.2	248
IL-12	136	1.5	157	1.2	163
TNF-a	145	5.4	161	3.7	204
IL-4	139	2.7	147	1.9	152

Negative is Sample Diluent (n=8)

10 pg/ml in sample Diluent (n=4)

LOD= Mean+3*Stdev. Neg

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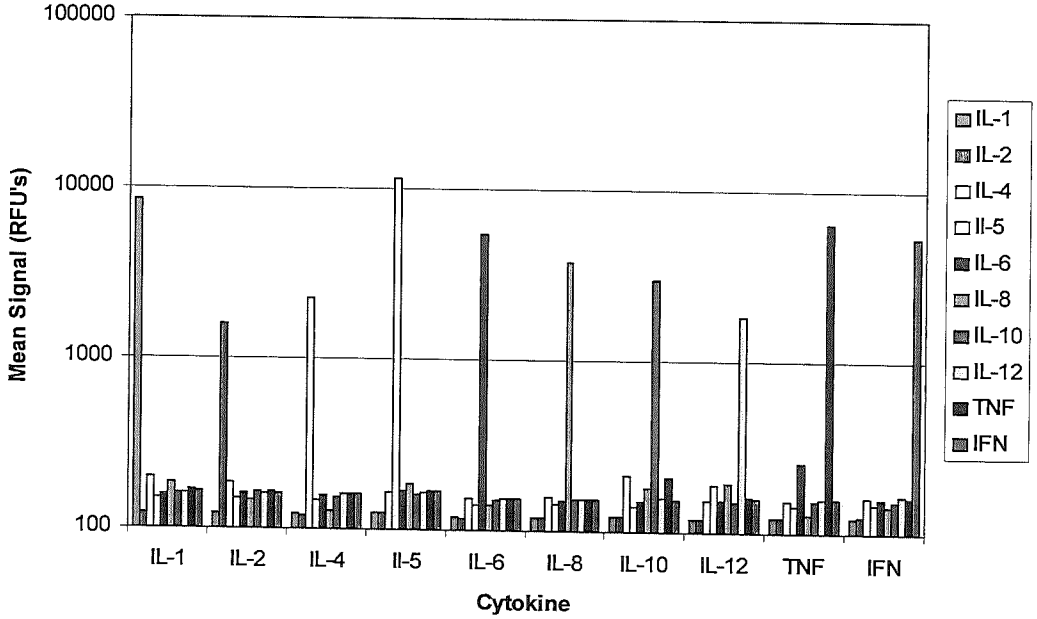
Multiplex Cytokine Assay Results

Specificity: Individual Standard @ 2500 pg/ml spike in Serum Diluent



Individual Standard @ 2500 pg/ml										
	IL-1	IL-2	IL-4	II-5	IL-6	IL-8	IL-10	IL-12	TNF	IFN
IL-1	**8416**	123	122	125	119	120	122	121	125	122
IL-2	123	**1615**	122	125	118	120	123	121	122	126
IL-4	199	185	**2258**	166	156	158	215	155	157	163
II-5	152	151	150	**11345**	142	145	141	191	145	148
IL-6	161	163	159	168	**5392**	151	151	157	259	159
IL-8	185	148	129	187	142	**3768**	183	196	128	146
IL-10	162	167	154	162	152	155	**2970**	153	155	155
IL-12	163	164	161	167	156	155	159	**1821**	158	166
TNF	170	167	164	169	155	155	212	163	**6376**	161
IFN	166	164	161	169	155	155	155	158	161	**5320**

-Specific Signal appears in diagonal axis

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Cytokine Summary

- Demonstrated a 10 Plex Cytokine Assays
- Excellent Precision < 10%
- Dynamic Range of at least 3 logs in linear range
- Sensitivity< 10 pg/ml
- Excellent Specificity
- User Friendly
  - No Pipetting of beads

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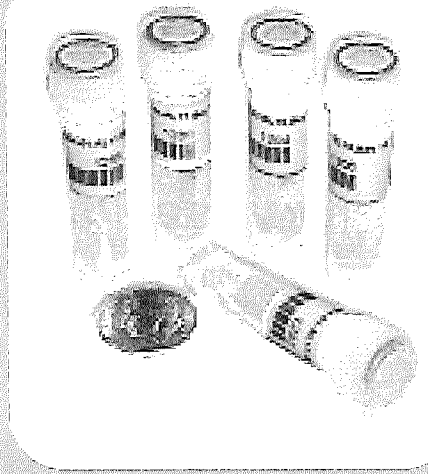
VeraCode Universal Beads

- Nucleic Acid Use
- Immobilized Capture Sequence
  - High Density
- Allows Rapid Assay Development
  - Synthesize Primer/Probe with complementary sequence
- Pre-screened Oligonucleotide Pairs
  - Eliminates Cross-reactivity
  - Secondary Structure, Hairpins, etc.
  - Equivalent Tm's



Unique Bead Code Types in Tubes

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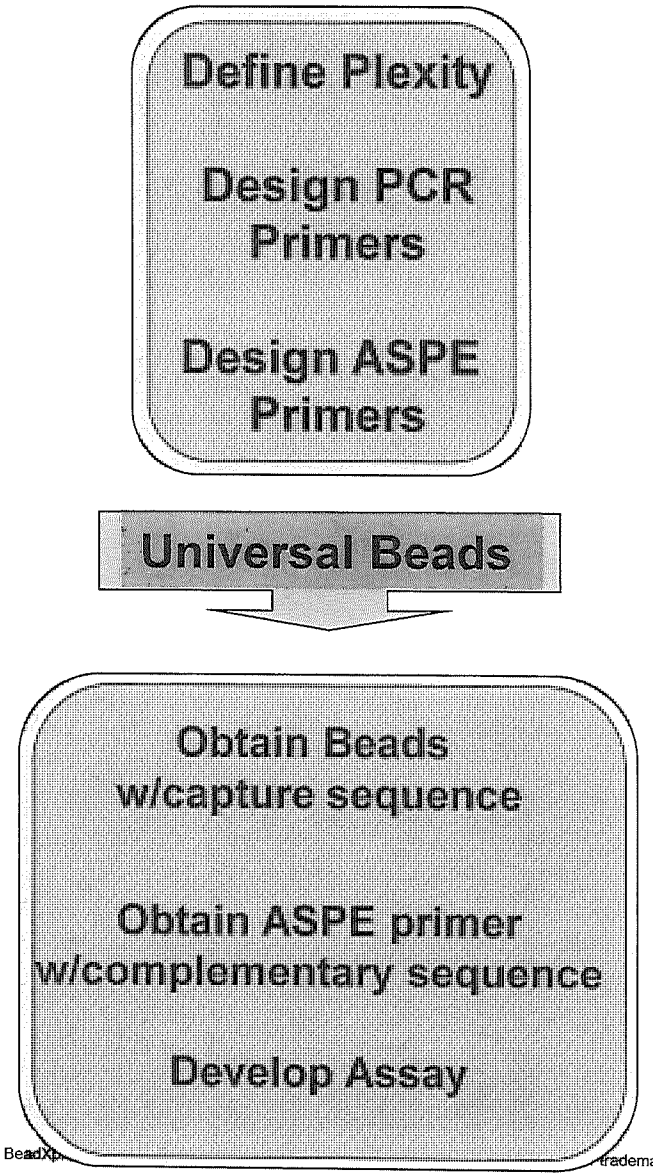
Assay Design For Genotyping (ASPE Chemistry)



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Multiplex Genotyping

- Allele-Specific Primer Extension Chemistry
  - Single Color
- Thrombosis Panel (4 Plex)
  - Factor V G1691A
  - Factor II G20210A
  - MTHFR C667T
  - MTHFR A1298C
- External Genomic DNA samples (n=29)
  - Molecular Essentials
    - 20 Samples w/ FV and FII genotypes
  - Children's Hospital of Eastern Ontario
    - 9 Samples w/ MTHFR667 genotypes

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EXHIBIT 3

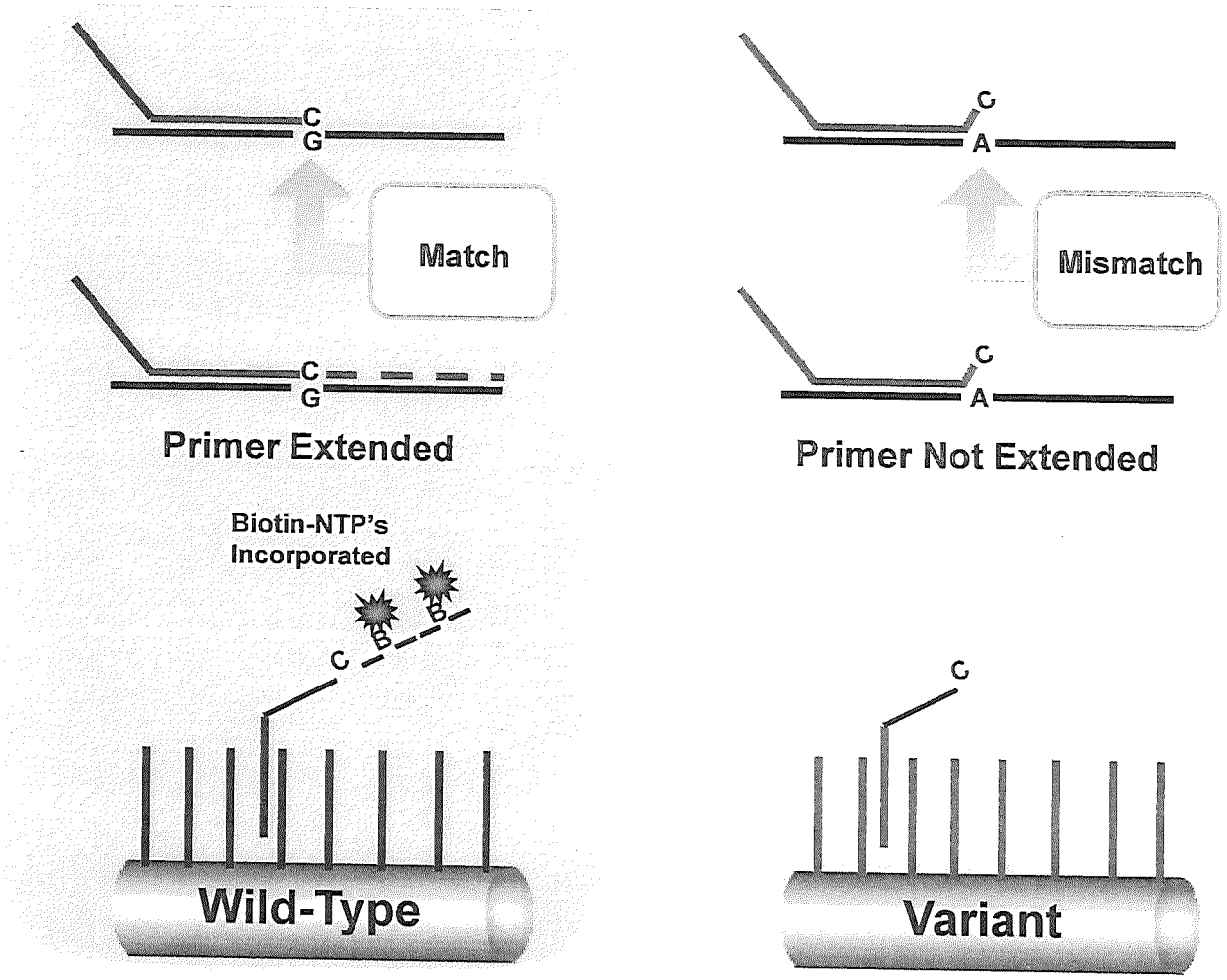
(Part III of III)

OF

DECLARATION OF GREGORY F. HEATH

Multiplex Genotyping Example

ALLELE-SPECIFIC PRIMER EXTENSION (ASPE)



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Multiplexing Genotyping Protocol

Multiplex PCR → Multiplex ASPE → Prepare Microtitre Plate

User defined Kitting Options

25 ul volume
25 ng gDNA

1:4 dilution
of PCR Products
In 20 ul

20-30 beads/well

Step 1: Add ASPE Sample → Step 2: Hybridize → Step 3: Stain with Label → Put plate in scanner

5 ul MPLX ASPE Product
to 45 ul Bead mix (1:10)

60 min. @ 45 C

15 min. @ RT

-No Wash Format

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External Genomic DNA Samples Analyzed (N=29)

Molecular Essentials

Sample ID	Genotype FV (G169A)	FII (G20210A)
1	Wt	Hz
2	Hz	Wt
3	Var	Wt
4	Hz	Hz
5	Wt	Hz
6	Hz	Wt
7	Var	Wt
8	Hz	Hz
9	Wt	Hz
10	Hz	Wt
11	Var	Wt
12	Wt	Wt
13	Wt	Hz
14	Var	Hz
15	Hz	Wt
16	Wt	Wt
17	Wt	Hz
18	Hz	Wt
19	Wt	Wt
20	Wt	Wt

(Nanogen/Third Wave/Roche Light Cycler)

Children's Hospital of Eastern Ontario

Sample ID	Genotype MTHFR 667
1	Var
2	Wt
3	Wt
4	Hz
5	Hz
6	Hz
7	Hz
8	Hz
9	Hz

(PCR/RFLP)

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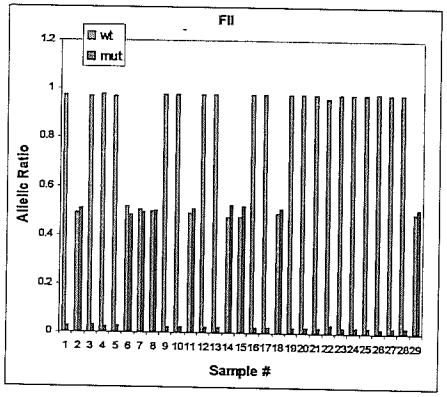
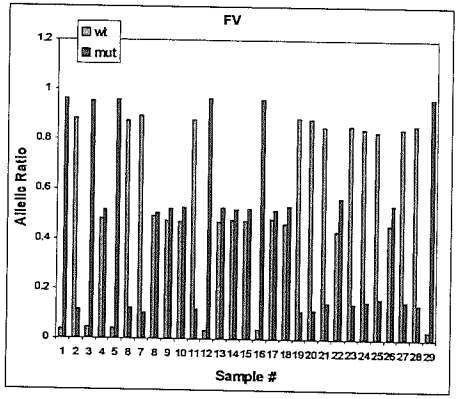
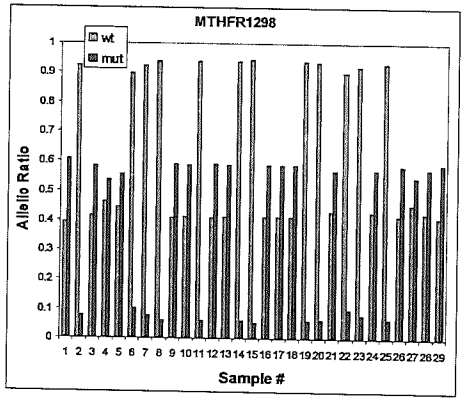
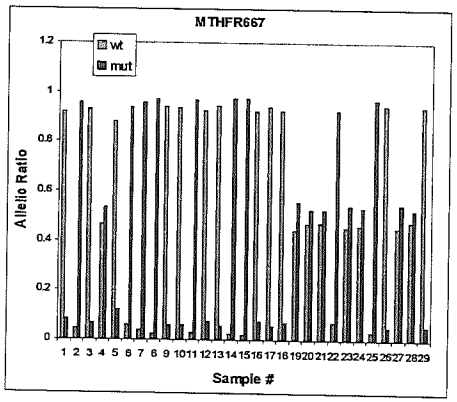
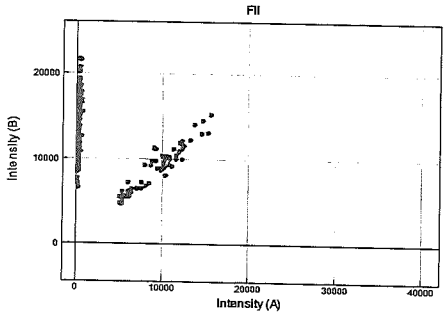
Low Plex ASPE Results – Thrombosis Panel

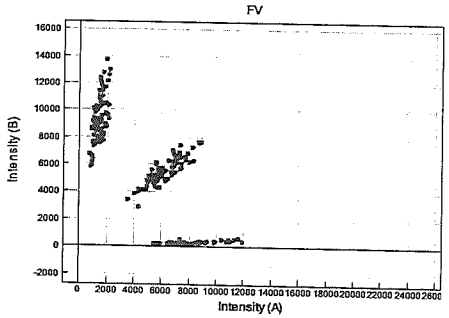


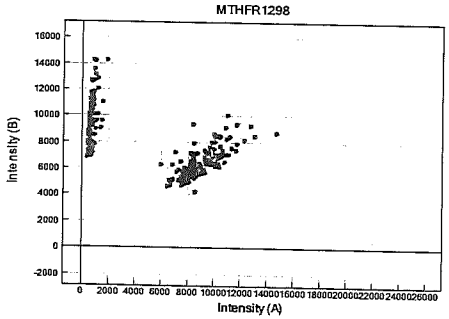


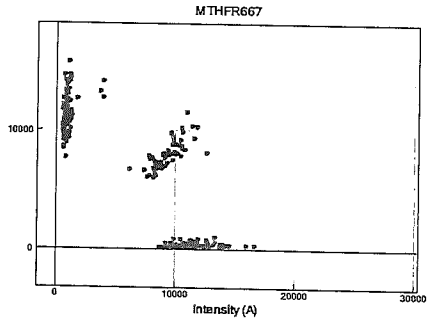












ILLUM-0059

- 100% reproducibility
- 100% concordant genotypes

Replicate CV (%)

SNP	wt	mut
FII	1.8	12.0
FV	5.9	5.8
MTHFR1298	4.2	8.7
MTHFR667	6.8	9.9

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Multiplex Genotyping Summary

- Developed a robust and simple Low Plex protocol
  - No wash steps
- Showed 100% concordance with external samples
- Flexibility to add or remove markers as desired
- User-friendly kitting tool for reduced pipetting

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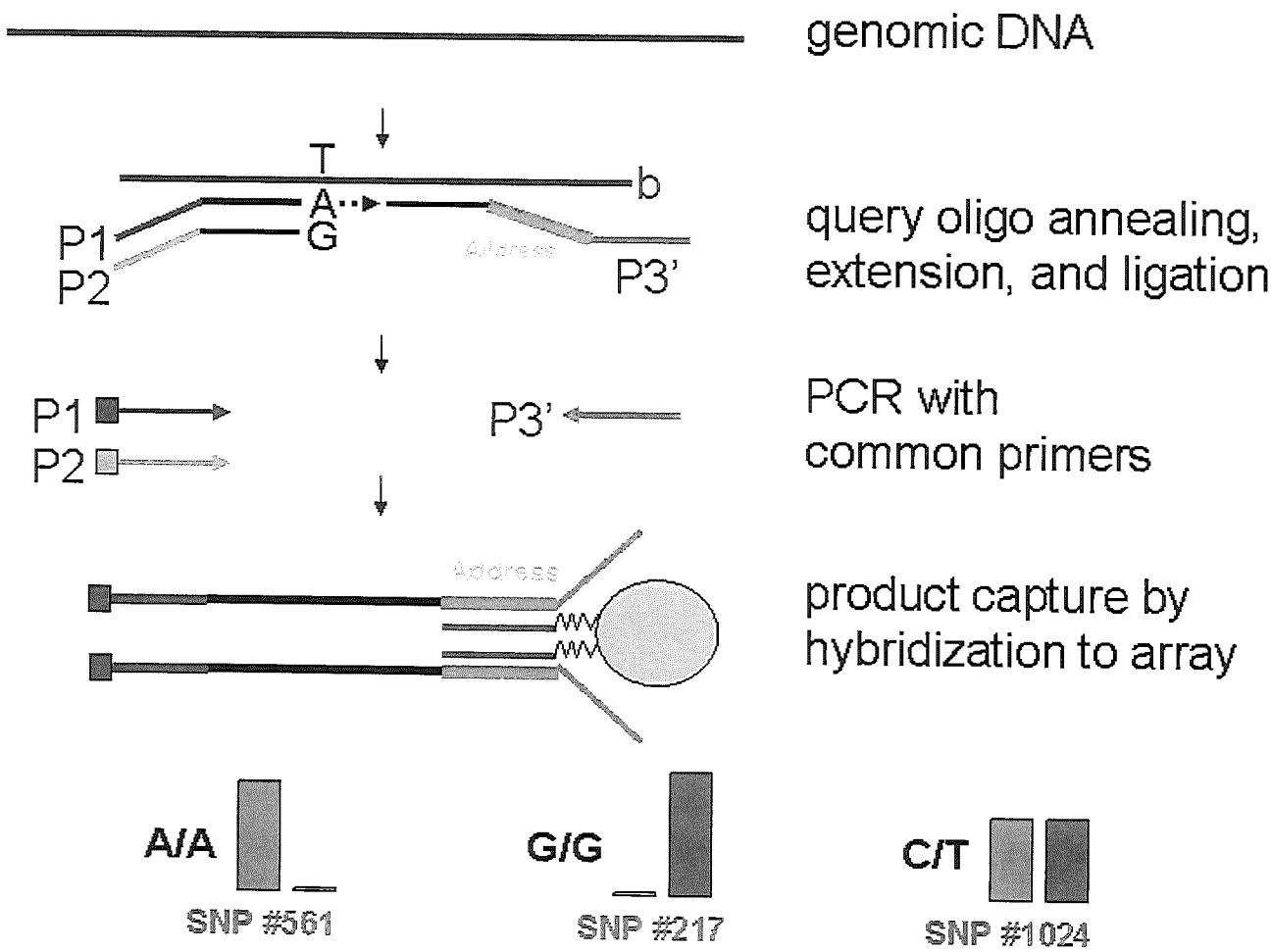
SNP Genotyping: GoldenGate™ Assay



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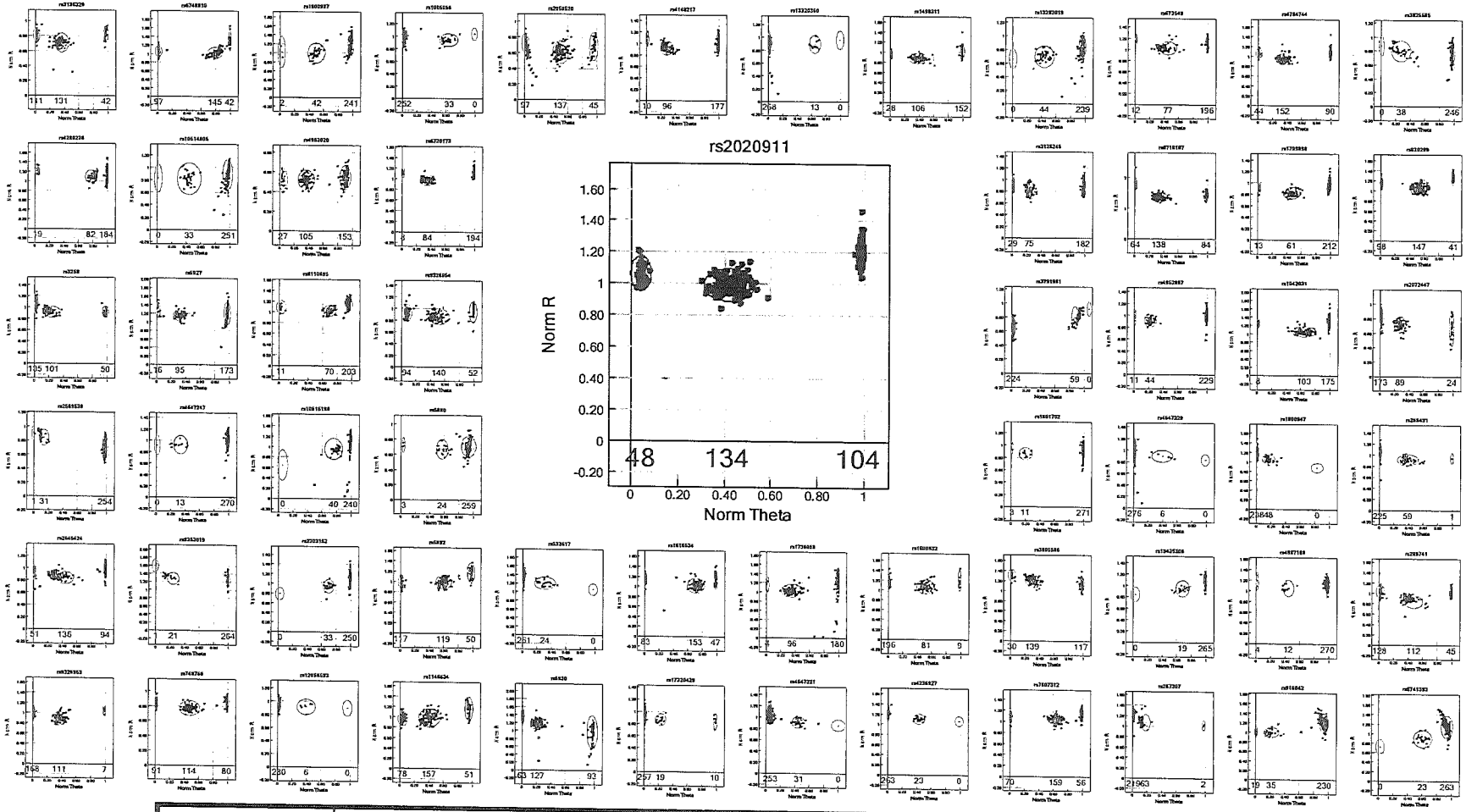
GoldenGate Assay Results



Reaction Multiplex	Samples Tested	Call Rate	Total # of Data Points	Reproducibility	Heritability
96	286	99.2%	41,184	100%	100%

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Summary

- One Platform: Multiple applications
- Two Color Detection System
- Unparalleled Multiplex Capabilities
- Flexibility to Accommodate Future Laboratory Needs

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Acknowledgements

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Illumina West	Steve Barnard Jerry Zhou Jo Yeakley Mickie Henshall
UC Irvine	Steve Lipkin
Children's Hospital of Eastern Ontario	Nancy Carson Alex MacKenzie
Molecular Essentials	Steve Cook

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Lab diagnostics: competition hots up in bead-based technology

Two high-flying publicly traded competitors that use bead technology in their multiplex arrays both revealed plans for enhancing their diagnostic portfolios at the annual scientific meeting of the American Association for Clinical Chemistry (AACC) in Chicago.

Illumina, a $73.5m company with a market cap of $1.6bn, has been marketing the genotyping services of its bead array technologies since 1998. But with the acquisition of privately-held CyVera in April 2005, the San Diego-based company now has bead-based technology that offers opportunities for in vitro and molecular diagnostic development.

VeraCode uses cylindrical glass microbeads measuring 240x28 microns. Each bead contains,a digital holographic element that, when excited by a laser, emits a unique code image that allows identification of the bead type.

Its digital coding can be used to identify the sample, the laboratory and the reagent kit, the company said.

The VeraCode technology will form the basis of the company's BeadXpress diagnostic platform, which is scheduled for market introduction before the end of the year.

On July 20, Illumina announced it was forming a diagnostic collaboration with the Bangalore, Indian company ReaMetrix, which will develop, validate and market diagnostic panels based on this new platform. ReaMetrix will hold rights in India, Illumina in the rest of the world.

Analysts and journalists dominated the company's July 25 dinner presentation on this latest technology, after Paolo Fortina, of Thomas Jefferson University in Philadelphia declared Illumina to be a company with "great potential" at an AACC briefing for analysts earlier that day.

The smaller of the two competitors is Luminex, with net sales of $42.3m and a market cap of $512m. Its x-Map technology performs discrete bioassays on the surface of colour-coded beads, known as microspheres, which are then read in a compact analyser. Using lasers and high-speed digital-signal processors, its analysers are capable of multiplexing up to 100 analytes in a single well simultaneously, identifying the bioassay and measuring the results, all in real time.

Since its foundation in 1995, Luminex has licensed its beads and systems to more than 50 strategic partners, including Digene, PerkinElmer, Tm Bioscience, Celera Diagnostics Abbott, Bio-Rad and Bayer. As a result, its technology has featured in 34 FDA-cleared products. Now the Austin, Texas, company has begun to develop its own test kits, as president Patrick Balthrop explained during a press conference at the AACC.

"There's plenty of opportunity available for both companies to compete in this market"

The company's first product, a 14-plex pneumococcal assay, used to determine immune responses to common pneumococcal vaccines, will be sold to reference labs later this year. The multiple, esoteric tests now available for this purpose are cumbersome to administer, Mr Balthrop explained. A second diagnostic line, a microRNA assay licensed from the Massachusetts Institute of Technology, will be marketed to research laboratories in the second half of this year for use in research on cancer, fat metabolism and for other purposes. Finally, the company just received a $300,000 research grant from the Defense Advanced Research Projects Agency, a branch of the US Army, to develop a chip-scale x-Map technology for bio-defence applications. Mr Balthrop could offer few details about the research, but did admit that the chip could eventually be leveraged for non-defence related uses.

Mr Balthrop said he does not feel that Illumina's move into bead-based diagnostics is a threat to his company. "We believe it is more of a validation event," he said. "It shows we're on the right track," he said. "There's plenty of opportunity available for both companies to compete in this market," he added.

Last week, Luminex announced that revenue for the second quarter of 2006 was $13.3m, a 25% increase compared with $10.7m on in the second quarter of 2005.

karen.riley@informa.com

Siemens' move to become first full-service diagnostic firm has rivals taking note

Siemens Medical Solutions formally entered the in vitro diagnostics industry on July 27, when it finalised its $1.86bn acquisition of the immunoassay company, Diagnostic Products Corporation (DPC).

The DPC deal is only the first – and smaller – of the two steps the German company is taking to create the world's first full-service diagnostics company. Later this year, the Erlangen company hopes to complete its $5.3bn deal to buy Bayer HealthCare's diagnostics division from the Leverkusen-based group, which recently acquired pharmaceutical rival Schering.

Siemens is already a giant in diagnostic imaging and health information systems. Bayer Diagnostics, based in Tarrytown, New York, and Los Angeles, California-based DPC, now gives the company a bridge between in vivo and in vitro solutions, explained Mohammad Naraghi, the senior vice-president for global business development, who engineered the two deals.

Siemens is especially excited about what the acquisitions bring it in the field of molecular medicine, enabling early detection and pharmacogenomics, and expanding the potential for screening programmes.

As Dr Naraghi explained, currently, when doctors identify a potentially cancerous lesion on an MRI or CAT scan, they must rely on a lab to test the biopsy sample. That might not be necessary under a combined Siemens company with access to DPC products, said Dr Naraghi, who trained as a cardiologist, worked on neural systems and earned two PHDs, one in physiology and another in biophysics.

DPC has 3% of the total IVD market, Bayer 10% (excluding blood glucose monitoring and blood screening sales), putting Siemens behind the No 2 player Abbott, with its 14% market share – but still well below Roche, the market leader with a 22% of the market. Both companies have posted far better-than-average sales growth for the diagnostics industry – 8% for Bayer and 10%, projected for this year, for DPC.

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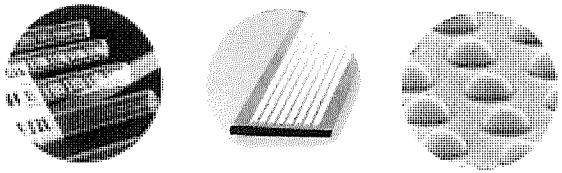

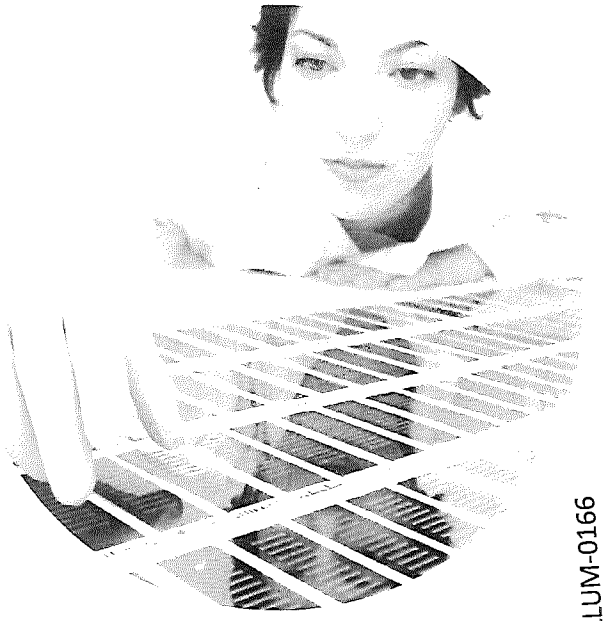

ILLUM-0166

VeraCode Technology – *From Research to Molecular Diagnostics*

Presented by:

Mickie Henshall,
Market Manager, Molecular Diagnostics

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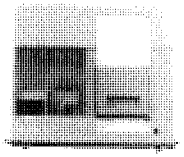
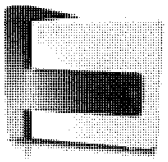
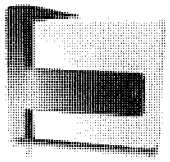
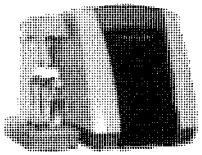
Most Complete Genomics Assay Portfolio

	Sequence-Based Discovery	Whole-Genome	Targeted Analysis		
APPLICATION					
TECHNOLOGY	Solexa Sequencing	BeadArray	BeadArray		VeraCode
PLATFORM	 Genome Analyzer	 iScan	 iScan		 BeadXpress
ASSAY	Sequencing by Synthesis	Infinium Assay Direct Hyb	Infinium Assay GoldenGate & DASL Assay		GoldenGate & DASL Assay
MARKER DENSITY	1base to >3GB	240K to 1M	6K to 60K (iSelect) 96 to 1536 (GoldenGate)		1 to 384-plex
			Custom	Standard	Custom
PRODUCT	Resequencing	HumanHap650Y	Infinium iSelect Genotyping Panels 6K-60K	Linkage-12	Methylation
	SNP & CNV Discovery	HumanHap650Y		CNV-12	
	De novo Sequencing	Human610-Quad	GoldenGate Genotyping Panels 96-1536	MHC GG	Carboxyl - Protein
	Tag Expression	Exon510-Duo	DASL Expression Panels 384-1536	African American Admixture GG	
	Transcript Profiling	HumanCNV370-Duo		CanineSNP20	
	ChIP Sequencing	Human 6/Ref-8 Gex	GoldenGate Methylation Panels 384-1536	BovineSNP50	
	MeDIP Sequencing	Mouse 6/Ref-8 Gex		Micro RNA	
	BiSulfite CpG	Rat Ref-12 Gex		Methylation Cancer Panel I	
	2008 Release	Genome-wide Methylation27			

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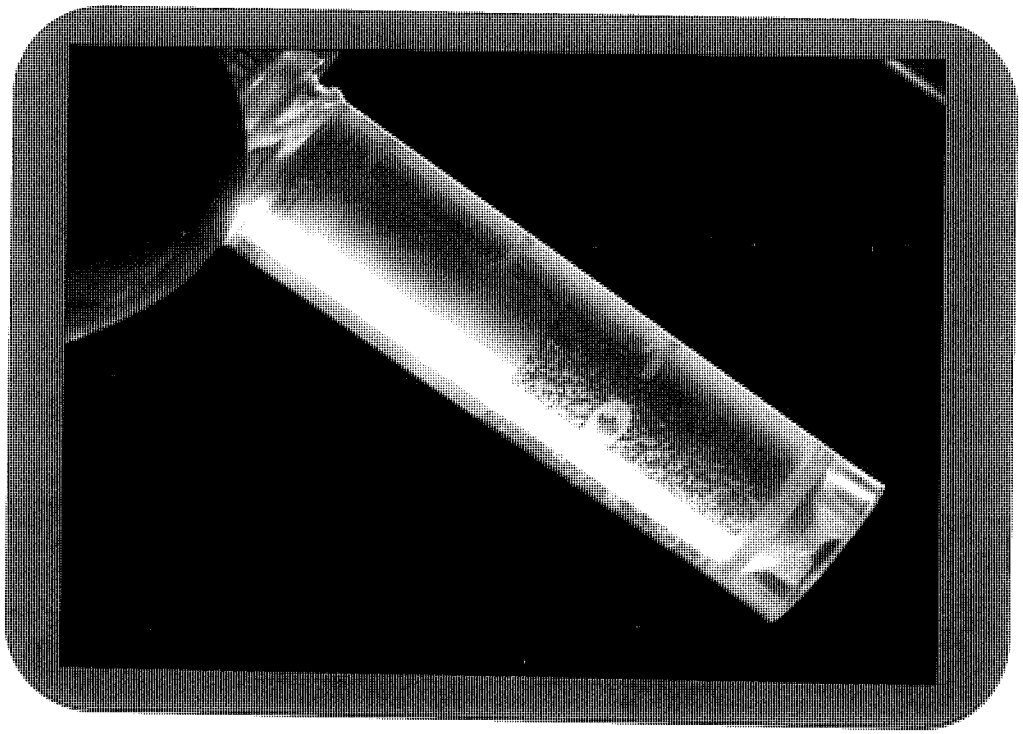
Illumina's Solution for Diverse Applications

VeraCode® Technology



- Cylindrical glass microbeads
- 240 µm length x 28 µm diameter

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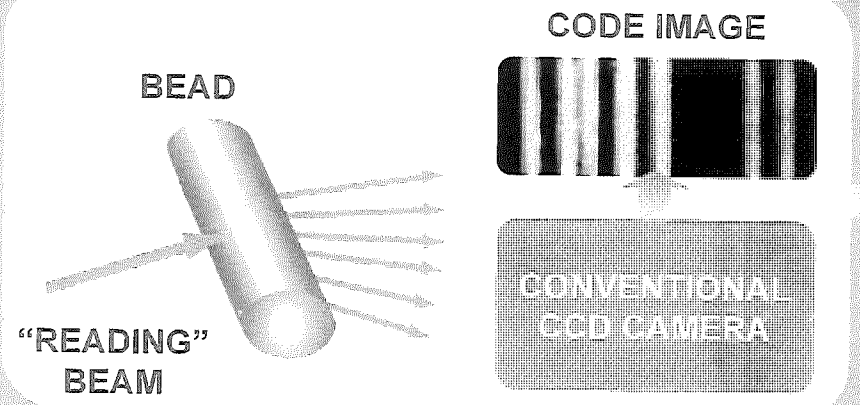
VeraCode Technology

CODE GENERATED BY CREATING EMBEDDED HOLOGRAPHIC DIFFRACTIVE ELEMENTS



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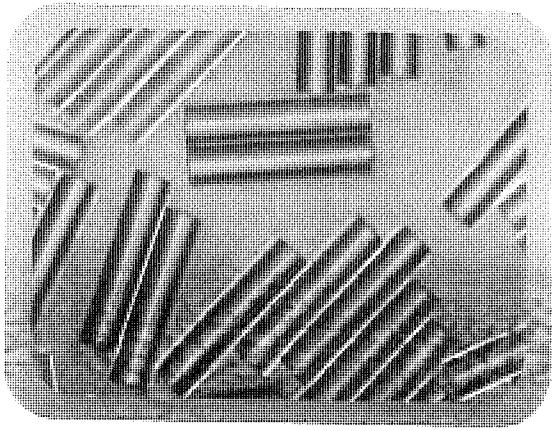

- High Density Codes Easily Imprinted (24 bit)
- Virtually Unlimited Unique Bead Codes Available – 626 unique codes used in launched products
- Glass Surface of Beads Ideal for Bioassays – numerous surface chemistries available
- Specific panels created easily with addition or removal of specific bead types

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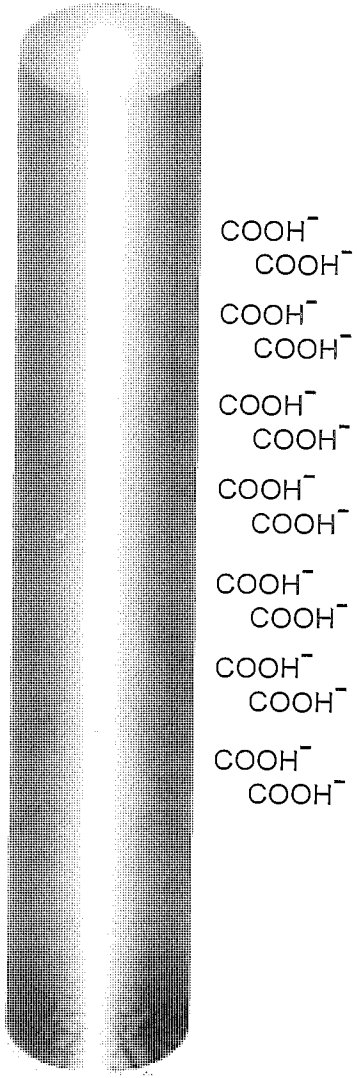
Carboxyl Beads: Chemistry of Attachment



PROTEIN ATTACHMENT: TWO-STEP PROCESS

Activate Surface → EDC/Sulfo-NHS → Covalently Bind

Antibodies
Antigens
Peptides
Streptavidin

NUCLEIC ACID ATTACHMENT: ONE-STEP PROCESS

EDC/Sulfo-NHS plus NH_2-Oligo

Nucleic Acids

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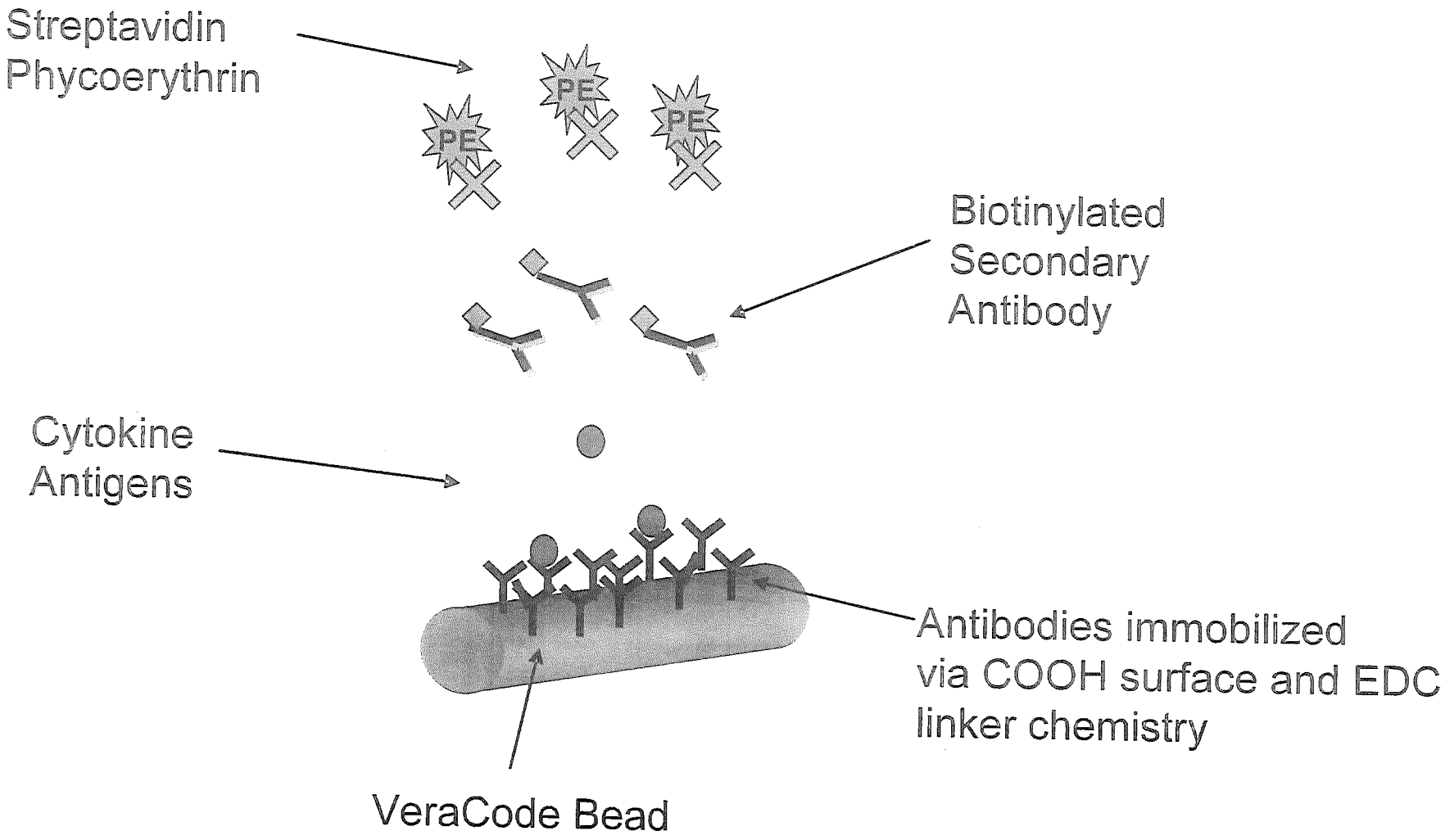
Cytokine Sandwich Assay



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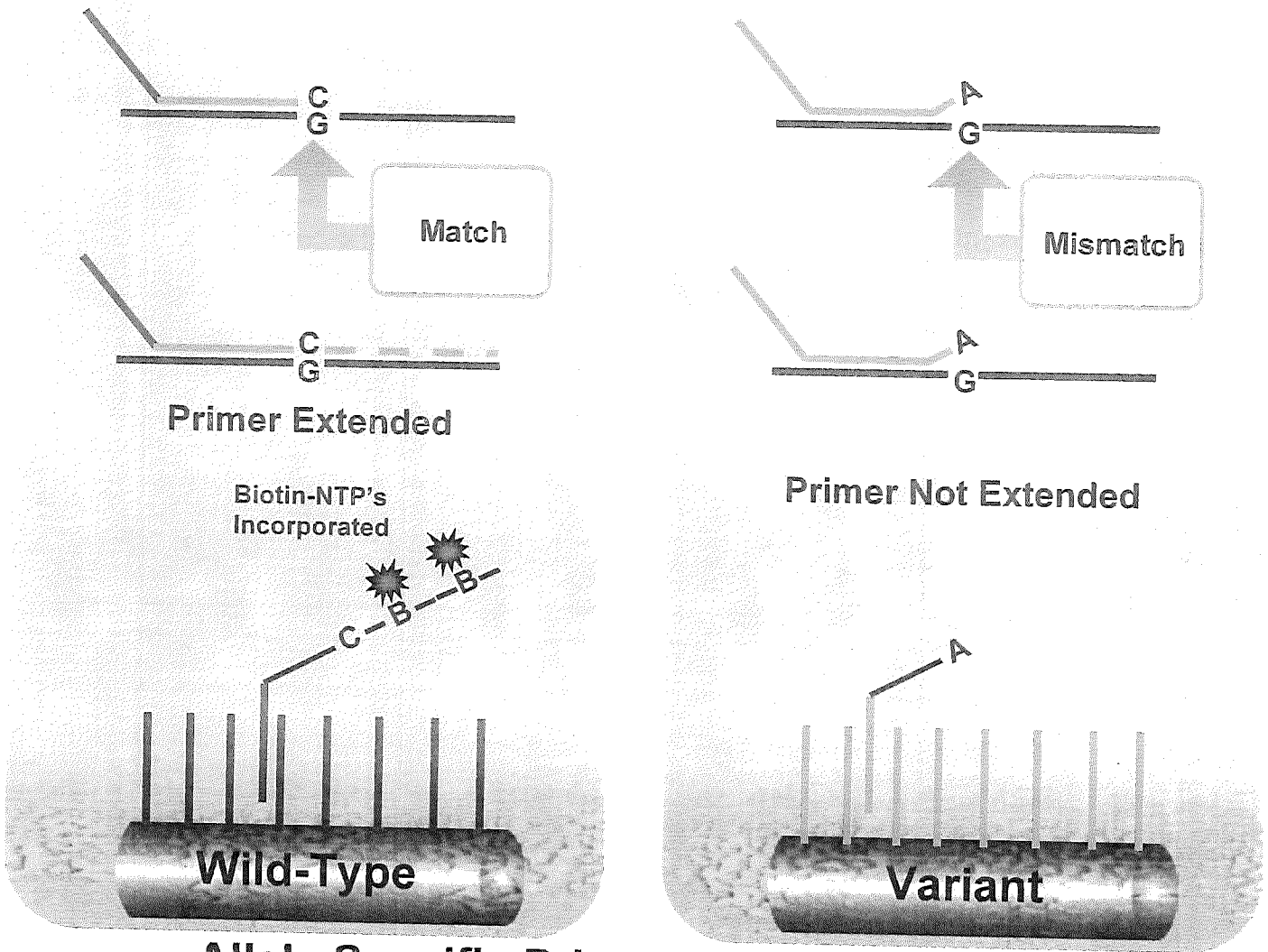
Universal Oligo Capture Beads



Allele Specific Primer Extension Assays

ILLUM-0172

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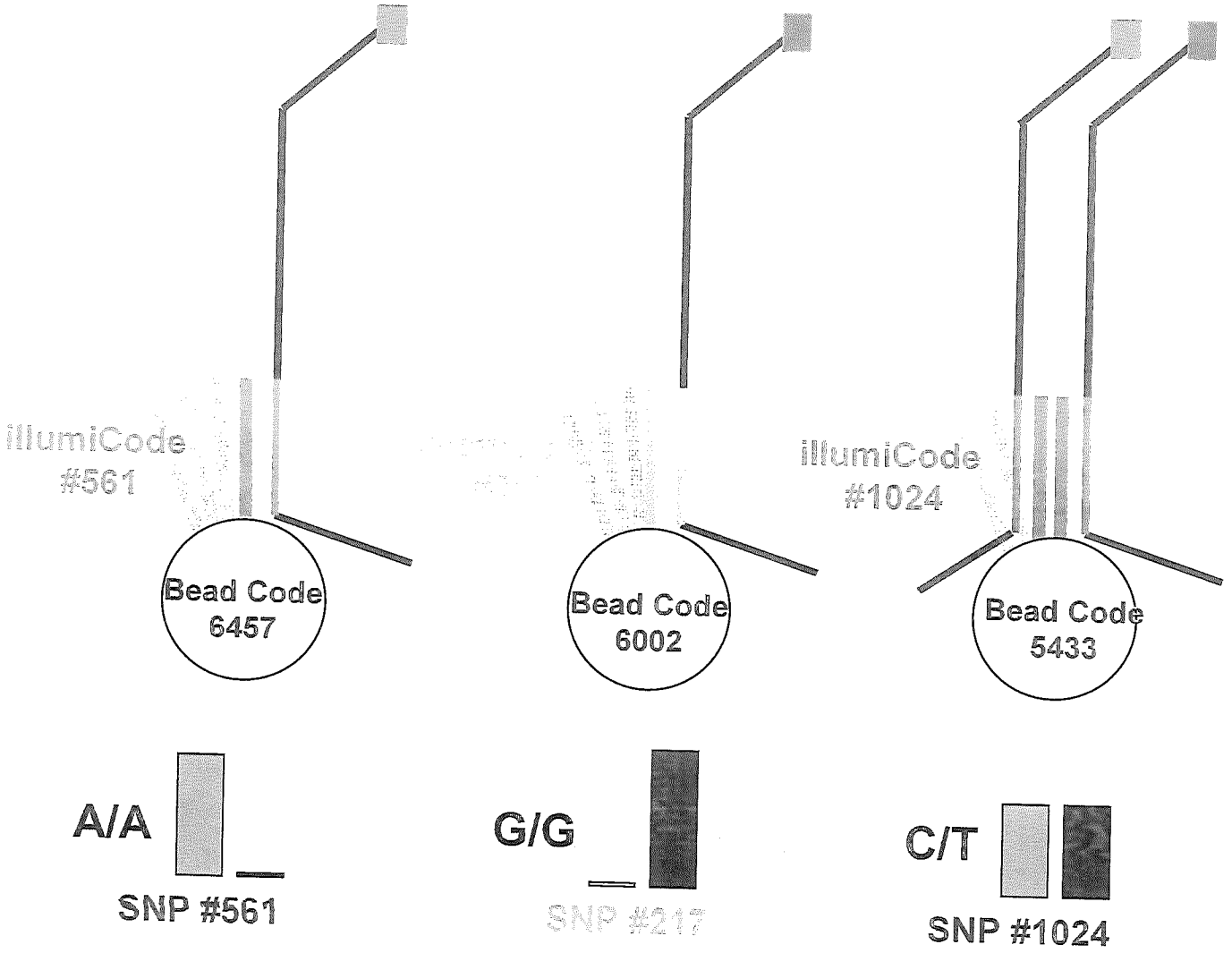
GoldenGate Assay – two color detection

Hybridization to VeraCode Beads – one SNP per bead type



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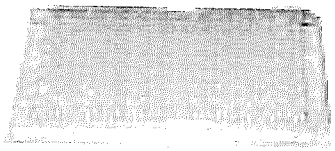
Easily adaptable to changing content requirements

VeraCode Beads Pre-plated into standard product

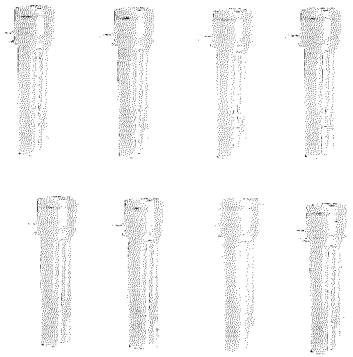


Beads Pooled in 96-well Plates

(96 & 384-plex/well)

+

Individual Tubes of VeraCode Beads



Customized panels created by pooling different tubes of beads

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Comprehensive VeraCode product portfolio

VeraCode Carboxyl Bead Sets

VeraCode Universal Capture Bead Sets

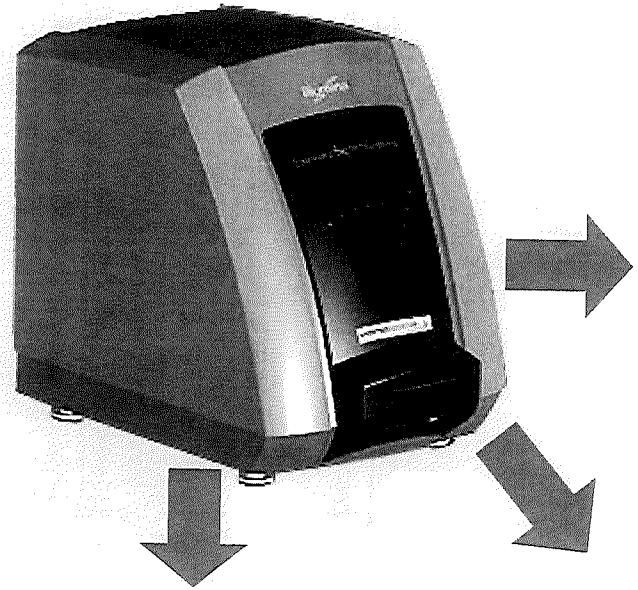
Custom GoldenGate Genotyping, 96 & 384-plex

DASL Custom Gene Expression, 32 to 384-plex

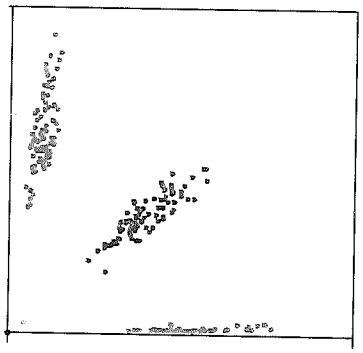
Custom GoldenGate Methylation, 48 to 384-plex

ILLUM-0175

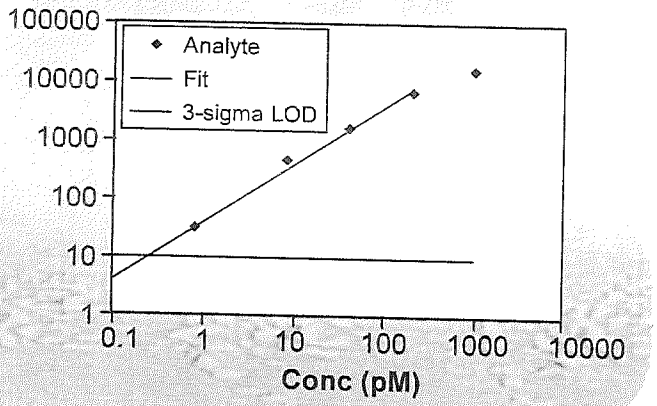
Analyzer for Multiple Applications



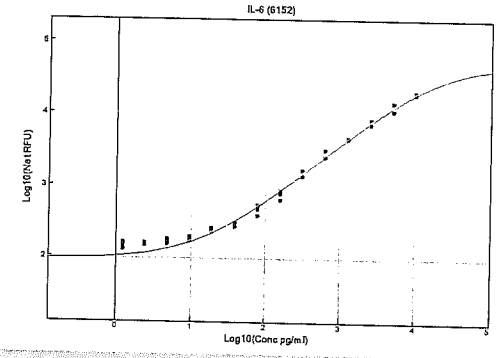
GENOTYPING



GENE REGULATION



PROTEIN EXPRESSION



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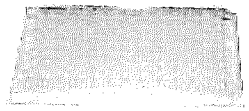
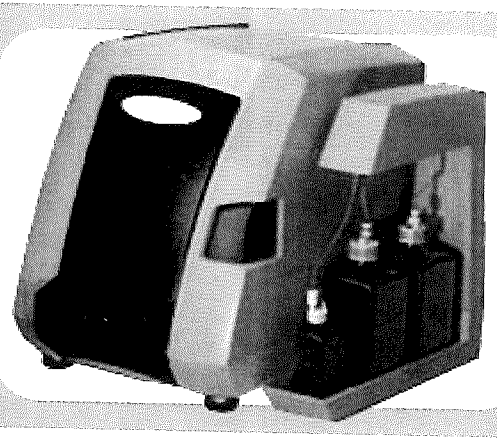
BeadXpress™ Reader

ASSAY BEAD KIT

SAMPLE PLATE



ASSAY CODE LIBRARY



DATA & LOG FILES

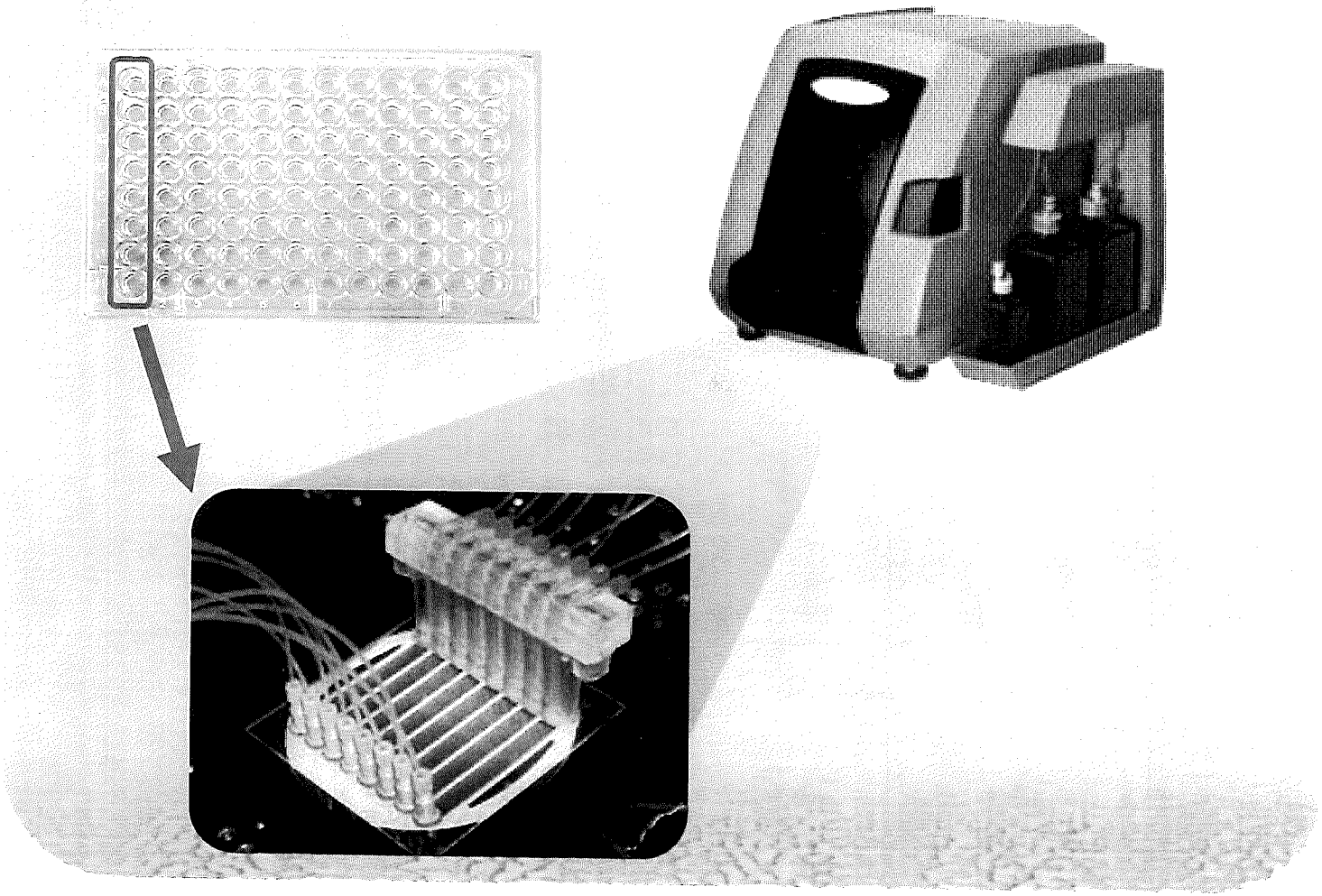
INSTRUMENT SPECIFICATIONS

SAMPLE DELIVERY FORMAT	Standard 96-well plate & Stripwell Plates
MULTIPLEXING PER SINGLE WELL	1 to 384
THROUGHPUT	120 samples/hr at 10-plex (two-color detection) 90 samples/hr at 96-plex (two-color detection)
DETECTION	Dual and single-color detection
AUTOMATION	Designed to be compatible with standard laboratory automation
REGULATORY	Developed under Regulatory Design Control (DHF)

ILLUM-0177

illumina®

BeadXpress Reader

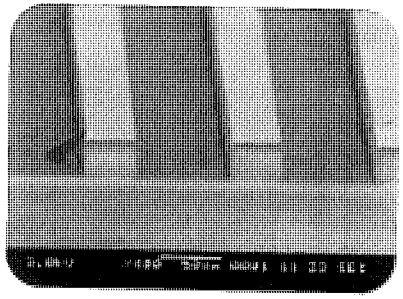


ILLUM-0178

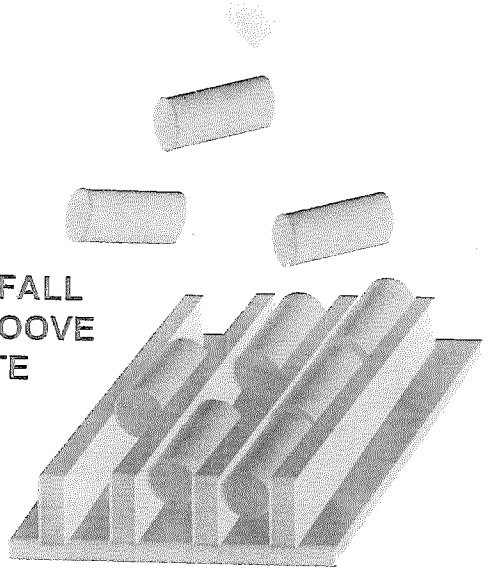
illumina®

VeraCode Technology

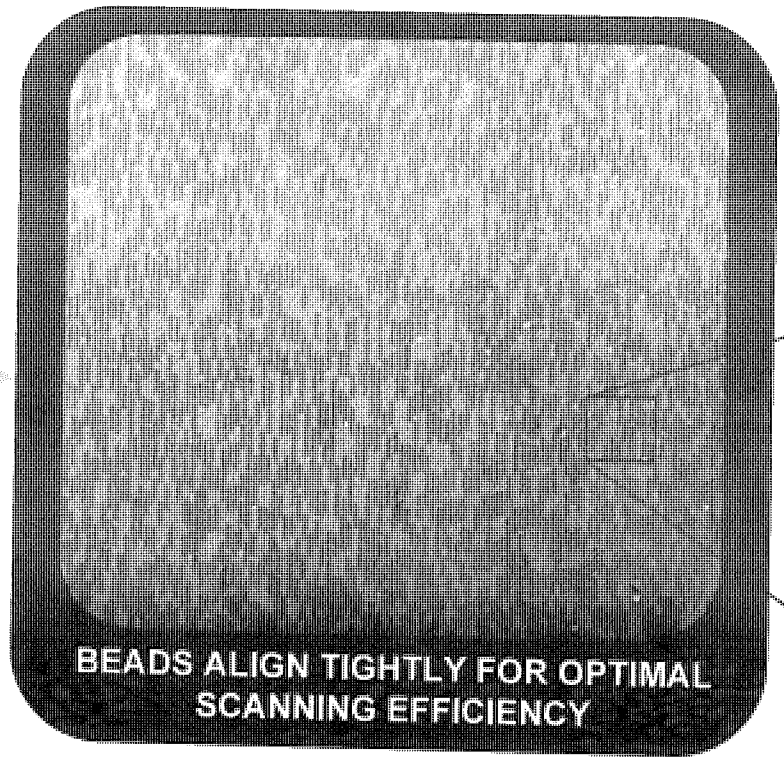
CAPILLARY FORCE ATTRACTS BEADS INTO GROOVES



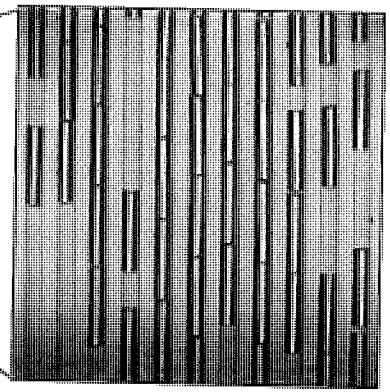
GROOVE PLATE CROSS-SECTION



BEADS FALL INTO GROOVE PLATE



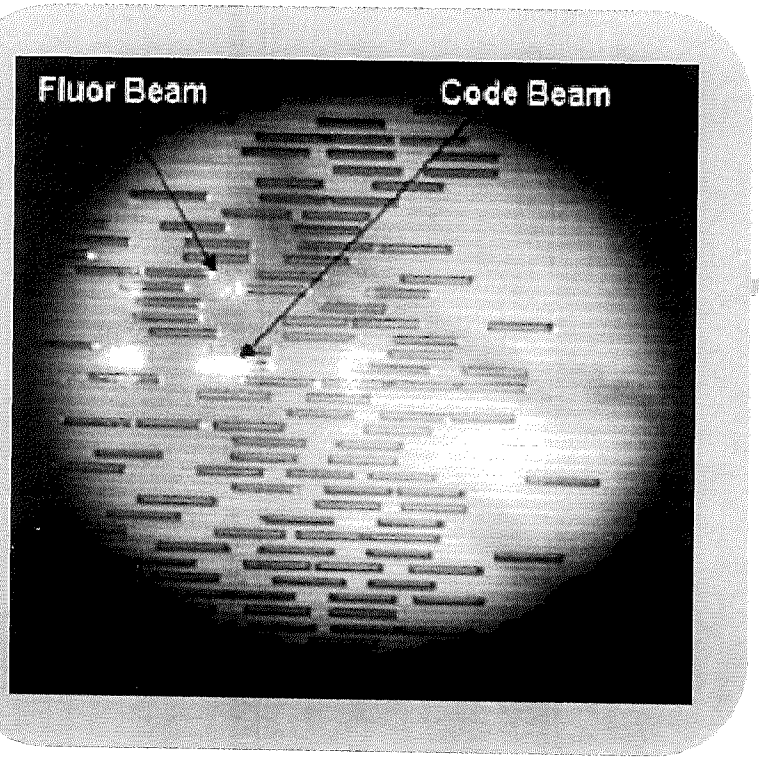
BEADS ALIGN TIGHTLY FOR OPTIMAL SCANNING EFFICIENCY

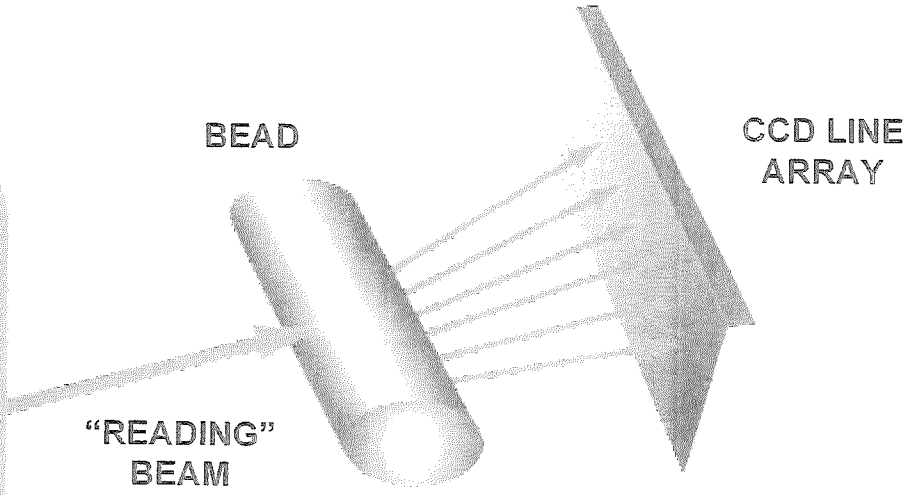


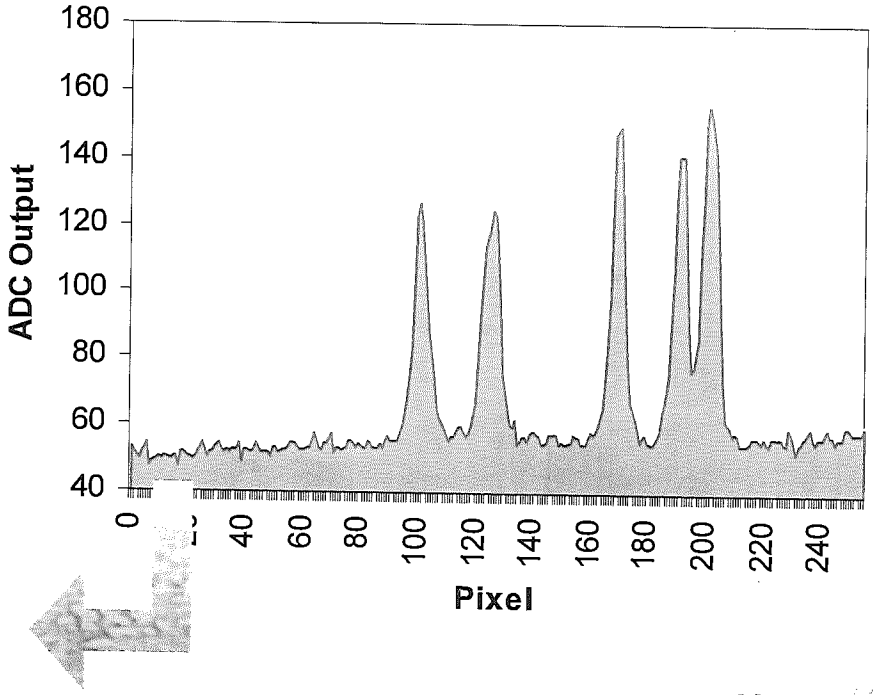
ILLUM-0179

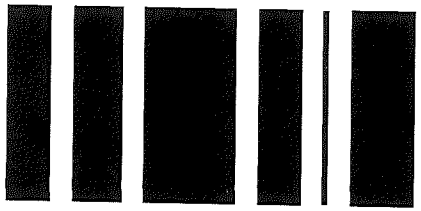
illumina®

Code Detection









ILLUM-0180

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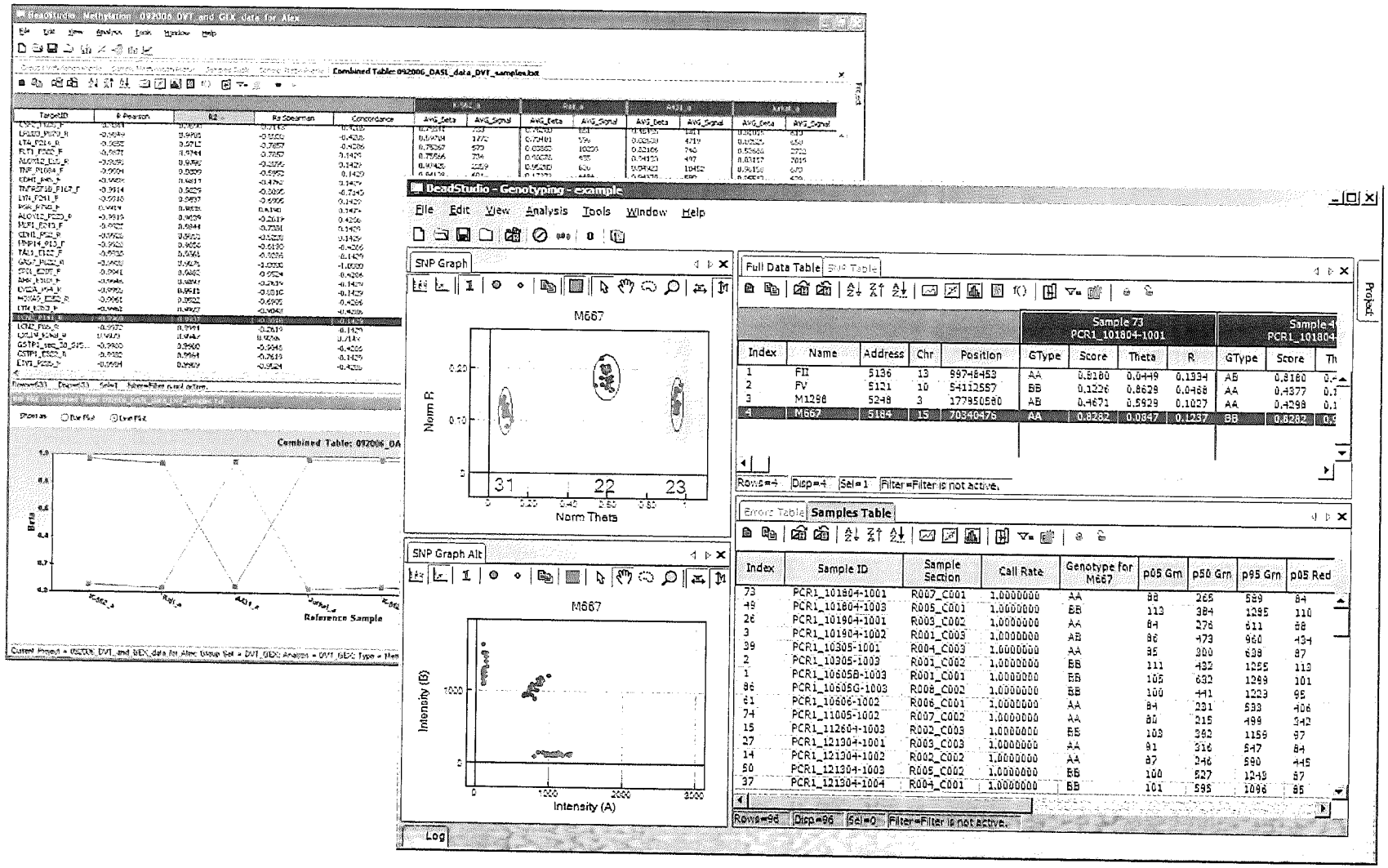
Data Analysis Streamlined with BeadStudio



ILLUM-0181

illumina

What's Next for BeadXpress

Expanded Custom GoldenGate genotyping multiplex ranges (48, 96, 144, 192, 288, 384...)

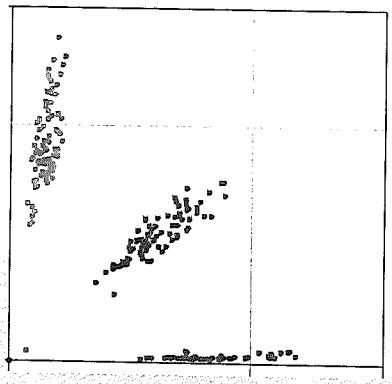
Reduced packaging of VeraCode GoldenGate kits and reagents

New release of VeraScan operating system

VeraCode GoldenGate training kits

ILLUM-0182

DIAGNOSTICS



510(k) submission to FDA

Faster (single day) GoldenGate assay

ADME Panel

Other applied panels

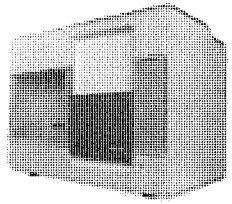
illumina

From Discovery to Molecular Diagnostics

Discovery | Focused Research & Validation | Molecular Dx

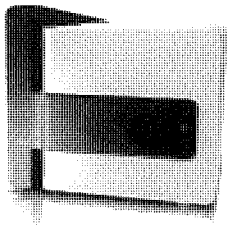
$>10^9$ 10^8 10^7 10^6 10^5 10^4 10^3 10^2 10 1

Whole Genome **Single Marker**



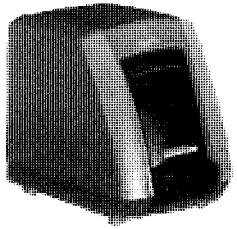
- WG Resequencing
- WG Gene Expression
- Micro RNA Discovery & Profiling
- WG ChIP-Seq
- Candidate-Region resequencing
- Whole Chromosome sequencing

Genome Analyzer



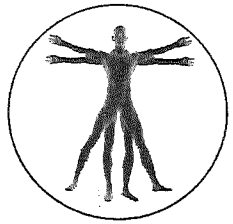
- Gene Expression
- WG Genotyping
- WG CNV
- Biomarker Discovery
- HT Biomarker/lead validation
- Custom genotyping
- Focused expression
- DASL for FFPE

iScan



- Low/mid density GT/GEX
- Protein applications
- Biomarker screening
- Biomarker panels

BeadXpress



ILLUM-0183

illumina

Illumina-ting the Origins of the Domestic Cat – Efficiency of the GoldenGate® Assay for VeraCode® in Cat Genetics

Leslie A. Lyons, PhD
Associate Professor
Department of Population Health & Reproduction (PHR)
School of Veterinary Medicine
University of California, Davis

ILLUM-0184

illumina®

Illumina and ReaMetrix to Collaborate on Molecular Diagnostics and Market Development; ReaMetrix Secures Non-Exclusive License to Market Diagnostic Panels in India

SAN DIEGO & SAN CARLOS, Calif.--(BUSINESS WIRE)--July 20, 2006--Illumina, Inc. (NASDAQ: ILMN) and ReaMetrix, Inc. announced today the formation of a diagnostic collaboration under which the companies plan to co-develop molecular diagnostic panels for a range of disease areas. Under the terms of the agreement, ReaMetrix will gain non-exclusive rights to market the resulting panels to the country of India and its more than one billion inhabitants. Illumina will retain rights to market the tests outside of India.

Illumina will supply VeraCode(TM) technology and other reagents for the tests. ReaMetrix will develop, validate and market diagnostic panels based on Illumina's upcoming BeadXpress(TM) platform, scheduled for market introduction before the end of the calendar year.

ReaMetrix will drive market development activities from its operation in Bangalore, India. According to Bala Manian, Ph.D., ReaMetrix Chief Executive Officer, "India's rapidly emerging healthcare system presents a tremendous opportunity to leapfrog current diagnostics and chart a new path with innovative molecular and pharmacogenomic testing. Teaming up with Illumina and its BeadXpress diagnostic platform, we see a significant opportunity to drive the evolution toward the efficiencies inherent in targeted, personalized medicine. In targeting the wide-open Indian market, we will be creating products that will drive value the world over."

According to Jay Flatley, President and CEO of Illumina, "Many of us in the genomics community know Bala Manian from past lives. Bala is a true visionary and we're looking forward to working closely with him and his team to develop and validate novel diagnostic panels that will help predict the risk of disease, enable earlier intervention and guide therapy. For Illumina, this agreement represents another important step forward into the clinical diagnostics market."

About Illumina

Illumina (http://www.illumina.com/) develops and markets next-generation tools for the large-scale analysis of genetic variation and function. The Company's proprietary BeadArray technology -- used in leading genomics centers around the world -- provides the throughput, cost effectiveness and flexibility necessary to enable researchers in the life sciences and pharmaceutical industries to perform the billions of tests necessary to extract medically valuable information from advances in genomics and proteomics. This information will help pave the way to personalized medicine by correlating genetic variation and gene function with particular disease states, enhancing drug discovery, allowing diseases to be detected earlier and more specifically, and permitting better choices of drugs for individual patients.

About ReaMetrix

ReaMetrix (http://www.reametrix.com/) is committed to becoming the leading provider of high-quality research and diagnostic assay solutions resulting in a transformation of the cost opportunities available in India into value for both the biotechnology and global health sectors. ReaMetrix' business model leverages local resources to address local markets, and the Company believes that its market

understanding gives it a competitive advantage in understanding and serving India as well as other developing nations.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: this release may contain forward-looking statements that involve risks and uncertainties. Among the important factors that could cause actual results to differ materially from those in any forward-looking statements are the costs and outcome of Illumina's litigation with Affymetrix, the Company's ability to scale and integrate CyVera technology, the ability to further scale oligo synthesis output and technology to satisfy market demand deriving from the Company's collaboration with Invitrogen, Illumina's ability to further develop and commercialize its BeadArray technologies and to deploy new gene expression and genotyping products and applications for its platform technology, to manufacture robust Sentrix (R) arrays -- including HumanHap BeadChips -- and Oligator(R) oligonucleotides, and other factors detailed in the Company's filings with the Securities and Exchange Commission including its recent filings on Forms 10-K and 10-Q or in information disclosed in public conference calls, the date and time of which are released beforehand. Illumina disclaims any intent or obligation to update these forward-looking statements beyond the date of this release.

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or
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Bala Manian, Ph.D., +1-650-620-9253 ext 102
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Dr. Sheri Miraglia, +1-650-620-9253 ext 109
sheri@reametrix.com
SOURCE: Illumina, Inc.

Illumina

Illumina Receives FDA 510(k) Clearance for VeraCode(R) Genotyping Test for Factor V (Leiden) and Factor II (Prothrombin)

SAN DIEGO, May 18, 2010 (BUSINESS WIRE) --Illumina, Inc. (NASDAQ:ILMN) today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) market clearance for the VeraCode (R) Genotyping Test for Factor V (Leiden) and Factor II (Prothrombin). The VeraCode Genotyping Test is comprised of the company's VeraCode digital microbead technology and proprietary assay chemistry. The BeadXpress(R) System, which received a separate 510(k) market clearance, is FDA-cleared for in vitro diagnostic use only with the VeraCode Genotyping Test for Factor V and Factor II.

About Illumina

Illumina (http://www.illumina.com) is the leading developer, manufacturer, and marketer of integrated systems for the analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations, and biotechnology companies. Our tools provide researchers around the world with the performance, throughput, cost effectiveness, and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information from advances in genomics and proteomics. We believe this information will enable researchers to correlate genetic variation and biological function, which will enhance drug discovery and clinical research, allow diseases to be detected earlier, and permit better choices of drugs for individual patients.

SOURCE: Illumina, Inc.

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illumina

Illumina Introduces VeraCode(R) ADME Core Panel for Pharmaceutical Research
Key Biomarkers Enable Researchers to Investigate Pharmacogenetic Variations Associated with Drug Metabolism

SAN DIEGO, Apr 07, 2010 (BUSINESS WIRE) --Illumina, Inc. (NASDAQ:ILMN) today announced the launch of its VeraCode ADME Core Panel designed to help researchers study genetic predispositions for differential drug response and adverse events. The VeraCode ADME Core Panel offers the most complete representation of the key biomarkers associated with drug absorption, distribution, metabolism and excretion (ADME) as standardized by pharmaceutical industry experts in the PharmADME Core List. Leveraging Illumina's innovative VeraCode technology, researchers using the product can analyze key ADME content in as little as one day, allowing studies to proceed faster and more efficiently than ever before.

"We selected the ADME Core Panel for its multiplex coverage of the key biomarkers associated with drugs in our initial study, and for its efficiency in processing samples," said Dan Masys, M.D., chair of Bioinformatics at Vanderbilt University. "We are looking for a set of variants that reliably predict an adverse effect from a medication, and have over 80,000 DNA samples with matched, de-identified medical records to support the study." Dr. Masys is leading the Vanderbilt Electronic Systems for Pharmacogenetic Assessment study using the VeraCode ADME Core Panel to generate an extensive pharmacogenetic database. This database will be widely used to link genotypes to drug response phenotypes extracted from electronic health record data.

The VeraCode ADME Core Panel offers:

High-value content: The panel contains 184 biomarkers in 34 genes, with the highest coverage of the PharmADME Core List. This list, produced by the PharmADME Working Group of industry and academic experts, provides comprehensive coverage of the most biologically relevant biomarkers spanning complex regions of the genome.

Rapid and precise genotyping assay: Using a highly specific and streamlined chemistry, DNA can be genotyped within 8 hours with less than 2.5 hours of hands-on time, enabling researchers to complete studies faster than ever before.

High-quality data: Two layers of specificity and integrated quality controls ensure data precision with an excellent call rate. In addition, the supporting software for VeraScan offers a convenient user interface that manages user authentication, logs system activity, and automatically translates genotype data into the star nomenclature used by researchers to analyze pharmacogenetic data.

"Understanding genetic variability associated with drug response and disposition is a key step toward the realization of personalized medicine, and the VeraCode ADME Core Panel will help enable this exciting transformation," said Jay Flatley, president and CEO of Illumina. "With the cost of bringing a new medicine to market now exceeding $1 billion and over $220 billion spent annually on medications in the U.S., it is critical that we look for savings in all stages of drug development. With its emphasis on rapid operation and high-quality data, the VeraCode ADME Core Panel can help bring safe and effective therapies to patients as quickly as possible."

For more information about the VeraCode ADME Core Panel, please visit http://www.illumina.com/VeraCodeADME.

About Illumina

Illumina (http://www.illumina.com) is the leading developer, manufacturer, and marketer of integrated systems for the analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations, and biotechnology companies. Our tools provide researchers around the world with the performance, throughput, cost effectiveness, and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information from advances in genomics and proteomics. We believe this information will enable researchers to correlate genetic variation and biological function, which will enhance drug discovery and clinical research, allow diseases to be detected earlier, and permit better choices of drugs for individual patients.

Forward-Looking Statements

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SOURCE: Illumina, Inc.

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illumina

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illumina®

Illumina Receives FDA 510(k) Clearance for Its BeadXpress(R) Multiplex Analysis System

Provides Clinically Validated Platform for the Next Generation of Molecular Diagnostic Tests

SAN DIEGO, May 04, 2010 (BUSINESS WIRE) --Illumina, Inc. (NASDAQ:ILMN) today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) market clearance for the company's BeadXpress system for multiplex genetic analysis. According to the FDA's indications of use, the BeadXpress system - consisting of Illumina's BeadXpress Reader and VeraScan software - is an in-vitro diagnostic device intended for the simultaneous detection of multiple analytes in a DNA sample utilizing VeraCode holographic microbead technology. The system is FDA cleared for in vitro diagnostic use only with FDA cleared VeraCode tests.

"This approval represents a significant and exciting transitional step for Illumina into the diagnostics field, where the potential is great for molecular medicine to make a real difference in the way disease is detected and ultimately prevented and treated," said Jay Flatley, president and CEO. "It demonstrates Illumina's ability to meet stringent regulatory requirements in designing and manufacturing an FDA-cleared in-vitro diagnostic device. This will serve as an important foundation for our future plans in the diagnostics area. Ultimately, our goal is to become a leader in translational medicine, focusing on complex diseases that benefit from high performance analysis, including genotyping, copy number, gene expression, methylation and protein analysis."

Illumina introduced the BeadXpress system in 2007 with Research Use Only kits for custom genotyping, gene expression, methylation and protein analysis. Since then it has been adopted by research, agricultural, industrial and pharmaceutical institutions worldwide. Utilizing uniquely inscribed digital microbeads, VeraCode technology provides high-quality data, broad multiplexing capability and assay flexibility. Illumina submitted the system for FDA review in September 2009.

"510(k) clearance opens up a wide range of new possibilities for our many clinical research and commercial partners, who can now pursue diagnostic development on our proven, high-performance BeadXpress platform," said Gregory Heath, Ph.D., senior vice president and general manager, Diagnostics. One of those partners is EraGen Biosciences, Inc., which concluded a licensing agreement with Illumina in 2009 to transfer their assays onto the BeadXpress System. "This clearance is a significant step forward in progressing our partnership in the clinical marketplace," said Irene Hrusovsky, M.D., president and CEO of EraGen Biosciences.

For more information, please visit http://www.illumina.com.

About Illumina

Illumina (http://www.illumina.com) is the leading developer, manufacturer, and marketer of integrated systems for the analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations, and biotechnology companies. Our tools provide researchers around the world with the performance, throughput, cost effectiveness, and

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SOURCE: Illumina, Inc.

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EXHIBIT 4

(Part I of II)

OF

DECLARATION OF GREGORY F. HEATH

Pour que chacun
vive en bonne santé

BD Worldwide Business Segments

Click to learn more about each of the following BD business segments:

- BD Medical
- BD Diagnostics
- BD Biosciences

BD Medical

BD Medical is among the world's leading suppliers of medical devices and a leading innovator in injection- and infusion-based drug delivery since 1906, when the Company built the first-ever facility in the U.S. to manufacture needles and syringes. The BD Medical segment is focused on providing innovative solutions to reduce the spread of infection, enhance diabetes treatment and advance drug delivery.

Products/Services	Customers Served
Needles and syringes	Hospitals and clinics
Intravenous catheters	Physicians' office practices
Safety-engineered and auto-disable devices	Consumers and retail pharmacies
Prefillable drug delivery systems	Governmental and nonprofit public health agencies
Prefilled IV flush syringes	Pharmaceutical companies
Insulin syringes and pen needles	Healthcare workers
Regional anesthesia needles and trays	
Self-injection systems	
Sharps disposal containers	
Closed-system drug transfer devices	

BD Diagnostics

BD Diagnostics is a leading provider of products for the safe collection and transport of diagnostics specimens, as well as instruments and reagent systems to accurately detect a broad range of infectious diseases, healthcare-associated infections (HAIs) and cancers. The BD Diagnostics segment focuses on improving health outcomes for patients by providing laboratories with solutions that improve quality, enhance laboratory system productivity and inform medical decisions.

Products/Services	Customers Served
Integrated systems for specimen collection	Hospitals, laboratories and clinics
Safety-engineered blood collection products and systems	Reference laboratories
Automated blood culturing systems	Blood banks
Molecular testing systems for infectious diseases and women's health	Healthcare workers
Microorganism identification and drug susceptibility systems	Public health agencies
Liquid-based cytology systems for cervical cancer screening	Physicians' office practices
Rapid diagnostic assays	Industrial and food microbiology laboratories
Plated media	

BD Biosciences

BD Biosciences is a world leader in bringing innovative diagnostic and research tools to life science researchers, clinical researchers, laboratory professionals and clinicians who are involved in basic research, drug discovery and development, biopharmaceutical production and disease management. The BD Biosciences segment is focused on continually advancing the science and applications associated with cellular analysis and products that help grow living cells and tissue.

Visit BD Biosciences

Products/Services	Customers Served
Fluorescence-activated cell sorters and analyzers	Research and clinical laboratories
Monoclonal antibodies and kits for cell analysis	Academic and government institutions
Reagent systems for life science research	Pharmaceutical and biotechnology companies
Cell imaging systems	Hospitals and reference laboratories
Laboratory products for tissue culture and fluid handling	Blood banks
Cell culture media and supplements for biopharmaceutical manufacturing	

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GEN-PROBE

ABOUT US | INVESTORS | NEWS | PRODUCTS & SERVICES | PIPELINE | SCIENCE

Technically Superior Products

Home ›

PRODUCTS

- Clinical Diagnostics
- Blood Screening
- Transplant & Transfusion
- Research Products

SERVICES

- cGMP Drug Development
- Discovery & cGLP Pre-Clinical
- cGCP Clinical Development
- Life Science Research
- CLIA Laboratory Services

- Product Catalog
- Package Inserts and MSDSs
- Customer Service

Gen-Probe has been providing solutions for molecular testing to labc record in providing technically superior products of the highest qualit -Probe is committed to meeting our customer needs with our menu o trained sales, technical support, instrumentation service, customer s satisfying the needs of our customers on an ongoing basis.

Gen-Probe is committed to providing innovative high quality diagnost exceed the expectations of our stakeholders.

This includes:

- Maintaining a shared quality vision and a focus on continuous in
- Understanding and responding to customer needs and the appli
- Continually promoting quality amongst our employees.

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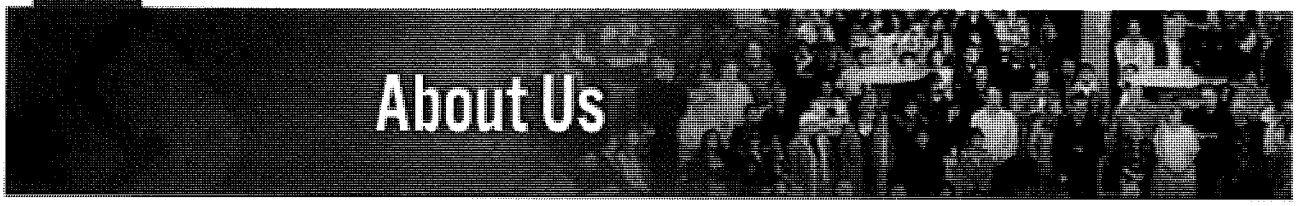


ABOUT US

Corporate Overview
Value of Diagnostics
Management Team
Contact/Request Info
Collaborations
Quality
Corporate History
Awards & Honors
Community Relations

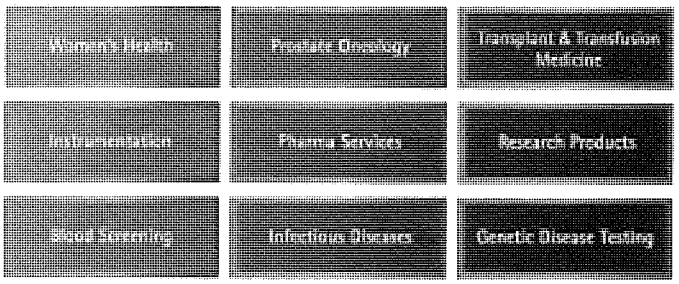
Product Catalog
Package Inserts and MSDSs
Customer Service

Corporate Overview

Gen-Probe is a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective molecular diagnostic products and services that are used primarily to diagnose human diseases, screen donated human blood, and ensure transplant compatibility.

Gen-Probe has nearly three decades of molecular diagnostics expertise, and received the 2004 National Medal of Technology, America's highest honor for technological innovation, for developing molecular assays and systems that help safeguard the blood supply.

Gen-Probe is headquartered in San Diego and employs approximately 1,400 people.



Research Products

Tepnel Pharmaceutical Services offers an established and comprehensive range of DNA extraction and purification kits to the pharmaceutical, biotechnology, clinical and academic research markets.

With over 20 years of experience in monoclonal antibody and immunoassay development, the Diaclone range of immunology products includes highly specific and sensitive monoclonal antibodies, ELISAs, ELISpots and multiplex assays.

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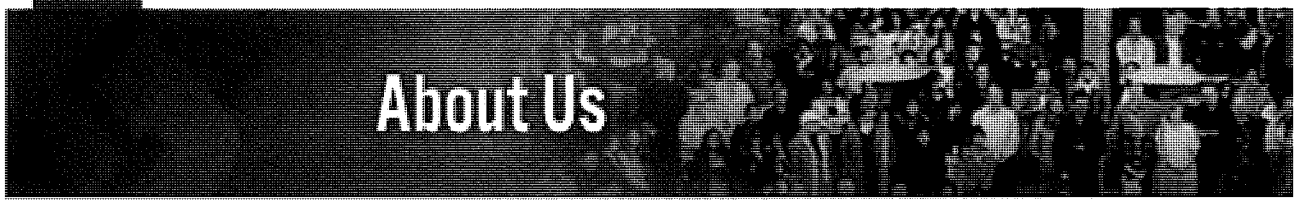
GEN-PROBE INCORPORATED, 10210 GENETIC CENTER DRIVE, SAN DIEGO, CA 92121, USA



ABOUT US

Corporate Overview
Value of Diagnostics
Management Team
Contact/Request Info
Collaborations
Quality
Corporate History
Awards & Honors
Community Relations

Product Catalog
Package Inserts and MSDSs
Customer Service

Value of Diagnostics

Diagnostic tests are an essential part of the health care process and provide critical information to physicians and patients. Diagnostics can help assess a patient's risk for disease, assist in the diagnosis of diseases, and help physicians determine what therapies or treatments are appropriate for a given patient. Not only can diagnostic tests improve health status and patient outcomes, they can also save health care dollars. In short, diagnostics promote early detection, which leads to more appropriate treatment, which in turn generates better medical and economic outcomes. For example, although diagnostics comprise only a small portion of total hospital spending - less than five percent - they influence up to 60-70 percent of health care decision-making.

Gen-Probe develops, manufactures and markets molecular diagnostics - also known as nucleic acid tests (NATs) - that provide fast, accurate, cost-effective results based on the human genome. Gen-Probe's NATs detect the unique genetic sequences of microorganisms that can cause infectious diseases or infect donated blood, as well as the genetic mutations that can cause certain kinds of cancer. By detecting disease-causing agents directly, through their unique genetic fingerprints, molecular diagnostic tests can provide faster, more accurate results than traditional methods such as antibody and culture testing. For example, Gen-Probe's tests for HIV-1 and the hepatitis C virus have helped reduce the risk of contracting these dangerous diseases from a blood transfusion to approximately one in two million.

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life technologies™

About Us

We are a global life sciences company

We believe in the power of science and appreciate its rigorous discipline. That's what drives our passion for innovation, leading to transformative offerings that support endeavors throughout the world.

Our extensive range of products and services, from instruments to everyday lab essentials, ensures quality and performance for every lab, every application. Customers in more than 160 countries count on us in their quest to improve life in meaningful ways.

$3.7 billion (2011 revenue)
10,400+ Employees
1,500+ Scientists
160+ Countries
50,000+ Products
4,000+ Patents
600,000+ Citations

Corporate Brochure

Research Sciences
Cell Biology
Genetic Analysis
Molecular Biology

Applied Sciences
Agriculture Biology
Animal Health
Bioproduction

Medical Sciences
Genomic Medicine
Molecular Diagnostics
Regenerative Medicine

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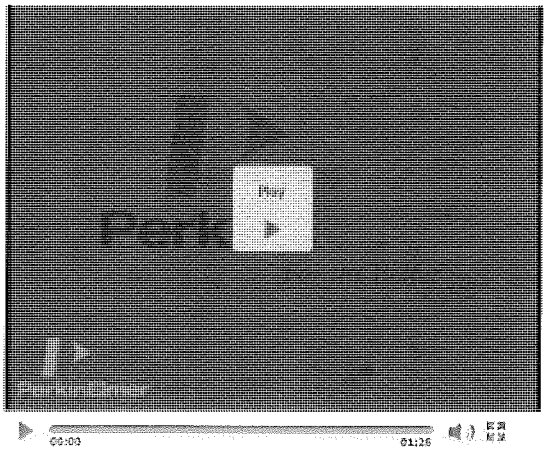
PerkinElmer
For the Better

About Us



Turning knowledge and innovation into action

As a global technology leader, PerkinElmer is taking action to harness the power of insights and transform them into knowledge to deliver innovative, differentiated solutions for our customers. From critical therapeutic and disease research and prenatal screening, to environmental testing and industrial monitoring, we are actively engaged in improving health and advancing quality and longevity of life all around the world.

From multi-vendor laboratory services, software and informatics, to clinical lab testing and unparalleled customer care, we have the people, tools and resources to help customers solve their business and scientific goals. Our core competencies, coupled with our commitment to excellence, provide a strong foundation for delivering optimal service and support. By encouraging exploration, ingenuity and integrity, together with teamwork and employee development, at PerkinElmer we live our mission, every day.

A Leader in Human Health

Whether it's testing newborns for life-threatening disorders, supporting scientists in finding better cures, or helping doctors treat disease, our focus on human health extends beyond the lab and into hospitals and homes. Our leadership position in the emerging field of personalized medicine enables us to provide solutions to meet customer needs across the value chain, from in vitro to in vivo imaging. With our innovative screenings and treatments, and development and knowledge of advanced life science tools, we help generate earlier medical insights, more accurate results, and more effective therapies.

- PerkinElmer Fact Sheet
- Corporate Capabilities Brochure
- Corporate Social Responsibility Report

A Leader in Environmental Health

Our work in environmental health improves the quality and sustainability of our environment and the security of people in the places where we live, work and play. Through a collaborative effort, we provide the insights, analytical instrumentation, and services that ensure clean air and water, and safer food and consumer products - the essential components of a safer, healthier, and better tomorrow.

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A 75 year history of innovation

April 19, 2012 marks PerkinElmer's 75th anniversary as a brand. A long-time leader in the scientific community, PerkinElmer has a rich history of innovation and making life better through major scientific industry-defining strides in human and environmental health.

VIEW TIMELINE

Key Facts

Mission:
Improving the health and safety of people and the environment

Ticker Symbol:
PKI (NYSE)

Revenue:
Approximately $1.9 billion in revenue

Chairman & CEO:
Robert F. Friel

Global Headquarters:
Waltham, MA

Operations in:
More than 150 countries in the Americas, Europe, Asia and Africa

Total Number of Employees:
Approximately 7,000

Number of Patents:
3,300

Solutions and Services for:

- Biomedical
- Chemicals
- Consumer Products - Manufacturing
- Energy
- Environmental
- Food, Beverage and Nutraceuticals
- Forensics
- Healthcare
- Life Science Research

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PerkinElmer
For the Better

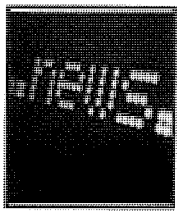
-

Life Science Research

Translate your discovery into results.

With a growing emphasis on translational insight, it is more important than ever to examine the molecular mechanisms of disease and be able to translate in vitro models into in vivo results. PerkinElmer offers leading solutions and renowned expertise in assays, imaging and informatics that will help you bring it all together.

Whether working in a well, cells, or small animals, now you can focus on your science, gain insight sooner and succeed faster.



Genetic Engineering & Biotechnology News

Read how PerkinElmer further established itself as a player in the personalized medicine arena through its acquisition of Caliper Life Sciences.

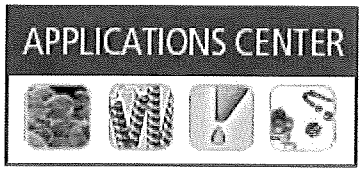
Read More

Events

Join us at PerkinElmer Owners Group

PerkinElmer Owners Group
June 7-8, 2012
Marriott Hotel
Newton, MA

Learn More



Applications Center

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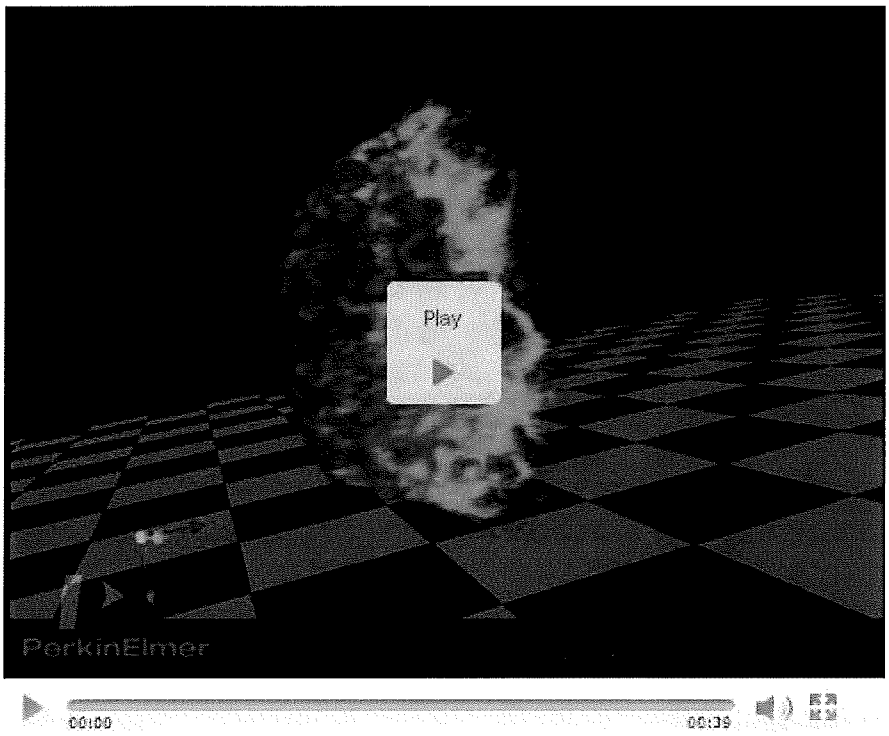
Visit the Life Sciences Applications Knowledge Base

Volocity Video

Volocity® 3D Image Analysis Software is the only solution that provides all the tools you need to visualize, analyze and validate 3D fluorescence images from a wide range of confocal microscopy, widefield and high content screening systems and is fully integrated for a seamless user experience.



Make discoveries and answer complex questions that you could not before. Visualize samples in 3D so they can be viewed from any direction for a more complete picture. Greatly improve your image and data quality with powerful restoration. Measure shapes, volumes and distances with precision. Relate cellular structure to function, and identify trends for a greater understanding.

Learn more about our Volocity 3D Image Analysis Software.

PerkinElmer
For the Better

Labeled Nucleotides

PerkinElmer is the world's leading supplier of labeled nucleotides, offering the broadest range of standard products as well as rapid custom synthesis options. We offer high purity radioactive, fluorescent and hapten labeled nucleotides to meet any need.

Labeled nucleotides are critical elements in life science research. They provide a means of nucleic acid sequence and are also used to measure cellular activity. Typical applications include:

- Southern and northern blotting for DNA and RNA sequence detection
- DNA sequencing with labeled dideoxynucleotides (Sanger method) as well as various next-generation techniques
- Localization of nucleic acid sequences within cells and tissues using in situ hybridization (ISH or FISH)
- Gene expression profiling with microarrays
- Measurement of cell proliferation by incorporation of tritiated thymidine
- Assessment of kinase activity with [γ-^{33}P]ATP

Products

Fluorescent and Hapten Labeled Nucleotide Analogs

Labeled nucleotides are powerful tools for detection of specific nucleic acid sequences in a wide range... View more

Radioactive Nucleotides

PerkinElmer provides the world's most complete line of 33P, 32P, 35S, 3H and 14C nucleotides, stocked... View more

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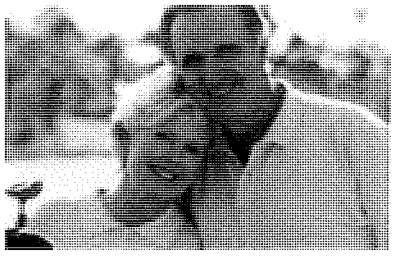
Clinical Diagnostics Systems



With reliable diagnostic methods for anemia, thyroid or reproductive dysfunction and diabetes, PerkinElmer helps provide security for members of society throughout their adult lives. In some countries, tumor marker assays for cancer detection and treatment monitoring are supplied.

Products listed here may not be available in all countries. For information on availability, please contact your local representative.

View Technologies

Cancer Screening, Diagnosis & Monitoring

With its unique series of products for PSA detection, PerkinElmer has spearheaded a new approach to... View more

Growth Hormone

Hemoglobinopathy

Instruments & Accessories

Reproductive Hormones & Infertility

Thyroid Screening, Diagnosis and Monitoring

A complete panel of Wallac DELFIA® and AutoDELFIA™ kits for assessment of thyroid function analytes... View more

Type 2 Diabetes Detection and Monitoring

More than 100 million people worldwide are affected by diabetes, but many are undiagnosed. This number... View more

Virology

These products are intended for research purposes only and are not approved for diagnostic use. View more

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Solutions for
- Animal Pathogens & Genotyping
- Biomedical Research
- Companion Diagnostics
- Drug Development
- Food Safety Testing
- Human Identity and Forensics
- Molecular Diagnostics

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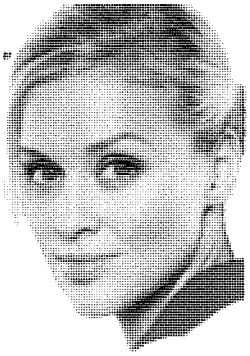
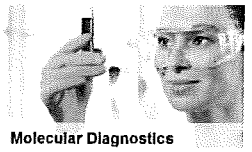
"Easier and faster — purify DNA in no time!"



Spotlight
- PCR Arrays for pathway profiling
- Assay Technologies
- HPV Testing
- Gene Expression Analysis
- Gene Silencing (RNAi)
- Epigenetics Research
- Genotyping
- Pyrosequencing Web resource

Quick Links
- New Products and Special Offers
- ProductFinder
- All Products
- Products by Genes (GeneGlobe)
- Technical Support Center
- Exhibitions / Webinars
- Handbooks

Genes & Pathways



Molecular Diagnostics

Automated Solutions

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- Discover the new HRM technology Web resource
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Ordering: 800-426-8157
E-mail Technical Service

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Whole Genome Amplification (WGA)

Researchers often face the problem of limited or insufficient DNA quantity for downstream analysis. QIAGEN whole genome amplification technology solves this problem by providing high yields of whole genomic DNA from small or precious samples. REPLI-g Kits and Service accurately copy the original source DNA — without bias — and the amplified DNA can be directly used in a range of genetic analyses.

This section of our Web site provides the resources you need for accurate and reliable whole genome amplification including a comprehensive WGA tutorial.

Product Focus

Direct and reliable amplification from paraffin sections with the new REPLI-g FFPE Kit.
more

Feature

Find out more about gene copy number analysis in our comprehensive WGA tutorial.
more

Resources

- WGA tutorial
- REPLI-g selection guide
- Application data
- References
- Brochure on genotyping

More Links

- Events/webinars
- Handbooks/protocols
- FAQs
- Request more information
- QuantiTect Whole Transcriptome Kit

Contact more

QIAGEN in USA
Technical: 800-DNA-PREP
(800-362-7737)
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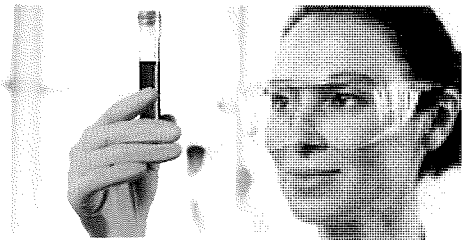

Molecular Diagnostics

At QIAGEN, one of our key goals is to support clinical decision-making and improve patient healthcare. As a leading provider for sample and assay technologies, QIAGEN provides complete solutions for sample collection, nucleic acid purification, pathogen detection, and genetic testing.

The broad range of solutions enables manual or automated sample processing in combination with downstream assay information

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Learn more Submit

Product Focus

Automate blood collection, stabilization, and transport for IVD use
PAXgene Blood RNA Kit IVD
QIAcube

Feature

Find the resources you need for identifying cervical cancer risk
more

Resources

Product Guide

More Links

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Products for US Customers

Pharmaceuticals in the US

Roche has brought many highly effective drugs onto the market and is a world leader in innovative cancer drugs. Other areas include viral infections, metabolic, central nervous system disorders and inflammatory diseases.
In the US our pharmaceuticals are marketed by Genentech.

- US product list
- Or visit our local website www.gene.com

Solutions for Diagnostics in the US

As the world leader in in-vitro diagnostics, we supply a wide range of rapid, reliable instruments and tests for disease screening and diagnosis in laboratories, at the point of care, and for patient self-management.

- US product list
- Or visit our local website www.roche-diagnostics.us

Products for Researchers in the US

Roche Applied Science supplies a broad array of instruments and highly specific reagents and test kits for use in the diverse research market.

The portfolio is especially strong in genomics and proteomics.

- www.roche-applied-science.com

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Roche Applied Science

Home >

Product Catalog

Cell Biology

- Growth Factors and Cytokines
- Oncology Research
- Cell Imaging Systems
- Transfection
- Cell Culture Reagents
- Mycoplasma Detection and Elimination
- Virus Research
- Reporter Gene Detection
- Apoptosis
- Cytotoxicity
- Cell Proliferation
- Cell Counter and Analyzer
- Real-Time Cell Analysis Systems

Sample Preparation

- Automated Sample Preparation
- Manual Sample Preparation

PCR

- Real-Time PCR Reagents
- PCR/RT-PCR Enzymes
- Real-Time PCR Systems

Microarrays

- Gene Expression
- Instruments
- Chromatin Immunoprecipitation-on-chip (ChIP-chip)
- DNA Methylation
- Software
- Comparative Genome Sequencing (CGS)
- Kits and Consumables
- Sequence Capture
- Comparative Genomic Hybridization (CGH)

Sequencing

- Genome Sequencer FLX System
- GS Junior System
- Assays
- GS FLX+ System

Discovery Reagents

- Nucleic Acid Analysis
- Protein Analysis
- Antibodies and Detection Substrates
- Nucleotides and Analogs
- Forensic Analysis
- Metabolic Analysis
- Laboratory Reagents
- Catabolic Analysis

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- Online Technical Support

Get in contact with our Sales Representatives

- Sales Representatives

Roche Prime Supply (RPS)

- On-Site Reagent Supply Program

For Technical Questions:
Phone: 800-262-4911

To order or for price information:
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Phone: 800-428-5433
FAX: 800-428-2883

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Roche Applied Science
P.O. Box 50414
9115 Hague Road
Indianapolis, IN 46250-0414

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Custom Biotech Products are: For further processing only unless otherwise indicated.

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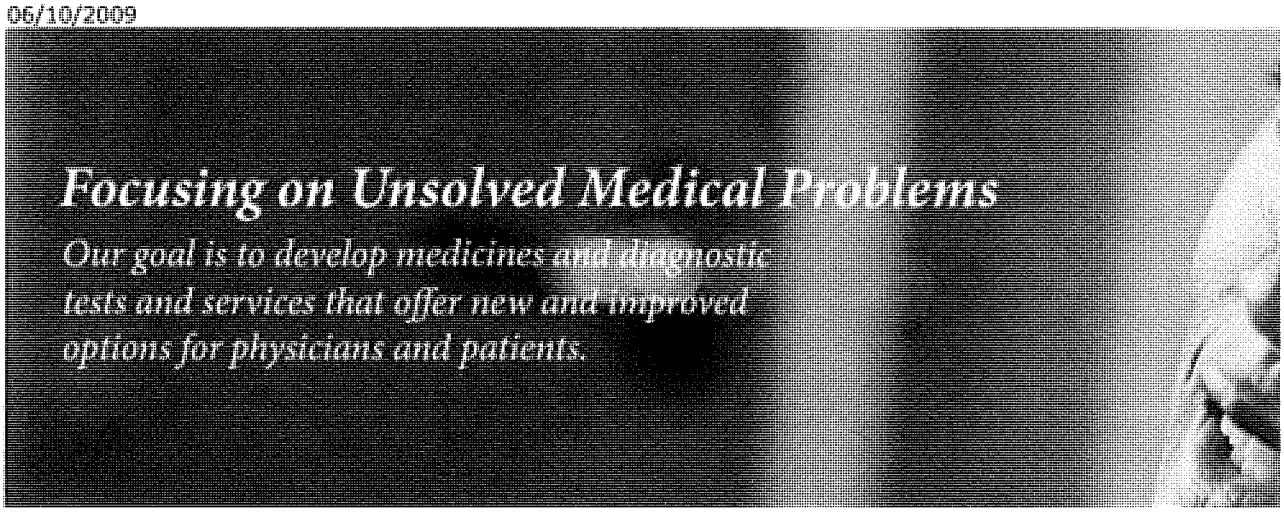
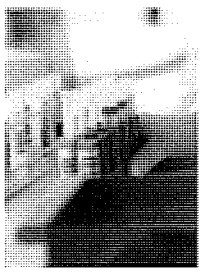
Roche USA

06/10/2009



Pharmaceuticals and Diagnostics

The Roche Group, including Genentech and Chugai, has brought many highly effective drugs onto the market and is a world leader in innovative cancer drugs. Other areas include viral infections, metabolic, central nervous system disorders and inflammatory diseases.
More



As the world leader in in-vitro diagnostics, Roche supplies a wide range of rapid, reliable instruments and tests for disease screening and diagnosis in labratories, at the point of care, and for patient self-management.
More

Personalized Healthcare

At Roche, our primary objective is to provide healthcare solutions that deliver superior options for diagnosis and treatment to clinicians and patients. As one of the world's leading healthcare companies with combined strengths in **pharmaceuticals and diagnostics**, no company is better suited for this task.
Roche's personalized healthcare approach uses new molecular insights and molecular diagnostic tests to better tailor medicines and better manage diseases.
More on www.roche.com

ILLUM-0682

Solutions for Diagnostics available in the US

Accu-Chek 360°
Accu-Chek Aviva System
Accu-Chek Compact Plus System
Accu-Chek Lancing Devices for Professionals
Accu-Chek Multiclix Lancet Device
Accu-Chek Smart Pix Device Reader
Accu-Chek Softclix Lancet Device
Accu-Chek Spirit Insulin Pump
Accutrend® Plus System
AmpliChip® CYP450 Test
BenchMark XT
CoaguChek® XS Plus system
CoaguChek® XS system
cobas b 221 Blood Gas system
cobas c 111 analyser
COBAS INTEGRA® Systems
cobas IT solutions
cobas p 512 and 612 pre-analytical systems
cobas s 201 system
cobas® 4000 analyser series
cobas® 6000 analyser series
cobas® 8000 modular analyser series
COBAS® AMPLICOR CT/NG Test
COBAS® AmpliPrep/COBAS® TaqMan® HCV Test
COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0
CONFIRM anti-ER(SP1)
CONFIRM anti-Ki-67 (30-9)
CONFIRM anti-PR(1E2)
DISCOVERY XT
E 170 module for MODULAR ANALYTICS EVO analyser
Elecsys® proBNP
Elecsys® Systems
LightCycler® Carousel-based System
LightCycler® MRSA Advanced Test
MODULAR ANALYTICS EVO solution
MODULAR PRE-ANALYTICS EVO
NexES Special Stains
PATHWAY HER-2/neu
Roche Custom Biotech
SYMPHONY
Urinalysis Systems
VIAS

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Agilent Technologies

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- Services & Support

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- Oscilloscopes, Analyzers, Meters
- Generators, Sources, Supplies
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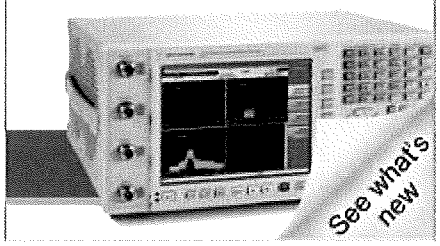
- PXI, AXIe, DAQ and Modular Solutions
- Additional Test & Measurement Products
- Services

ILLUM-0685

Agilent automation solutions for next-gen sequencing labs

Transform manufacturing test & accelerate wireless devices to market



Solutions & Applications

Solutions

- Biopharma
- Clinical Research
- Energy & Fuels
- Environmental
- Food Testing & Agriculture
- Forensics & Drug Testing
- Genomics
- Geochemistry, Metals & Mining
- Homeland Security

Solutions

- Integrated Biology
- Materials Testing & Research
- Metabolomics
- Pharmaceutical
- Proteomics & Protein Sciences
- Semiconductor Analysis
- Specialty Chemicals
- Vacuum Solutions

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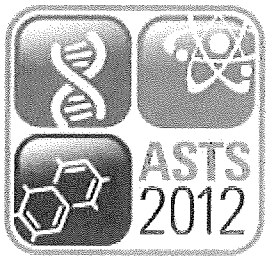

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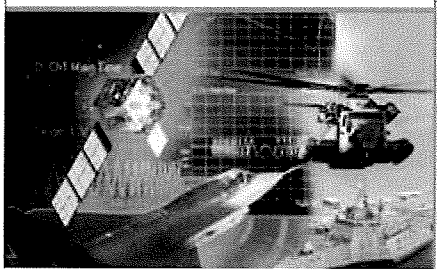

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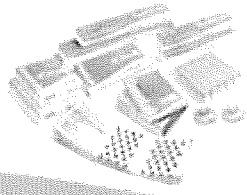

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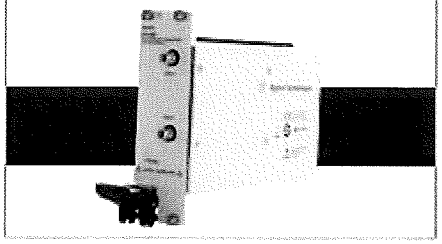

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Agilent Technologies offers you a comprehensive portfolio of innovative solutions – from improving lab productivity for chemical analysis, to vacuum systems, to workflow solutions developed to facilitate unlocking the complexities of living systems. Our experts possess in-depth understanding of issues across a broad spectrum of applications. Agilent's latest technologies are developed for your leading edge research programs. We help you stay current with emerging applications and approved methods, while our integrated workflow solutions deliver accurate, comprehensive data helping you make informed decisions accelerating your time to results. Learn more about the latest solutions and applications for your industry below.

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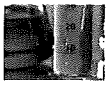

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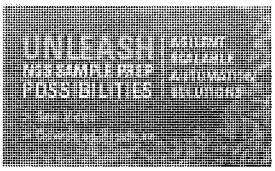

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- Protein Int
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Genomics Solutions

Agilent understands the importance of being your partner in genomic research. By providing a comprehensive suite of high quality genomics arrays, reagents, instruments and software, your work is advanced with flexibility, sensitivity and specificity vital to answering biological questions. Whether you are using gene expression, cloning and quantitative PCR, comparative genomic hybridization to detect copy number variation or selecting for the human exome to sequence regions of interest, Agilent provides the innovation and reliability your research requires.

Segments

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Cloning

Comparative Genomic Hybridization (CGH)

Copy Number Variants (CNV)

DNA Methylation

DNA Sizing & Quantification

Food Testing

Gene Expression

microRNA

Mutagenesis

Next-Gen Sequencing

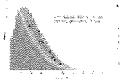
RNA Quality Control

Next Generation Sequencing

Harness the Power

Next Generation Sequencing has changed what is possible in the field of genomics. The ability of the researcher to elucidate the underlying genomic mechanisms of biological systems has revolutionized our understanding of biology itself and will only continue to do so. Agilent provides a range of tools that help improve the efficiency of the next generation of sequencing workflow.

Learn More



Literature Highlights

Workflow tools for optimizing the power and efficiency of Next Generation Sequencing

Agilent's SureSelect Target Enrichment System: Bringing Cost and Process Efficiency to Next-Generation

QPCR Designed for You

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Automation

Bioanalyzer Sample QC & Quantitation

Bioinformatics Software

Cloning & Competent Cells

Microarrays

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- CGH+SNP Microarrays
- ChIP-on-chip Microarrays
- CNV Microarrays
- Custom Microarray Design
- DNA Methylation Microarrays
- Gene Expression Microarrays
- Hybridization
- Microarray Data Analysis
- Microarray Hardware
- microRNA Microarrays
- References & Controls
- Wash Solutions

Mutagenesis

Northern & Southern Blots

Nucleic Acid Sample Preparation

PCR & Reverse Transcription

Protein Interaction & Signal Transduction

Real-Time/Quantitative PCR

Target Enrichment

Total RNA & cDNA Libraries

Toxicology

Transfection & Protein Expression

Microarrays

Powered by SurePrint technology

The Agilent DNA microarray sits at the center of an integrated research platform designed to provide you with dynamic tools to perform research on your own terms.

Focused on sensitivity

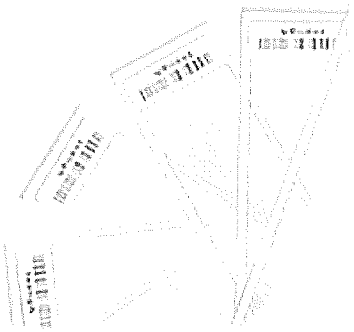
Agilent's microarrays provide superior sensitivity, enabling a clear path from data to decisions. Our 60-mer oligonucleotide probes are synthesized in situ, resulting in highly reproducible features and six times the signal-to-noise ratio of other microarrays.

Engineered for flexibility

Agilent's SurePrint inkjet technology prints oligonucleotides on the fly, enabling total control over array content with no compromise in cost, data quality or scalability. Combined with our web-based portal for custom array design, you now have the capability to move from idea to experiment quickly and easily.

Designed for integration

From sample preparation to data analysis, the Agilent DNA Microarray Platform provides the components you'll need to implement an integrated experimental workflow.



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Automation

Bioanalyzer Sample QC & Quantitation

Bioinformatics Software

Cloning & Competent Cells

Microarrays

Mutagenesis

Northern & Southern Blots

Nucleic Acid Sample Preparation

- DNA Purification
- Nucleic Acid Extraction
- RNA Purification

PCR & Reverse Transcription

Protein Interaction & Signal Transduction

Real-Time/Quantitative PCR

Target Enrichment

Total RNA & cDNA Libraries

Toxicology

Transfection & Protein Expression

Nucleic Acid Sample Preparation

High quality results start with the purest samples

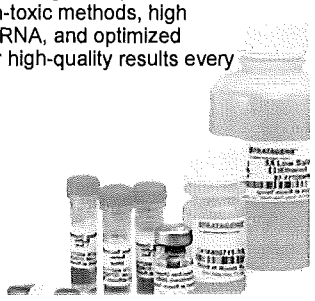
Agilent reagents enable the scientist to quickly and easily purify and analyze a wide range of nucleic acids—DNA, RNA, gDNA, mRNA, miRNA, plasmid DNA—from virtually any kind of sample for downstream analysis. No matter the application, Agilent's portfolio of reagents and analysis tools ensure the highest quality samples for high-confidence results.

A kit for every need

With products like our line of Absolutely RNA Kits, researchers can purify RNA from cells, tissues and archived samples, while our StrataPrep kits enable DNA purification from gels, PCR reaction mixtures and mammalian tissues.

Purity you can count on

Achieve the highest level of purity, free from contamination and degradation, even when working with the most challenging samples, such as FFPE tissue samples. Agilent's portfolio features non-toxic methods, high quality total RNA, and optimized protocols for high-quality results every time.



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Bioinformatics Software

GeneSpring

Cloning & Competent Cells

Microarrays

Mutagenesis

Northern & Southern Blots

Nucleic Acid Sample Preparation

PCR & Reverse Transcription

Protein Interaction & Signal Transduction

Real-Time/Quantitative PCR

Target Enrichment

Total RNA & cDNA Libraries

Toxicology

Transfection & Protein Expression

Bioinformatics Software

Integrate data and results from multiple applications

Agilent provides a full range of bioinformatics software tools to enable robust visualization and analysis of genomic datasets across a range of applications. GeneSpring software is the industry standard for gene expression analysis, miRNA and splicing analysis, and now includes DNA-Seq and RNA-Seq support for Agilent's SureSelect target enrichment platform. Agilent's bioinformatics solutions help researchers make the most of their data, and get answers they can trust.

Multi-application analysis

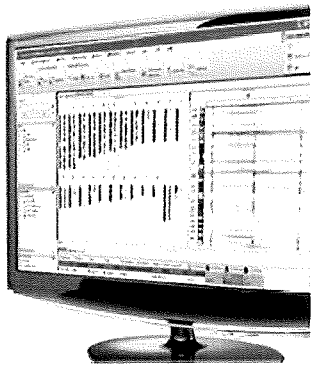
Agilent's bioinformatics tools are designed to enable joint analysis across multiple applications, within—and beyond—genomics.

Data in biological context

Agilent's bioinformatics tools enable researches to put their results into a biological context using pathway analysis, Gene Set Analysis, and GO analysis.

GeneSpring NGS - Optimized for SureSelect Target Enrichment

GeneSpring GX - The Gold Standard for Microarray and qPCR Analysis



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Agendia and Agilent Technologies Announce Plans to Jointly Develop New Diagnostic Tests, Extend Supply Agreement

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AMSTERDAM, The Netherlands, and SANTA CLARA, Calif., April 22, 2008

Agendia BV, a world leader in the rapidly evolving field of molecular diagnostics, and Agilent Technologies Inc. (NYSE: A), today announced terms under which they intend to collaborate to develop new in-vitro diagnostic tests. In addition, the two companies announced an agreement in which Agendia products will continue to be supplied on Agilent microarrays through Dec. 31, 2011. Agilent has been manufacturing the components for the Agendia assay since its inception in 2003. The financial terms of the agreement were not disclosed.

"We've established and enjoyed a strong business relationship with Agilent since the incorporation of Agendia," said Dr. Bernhard Sixt, CEO and co-founder of Agendia. "These activities, including joint research and development, have allowed our two companies to forge an even closer strategic alliance focused on Agendia's core competencies, namely the discovery of biomarkers and development of new diagnostic tests for clinical use, which are regulated under the new IVDMIA guidelines of the FDA."

"We're proud that Agendia has selected Agilent to move forward with their critical work in diagnosing breast cancer," said Yvonne Linney, Ph.D., vice president and general manager, Genomics at Agilent. "We eagerly anticipate expanding our role beyond the manufacturing of Agendia products on the Agilent microarrays to helping them build validated diagnostic cancer tests, as well as developing and expanding the company's worldwide distribution channels."

Last year, Agendia's MammaPrint, a molecular diagnostic tool developed to help physicians make informed decisions in treating breast cancer, became the first IVDMIA microarray-based diagnostic test cleared by the United States Food and Drug Administration (FDA). The tests, which are manufactured on Agilent microarrays, are performed at Agendia's laboratory in The Netherlands. Agendia also offers DiscoverPrint, a gene expression-based service for improving the efficacy of clinical trials, and CupPrint, a diagnostic test designed to identify the origin of a metastasis in a cancer type called "Cancer of Unknown Primary." These are also manufactured using Agilent microarrays.

Both companies will share information about their research into genetic biomarkers and jointly assess the commercial potential of each opportunity.

About Agilent Technologies

Agilent is a leading provider of research microarrays used to analyze gene expression, microRNA, comparative genomic hybridization and ChIP-on-chip. More information about Agilent microarrays is available at www.opengenomics.com. Agilent Technologies Inc. (NYSE: A) is the world's premier measurement company and a technology leader in communications, electronics, life sciences and chemical analysis. The company's 19,000 employees serve customers in more than 110 countries. Agilent had net revenue of $5.4 billion in fiscal year 2007. Information about Agilent is available on the Web at www.agilent.com.

About Agendia

Agendia BV, located in Amsterdam, The Netherlands, is a world leader in gene expression analysis-based diagnostics. With three products on the market and an expanding market base, the company focuses on the development and commercialization of diagnostic tests using tumor gene expression profiling. Agendia was the first company to receive FDA clearance for its breast cancer test, MammaPrint, which predicts the risk of breast cancer recurrence. Its second microarray product, CupPrint, is a diagnostic test designed to

identify the origin of the primary tumor in "Cancer of Unknown Primary." Agendia also recently presented data to be developed into its new clinical colon cancer prognosis test, ColoPrint, which is currently undergoing further validation. Agendia maintains close ties with leading academic centers around the world to develop state of the art diagnostic tests for cancer. The company also offers its expertise and its DiscoverPrint service to pharmaceutical and biotech companies focusing on development of highly effective precision therapeutics in oncology. For more information on Agendia, visit www.agendia.com.

# # #

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Agilent Technologies and Integrated Diagnostics Enter Strategic Partnership to Develop Protein-Based Assays for Early Disease Detection

10 January 2012

SANTA CLARA, Calif., and SEATTLE, Wash., – Agilent Technologies Inc. (NYSE: A) and Integrated Diagnostics today announced a strategic partnership to develop assays that detect major human diseases at very early stages to improve treatment outcomes.

Integrated Diagnostics, an emerging leader in molecular diagnostics, is creating large-scale, blood-based molecular diagnostics that leverage advances in proteomics and genomics to detect diseases such as lung cancer and Alzheimer's at their earliest stages. Agilent manufactures a wide range of analytical instrumentation, including liquid chromatography, mass spectrometry and automation systems. Officials of both organizations see an opportunity to rapidly turn medical breakthroughs into diagnostic assays by combining efforts to focus on protein and peptide biomarkers of disease.

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"Agilent provides an innovative and forward-looking platform and expertise to enable the development and deployment of next-generation multiplexed proteomic assays," said Paul Kearney, Ph.D., president and chief scientific officer, Integrated Diagnostics. "Integrated Diagnostics will bring expertise in assay development, technology strategy, study design, clinical development, commercialization and systems informatics to leverage the Agilent technology solution. Together, we intend to realize the potential of clinical proteomics today as well as establish the technological platform and strategy for the field. Our partnership with Agilent will allow us to realize the advantages of using a single technology platform from discovery and verification through to commercialization."

"Agilent and Integrated Diagnostics share the vision of harnessing the power of an integrative systems biology approach to solving some of mankind's most vexing health challenges," said Gustavo Salem, vice president and general manager of the Biological Systems Division at Agilent. "It's very exciting to be at the forefront of helping technology migrate from the research lab to the clinic, in this case developing next-generation workflows to improve protein-based LC/MS assays."

As part of the partnership, Integrated Diagnostics purchased two Agilent 1290 Infinity UHPLC systems, two 6490 iFunnel triple quadrupole mass spectrometry systems and two 1260 LCs with ultraviolet detectors for the project.

The partnership will develop high-throughput automated workflows to include sample preparation and LC MS/MS analysis. Participants expect accelerated biomarker discovery to be fueled by novel sample-prep technology, fast liquid chromatography and ultra-sensitive ion funnel triple quadrupole mass spectrometry.

The technology opens the possibility of screening for several hundred biomarkers in a single assay, in a very high-throughput and quantitative fashion, according to Agilent.

About Integrated Diagnostics

Integrated Diagnostics is developing large-scale, blood-based molecular diagnostics that detect important diseases like lung cancer and Alzheimer's at their earliest stages by simultaneously monitoring tens to hundreds of disease markers. The company, founded in October 2009 by systems biology pioneer Dr. Lee Hood, is creating a new generation of personalized medical solutions using sophisticated informatics for biomarker selection and a novel class of synthetically created diagnostic and therapeutic agents with antibody-like properties: protein-catalyzed capture agents. Integrated Diagnostics' mission is to build a new generation of low-cost, large-scale diagnostic assays for early detection of serious diseases. The company is conceptually based on a systems view of disease where pathophysiology arises from disease-perturbed networks of proteins, genes, and other molecules. Investors include InterWest Partners, The Wellcome Trust, and BioTechCube Luxembourg. Foundational intellectual property is exclusively licensed from the Institute of Systems Biology and Caltech. Learn more at www.integrated-diagnostics.com

About Agilent Technologies

Agilent Technologies Inc. (NYSE: A) is the world's premier measurement company and a technology leader in chemical analysis, life sciences, electronics and communications. The company's 18,700 employees serve customers in more than 100 countries. Agilent had net revenues of $6.6 billion in fiscal 2011. Information about Agilent is available at www.agilent.com.

# # #

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Media Inquiries:

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Cell: (415) 902-1241
eliot@eliotdobris.com
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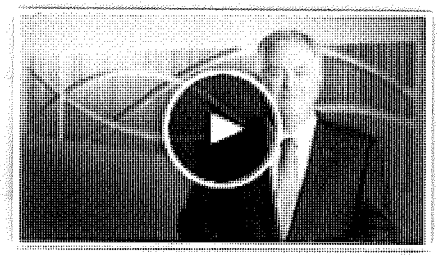

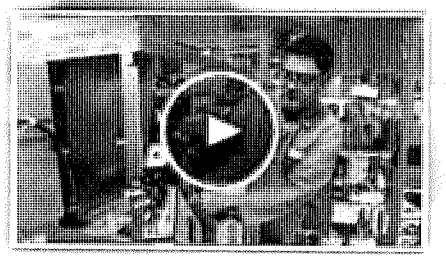

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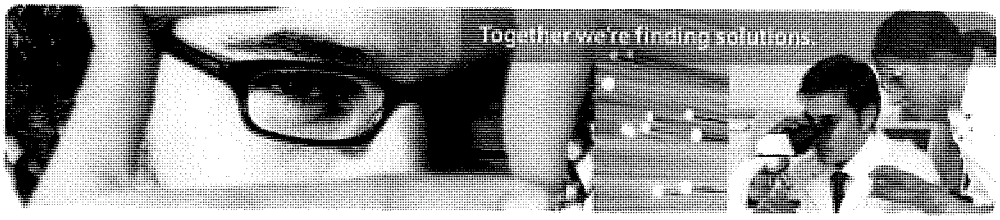

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Innovative solutions that streamline complex processes

Each step of the Discovery process can be extremely time consuming and costly. Accuracy, quality, efficiency and knowledge are critical to your operations success. When you partner with Beckman Coulter, our team of experts in the field of Life Science work closely with you to understand the intricacies of your everyday operation, as well as your most complex challenges, to offer innovative solutions and ensure your success—our #1 priority.

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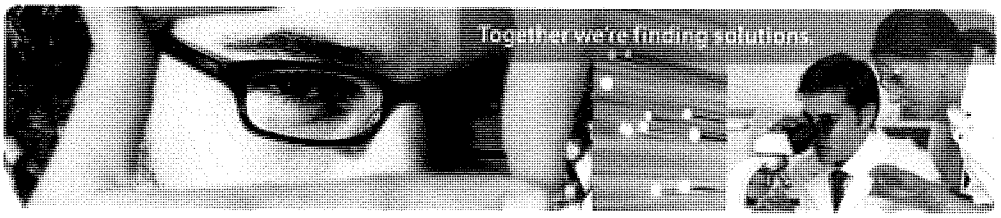

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Cellular Solutions

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Drug Discovery & Development

Small Molecule Analysis

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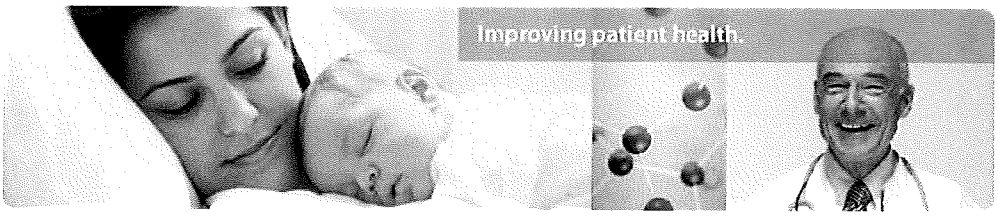

Diagnostics - More solutions to optimize the laboratory

Applications and expertise focused on the diagnostics laboratory

To successfully increase laboratory performance, it's important to choose a partner who offers the breadth of diagnostic tests, instruments and information systems needed to streamline your laboratory. Beckman Coulter brings a proven track record in best-in-class laboratory-solutions design, along with a broad spectrum of diagnostic tests. As a collaborative partner, we work with you to maximize quality, workflow and operational efficiency, meeting your specific needs every step of the way.

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- Hemostasis
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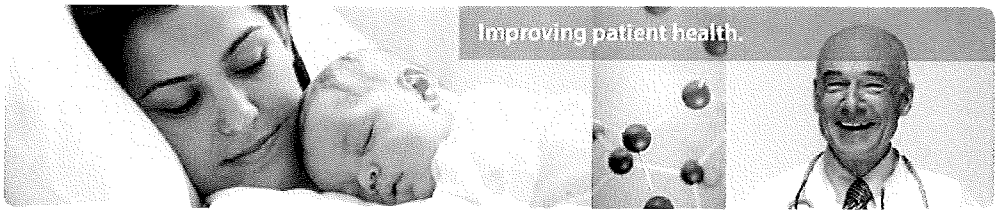

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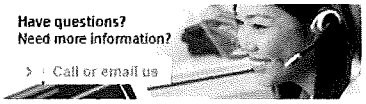

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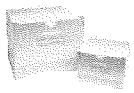

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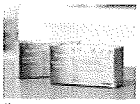

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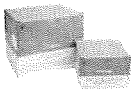

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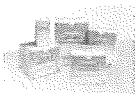

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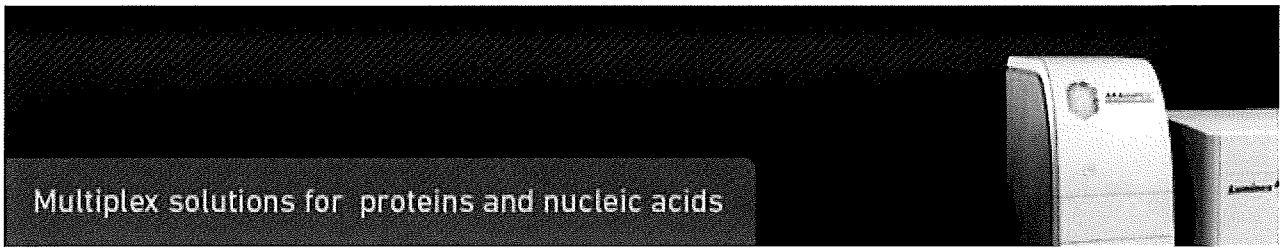

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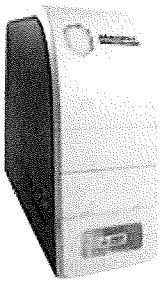

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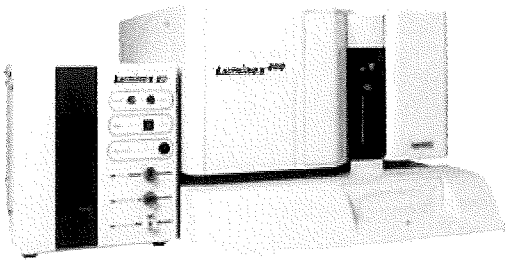

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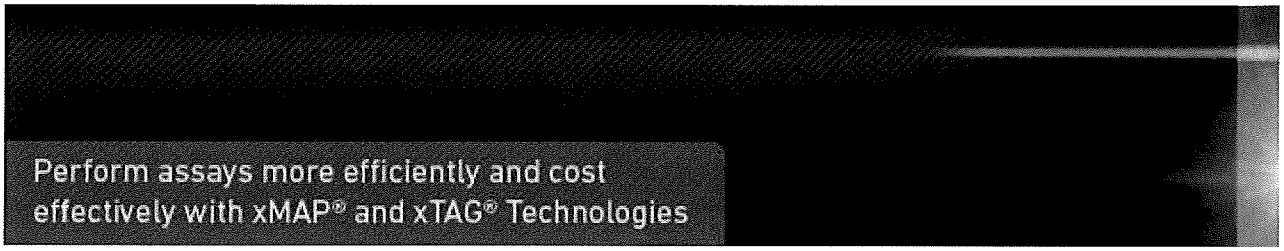

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EXHIBIT 4

(Part II of II)

OF

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Journal of reviews proteome research

Proteomics: From Basic Research to Diagnostic Application. A Review of Requirements & Needs†

Frank Vitzthum,*,‡ Fritz Behrens,‡ N. Leigh Anderson,‖ and John H. Shaw§

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For several years proteomics research has been expected to lead to the finding of new markers that will translate into clinical tests applicable to samples such as serum, plasma and urine: so-called in vitro diagnostics (IVDs). Attempts to implement technologies applied in proteomics, in particular protein arrays and surface-enhanced laser desorption ionization time-of-flight mass spectrometry (SELDI-TOF MS), as IVD instruments have initiated constructive discussions on opportunities and challenges inherent in such a translation process also with respect to the use of multi-marker profiling approaches and pattern signatures in IVD. Taking into account the role that IVD plays in health care, we describe IVD requirements and needs. Subject to stringent costs versus benefit analyses, IVD has to provide reliable information about a person's condition, prognosis or risk to suffer a disease, thus supporting decisions on treatment or prevention. It is mandatory to fulfill requirements in routine IVD, including disease prevention, diagnosis, prognosis, and treatment monitoring or follow up among others. To fulfill IVD requirements, it is essential to (1) provide diagnostic tests that allow for definite and reliable diagnosis tied to a decision on interventions (prevention, treatment, or nontreatment), (2) meet stringent performance characteristics for each analyte (in particular test accuracy, including both precision of the measurement and trueness of the measurement), and (3) provide adequate diagnostic accuracy, i.e., diagnostic sensitivity and diagnostic specificity, determined by the desired positive and negative predictive values which depend on disease frequency. The fulfillment of essential IVD requirements is mandatory in the regulated environment of modern diagnostics. Addressing IVD needs at an early stage can support a timely and effective transition of findings and developments into routine diagnosis. IVD needs reflect features that are useful in clinical practice. This helps to generate acceptance and assists the implementation process. On the basis of IVD requirements and needs, we outline potential implications for clinical proteomics focused on applied research activities.

Keywords: in vitro diagnostic • clinical chemistry • clinical proteomics

Introduction

Proteomics opens new horizons in many research areas of life sciences. This is particularly true for research efforts in the field of medicine. Clinical proteomics may be defined as a subset of proteomics activities in the field of medicine, which promises to accelerate the discovery of new drug targets and protein disease markers useful for in vitro diagnostics (IVD). IVD is based on the extracorporeal analysis of tissues and body fluids. Thus, it is expected that new pharmaceutical treatment opportunities will emerge and that the number and value of protein diagnostics will increase. The latter is of special interest, because reliable diagnostic information, in particular IVD data, is essential for choosing the appropriate intervention.[1]

Technologies applied in proteomics research, in particular SELDI-TOF MS and protein array techniques, are thought to be moving from research-focused applications to clinical laboratories as routine instruments for protein analysis.[2] In conjunction with the routine implementation of such technologies in the clinical laboratory it has been argued that multi-marker profiling approaches or pattern signatures will be the next generation of protein IVD's and shift paradigms in IVD.[3]

These goals and expectations for clinical proteomics should be assessed critically in view of the role of IVD in health care. We believe that the success of clinical proteomic marker searches and of the technologies applied in proteomics and their ability to enter routine IVD testing depends on the ability

† Part of the Biomarkers special issue.

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to fulfill IVD requirements and to adequately address IVD needs.[4] Thus, we set out to provide an industry perspective on the role of IVD in health care, a view of the requirements and needs of IVD, and the potential implications for clinical proteomics that should be considered, if a timely and effective transfer of research results to laboratory diagnostics is sought.

Role of in Vitro Diagnostics in Health Care

IVD plays an essential role in health care by (1) providing reliable information about a person's condition and (2) supporting treatment decision making,[5] both occurring in conjunction with a physicians' examination, which may include anamnesis, physical examination, and in vivo diagnostics (e.g., computed tomography and nuclear magnetic resonance imaging). A third purpose, which has been proposed by McNeil and Adelstein,[6] is to better understand disease mechanisms and evolution. This last purpose is outside the realm of routine IVD, but is nevertheless important, since it should provide better IVDs that will hopefully enter that realm.

IVD tests are estimated to contribute up to 94% of the objective data in clinical records and may influence 60−70% of critical decision making.[1,7] In addition, major cost reductions within the worldwide health expenditures could be achieved through a more efficient use of IVDs or better IVDs (www.VDGH.de).

Despite the importance of IVD and the essential role of the clinical laboratory, it usually accounts for less than 5% of the expenditures in clinics (www.VDGH.de).[1,7] The proportional share of laboratory costs in worldwide health expenditures is even lower, accounting for around 1% to 2% of the health care costs (www.VDGH.de). Even so, the expenditures necessary for laboratory diagnosis are often deemed too high, and the value of laboratory diagnosis is very often underestimated.

Together with the financial constraints in health care, this misperception generates enormous cost pressure on clinical laboratories and consequently on any equipment or test provider that serves this market directly or indirectly. For this reason, stringent cost and benefit considerations are a permanent challenge in IVD and in the translation of research applications generated by clinical proteomics into useful tests for the clinical laboratory.

Nevertheless, IVD testing represents a significant value proposition for improving outcomes, shortening hospital stays, etc. and substantially reducing the costs associated with healthcare. Though there will continue to be a need to justify the costs associated with IVD tests, the primary responsibility of IVD is to help reduce mortality, morbidity and improve the quality of life. It is evident that IVD can help to save lives and costs (www.VDGH.de).[8] There will continue to be great potential for improving IVDs and this dynamic offers clinical proteomics various opportunities.

Considerations Underlying Industry Perspectives and Decision Making Processes

A decision making process in the diagnostics industry has been outlined comprehensively by Zolg and Langen.[9] From the perspective of an IVD company, new markers and technologies must lead to products that improve diagnosis and also give a reasonable return on investment. Each company has to consider numerous factors before investing the limited human and financial resources at its disposal (List 1). A detailed discussion of these aspects is outside the scope of this article. Thus, we will focus on the crucial necessity to fulfill the requirements of the IVD market and to address unmet diagnostic needs.

List 1: Overview on critical IVD requirements, additional needs, and IVD industry considerations.

Critical IVD requirements:

1. Tests have to provide definite and reliable diagnostic information, that support decisions on interventions (prevention, treatment or non-treatment)
2. Test accuracy should meet objective specifications, e.g. imprecision of a measurement < 0.5 CV_I and bias < $0.250 \cdot (CV_I^2 + CV_G^2)^{1/2}$
3. Based on disease frequency and determined by the desired positive and negative predictive values, tests have to exhibit a required level of diagnostic accuracy, including both diagnostic sensitivity and diagnostic specificity.

Additional IVD needs that reflect considerations of clinical laboratories and physicians upon the implementation of tests or instruments:

- Costs
- Ease of use
- Automation
- Throughput
- Turn-around-time
- Down time
- Reliability
- Service quality and continuity
- Menu breadth
- Open channels (for non-proprietary tests)
- Instrument footprint
- Connectivity to the laboratory information management system (LIMS)
- Compatibility with existing laboratory processes (e.g. application of serum or plasma specimens and pre- and post-analytics)

IVD industry considerations

- Address diagnostic needs
- Return on investment
- Strategic fit
- Portfolio compatibility of new technologies
- Portfolio and instrument compatibility of new tests and markers (technical feasibility)
- Requirements of research and development phases and processes
- Manufacturability
- Marketing and sales
- Post-sales customer support
- Challenges and risks of entering the market (e.g. competitive situation, market acceptance, regulatory requirements, reimbursement, third party patent rights)

Addressing Diagnostic Needs Justifies the Significant Efforts for Product Development

The significant efforts and risks associated with product development are justified, if a new test addresses major diagnostic needs.

Examples of major diagnostic needs are cardiovascular diseases, infectious diseases, malignant neoplasms, and chronic diseases of the central nervous system, among others. It is encouraging to see that proteomics strives to address these diseases,[10] in particular cardiovascular diseases.[11−15] Cardiovascular disease, the leading cause of death worldwide (http://www.who.int/whr/2004/annex/topic/en/annex_2_en.pdf), represents a particularly telling example.

Acute cardiac events and chronic heart failure both have a long history in the patient. There is an unquestionable need for early determination of disorders which might eventually lead to these events and once they occur provide reliable information on the event itself, about the prognosis, and adequate treatment. In the area of infectious disease, increased crowding of domestic animals interacting with the ever denser and more mobile human population create chains of infections within the species but also across species. Early diagnosis and measures to prevent spread of infectious agents are of increasing concern. As the populations of industrialized countries grow to include proportionally older individuals, diseases of aging like cancer and chronic disorders of the central nervous system are of growing importance in our society and need to be better addressed by diagnostics and treatment measures.

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It is Essential to Fulfill IVD Requirements and Advantageous to Address IVD Needs

To fulfill the requirements and meet needs of the IVD market (List 1) it is essential to provide valuable diagnostics at acceptable costs. Valuable diagnostics fulfill basic IVD requirements, i.e., they have to accomplish the following:

(1) provide most definite and reliable diagnostic information, that supports decisions on intervention (prevention, treatment or nontreatment)

(2) meet objective specifications to show sufficient *test accuracy*, including both

- precision of the measurement and
- trueness of the measurement, and

(3) exhibit the required level of *diagnostic accuracy*, including both

- diagnostic sensitivity and
- diagnostic specificity

determined by the desired *positive predictive values* and *negative predictive values*, which depend on *disease frequency* (prevalence and incidence).

From a regulatory and IVD industry perspective it appears advantageous to consider the following descriptions and examples, which could facilitate a smoother transition of clinical proteomics findings and developments from basic research to routine diagnostic applications.

Valuable Diagnostic Tests Provide Most Definite and Reliable Information to Support the Decision Making on Interventions

A diagnostic test that does not result in information that supports decisions on interventions, i.e., treatment, nontreatment or prevention, including risk stratification and prognosis, is of limited value, even if the result is interesting from a research viewpoint. The most successful tests are those that provide a clear-cut basis for prevention, treatment alternatives or nontreatment. An excellent example for markers that provide definite and reliable diagnostic information impacting medical practice is cardiac troponins (cTns).[16] cTns have been demonstrated to significantly improve sensitivity and specificity in the detection of acute myocardial infarction (AMI) compared to other diagnostic methods, in particular the combination of electrocardiography (ECG) and the traditional markers.[17]

In this case, a new diagnostic category, known as acute coronary syndrome (ACS), including AMI as the most serious form of the ACS, had to be established to accommodate troponin positive patients who did not meet the WHO criteria for AMI that time.[16] The test was able to detect real disease more sensitively (i.e., smaller infarcts) than previous diagnostic methods. According to recommendations by The Joint European Society of Cardiology and American College of Cardiology (ESC/ACC) Committee a redefinition of myocardial infarction has been proposed and ECG is still required, but no longer sufficient to diagnose AMI.[18] Any detectable cTn above a defined threshold in a patient's circulation is a sign of myocardial damage, which requires medical intervention.[16]

Accuracy of Measurement is an Essential Performance Characteristic which Encompasses Precision and Trueness of Measurement

The accuracy of measurement (test accuracy) is the closeness of the agreement between the result of a measurement and a conventional true value of the measurand. It includes both precision and trueness of measurement.[19,20] Test accuracy is usually not defined by a numerical value in terms of the measurand. It is an essential performance characteristic, because it is usually critical to achieve the required level of diagnostic accuracy (see below, Figure 1). Thus, failure to achieve sufficient test accuracy can under some circumstances endanger patients.

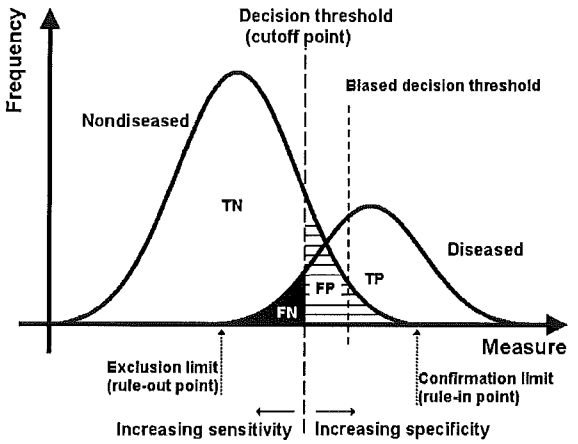

Figure 1. Dependence of the frequency of a nondiseased population and a diseased population versus a measure shows the relationship between sensitivity and specificity, decision thresholds (cutoff points), predictive values, and test accuracy. For simplicity hypothetical Gaussian distributions are displayed. The measure typically denotes results of a surrogate test or a test for contributory diagnostic evidence (e.g., single and multiple analytes or patterns). A pathognomonic test (gold standard), which constitutes definitive diagnostic evidence, is used to assign diseased and nondiseased. Sensitivity is defined as true positive/true positive + false negative; TP/(TP + FN). Specificity is defined as true negative/(true negative + false positive); TN/(TN + FP). Sensitivity and specificity in the populations is determined by the position of the cutoff point. Clearly, there is a reciprocal relationship between sensitivity and specificity. By choosing different cutoff points a single test can be used differently. To confirm the presence of a disease the rule-in threshold (test with high specificity) is used while the rule-out threshold (test with high sensitivity) is used to exclude disease presence. To determine the performance of a test in a population, it is important to know what proportion of positive tests correctly indicate the presence of the disease (positive predictive value, PPV), i.e., TP/(TP + FP), and if a test is negative, what proportion indicates absence of the disease (negative predictive value, NPV), i.e., TN/(TN + FN). Disease frequency, (TP + FN)/(TN + FP), i.e., $AUC_{diseased}/AUC_{nondiseased}$, affects these values. For example, the PPV decreases with decreasing frequency of the disease according to (values have to be multiplied appropriately if PPV is supposed to be displayed in percent):[21] PPV = TP/(TP + FP) = frequency × sensitivity/(frequency × sensitivity) + (1 − frequency) × (1 − specificity)). The impact of test accuracy depends on imprecision that skews and broadens curves (not displayed) and bias that shifts curves (displayed as biased decision threshold). Of note, when the assessment of surrogate tests is performed by using only a population comprising the "sickest of the sick" and the "wellest of the well"[5] one can easily imagine that diseased an nondiseased will be unrealistically separated. The performance of the surrogate test will then usually be overestimated.

Precision of Measurement. Precision of measurement (test precision) is the closeness of agreement between independent test results obtained under stipulated conditions. Precision depends on the distribution of random errors. The measure of precision is usually expressed in terms of imprecision. The

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imprecision of measurements is the estimated random component of error deduced from the statistical distribution of repeatedly measured values. In IVD imprecision is mainly expressed by the coefficient of variation (CV: standard deviation divided by the mean).[19,21,22]

Precision of a distinct measurement procedure can be subdivided according to specified conditions.[19]

Repeatability of results of measurements can be defined as closeness of the agreement between the results of successive measurements of the same parameter carried out under the same conditions of measurement. These conditions are called repeatability conditions. Repeatability conditions include the same measurement procedure, the same observer, the same measuring instrument, used under the same conditions, the same location, and repetition over a short period of time. Repeatability is often termed in laboratory medicine "within-run" imprecision, a term now considered obsolete.[19]

Reproducibility relates to change in conditions, i.e., different laboratories, instruments, operators, and measuring systems (calibrants, reagent batches, etc.), a wide range of patient samples exhibiting unusual features and is often termed interlaboratory imprecision or total imprecision. The term total imprecision is likewise considered obsolete.[19]

It is important to note that IVD precision figures are typically given as interlaboratory precisions, a much wider scope of variation than covered by usual proteomics studies, which typically deal with precision within a run in one laboratory. Even so, total interlaboratory test imprecision in IVD is typically in the range of 1.5−10% CV (much less than typical values found in proteomics applications).

Trueness of Measurement. The trueness of a measurement is the agreement between the average value obtained from a large series of test results and a nationally or internationally accepted reference value (true or conventional true value). It denotes the systemic error component, expressed as bias.[19,20]

Reference materials and reference methods are the best guarantee for correct calibration and thus trueness of measurement.[20] A reference method or reference measurement procedure is defined as a thoroughly investigated measurement procedure, clearly and exactly describing the necessary conditions and procedures, for the measurement of one or more property values that has been shown to have trueness of measurement and precision of measurement commensurate with its intended use and that can therefore be used to assess the accuracy of other measurement procedures for the same property(-ies), particularly in permitting the characterization of a reference material.[23]

Of note, reference methods do not necessarily represent internal/procedural controls that may be used together with external controls in laboratories for quality control purposes.[24] Internal/procedural controls are designed into a system to monitor one or more components of errors including errors of the analytical process (e.g., reagent function), operator variance (e.g., sample processing and handling), and environmental factors (e.g., variations in temperature, humidity). External controls are not designed into a test system. They are materials similar to patient samples with expected properties commercially prepared or inhouse prepared samples, proficiency test samples with confirmed results, reference or control organism strains, patient specimens with established values previously tested, and control materials (other than those lots used to calibrate the system, i.e., standards). Reference materials are materials or substances with properties that are established for the use as standards, calibrators, controls, the verification of a measurement method, or the assignation of values, e.g., conventional true values.[20,21] As it is not always possible to determine the true value by a measurement that is associated with a systematic and random error, it is useful to define a single conventional true value that is preferentially internationally accepted, e.g., as is the case with glycated hemoglobin.[25] Instead of dealing with different "true values" depending on the method applied, physicians can rely on a single conventional true value. Thus, the implementation and application of reference materials can help to reduce the risk of uncertain or incorrect data interpretation.

Usually, highly purified chemicals are weighed out for the preparation of a solution with a specified concentration or for the calibration of solutions of unknown strength. A secondary reference material usually contains one or more analytes in a matrix that reproduces or simulates the expected. The values, e.g., conventional true values, have been assigned by a formal process of value transfer from a primary reference material. Certified reference materials (CRM) are usually also matrix based and have one or more of its values certified by a technically valid procedure. CRMs are accompanied by or traceable to a certificate or other document of a certifying body. Standard reference materials are CRMs and a trademark name of the National Institute of Standards and Technology. Tertiary reference materials are typically industry standards, calibrators, and controls that contain one or more analyte in an appropriate matrix. The concentration of the analytes is usually based on secondary reference materials.

Objective Test Accuracy (Both Trueness and Precision of Measurement) Specifications Have to be Met in IVD. For established diagnostic tests, objective test accuracy specifications are available to judge analytical performance characteristics.[26] Specifications may be derived from professional recommendations, e.g., guidelines from international, national expert groups, institutional groups, expert individuals, from regulatory and legislation authorities, from organizers of external quality assessment schemes and proficiency testing programs or simply from published data on the state of the art. For example, for cTn assays a CV of 10% reproducibility at the 99th percentile limit is suggested.[27] The 99th percentile of a reference control group denotes the decision limit. A percentile is a value on a scale of one hundred that indicates the percent of a distribution that is equal to or below it. cTns indicate myocardial necrosis when the maximum concentration exceeds the decision limit on at least one occasion during the first 24 h after the index clinical event.

Test accuracy specifications may also be assessed through the impact of the trueness of a measurement expressed as bias and the imprecision of a measurement on diagnostic sensitivity and specificity and the consequences for clinical decision making for specific clinical situations.[28] More general test accuracy specifications refer to the two major IVD scenarios, i.e., (1) monitoring individual patients and (2) diagnosis using reference intervals. Here, test accuracy specifications may best be based on the components of biological variation within subjects (CV_I) and between subjects (CV_G). A common view is that imprecision of a measurement should be below $0.5 \times CV_I$ and bias should be below $0.250 \cdot (CV_I^2 + CV_G^2)^{1/2}$ [26] (Table 1).

Of note, a test has to be sufficiently robust and specific to cope with matrix effects and interferences and still fulfill the required specifications of precision. Interferences or interfering substances are often considered to be components of the

ILLUM-0715

Table 1. General Test Accuracy Specifications Including Both, Imprecision of the Measurement and Trueness of the Measurement (expressed as bias)[26a]

	specifications		
	optimal	desirable	minimum performance
imprecision	$< 0.25 \cdot CV_I$	$< 0.5 \cdot CV_I$	$< 0.75 \cdot CV_I$
bias	$< 0.125 \cdot (CV_I^2 + CV_G^2)^{1/2}$	$< 0.250 \cdot (CV_I^2 + CV_G^2)^{1/2}$	$< 0.375 \cdot (CV_I^2 + CV_G^2)^{1/2}$

[a] Specifications depend on within-subject (CV_I) and between-subject (CV_G) variations.

sample that contribute to the measurement signal, e.g., hemoglobin in specific photometric analyses. Matrix effects do usually not contribute directly to the measurement signal but indirectly through physical or physicochemical properties of the sample, e.g., viscosity, adsorption processes, reaction acceleration, or inhibition.

Test precisions of clinical analyzers may be used as an orientation guide for precision specifications, too. For example, in a multicentric evaluation of analytical performance of 33 protein assays a dedicated immunoassay analyzer exhibited a median total CV of 3.4% with a 2.5th and 97.5th percentile of the imprecision distribution at 1.3% and 13.0%.[29]

It is Advantageous to Address Needs that Contribute to the Overall Performance. Besides the requirements regarding test accuracy, it is advantageous to address needs that contribute to the overall performance characteristics (List 1). Costs associated with a test, including the instrument and consumables, which may be summarized in terms of cost per reportable result, are important factors for the acceptance of a test and have to be balanced in view of potential savings achieved by performing a test. Depending on the field of application, features such as ease of use, degree of automation, throughput, turn-around-time, menu breadth, open channels (for nonproprietary tests), instrument footprint, connectivity to the laboratory information management system, service quality and continuity have to be addressed. In conclusion, tests, assay formats and instruments have to fulfill objective quality specifications and should be at least compatible with the state of the art.

The compatibility of a new test's format with existing diagnostic test processes, i.e., preanalytics, actual analysis, and post-analytics, may also factor into the overall performance characteristics. Preanalytical processes include the order of the test(s) based on the physician's request to support diagnosis of a patient, sample collection, transportation of the sample, accession of the sample into the laboratory, processing of the sample (e.g., centrifugation, sorting, aliquoting, loading of the instrument), reagent setting and calibration of the instrument, and match ordered test(s) and sample. Post-analytical processes include approval of test results, their collection, transmission, appropriate display (e.g., charts) and documentation, waste disposal, sample storage, inventory, and order management, and payment of invoices.

Some of the processes mentioned above are of particular importance for proteomic studies. First, it is crucial to have detailed information on the donor, e.g., on gender; age; dietary, smoking, alcohol consumption and other habits; patient history; medication; pregnancy; post/pre-menopausal; suspicion or confirmed diagnosis of disease(s); clinical laboratory results; etc.

The specimen type used, its collection, transportation, processing, storage, etc., and the respective stability of a marker can dramatically influence the concentration and integrity of a marker.[30] This together with matrix effects from the other constituents of the respective sample have a significant impact on diagnostic performance and obviously on the success of research activities, too.[21,31–33] Biological specimens used for diagnosis include whole blood, serum, plasma, urine, cerebrospinal, synovial, amniotic, pleural, pericardial, peritoneal, cervical, seminal fluids, nipple aspirates, sweat, saliva, exhaled air, various types of solid tissues, feces, etc.[34,35] Serum is the specimen most frequently applied in IVD followed by different plasma types and urine,[36] while the pathology laboratory generally requires tissues and cells, e.g., erythrocytes, platelets, lymphocytes, etc. for cytopathological investigations.

Every specimen type has its pros and cons with respect to the scope of a study and the technologies applied. There is no such thing as a universal or ideal specimen type that could be generally recommended. Often, it is necessary to work with the specimens that are available anyhow. However, if possible, one should avoid choices of specimens and processing procedures that inherently preclude some future analysis. Blood is easily accessible and there are usually no contraindications to a standard blood draw. Serum and plasma display moderate variability if compared to other specimens such as urine. Nevertheless, serum and different plasma types exhibit significant variability. On the other hand, they are considered to mirror best the whole human proteome.[37] Serum allows for various testing including electrolytes, proteins, peptides, metabolites, etc. This is particularly advantageous, if additional testing ("adds on") as a consequence of a first result is required, because it may eliminate the need of additional blood draws and thus saves time. To have maximal freedom of testing and because of limitations regarding the draw of various different specimen types, ideally one specimen type should be applicable for all determination. However, some blood constituents require special collection and storage conditions.[38]

Plasma, in particular heparinized plasma, is preferred when a quick answer is critical, because clotting time is saved. Citrated plasma is mainly applied for coagulation analysis. Anticoagulants, preservatives, and other additives influence the composition of the specimen and may interfere with certain analysis.[21,38] Thus, it is of importance to carefully select the application of these compounds in blood collection tubes or their addition at a later point after the collection process.[30,35]

The collection of a specimen is crucial, too.[32,33] For example, for blood specimens it is important to consider how the blood was drawn. Factors such as timing of collection, position of the patient (lying, seated) and the time period the patient was in this position (impacting hematocrit), stress for the patient associated with the blood collection, type of collection (venipuncture, arterial puncture, skin puncture, etc.), site of collection and its preparation (e.g., cleaning of the site), tourniquet technique (e.g., time of venous occlusion), order of sampling (first, second, third tube), the quantity of blood withdrawn (e.g., dilution of citrated plasma), and obviously the person who

ILLUM-0716

draws the blood impact the composition of the specimen. The same is true for parameters of collection devices or collection sets applied, e.g., needle gauge, single draw or multi-draw needles, and bag or tube types applied. Here, the material (glass or plastic) should be considered as well as other features such as siliconized tubes (potential activation and acceleration of clotting, reduction of adhesion of clots), gel or nongel separators (gel serves as a mechanical barrier, which eliminates the changes that occur when the clot or cells are in contact with serum or plasma), and additives such as clotting coagulants and preservatives.

The main factors that should be considered upon transportation are timing and temperature among others. Processing techniques may also impact the quality of a specimen.[32,33] The coagulation process to gain serum may depend on volumes, clot activator (type, concentration), clotting time, and temperature. G-force, duration and temperature are factors that have to be considered upon centrifugation of serum and plasma. For plasma samples activation of platelets at low temperatures can be an issue. Also, platelet depletion and the technique applied (second centrifugation step or filtration) may be considered.[32] Storage is another important aspect. The influence of freezing and thawing procedures, storage formats, temperature and duration as well as repeated freeze and thawing can significantly impact the quality of specimens.[32,33,39]

In conclusion, to ensure a high degree of consistency and to reduce the risk of error in subsequent analyses, strict adherence to optimized protocols or standard operating procedures is mandatory for each sample throughout the whole process, which has to be subject to thorough quality assurance and control procedures including documentation.[40-45]

Diagnostic Accuracy: The Ability to Discriminate States of Health and Disease

The diagnostic accuracy, i.e., diagnostic sensitivity and diagnostic specificity, of a test is its ability to discriminate between alternative states of health and disease. Frequently, there are more than two states to be differentiated. However, the clinical question can often (but not always) be dichotomized where the objective is to separate patients into two groups based on the presence or absence of a certain disease (Figure 1). In 1971, Lusted postulated that the measure of the performance of the observer measures the worth of a diagnostic test and that receiver (or relative) operator characteristic or receiver operating characteristic (ROC) curves (Figure 2) provide an ideal means of studying observer performance.[46] Since then, ROC curves have been widely used to determine the diagnostic accuracy of a test in IVD and clinical proteomics.

Receiver Operator Characteristic (ROC) Curves: Sensitivity versus 1-Specificity. To outline major challenges associated with laboratory tests and clinical proteomics approaches, basics of diagnostic performance measures are briefly outlined. ROC curves represent graphically the inverse relationship between specificity or 1-specificity and sensitivity (Figure 2). Sensitivity is the ability of a test to detect the condition of interest, for example the number of true positives of an affected group, i.e., detection of disease when it is truly present. Specificity is the number of the true negative results of the unaffected group, i.e., recognition of condition absence when it is truly absent. 1-specificity is the number of false positives. As the reliability of determinations of sensitivity and specificity depend on the size of the chosen population, it is essential to provide the 90%

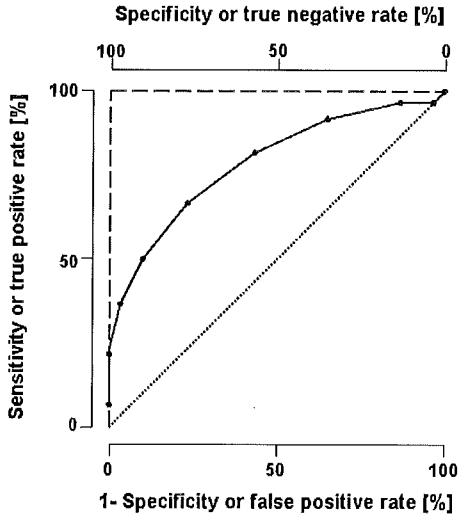

Figure 2. Receiver operating characteristic (ROC) curves are used to determine the diagnostic accuracy of an assay. When population overlap completely, no differentiation between diseased and nondiseased is possible (dotted line), leading to a useless test with an AUROC of 0.5. When there is no overlap, the ROC curve superimposes along the axes (dashed line). This perfect test has an AUROC of 1. Typically, there is a distinct overlap of populations as outlined in Figure 1, which creates ROC curves between the two extremes, e.g., the displayed hypothetical curve (solid line with dots).

or 95% confidence intervals, because this gives a clearer picture of the strength of the data.[47] Details have been extensively outlined elsewhere.[21,22,47-49]

AUROC: A Measure of Diagnostic Accuracy. A summary measure of diagnostic accuracy is the area under the ROC curve (AUROC), which incorporates sensitivity and specificity. It represents the overlap between the healthy and diseased population. An AUROC of 1 would represent a perfect diagnostic accuracy (no population overlap) and an AUROC of 0.5 would represent no difference between groups (no diagnostic value). It is rather unlikely that a diagnostic test reaches an AUROC of 1, because it is hardly possible to select a medical decision level or cutoff point that completely discriminates between two groups. Thus, the major challenge of IVD tests lies in the selection of the right cutoff points, i.e., sacrifice sensitivity for specificity or vice versa.

Of note, complex diseases, where it is necessary to differentiate multiple disease states, co-morbidities or mimics, and chameleons usually hamper the finding of efficient cutoff points to achieve high diagnostic accuracy. In addition, these diseases often exhibit complex time-dependent physiological or pathological processes, which may aggravate the finding of single IVD markers useful to differentiate states. For example, it is challenging to find IVD marker(s) to rule-in ischemic stroke within the first 3 h after onset of symptoms, which is the treatment window for thrombolytic therapy. As the acquisition of cerebrospinal fluid is usually contraindicated serum or plasma markers are needed. The crossing of the blood–brain-barrier by potential brain specific markers into the circulation within a short time frame and eventual renal clearance processes challenge the finding of appropriate markers. Finding a rule-in marker for ischemic stroke is also challenging, because of the heterogeneous etiology of stroke. Ischemic strokes have to be discriminated from hemorrhagic strokes (subarachnoidal, intracranial) and transient ischemic attacks and multiple

ILLUM-0717

mimics such as alcohol withdrawal, hypoglycemia, intoxication, seizures (epileptic), amnesia, multiple sclerosis, migraine, tumors, closed head injuries, infections, and inflammatory processes (meningitis, encephalitis, abscesses). This example also clarifies, why laboratory diagnosis is often based on the combination of tests (see below).

Predictive Values Display How a Test Will Perform in a Population and Denote the Probability of the Patient to Have the Diagnosed Condition

To assess the diagnostic accuracy of a test when applied to a population, the effect of disease frequency has to be considered. Critical parameters of the diagnostic performance of a test are predictive values (PVs). The PV of a positive test result (PPV) is the percentage of patients with positive test results that are diseased. The PV of a negative test result (NPV) is the percentage of patients with negative test results that are nondiseased. PVs are not measures for the intrinsic diagnostic accuracy of a test, they are a function of both the sensitivity and specificity of a test and the frequency of a disease (see text of Figure 1). Whether prevalence or incidence is more adequate to determine predictive values is determined by the particular application. The incidence of a disease is the number of cases that arise during a distinct period of time in a given population. The prevalence is the frequency of the disease at a certain point in time in a given population.

As the decrease of disease frequency goes along with a decrease of the PPV, even tests with high sensitivity and specificity fail as screening tests when applied to the general population with a low disease frequency. For example, the comparatively low prevalence of distinct cancers is one of the reasons, why it is so difficult to implement cost-effective cancer screening tests as routine screening tools. Even the prostate specific antigen (PSA) test, the only FDA-approved serum IVD cancer screening test to-date is questioned to be useful as a prostate cancer screening tool, because of the limited predictability and the absence of prognostic value. Elevated PSA values do not tell, if the cancer is aggressive or not and if any surgery would save years of life at the cost of significant morbidity. In view of these aspects and because of the heterogeneity of cancer, it is an extremely difficult charter, to find routine screening markers for distinct cancer types. But as cancer is one of the leading causes of death (http://www.who.int/whr/2004/annex/topic/en/annex_2_en.pdf) and as early, presymptomatic diagnosis dramatically improves the odds of successful treatment, there is undoubtedly an unmet diagnostic need.

Clearly, the results of a diagnostic test cannot be assessed properly, without knowing the probability of the condition before the test is performed.[5] However, the PVs are post-test probabilities of the condition (revised or posterior probabilities). When a patient's history, signs and symptoms, or results of independent diagnostic tests performed previously are available, the pretest probability (the probability of the condition before the test is applied) has to be taken into account. The determination of the pretest probability, e.g., by Bayes' theorem, is beyond the scope of this article. It has been extensively reviewed elsewhere.[5,21,49,50]

Different Approaches to Perform and Combine Multiple Tests

According to the aspects mentioned above, two or more tests are often performed to diagnose patients. There are two basic approaches of multi marker testing in the diagnostic laboratory: (1) the series approach, i.e., test A is applied first and all those specimens with a positive result are retested with test B or vice versa, etc., or (2) the parallel approach, i.e., tests A and B are measured at once. The advantage of serial testing is the typically positive impact on pretest probability and consequently on PVs and its cost-effectiveness, in particular for the screening of large populations for a rare condition, because most patients receive only one test. The potential disadvantage is the delay in treatment while waiting for the results of subsequent tests.

There are different ways in which test results can be combined, e.g., by the OR rule or the AND rule.[49] For parallel testing, the rules are as follows:

OR rule: The diagnosis is positive, if either test A or test B is positive. Both tests must be negative for the diagnosis to be negative.

AND rule: The diagnosis is positive only, if both test A and test B are positive. Either test A or test B can be negative for the diagnosis to be negative.

When the serial testing process is performed the common decision rules are as follows:

OR rule: If the first test is positive, the diagnosis will be positive; otherwise, the second test is performed. If the second test is positive, the diagnosis will be positive; otherwise, the diagnosis will be negative.

AND rule: If the first test is positive, apply the second test. If the second test is also positive, the diagnosis will be positive; otherwise the diagnosis will be negative.

The sensitivities and specificities for the OR rules and the AND rules are the same for the parallel and the serial approach.[49,51] For the OR rule, the sensitivity is higher than either test individually ($Se_A + Se_B - Se_A \times Se_B > Se_A \cup Se_B$), but the specificity is lower than either test individually ($Sp_A \times Sp_B < Sp_A \cup Sp_B$). With the AND rule it is vice versa. The specificity is higher than either test individually ($Sp_A + Sp_B - Sp_A \times Sp_B > Sp_A \cup Sp_B$), but the sensitivity is lower than either test individually ($Se_A \times Se_B < Se_A \cup Se_B$).

The AND approach appears attractive to exclude the presence of a disease, because sensitivity is increased, though as a tradeoff, specificity is lower. When negative, these AND testing profiles may have a high NPV. Therefore, they are useful for clinicians to rule-out a variety of diagnoses. In the diagnostic workup, the OR approach may be preferentially performed. This approach is very predictive of the presence of a particular disease, confirmation or rule-in, because of the high specificity. Of course, when more than two tests are applied a flexible combination of series and parallel testing and the OR or AND rule may also be performed. Nevertheless, even the use of multiple tests of independent markers does not resolve the tradeoff between sensitivity and specificity[21] and issues associated with positive and negative predictive values.

Here, it should be noted that a set of observations can also be considered as a single multivariate observation (patterns or profiles) and interpreted as such by a multivariate comparison. A multivariate reference or decision region can prevent the addition of false-positive results, which is usually the case for the performance of multiple, univariate comparisons. The generation of algorithms to efficiently combine diagnostic information, e.g., by neuronal networks, has been shown to increase diagnostic accuracy.[52]

The contribution of the diagnostic accuracy of single or multiple laboratory tests has to be seen in concert with

ILLUM-0718

Table 2. Purposes for the Application of IVD Tests or Respective Marker Types

marker type	examples
Acute markers are used when an acute disease event occurs and should help in the process of differential diagnosis to provide the information necessary for a specific treatment.	cTns that are used to rule-in AMI and B-type natriuretic peptide (BNP) and N-terminal pro BNP (NT-proBNP) to rule-out heart failure in patients with acute dyspnoe.[16,78]
Screening markers identify diseased preferentially in an asymptomatic stage within a population to start treatment as soon as possible, which usually goes along with a high treatment success. Generally, screening markers are applied in population subgroups with increased risk and disease frequency to achieve adequate PVs.	The detection of protein in urine, in particular albumin, is a screening tool for renal diseases.[79]
Primary risk assessment markers are used to assess the risk of a healthy individual to suffer from a disease in the future.	Total cholesterol, triglycerides, LDL cholesterol, HDL cholesterol, high sensitivity C-reactive protein (hsCRP), among others are markers used for primary cardiovascular risk assessment.[53,55]
Secondary risk assessment, prognostic or progression markers are used to determine how the disease may potentially develop, the risk of a diseased patient to suffer recurrent or other disease events, etc.	Cardiac troponins are used in the secondary risk assessment for AMI patients as an indicator for the risk of adverse outcomes, i.e., morbidity and mortality.[16] As primary risk assessment markers, secondary risk assessment markers help to determine aggressiveness of a treatment and balance the benefits and side effects.
Disease staging or classification markers help to classify different disease states.	Determination of certain proteins in urine, kidney and urinary tract diseases can be classified into prerenal, renal, and postrenal.[79]
Treatment response stratification markers are used to predict the likeliness of a response to a pharmacon before its application to prevent adverse effects and to initiate the most effective therapeutic treatment.	Hemostasis markers may be determined before a distinct anticoagulation therapy is started.[22] Viral resistance markers and antibiotics resistance testing in bacteria are further examples.
Treatment or therapeutic monitoring markers are used to determine and monitor the effectiveness of a treatment.	Blood lipids are applied to follow the impact of exercise, nutrition, and eventually therapeutic interventions.
Therapeutic drug monitoring is based on the determination of pharmaca administered to treat a patient. In this sense, it is not a marker type, but listed for the sake of completeness.	Immunosuppressive drugs, like sirolimus, everolimus, tacrolimus, and cyclosporin A, have to be monitored closely to prevent graft rejection and to minimize adverse therapy effects.[75]
Compliance markers provide information on treatment compliance.	Glycosylated hemoglobin A (HbA1c) can be used to monitor insulin therapy compliance[80] and carbohydrate deficient transferrin (CDT)[81] may be applied to control compliance with alcohol withdrawal therapy.

complementary diagnostic information to support precise treatment decision making, too. As outlined above, patient information from the physicians' examination are crucial. For example, parameters such as age, smoking, high blood pressure, family history of myocardial infarction, diabetes mellitus, etc., in concert with laboratory markers such as LDL cholesterol, HDL cholesterol, and triglycerides, among others, are major factors included in algorithms for the risk assessment of acute coronary events.[53]

Requested Diagnostic Information Determines the Required Diagnostic Accuracy

As outlined above, the disease type, its complexity, and its frequency within a given population, determine diagnostic accuracy requirements and how to perform and combine multiple tests to achieve appropriate PVs. Thus, diagnostic accuracy requirements are also determined by the requested diagnostic information or marker type, because this determines disease frequency and degree of differentiation between disease states. Different diagnostic applications of disease-specific proteins have been outlined comprehensively by Zolg and Langen.[9] Main IVD marker types are presented in Table 2.

In most cases of laboratory diagnosis, the same analytes can also be used for different diseases and as different marker types (Table 2) to obtain different diagnostic information. For example, CRP is the classic acute phase protein.[54] High concentrations of CRP indicate acute inflammatory processes.[54] whereas persistent low concentrations of CRP are used as a primary cardiovascular risk assessment marker.[55] cTns are applied as acute markers for the event (AMI) itself, to determine the size of the damage, and they also provide prognostic information.[16]

Tests for Definitive Diagnostic Evidence, Surrogate Tests, and Tests Providing Contributory Diagnostic Evidence

Tests are also classified by their role in the diagnostic process[56] as pathognomonic tests, surrogate tests, and tests that provide contributory diagnostic evidence. Obviously, this classification may not be entirely clear-cut in practice.[47] Pathognomonic tests (tests for definitive diagnostic evidence) are defined (or assumed) to uniquely define a disease and are used in the classification of diseased and nondiseased. Therefore, these tests are used as "gold standards" to assess the diagnostic accuracy of alternative tests (Figure 1). By definition a pathognomonic test displays the highest attainable diagnostic accuracy. Clearly, this assumption can only be validated by comparison to a less well-established test, which may subsequently be shown to better uniquely define the disease.[47] Usually, the pathognomonic test, e.g., a biopsy, is expensive, elaborate, time-consuming, unpleasant for the patient, or associated with a morbidity or even mortality risk. A surrogate test is used as a substitute for a pathognomonic test. A test for

ILLUM-0719

contributory diagnostic evidence contributes to, but does not establish itself, a diagnostic decision. Typically, surrogate tests or tests for contributory diagnostic evidence are inexpensive, less unpleasant for the patient, and display little association with morbidity or mortality. On the other hand, they are associated with diagnostic inaccuracy.

Discovery, Confirmation and Exclusion Tests

Pathognomonic tests, surrogate tests or tests providing contributory diagnostic evidence may be classified as outlined in Table 2. Their use for the discovery, confirmation or exclusion of a disease allows for another level of classification.[57] A discovery test is used in disease screening (Table 2), a confirmation test to confirm (rule-in, test with high specificity) a suspected disease, and an exclusion test to exclude (rule-out, test with high sensitivity) the presence of a suspected disease. By applying different decision thresholds (cutoffs or cut-points) more than one of these purposes can be served by a single test and the respective marker (Figure 1). When a disease is serious and should not be missed, a disease is treatable, false positive results do not have serious psychological or economic consequences for the patient, e.g., neonatal screening for phenylketonuria or hypothyroidism, an exclusion test is used. When a disease is not treatable or curable, the knowledge that the disease is absent is reassuring to the patient, and false positive results have serious psychological or economic consequences for the patient, e.g., multiple sclerosis and advanced carcinoma, the confirmation test is used.[47]

Potential Implications on Applied Clinical Proteomics

If a smooth transition of clinical proteomics findings and developments to routine diagnosis is desired, then it is important to fulfill IVD requirements and address needs (see above and List 1). The requirements and needs should be considered differently depending on the objective.

Considerations for the Search for New IVD Markers

The choice of the disease, the desired diagnostic information or marker type (Table 2), and the performance of any existing diagnostic procedures determine the diagnostic accuracy that has to be achieved by tests based on a single or multiple new marker(s). It is also advisable to consider that the initial search for new IVD markers should allow for transition to routine IVD instruments (typically as immunoassays) and preferentially lead to serum or plasma tests of the marker candidates, if the marker is supposed to be tested in the clinical laboratory. This does not necessarily mean that serum or plasma is always the primary choice of specimen for the initial search for new markers. Concentration issues and other considerations may propose to start with solid tissues or other fluids.[58,59] If a new marker requires a new technology platform, then its use will be substantially delayed while the clinical laboratory community evaluates the platform and investigates the economics of the test. Typically an investment in a new platform is not justified if it provides only a single new test.

The preanalytical processes, i.e., acquisition of the sample and its handling, should be transferable to the routine environment. Thus, acceptance of a marker whose routine detection required a novel method of serum collection would be inhibited in comparison to an equivalent marker measurable in standard serum or plasma. The single immunoassay test per tube is ideal for optimization of individual assay performance to reach specifications, regarding specimen types, concentration range, precision of the measurement, trueness of the measurement (calibration and traceability to reference materials), correlation to other methods (in particular reference methods), cross-reactivity, matrix effects and interferences, e.g., hemolysis (which generates a red color interfering with some colorimetric assays), icterus (in which high levels of the yellowish pigment bilirubin interfere), lipemia (in which turbidity from lipoprotein particles interferes with some optical measurement techniques), interfering antibodies in the sample (which can, for example, bind directly to one of the antibodies in a sandwich immunoassay and give a false signal) and other substances. Standardization, quality control and assurance including detailed and appropriate documentation, if possible according to standard operating procedures[40-45] is of particular importance for preanalytical processes to provide samples of high quality, but obviously important for the subsequent diagnostic processes, too.

For an initial search for marker candidates, a phase I study, it may be legitimate to focus on the most prominent disease states and keep the sample number to a minimum. The number of samples needed for a phase I study depends on the conjectured diagnostic accuracy and the ratio of diseased samples to controls.[48]

Proteomics appears to be a useful tool for such initial studies, because it provides information on a huge number of proteins and protein variants at once. To facilitate transition to routine diagnosis with its requirements for diagnostic accuracy and test accuracy, it is advisable to switch to an assay format or instrument for subsequent study phases, which is routinely used in the diagnostic laboratory, e.g., switch from MS to ELISA.

This also applies to multi-marker approaches, if a reasonable number of markers to be combined is not exceeded. The tests can be performed serially or in parallel and the reported results can be combined by the AND or OR approach as well as multivariate analyses with high flexibility including other test types, e.g., electrolytes, functional hemostasis test, etc. and of course additional diagnostic information, e.g. age, gender, body weight, etc.

The validation, including subsequent study phases, will establish the value of emerging markers, alone or in combination, and show if they are robust enough to move to IVD. Validation may be defined as documented evidence that the specific, unequivocally described method, process, or technology, operating within the established parameters, performs effectively and reproducibly to produce a result that meets predetermined specifications and quality attributes within given variations with a high degree of statistical assurance.

In phase II studies, accuracies of two or more diagnostic tests are often compared. Patients difficult to diagnose with early or atypical disease, other conditions that might interfere with the test, and controls with conditions that mimic the disease of interest challenge the candidates.

The hurdle in phase III studies is usually to assess and compare diagnostic accuracy of different tests. Here, the value of a test is determined in a defined but generalizeable population, i.e., in a clinical trial with a large cohort of patients with the selection of appropriate controls.[48] The costs of such studies are a major issue when one considers that the margins in the diagnostic industry are much smaller than the margins in the pharmaceutical industry. Also, the pressure of the funding bodies appears to be greater for diagnosics.

ILLUM-0720

Transition of Technologies Applied in Proteomics Research, Namely Protein Arrays and Mass Spectrometry, to Routine IVD

One of the major challenges of technology transition from proteomics research to IVD is the test accuracy, both precision and trueness (see above). To prove test accuracy, it is necessary that the technologies applied enable the application or establishment of guidelines and standard operating procedures[32,60] in concert with quality control, quality assurance, and standardization measures, e.g., by applying reference material.[61] The establishment of or the correlation to reference materials and reference methods are the best guarantee for correct calibration and thus trueness of measurement[20] to meet specifications, e.g., those of Table 1. This is particularly important for the establishment of common reference intervals and cutoff points to allow for harmonized clinical decision making and disease management. Patient monitoring over time is one example that does clearly illustrates the requirement of high test accuracy, in particular trueness of the measurement that has to be maintained over time. The application and implementation of reference materials in proteomics as currently applied in IVD may be one of the first steps to account for this challenge. A review on reference materials and the benefits of their application in clinical proteomics is beyond the scope of this article, though.

The parallel measurement of many different proteins is the inherent characteristic of technologies applied in proteomics research. The yet unresolved questions are due to the extremely different concentrations of the proteins to be measured in a very complex matrix like serum. A vivid example in inflammatory processes is the simultaneous determination of the abundant haptoglobin (Hp) (adult serum or plasma reference intervals calculated in relation to IFCC/BCR/CAP Certified Reference Material 470 are 0.03−0.20 g/L for Hp 1−1and Hp 2−2, and 0.04−0.20 g/L for Hp 2−1) and the traces of interleukin 6 (serum or plasma reference interval < 10 ng/L).

An interesting feature of the technologies applied in proteomics research, is the application of small sample volumes down to a few microliters. However, this is currently not critical in routine IVD since most current-generation clinical analyzers require less sample and reagent volumes than was previously the case.

The decision to apply single laboratory tests on standard instruments optimized for each protein or microarray or MS technologies will probably depend on the number and type of different proteins that need to be measured in parallel to provide a diagnostic result, the diagnostic accuracy and the test accuracy.

Challenges for Protein Array Technologies. High density protein arrays may be suited for high throughput screening and discovering initial correlations, but low density arrays seem to be more likely to reflect some aspects of IVD requirements and needs.[62,63] Performance, manufacturing, intellectual property issues, regulations and application challenges should be addressed for a smooth introduction of this technology into the IVD market.

Performance specifications (see above) like test precision, compatibility of multiple assay components, compatibility of concentration ranges of the different analytes, cross-reactivities, matrix effects, and interferences appear to be especially challenging when different proteins are to be measured in parallel in a single vessel. To achieve test trueness, significant efforts will be necessary to generate adequate and more complex controls and standards, and ultimately reference materials.

The manufacturing process will be more complex, but one may expect an increase of the overall efficiency with respect to the manufacturing time and costs through consolidation of multiple tests in a single package. However, lot to lot variability and stability of spotted arrays could be an issue. Quality control will be more difficult and troubleshooting of failures becomes more complicated. Final quality control failures for single analyte performance will compromise the entire product. The batch processes used to manufacture beads, e.g., for "bead arrays", at least partially circumvent some of these issues.

Third-party patents frequently have to be accessed before commercial use of technologies, tests, reagents (e.g., antibodies or antigens) applications, etc. Availability of licenses and costs may restrict the number of components that can be employed for a given multi-marker array and thus hamper its application in IVD. The inhibiting effect of "royalty-stacking", well-known in the pharmaceutical industry may become especially significant for multi-marker arrays.

From a regulatory perspective more complex evaluations and validations, which include the assay format and the instruments themselves, will require large cohort studies and significant registration efforts. Recalls of the whole system due to inappropriate performance of a single component affect customers' access to multiple tests. Different reimbursement rates and usage of the single analytes, the combination of markers, or a distinct microarray, also in view of regional distinctions, could also hamper the application of microarrays. The flexibility of the customer to perform serial testing or only testing a subset of tests is impaired with regard to financial trade offs, too.

Mass Spectrometry in IVD: Challenges Associated with the Detection of Proteins and Protein Profiles and a Successful History of the Determination of Low Molecular Weight Compounds. Some of the aspects outlined for arrays (see above) also apply to MS technologies, in particular to those that use arrays or chips such as surface-enhanced laser desorption/ionization time-of-flight (SELDI-TOF) MS. Recently, Aivado et al.[64] demonstrated that automation, analysis of replicates, and standardization of the drying process significantly decreased imprecision of SELDI-TOF MS protein analyses. After optimization CVs ranged from 25.7% to 32.6% depending on the signal-to-noise ratio threshold used. Even though lower imprecisions for SELDI-TOF MS protein analyses, e.g., CVs less than 10% have been reported,[65] in view of precision requirements (see above and Table 1) further improvements are required for the application of SELDI-TOF MS in protein IVD.

However, as the SELDI-TOF MS approach is thought to generate profile signatures that correlate to a disease, it will be interesting to see to what extent profile signatures and algorithms improve diagnostic accuracy.[2,3] This improvement will need to be substantial to compensate for the lack of accuracy in the measurement of individual analytes, as well as many additional issues associated with SELDI-TOF MS analysis and studies that have been extensively discussed elsewhere.[66−71]

The concept of profiling has a long history in laboratory medicine (e.g. serum protein electrophoresis), and thus it is not a shift in paradigms[3] but it could rather be expected that novel profiling approaches, e.g., via MS technologies, would also contain diagnostic information. Especially, as it may appear unlikely that a single marker will be sufficient to adequately diagnose complex diseases in its early phase (see above).

ILLUM-0721

On the other hand, the number of distinct discriminators commonly found in profiles[65,67,69,71] reveals that a few signals/markers are usually sufficient for diagnosis. This may eliminate the need for complete pattern or profile information for routine IVD applications—the needles within the haystack are of interest, not the haystack itself that actually obstructs the view on the needles. Consequently, a limited number of single immunoassays whose individual results are combined by an algorithm would be sufficient or even advantageous for accurate diagnosis (see above). Ultimately, even single markers have been and may be found in future that are useful for the diagnoses of complex diseases.

Besides the MS approach of profile signatures without identifying measured components, MS is widely used to detect distinct, identified analytes. Identifying analytes allows for the development and implementation of reference materials for standardization, calibration, recovery determination, quality control, and quality assurance.[66] For the detection of distinct low molecular weight molecules MS has been used as a diagnostic instrument in IVD for many decades,[68] e.g., for newborn screening to detect inborn errors of metabolism,[72,73] toxicology and forensic applications,[74] immunosuppressive drug testing,[75] drugs of abuse,[76] and doping of athletes.[77] In these applications, appropriate internal standards are used to achieve appropriate test accuracy. MS analyses are even applied as reference methods. For example, the determination of a distinct glycated peptide is used as an IFCC (International Federation of Clinical Chemistry) reference method for the determination of hemoglobin A1c with inter-laboratory CVs of 1.4% to 2.3%.[25] This form of MS technology, quite distinct from the use of unidentified feature patterns, is a potential alternative for use in the validation and small-scale application of novel diagnostic assays.

Conclusions

As candidate diagnostic markers begin the process of adaptation to IVD use, much time and effort can be saved by recognizing at the outset the important criteria by which IVD tests are judged. An IVD test is not simply a better or cheaper measurement than can be obtained with the technologies used for discovery: it is also a measurement that has a fairly definite meaning in the context of the patient's overall clinical picture and especially treatment. In many ways, new markers should be considered separately from new measurement technologies: a new marker could be brought into use much more rapidly as a test on an existing, validated platform (e.g., immunoassay) than on a novel technology platform whose acceptance is naturally slowed by economic (new clinical lab investment), regulatory, and other factors. This fact argues strongly that candidate IVD markers should be identified and fully characterized as part of the discovery process, and should then transition to a technology base better suited to adoption in the clinical laboratory. The opportunity to combine immunoassay technologies and MS, which would be applied as a sophisticated detector that can unambiguously identify ligands appears to be attractive. On the other hand, the costs associated with the application of MS as a detection unit in comparison to other detection technologies are currently considered prohibitive and most MS instrumentation falls far short of the robustness, automation, and user-friendliness required for routine laboratory operation. Nevertheless, while immunoassays dominate IVD protein measurements presently, it appears that the challenges of multiplexing such tests (e.g., on arrays) are sufficiently daunting that quantitative mass spectrometry may have value as an additional format for multiplexing protein measurements in the future given aggressive technology development.

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ILLUM-0722

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ILLUM-0723

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Reviews

Microarray-Based Genomic DNA Profiling Technologies in Clinical Molecular Diagnostics

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BACKGROUND: Microarray-based genomic DNA profiling (MGDP) technologies are rapidly moving from translational research to clinical diagnostics and have revolutionized medical practices. Such technologies have shown great advantages in detecting genomic imbalances associated with genomic disorders and single-gene diseases.

CONTENT: We discuss the development and applications of the major array platforms that are being used in both academic and commercial laboratories. Although no standardized platform is expected to emerge soon, comprehensive oligonucleotide microarray platforms—both comparative genomic hybridization arrays and genotyping hybrid arrays—are rapidly becoming the methods of choice for their demonstrated analytical validity in detecting genomic imbalances, for their flexibility in incorporating customized designs and updates, and for the advantage of being easily manufactured. Copy number variants (CNVs), the form of genomic deletions/duplications detected through MGDP, are a common etiology for a variety of clinical phenotypes. The widespread distribution of CNVs poses great challenges in interpretation. A broad survey of CNVs in the healthy population, combined with the data accumulated from the patient population in clinical laboratories, will provide a better understanding of the nature of CNVs and enhance the power of identifying genetic risk factors for medical conditions.

SUMMARY: MGDP technologies for molecular diagnostics are still at an early stage but are rapidly evolving. We are in the process of extensive clinical validation and utility evaluation of different array designs and technical platforms. CNVs of currently unknown importance will be a rich source of novel discoveries.
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Human DNA mutations range from single-nucleotide changes to whole-chromosome alterations. At the small-size end of the mutation spectrum, de novo changes in single base pairs occur at the rate of about 1.7×10^{-8} per base pair per generation *(1)*. It is estimated that there are 2 nonsilent point mutations in each newborn *(2)*. At the large-size end of the mutation spectrum, alterations in chromosome number causing aneuploidy affect about 0.3% of live births *(3)*. In between are microscopic and submicroscopic genomic rearrangements involving different segments of chromosomes that may affect many genes or exons of a gene. The de novo rate of mutation of copy number variants (CNVs)[5] in each newborn has been estimated as 1 in 8 for deletion and 1 in 50 for duplication *(2)*, which are between the rates for de novo point mutations and chromosomal aneuploidy. Recent studies have shown that the human genome contains many CNVs *(4–7)*, which are the result of a distant (inherited) or current (de novo) loss or gain of genomic sequences.

A portion of these alterations will produce a change in the human phenotype and in extreme cases will cause abnormal development and medical conditions. The purpose of clinical genetic diagnostics is to detect such mutations effectively and to correlate these changes with corresponding medical conditions. Various methods have different resolutions that reveal different sizes of genomic imbalance (Fig. 1).

Point mutations can be detected effectively with the Sanger sequencing method after specific amplification of target regions by the PCR. The detection of chromosomal aneuploidy and large rearrangements are within the repertoire of traditional cytogenetics.

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[5] Nonstandard abbreviations: CNV, copy number variant; FISH, fluorescence in situ hybridization; MLPA, multiplex ligation-dependent probe amplification; MGDP, microarray-based genomic DNA profiling; CGH, comparative genomic hybridization; SNP, single-nucleotide polymorphism; BAC, bacterial artificial chromosome; UPD, uniparental disomy; ASD, autism spectrum disorder; pCNV, pathogenic CNV; bCNV, benign CNV; uCNV, CNV of unknown importance.

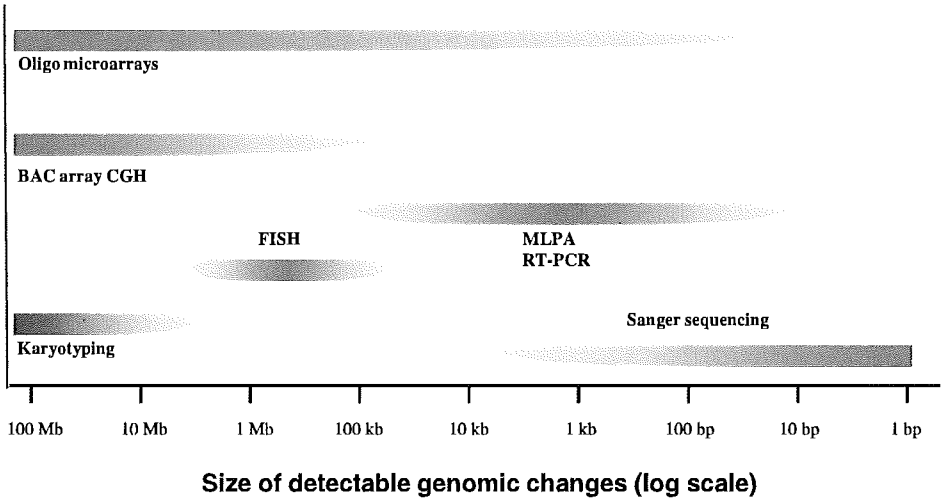

Fig. 1. Various methods with different resolutions detect different sizes of genomic changes.

Point mutations (changes in single or multiple base pairs up to kilobase pairs) can be detected with Sanger DNA sequencing. Karyotyping can detect large chromosomal rearrangements with low resolution (down to 5 Mb). FISH provides much higher resolution (down to 100 kb) for detecting submicroscopic genomic imbalances, but it interrogates only selected loci at one time. MLPA and real-time PCR (RT-PCR) complement FISH and DNA sequencing, but all of these methods suffer from a low information content, limited throughput, and the requirement of choosing candidate targets before the test. Microarrays [BAC and oligonucleotide (oligo)] are capable of detecting both microscopic and submicroscopic copy number changes for the whole genome in a single assay. The high-resolution microarrays (oligo CGH arrays and SNP hybrid arrays) provide the most efficient means to identify genomic imbalance widely (down to kilobase pairs and approaching base pair resolution).

Fluorescence in situ hybridization (FISH) represents a merging of cytogenetic techniques with molecular technology. Such a merger and its applications in the clinical setting were necessitated by the discovery of a set of submicroscopic genomic imbalances associated with specific clinical manifestations (collectively known as microdeletion and microduplication syndromes), but this method interrogates only selected loci at a time. Other techniques designed to detect copy number changes, such as multiplex ligation-dependent probe amplification (MLPA) and real-time PCR, are complementary to those of FISH and DNA sequencing, but all of these methods suffer from low information content, limited throughput, and the requirement of choosing candidate targets before the test.

Microarray-based genomic DNA profiling (MGDP) technologies are capable of detecting both microscopic and submicroscopic copy number changes for the whole genome in a single assay. They provide unprecedented sensitivity and cost-effectiveness for a large group of mutations that have evaded conventional approaches, and they are changing clinical practices. MGDP may be used as a first-tier tool in clinical genetics for many conditions previously evaluated via conventional cytogenetic approaches. We review the current status and some considerations regarding the clinical applications of MGDP technologies.

Development of Genomic DNA Profiling Microarrays

Microarrays have been widely used for gene expression analysis in the past decade; however, it is worth mentioning that DNA microarrays were initially designed for interrogating vast amounts of genomic sequence polymorphisms and variants. The intention to use microarrays for diagnostic purposes was deeply rooted from the very beginning. There are 2 major microarray platforms for genomic DNA profiling—comparative genomic hybridization (CGH) arrays and genotyping arrays—which were developed in parallel yet interactively. Regardless of the technical differences in chip manufacturing and probe types used with these platforms, they share the same principle and rely on the specific hybridization of target and probe sequences. CGH arrays use a 2-color scheme. The method infers the copy number changes in a test sample by comparing it with a reference sample. Genotyping arrays, on the other hand, do not use a control sample; rather, they use the intensity of the hybridization signal to in-

ILLUM-0725

dicate the relative DNA copy number. In addition, genotyping arrays provide information on single-nucleotide polymorphism (SNP) genotypes.

TRANSFORMATION OF CGH MICROARRAYS FROM LOW-RESOLUTION TARGETED BAC ARRAYS TOWARD WHOLE-GENOME HIGH-DENSITY OLIGONUCLEOTIDE ARRAYS

CGH was first reported by Kallioniemi et al. in 1992 to interrogate cancer genomic DNA with metaphase chromosomes as probes *(8)*. The basic strategy of the technique is to differentially label the DNA from cancer cells and the DNA from healthy reference cells with different fluorochromes and to cohybridize the labeled samples to a metaphase spread from a healthy reference cell. The ratio of the intensities of the 2 fluorochromes reflects the copy number differences between cancer cells and healthy cells. Because this technique uses metaphase chromosomes as probes for hybridization, it is now also called "chromosome CGH." In essence, chromosome CGH is similar to FISH painting, which uses labeled DNA from the entire genome as the probe set. This technology permits a genome-wide survey and identifies the genomic imbalance at different regions of specific chromosomes. Although chromosome CGH has demonstrated its effectiveness in detecting larger genomic imbalances in the cancer genome, the detection power has ultimately been limited by the resolution of a metaphase chromosome.

The major breakthrough in CGH came from microarray technology about a decade ago. Instead of hybridizing labeled genomic targets to metaphase chromosomes, the new scheme uses cloned genomic DNA as probes in a microarray format. Because these probes contain sequence information that permits their specific localization in the human genome, the regions with a genomic imbalance can be delineated by data-visualization software that denotes all of the probes along the genome. The resolution of microarray-based CGH, which is determined by the density and size of the probe, is a substantial improvement over chromosome CGH.

The first CGH microarray, termed matrix CGH, was developed in 1997 by Solinas-Toldo et al. with cosmid and plasmid artificial chromosome clones as probes *(9)*. Subsequently, bacterial artificial chromosome (BAC) clones *(10)* and cDNA clones *(11)* were used to construct CGH microarrays. Subsequent improvements were focused on increasing the probe density and array coverage, as well as improving the signal-to-noise ratio.

The most recent advancement in CGH microarrays has been the use of oligonucleotide sequences as probes *(12)*. Compared with BAC arrays, oligonucleotide arrays have several advantages, including:

1. Reproducibility. As opposed to BAC arrays, in which the content of the probe (i.e., PCR product of a BAC clone) varies from batch to batch, the probe sequences in oligonucleotide arrays are uniformly defined and devoid of highly repetitive sequences. Consequently, oligonucleotide arrays are more reproducible.
2. Sensitivity and specificity. The smaller interprobe spacing of oligonucleotide arrays offers a much higher probe density for better detection of smaller genomic imbalances and more accurate breakpoint mapping, therefore providing much improved sensitivity over BAC arrays. The fact that oligonucleotide probes are selected from the reference human genome sequence allows all users to use any sequence of interest as a potential target, providing a specificity that is impossible with BAC arrays, in which clones can be selected only from existing libraries and need to be validated for their physical location.
3. Customization. Oligonucleotide probes are synthesized in situ on the arrays, allowing for easy customization of content. In addition, many commercial manufacturers offer a large number of preselected array CGH oligonucleotide probes and computer interfaces, making custom design and updating of CGH arrays quite feasible and fast for clinical laboratories, whereas BAC arrays are cumbersome to update and time-consuming for printing.
4. Robustness and reliability. The substantially increased capacity of oligonucleotide arrays enables multiprobe confirmation for a single event (the detection sensitivity and specificity are a function of consecutive probes), as well as increased robustness because the higher signal-to-noise ratios provide higher confidence in CNV diagnosis *(13–15)*.

IMPROVEMENT OF GENOTYPING ARRAYS FROM LOW-RESOLUTION SNP ARRAYS TO HIGH-RESOLUTION HYBRID ARRAYS THAT INTEGRATE SNP AND CNV PROBES

Whereas CGH arrays successfully combine microarray technology with CGH, genotyping arrays for CNVs arose from SNP arrays that were originally designed for sequencing *(16)*, genotyping *(17)*, and gene expression *(18)*. These SNP arrays with short oligonucleotides were developed by Affymetrix with their proprietary photolithographic technology *(19)*. Since then, the density of SNP arrays has been growing constantly. The DNA chips designed to genotype 10×10^3, 50×10^3, 100×10^3, 500×10^3, and even more SNPs have allowed improved detection resolution.

At about the same time that Agilent Technologies developed long oligonucleotide–based whole-genome CGH arrays with their ink-jet technology *(20)*, Affymetrix SNP arrays demonstrated their ability to detect changes in genomic copy number in addition to genotyping *(21–23)*. Similarly, Illumina used a

ILLUM-0726

Table 1. Major commercial oligonucleotide array platforms and their current products.

Company	Array platform	Resolution (median probe spacing)	Probe number	Oligonucleotide probe type	Detection
Agilent Technologies, Santa Clara, CA	4x44K CGH array	43 kb	43 000+	60-mer	CNV
	8x60K CGH array	41.4 kb	55 000+		
	2x105K CGH array	21.7 kb	99 000+		
	4x180K CGH array	13 kb	170 000+		
	244K CGH array	8.9 kb	236 000+		
	2x400K CGH array	5.3 kb	411 000+		
	1 Million CGH array	2.1 kb	963 000+		
Affymetrix, Santa Clara, CA	Genome-Wide Human SNP Array 6.0	0.7 kb	906 600 SNP probes and 946 000 CNV probes	25-mer	CNV, genotype, and LOH[a]
Illumina, San Diego, CA	HumanCNV370-Quad DNA analysis BeadChip	4.9 kb	320 000 SNP probes and 60 000 non-SNP probes for CNVs	50-mer	CNV, genotype, and LOH
	Human610-Quad DNA analysis BeadChip	2.7 kb	550 000 SNP probes and 60 000 non-SNP probes for CNVs		
	Human1M-Duo BeadChip	1.5 kb	1.1×10^6 SNP and CNV probes targeting exons		
NimbleGen, Madison, WI	HG18 CGH 4x72K WG Tiling v2.0	40 kb	72 000	50- to 75-mer	CNV
	385K WG Tiling, single array	6.27 kb	385 000/array		
	385K WG Tiling, 4-set array	1.57 kb			
	385K WG Tiling, 8-set array	713 bp			

[a] LOH, loss of heterozygosity.

different manufacturing approach in commercializing BeadChips for genotyping and copy number analysis *(24)*.

Table 1 lists the currently available oligonucleotide-array platforms for genomic DNA profiling. Reduced manufacturing costs, unprecedented detection power, and the feasibility of custom design/updates have made these arrays attractive in basic and translational research.

The major advance in genotyping arrays for genomic profiling is the development of hybrid genotyping arrays, i.e., the Affymetrix Genome-Wide Human SNP Array 5.0 and the latest 6.0 version, which combines SNP probes for genotyping with CNV probes for detecting changes in copy number *(25)*. The SNP Array 5.0, which is the prototype of the hybrid array, contains 500 000 SNP probes for genotyping and 420 000 nonpolymorphic probes for CNV analysis. Among the nonpolymorphic probes, 320 000 probes were chosen to provide even spacing across the genome, concentrating on areas not represented by SNPs, and the remaining 100 000 probes covered 2000 known CNVs (50 probes per CNV). The SNP Array 6.0 has 906 600 SNP probes, 744 000 copy number probes evenly spaced along the genome, and another 202 000 probes that target 5700 previously reported CNV regions. Thus, a single 6.0 array offers a total of 1.8 million probes for simultaneous SNP genotyping, CNV analysis, and loss-of-heterozygosity detection.

Although the Affymetrix SNP Array 6.0 (hybrid arrays) is mainly a research tool at the moment, many diagnostics laboratories are actively validating this platform for clinical applications. Although long-oligonucleotide CGH arrays do not have as many probes as short-oligonucleotide genotyping arrays, the signal-to-background dynamic range is generally better with long-oligonucleotide CGH arrays; however, the rich genotyping information, in addition to the CNV data offered by the hybrid arrays, provides additional value to the platform. For instance, the genotyping data simultaneously provide information regarding

ILLUM-0727

the parent of origin for the detected de novo CNV if parental samples have also been examined. The most important advantage of the hybrid arrays is their capability of detecting copy number–neutral genomic rearrangements, namely uniparental disomy (UPD), through loss-of-heterozygosity analysis. In the long run, the genotyping information can be used for SNP-association analysis.

Translational Research and Applications of MGDP Technologies for Patient Samples

MGDP technologies have been used extensively in clinical and translational research for interrogating patient samples. These studies provided crucial information about clinical utility before their diagnostic applications. A recent review by Stankiewicz and Beaudet *(26)* summarized the applications of microarrays for CGH, primarily dealing with low-resolution or targeted BAC arrays in the evaluation of patients with dysmorphic features, developmental delay, and/or idiopathic mental retardation. The published data produced with different array platforms and patient cohorts indicate an overall detection rate for pathogenic genomic imbalance of patients with multiple congenital anomalies and/or developmental delay/mental retardation of 12%–18%. Only 3%–5% of such patients can be detected by G-banded karyotyping, and an additional 9%–13% can be detected by microarray-based tests *(26)*. As expected, the detection rate is higher with whole-genome tiling arrays than with targeted arrays. A series of such studies overwhelmingly verified the superior sensitivity and detection power of array CGH compared with karyotyping and FISH analysis. As mentioned above, the most important advance in array CGH is replacing BACs with oligonucleotides. Similarly, short-oligonucleotide arrays have also been validated against and found superior to BAC arrays.

INTERROGATING SAMPLES FROM PATIENTS AND HEALTHY INDIVIDUALS WITH OLIGONUCLEOTIDE ARRAYS

Oligonucleotide CGH arrays became commercially available in 2004 and now include platforms from Agilent Technologies *(20)*, NimbleGen *(27)*, Affymetrix *(28)*, and Illumina *(24)* (Table 1). In-house spotted-oligonucleotide arrays *(29)* and custom-designed oligonucleotide CGH arrays *(13, 14, 30–32)* have also demonstrated high sensitivity and reproducible detection of genomic imbalance in testing with samples from patients and healthy individuals. Consequently, many laboratories have shifted from BAC arrays to oligonucleotide arrays *(15)*. Some diagnostic laboratories that provide large-scale services are now using oligonucleotide arrays for clinical diagnostics.

The initial implementation of oligonucleotide CGH arrays for clinical applications focused on targeted pathogenic genomic regions. Shen et al. developed targeted oligonucleotide arrays that used Agilent custom arrays to interrogate 179 clinically relevant genomic loci *(14)*. The multiplex arrays demonstrated results that were 100% concordant with the findings from BAC arrays, showing very high sensitivity. In addition, smaller genomic imbalances that were not detectable by BAC arrays were reliably detected with this oligonucleotide-array system *(14)*. Similarly, Ou et al. emulated BAC arrays with oligonucleotide probes and created an array of 44 000 oligonucleotides that verified an enhanced ability for detecting copy number changes compared with BAC arrays *(13)*. In addition to showing the superior analytical sensitivity of oligonucleotide arrays compared with BAC arrays, these studies also demonstrated the convenience of oligonucleotide-array design and manufacturing. Aradhya and Cherry used samples from 20 patients with dysmorphic features, developmental delay, or mental retardation to directly compare the performance of whole-genome BAC arrays of 1-Mb resolution (Spectral Chip 2600; PerkinElmer) with that of Agilent whole-genome oligonucleotide CGH arrays of 35-kb resolution *(33)*. All of these patients had a typical karyotype. Ten clinically important genomic-imbalance events were detected with the oligonucleotide arrays, whereas only 6 were detected with the BAC arrays. The study clearly demonstrated the superior effectiveness of the oligonucleotide arrays. Because of the large size of the BAC clones and the widespread nature of CNVs, BAC arrays provide very low specificity for detecting CNVs. Conversely, oligonucleotide arrays avoid repeat sequences via the selection of probes that avoid nonspecific regions.

With the intention of improving the capture of frequent subtelomeric imbalances associated with developmental delay/mental retardation, custom-designed oligonucleotide CGH arrays were developed with improved coverage in subtelomeric regions. Exploiting the design concept used earlier in BAC arrays *(34)*, Toruner et al. *(32)* randomly removed one third of the probes from an off-the-shelf Agilent whole-genome CGH array of 44 000 probes and replaced them with 14 000 subtelomeric probes. The resulting arrays provided 5-kb resolution in subtelomeres and 125-kb resolution in the remaining genome. The oligonucleotide CGH array–based molecular ruler *(31)*, another design that emerged at nearly the same time, provided 50-kb resolution for subtelomeric regions and 75-kb resolution for the rest of the genome. This array detected a subtelomeric genomic imbalance of 10.9% and a pathologic imbalance of 4.7% genome wide in clinical samples *(30)*. These custom designs provide

ILLUM-0728

Table 2. Exon-level DNA-profiling arrays.

Reference	CGH array platform	Target gene(s)[a]	Specific probe no.	Resolution
Rouleau et al. (39)	Agilent 11K array	BRCA1	1679	NA[b]
del Gaudio et al. (40)	Agilent 44K array	DMD	8769	NA
Staaf et al. (41)	Agilent 4x44K array	BRCA1, BRCA2, MSH2, MLH1, PTEN, and CDKN2A	9612	<500 bp, partial exon
Saillour et al. (42)	NimbleGen tiling array	CFTR, SGCA, SGCB, SGCD, SGCE, SGCZ, and DMD	72 500	Single exon and mosaic
Hegde et al. (43)	NimbleGen tiling array	DMD	385 747 (mean spacing, 5 bp)	Single exon and mosaic
Wong et al. (44)	Agilent 44K array	130 Nuclear genes involved in metabolic and mitochondrial disorders	≅44 000 (mean spacing, 250–300 bp)	Single exon and mosaic

[a] BRCA1, breast cancer 1, early onset; BRCA2, breast cancer 2, early onset; MSH2, mutS homolog 2, colon cancer, nonpolyposis type 1 (E. coli); MLH1, mutL homolog 1, colon cancer, nonpolyposis type 2 (E. coli); PTEN, phosphatase and tensin homolog; CDKN2A, cyclin-dependent kinase inhibitor 2A (melanoma, p16, inhibits CDK4); CFTR, cystic fibrosis transmembrane conductance regulator (ATP-binding cassette sub-family C, member 7); SGCA, sarcoglycan, alpha (50kDa dystrophin-associated glycoprotein); SGCB, sarcoglycan, beta (43kDa dystrophin-associated glycoprotein); SGCD, sarcoglycan, delta (35kDa dystrophin-associated glycoprotein); SGCE, sarcoglycan, epsilon; SGCZ, sarcoglycan zeta.
[b] Data not available.

enhanced coverage for clinically relevant regions, as well as decent coverage for the rest of genome for better measurement of the sizes of imbalance events.

Compared with oligonucleotide CGH arrays, fewer clinical applications have been studied on genotyping arrays. Friedman et al. used the Affymetrix 100K SNP arrays to investigate genomic imbalance *(28)*. Eight control trios that included the unaffected parents and an affected child with a previously recognized chromosomal abnormality or UPD were studied. The Affymetrix array detected the known abnormalities in all control cases, including 4 cases of UPD. The array also detected de novo deletions as small as 178 kb among 100 idiopathic mental-retardation patients with a typical karyotype. In addition, Ming et al. used the 50K Xba chip from the Affymetrix 100K array set for a similar study of patients with multiple congenital anomalies *(35)*. Although both studies illustrated the sensitivity and detection power of Affymetrix arrays for investigating genomic imbalance, the analytical sensitivity and cutoff for detecting copy number–neutral UPD have yet to be firmly established.

Flexible probe selection permits easy design of oligonucleotide arrays that can detect deletions and duplications at the exon level of specific genes (Table 2). Although PCR products for *NF1*[6] (neurofibromin 1) *(36)*, *NF2* [neurofibromin 2 (merlin)] *(37)*, and other large, clinically important genes *(38)* have been used to develop exon-level microarrays, the current manufacturing technology for oligonucleotide arrays has simplified the process so that it is more accessible to ordinary laboratories. These custom-designed, target gene–specific arrays detect duplication as effectively as deletion at the single-exon level, with more precise breakpoint mapping *(39–44)*. Targeting panels of genes associated with one disease at the exon level is attractive for molecular diagnostics.

GENOMIC IMBALANCES IN AUTISM SPECTRUM DISORDERS

Autism spectrum disorders (ASDs) are complex, pervasive developmental-delay disorders characterized by impairments in communication, social interaction, and behavior. Studies of twins have suggested a strong genetic component to ASD. Thus far, few contributory genes have been identified, but cytogenetic changes have been one of the most consistent identifiable causes of autism. Changes detectable by high-resolution G-banding have been reported in 3%–5% of autism patients *(45)*, involving the chromosomal regions at 2q37, 5p15, 11q25, 16q22.3, 17p11.2, 18q21.1, 18q23, 22q11.2, 22q13.3, and Xp22.2p22.3 *(46)*. MGDP is a powerful new venue for exploring the complex nature of ASD genetics. Jacquemont et al. *(47)* used whole-genome 1-Mb BAC CGH arrays to interrogate 29 syndromic autism patients with typical karyotypes and found that more than a quarter of the patients showed spontaneous pathogenic copy number changes. The size of the imbalances ranged from 2 Mb to 17.3 Mb. This study highlighted the immense effectiveness of array CGH in genetic analysis of patients with autism. It

[6] Human genes: NF1, neurofibromin 1; NF2, neurofibromin 2 (merlin); PARK2, Parkinson disease (autosomal recessive, juvenile) 2, parkin; DMD, dystrophin.

ILLUM-0729

Table 3. Detection rate of clinically relevant CNVs in ASDs by array technologies.

Reference	Array platforms	Actual resolution	Patient cohort	De novo CNV detection rate
Jacquemont et al. (47)	BAC CGH array	1 Mb	29 Syndromic autism	27.5% (8 of 29)
Sebat et al. (48)	Oligonucleotide CGH array	35 kb	118 Sporadic autism	10.2% (12 of 118)
			77 Multiplex[a] familial autism	3% (2 of 77)
Szatmari et al. (49)	Affymetrix 10K SNP array	476 kb	173 Families, simplex	5.8% (10 of 173)
Weiss et al. (50)	Affymetrix 5.0 array	30 kb	751 AGRE families	6.7% (50 of 751)
Christian et al. (51)	BAC CGH array	Tiling 19K set	397 AGRE samples	2.3% (9 of 397)
Marshall et al. (52)	Affymetrix 500K SNP array	75 kb	427 ASD families	6.3% mean (27 of 427); 7.1% (4 of 56) in simplex families; 2% (1 of 49) in multiplex families
Morrow et al. (56)	Affymetrix 500K SNP array and targeted BAC CGH array	75 kb	42 Consanguineous samples, multiplex	0
			52 Consanguineous samples, simplex	1.9% (1 of 52)

[a] Multiplex, family with ≥2 ASD patients; simplex, family with 1 ASD patient; AGRE, Autism Genetic Resource Exchange.

also demonstrated that extensive genomic imbalances are an important underlying cause of syndromic ASD.

In another study that used oligonucleotide arrays with much higher resolution, Sebat et al. *(48)* revealed the importance of de novo CNVs as genetic risk factors for sporadic ASD. Subsequent studies have provided further evidence to support the notion that copy number changes are strongly associated with idiopathic ASD *(49–55)*. Array technology has detected pathogenic CNVs in 5.8%–10.2% of sporadic ASD patients (Table 3), whereas the rate is consistently low in familial ASD patients (2%–3%). This finding suggests that there are 2 different ASD genetic mechanisms: sporadic ASDs are more likely to be caused by de novo deletions or duplications, whereas familial ASDs are more likely to be due to other types of inherited mutations. Array studies with consanguineous families further demonstrated the existence of recessive gene mutations that are largely not genomic deletions or duplications *(56)*.

Collectively, these studies clearly demonstrate the clinical value of genomic profiling in the evaluation of autism. It is strongly evident that the detection yield of MGDP is much more consistent and higher than traditional cytogenetic techniques *(57)*.

Clinical Validation and Diagnostic Applications of MGDP Technologies

CLINICAL VALIDATION—SENSITIVITY AND SPECIFICITY

As for any new technology, systematic validation is required before MGDP can be used for routine clinical applications *(14, 58, 59)*. The validation process should test all aspects of a new technology, but most importantly the sensitivity and specificity. Sensitivity and specificity are often tested by means of a positively testing cohort with known mutations that have been identified with a well-accepted technology. In the case of MGDP, results from karyotyping and FISH studies are often used. Typically, sensitivity testing examines the false-negative rate, and specificity testing inspects the false-positive rate; however, several aspects of MGDP validation are unique.

Microarray technology is analog in nature. The change in genomic copy number is reflected by a change in signal intensity or a color shift (red vs green) of the microarray features (probe spots). The first critical step is to define the analytical resolution, i.e., the size of CNV that can be detected reliably. Assuming that the feature-analysis software is well established for each array platform (not necessarily the case), CNV calling depends on the algorithm used. Owing to the different array platforms and probe densities, the analytical resolution of each array needs to be specifically defined. It is important to note that sensitivity and specificity vary, depending on the number of consecutive probes examined. Higher sensitivity and specificity can be achieved when more consecutive probes are used. In addition, the signal-to-background ratio for a deletion or duplication changes with the array platform, the labeling chemistry, and the hybridization protocol. Thus, it is necessary to define an appropriate threshold for each clinical-array design. For example,

Table 4. Clinical utility of diagnostic genomic-profiling microarrays.

Reference	Array platform	Sample size, n	GI[a]/CNV size	pCNV	bCNV	uCNV
Shaffer et al. (65)	Signature Genomic targeted BAC CGH array	8789	≥200 kb	6.90%	1.20%	3.90%
Lu et al. (66)	Baylor CMA V4 targeted BAC CGH array	775	≥1 BAC clone	7.60%	10%	0.60%
	Baylor CMA V5 targeted BAC CGH array	1738	≥1 BAC clone	8.90%	8.1%	1.70%
Pickering et al. (67)	Spectral Genomics Spectral Chip 2600 and Constitutional Chip	1176	≥1 BAC clone	9.86%	3.99%	
Aston et al. (68)	Spectral Genomics Spectral Chip 2600 and Constitutional Chip	669	≥2 BAC clones	10.8%	NA	
Baldwin et al. (30)	Targeted plus whole-genome oligo CGH array	211	>500 kb	15.64% (10.90%, targeted; 4.74%, backbone)	8.53% (6.16%, complex; 2.36% familial)	1.90%
Shen et al. (14)	Agilent 2x11K focused oligo CGH array	211	≥3 Consecutive probes, smallest 23 kb	11.9%	4.26%	
Fan et al. (69)	Agilent 44K whole-genome oligo CGH array	100	≥3 Consecutive probes, smallest 17 kb	15%	0.72/case	
Xiang et al. (70)	Agilent 44K whole-genome oligo CGH array	50	>500 kb	6.00%	12.00%	

[a] GI, genomic imbalance; CMA, chromosomal microarray analysis; NA, data not available; oligo, oligonucleotide.

chromosomal mosaicism is not so rare in patients with birth defects and mental retardation. BAC arrays have found 8% of abnormal findings to be mosaic mutations; however, different array platforms have different sensitivities for detecting mosaicism *(60–62)*.

Because microarray technology has much higher resolution than karyotyping and FISH, its analytical resolution cannot be assessed by karyotyping or FISH. In many cases, additional CNVs not detectable by karyotyping or FISH were identified with array technologies. Therefore, other technologies covering smaller-scale mutations, such as MLPA, real-time PCR, or even PCR/sequencing, should be used for validation purposes *(14)*.

CLINICAL VALIDATION—PLATFORM PITFALLS

It is also necessary to check for missing spots on the array that may be clinically important. For example, some commercial arrays do not cover the pseudochromosomal regions of chromosomes X and Y. On the other hand, poor-performing probes (mismapped or poorly hybridizing probes) should be taken out of the array *(59)*. The latter action is particularly necessary in BAC arrays because one mismapped or poorly hybridizing clone will appreciably affect detection sensitivity and specificity. Most of these poorly hybridizing BAC clones may contain low-copy repeats. Thus, the presence of low-copy repeats is more of a problem in the BAC probe than the oligonucleotide probe, whereas oligonucleotide probes that do not perform well may contain secondary structure. Identifying such bad probes and removing them will improve array performance considerably *(14)*. Although such probes cannot be removed from commercial chips, posthybridization data analysis (data filtering) can provide an alternative solution for amending this problem.

It has been suggested that a minimum of 30 abnormal samples be used for clinical validation *(58)*; however, the region and size of the genomic imbalance that the abnormal cases cover are more important than the actual number. Ideally, every probe should be evaluated with abnormal samples. For this purpose, aneuploidy cell lines, as well as samples with well-defined genomic imbalances of different sizes, are very valuable.

UNDERSTANDING CNVs

The most important issue for array interpretation in clinical genetic testing is to define the nature of the identified CNVs *(63)*. In general, CNVs can be categorized into 3 major groups: CNVs with established pathogenicity (pCNVs), i.e., deletions/duplications that overlap with re-

ILLUM-0731

gions associated with defined genomic disorders or disrupt known disease genes; CNVs of a benign nature (bCNVs), i.e., deletions/duplications repeatedly observed in nonpathologic individuals and with no evidence of an association with any particular clinical phenotype; and CNVs with unknown importance (uCNVs), i.e., deletions/duplications without an established association with any genomic disorder and involving genes of unclear clinical importance [*(14, 30, 65–70)*, Table 4]. Even when bCNVs and uCNVs are intentionally avoided during array design, a large percentage of the identified imbalances often belong to bCNVs or uCNVs, because a substantial number of novel CNVs are still being discovered (Table 4).

We anticipate that many of CNVs of currently unknown importance (uCNVs) will eventually be confirmed as bCNVs as more precise knowledge about their locations, distributions, and frequencies in healthy populations becomes available. Meanwhile, the accumulating evidence from clinical (phenotyping), genetic (inheritance and segregation), and functional (gene content and expression) studies may reveal a portion of these uCNVs to be pathogenic. We believe that uCNVs are a rich source for identifying novel genetic risk factors for a variety of medical conditions.

Our understanding of CNVs will certainly improve with systematic CNV-discovery efforts *(64)*. At the same time, continued studies of genotype–phenotype association are also essential. Public databases such as DECIPHER (https://decipher.sanger.ac.uk/) represent such an effort. In the meantime, many novel CNVs are being discovered in clinical samples with the help of high-resolution whole-genome arrays. Databases derived from clinical samples are also a rich source for evaluating genotype–phenotype correlations. Eventually, this knowledge will make it possible to minimize the detection of bCNVs and maximize the detection of clinically important regions.

CLINICAL-DIAGNOSTIC UTILITY

The first-generation arrays designed for clinical use were targeted BAC CGH arrays developed in house at the Baylor College of Medicine *(34)* and Signature Genomic Laboratories *(71)*. Both arrays were designed to cover regions of known genomic disorders, as well as all subtelomeric regions. Array-CGH and FISH results showed 100% concordance. In addition, array CGH detected changes missed by prior karyotyping or FISH. A similar design was also available commercially, the Constitutional Chip by Spectral Genomics *(72)*. The Constitutional Chip also included backbone clones to cover the rest of the genome with an interval of about 1 Mb. Since that time, more BAC clones (from 589 to >4600) have been selected to cover additional clinically relevant regions (approximately 40–150 recognized genomic disorders/syndromes), improving detection rates from 5.6% in the first-generation BAC arrays to 10.8% in later arrays *(68, 73)*.

The clinical utility of oligonucleotide arrays has not yet been evaluated in large clinical studies; however, the current data indicate that the detection rate is higher than for BAC arrays (Table 4). High-resolution whole-genome oligonucleotide arrays have identified small novel microdeletions and microduplications in 16p11.2 that are associated with mental retardation/autism *(50, 53)*, have helped to circumscribe critical regions such as 17q21.31 *(74)*, and have identified intragenic deletions/duplications in large genes, such as *PARK2* [Parkinson disease (autosomal recessive, juvenile) 2, parkin] and *DMD* (dystrophin) (Y. Shen et al., unpublished data).

Common clinical indications for MGDP-based diagnostics testing include developmental delay, multiple congenital anomalies, dysmorphic features, unexplained mental retardation, seizure disorders, ASDs, and other neurologic/psychiatric disorders such as schizophrenia, as well as prenatal diagnosis, including spontaneous abortion or fetal demise.

Conclusion and Future Development

Microarray-based clinical molecular diagnostics technologies such as MGDP have gone beyond the stage of "coordinated and concurrent FISH analysis" *(75)* and extended into loss-of-heterozygosity testing and possibly methylation profiling. Current MGDP technologies are capable of detecting genomic imbalances of any size but do not reveal positional or orientational information. FISH analysis has largely been responsible for providing positional information. FISH is also instrumental in testing for translocations in parental samples for de novo CNVs that have been identified in probands. MGDP has much better resolution than FISH, however. The field would benefit immensely from a tool with the localization capability of FISH and the resolution of whole-genome oligonucleotide arrays. Advanced next-generation sequencing platforms may eventually provide digital profiling for detecting copy numbers and positional alterations simultaneously. Therefore, DNA-diagnostics profiling may soon extend beyond microarray-based technology, from analog analysis to digital analysis.

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ILLUM-0733

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OUTLOOK — BIOMARKERS

Diagnostics and biomarker development: priming the pipeline

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Abstract | The decrease in the rate at which novel medical products are reaching the market, despite major scientific achievements and investment that might have predicted otherwise, is causing much concern. Although this 'pipeline problem' has often been discussed in the context of drug development, it is also crucial to examine the unique characteristics of the pipeline for biomarkers and diagnostics. Here, we characterize the pipeline problem for biomarkers and diagnostics, and consider what steps could be taken to solve it.

The current 'pipeline problem'

The translation of basic research to clinical practice is a priority for academia, government and industry, both in the United States and in other countries. The current focus on translation stems from concern that the level of investment in research is not being reflected in improved clinical outcomes, and there is particular concern that the benefits from the 'genetic revolution' have been slow to arrive.

In the United States, which is the primary focus of this article, an emphasis on translation is evidenced by the National Institutes of Health (NIH) Roadmap initiative (see Further information) and the US FDA's Critical Path Initiative (CPI) for drugs and diagnostics[1]. The CPI provides an analysis of the 'pipeline problem', which is broadly defined as a decrease in the rate of introduction of new drugs and diagnostics to the market in recent years, despite major scientific achievements and investment that might have predicted otherwise. The initiative is in part based on the premise that changes in regulation have the potential to stimulate the translation of science to the clinic and market.

Issues regarding biomarkers and diagnostics have emerged as crucial components of the CPI Opportunities Report[2]. It could be argued that the pathway from development of biomarkers and diagnostics to market is inherently different than that for drugs, and so changes implemented by the FDA to stimulate innovation in drug development might not similarly translate to innovation in development of biomarkers and diagnostics. As novel gene-based diagnostics proliferate they will be increasingly important to drug development, approval and clinical practice. Clearly, a translation problem in diagnostics will directly influence the translation of drugs to clinical practice, even for drugs that are developed and approved. An important step now is to synthesize available information to assess the relevance of regulatory and policy changes to facilitate the development of biomarkers and diagnostics. It is important to understand whether and how the 'pipeline problem' in diagnostics and drugs can differ, especially because it is anticipated that the co-development of drugs and diagnostics could soon be the prevailing model.

With this in mind, in this article, we characterize the 'pipeline problem' as it relates to diagnostics and biomarker development in the United States based on a review of the relevant published and web literature, interviews and meeting presentations (BOX 1). Our review is based on interview and meeting data in addition to the peer-reviewed literature, with the aim of providing a more current and in-depth assessment than a literature review alone, and so also reflects our own interpretations, as well the opinions of our interviewees.

Is there a diagnostics pipeline problem?

A crucial concept in the development and adoption of diagnostics is the 'product pipeline': the development process from initial design or discovery to the finished diagnostic including implementation and post-marketing surveillance. One key measure of the pipeline problem for new drugs noted in the CPI is the increasing level of expenditures (public and private) with a simultaneous decrease in the number of submissions of New Drug Applications (NDAs) for new molecular entities (NMEs) and/or original Biologic License Applications (BLAs). The Advanced Medical Technology Association (AdvaMed), the primary trade association representing medical devices, subsequently examined data on new medical device submissions and concluded that during the same 10-year period there was actually an increase in the number of device-related submissions. In comments to the FDA, AdvaMed states, "The significance of this finding is that we believe the factors driving medical device innovation may differ considerably from those that produce new drugs and biological products."[3]

> The factors driving medical device innovation may differ considerably from those that produce new drugs and biological products.

Yet despite the fact that diagnostic submissions might not be decreasing, the overarching belief of thought leaders is that a pipeline problem does exist for diagnostics development. However, it is believed that the pipeline problem for diagnostics is more at the 'front end' — in earlier stages of discovery and development. Data on approval submissions are therefore insufficient for understanding the pipeline problem.

What, then, are the key issues relevant to the diagnostic pipeline and how are these different from those for drugs? Below we discuss some of the issues raised in the literature and in our interviews.

What is the problem?

The pipeline problem for diagnostics is multifaceted. The extent to which all diagnostics (in-house or FDA approved) identify clinically relevant biomarkers — biomarkers truly indicative of improved clinical outcomes — is a key issue. For example, Tsongalis has noted that industry is rapidly providing reagents under the analyte-specific reagent (ASR) rule (BOX 2), but raised the crucial question of which of these are most useful in patient care[4]. More generally, there is concern that diagnostics and biomarkers have not been widely proven to change clinical outcomes. Importantly, no regulatory authority for diagnostics considers clinical utility for test approval (discussed in more detail below). According to Janet Woodcock of the FDA, biomarker development will need data pooling, synthesis and analysis; identification of what is known, not known and what can be known through studies; and finally using

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Box 1 | Summary of sources and interview questions

We located relevant articles in the PubMed database and identified with the Google Internet search engine, as well as literature found on relevant websites (for example, AdvaMed, Biotechnology Industry Organization (BIO) and FDA). We also based our findings on a convenience sample of semi-structured interviews (n = 19) with key thought leaders/experts between November 2004 and December 2005. We interviewed a wide range of individuals from industry or who are consultants to industry, including individuals from biotech/genetics/start-up/venture capital companies (n = 5), diagnostics companies (n = 3), pharmaceutical companies (n = 4) and health insurers (n = 1). We interviewed one individual from government. We also interviewed academics with knowledge of the pharmaceutical and health insurance industries (n = 5). Interviews were anonymous and are therefore not specifically cited in the text. Lastly, information comes from six national scientific meetings focused on the applications of genomic science to drug development*.

Primary interview questions:

- Do you think there is a pipeline problem for biomarkers and diagnostics? If so, why?
- How is this similar/different to the pipeline problem for drugs?
- What should be the FDA's, industry's and academia's role in solving the problem?

*FDA/DIA Workshop on Pharmacogenomics in Drug Development and Regulatory Decision Making, 11–13 April 2005; FDA/DIA Workshop on Application and Validation of Genomic Biomarkers for use in Drug Development and Regulatory Submissions, 6–7 October 2005; HHS Secretary's Advisory Committee on Genetics, Health, and Society, October 2005; Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Project Meetings, May & October 2005; The Canary Fund Realizing the Promise: Early Detection of Cancer, First Annual Symposium and Workshop, Stanford University, 24–25 May 2005.

what is identified, learned and developed about biomarkers to facilitate translation to clinical practice[5].

The regulatory structure for laboratory tests (BOX 2) results in many tests being offered outside of the purview of the FDA. Nonetheless, AdvaMed reports that the overwhelming majority of its members (84%) believe that FDA regulatory requirements are one of the top factors affecting their ability to develop new technologies[6]. As genomic-based diagnostics are increasingly co-developed with drugs or not approved as lower-risk devices or ASRs (as in the case of the AmpliChip[7]), the FDA is likely to have an important role in generating solutions to translating this research to clinical practice. Regulatory strategies for diagnostics will need to be considered within a model that adequately reflects the nature of the development of diagnostics (highly iterative and dynamic, as discussed below), while at the same time increasingly including drug development.

Box 2 | Regulatory structure for diagnostics

Both the FDA and the Centers for Medicare and Medicaid Services (CMS) regulate diagnostic tests in the United States. In general, regulatory requirements depend on the setting and intended use of diagnostic testing. The FDA regulates tests that are sold as kits or systems in interstate commerce. CMS, through the Clinical Laboratory Improvement Amendments (CLIA), oversees laboratory testing services commercially offered at single sites, in-house or 'home-brew' tests. Reagents intended for use in in-house tests can either be developed 'in-house' or sold commercially to CLIA approved laboratories as analyte-specific reagents (ASRs). ASRs do not typically require full FDA pre-market review (PMA) although there are some exceptions for high-public health-risk reagents.

For further information on the regulation of diagnostics, see REF. 42; on FDA guidance on drug-metabolizing enzyme genotyping systems, see REF. 43; and on ASRs, see REF. 44.

In addition to the regulation and development model, two issues stood out as major reasons for the diagnostic pipeline problem: money, and lack of samples for validating and testing biomarkers. With respect to the first issue, key concerns are the level of investment in diagnostics and the amount of reimbursement for their use (discussed in more detail below). The inability to 'capture value' creates disincentives for both industry and the venture capitalist community to invest in diagnostics. In particular, one of our interviewees stated that some diagnostics companies, particularly smaller firms, do not understand how to demonstrate value and what it takes to get a product to market.

With respect to the lack of samples, the availability of samples is considered instrumental to the development (or lack thereof) of diagnostics because an abundance of samples is crucial for determining test performance (analytical validity, clinical validity and clinical utility). Regulation, ethical and legal concerns, and practicality and feasibility issues are believed to hinder obtaining and using samples.

However, a key point is that as the FDA (and others) forge ahead with improving the translation of diagnostics (and drugs/devices), *innovation* must be appropriately balanced with *evaluation*. Drugs and diagnostics might fail to make it to market because they add little marginal value, and thus these failures should not be viewed as part of the pipeline 'problem'. Any discussion of pipeline issues must therefore also consider the value of what is in the pipeline. One proposed solution is to focus more effort on understanding how good a diagnostic would need to be to add value, which can be done via economic modelling and 'what if' analyses (BOX 3).

It is important to recognise that there is an inherent tension between improving the pipeline and increasing the safety of new drugs. The FDA is under pressure to do both, but our interviews suggested that there is inadequate understanding by the public and policy-makers about the trade-offs involved. As one illustration, some thought leaders felt that there would soon be a public health crisis about 'home brew' tests (BOX 2) because there would be a quality lapse that, in conjunction with recent safety-related events, would prompt a 'crisis'. However, home-brew tests are poorly understood by the public and therefore any 'crisis' might prove to be a false or inappropriate one.

Are diagnostics and drugs really different?

Development models. In responding to public comments on the FDA CPI report, AdvaMed argues that a key difference between drug and diagnostic development is that fundamental technologies and the medical devices that incorporate them are typically designed rather than discovered[3]. Consequently, diagnostic development might be characterized by continuous modifications throughout product life cycles. Typically, diagnostic development involves an iterative process (for example, performance characteristics are continuously fed back into the design) so that diagnostics can ultimately be shown safe and effective for their intended use, which are the FDA criteria for approval[8]. However, it is not uncommon to make modifications to existing devices for new uses[3].

FIGURE 1 shows a comparison of the FDA CPI paper's general medical product development model and one proposed by representatives of the diagnostic industry at an industry/FDA roundtable to more

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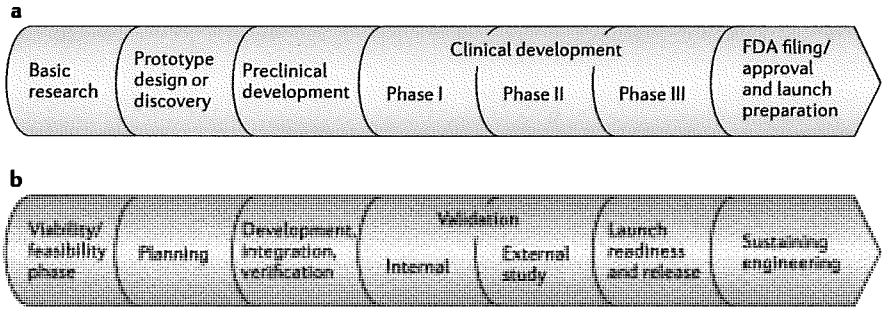

Figure 1 | **Medical products and diagnostics development models.** Comparison of the FDA Critical Path Initiative paper's general medical product development model and one proposed by representatives of the diagnostic industry to more specifically focus on diagnostics. **a** | FDA medical product development model (adapted from REF. 1). **b** | FDA model adapted for diagnostics[9].

specifically focus on diagnostics[1,9]. The comparison of the two models highlights both differences and similarities, which will be particularly important to understand as the market moves towards more co-developed products. For example, the diagnostic development model notes that there are several points of entry to the market for diagnostics. Diagnostics can be directly accessed by the patient from a retail supplier, such as an online diagnostic test provider, a clinician, a hospital or academic medical centre or a laboratory (reference or clinical laboratory)[10].

Regulation of diagnostics. Diagnostics can be viewed simultaneously as less regulated and more highly regulated than drugs. As described in BOX 2, ASRs typically do not require full FDA pre-market review. However, some believe that diagnostics are inherently held to a stricter standard than drugs. One interviewee felt that, because a drug can be approved even if it only works in 10% of the population and/or could be compared with placebo for approval, drugs undergo less rigorous evaluation than diagnostics, which are often evaluated for equivalence to similar tests.

There is a widespread belief that co-developed drugs and diagnostics will soon be the prevailing business and development model (for example, similar to HER2/*neu* tests and the anti-HER2 monoclonal antibody trastuzumab (Herceptin; Genentech), which is used to treat HER2-positive breast cancers), and it is felt that the FDA is being proactive in adapting to these changes. However, the FDA has traditionally independently regulated the two areas[11], and so there is some concern about the capacity of the FDA to jointly review co-developed products adequately and the ability of the FDA centres to work together.

Reimbursement. Reimbursement can be considered the ultimate incentive for industry to bring products to the market, yet it is a poorly understood topic. Indeed, reimbursement rates have been a highly charged issue for industry, government and insurers (see, for example, REF. 12). It is believed that inadequate reimbursement is a key (if not the key) reason for not developing diagnostic products. At least two government-commissioned reports have recommended a re-evaluation of reimbursement rates for diagnostics[13] and for genetic tests more specifically[14]. Although there are ongoing discussions to amend rates, the high potential costs of novel technologies has been of particular concern within the paradigm of cost containment[15].

Some believe that industry will be driven to use pharmacogenomics and develop biomarkers and companion diagnostics by payers (and to a lesser degree, regulators) who will demand some sort of selection of patients where drug prices were skyrocketing. However, others feel that payers can only respond reactively rather than proactively. Diagnostics have historically been perceived as being of lesser value than drugs and thus there is more reluctance to pay high prices for diagnostics. The concern among insurers is that using expensive tests for large populations will wipe out any potential savings from targeting drugs. Diagnostics might also be undervalued because the entire sequence of events is not considered — for example, using a test can reduce the need for expensive procedures. This is an area where modelling and economic analyses can be very insightful (BOX 3).

Inadequate reimbursement rates might not only limit availability but could also create an incentive *not* to seek FDA approval. One of our interviewees noted that if the test is FDA approved then it is more likely to get Medicare reimbursement approval and subsequently private insurer approval, resulting in potentially wider utilization but *lower* rates of reimbursement. Conversely, if the test is developed for in-house use, it is more likely that prices are negotiated directly with stakeholders who value the test information and are who are therefore willing to pay more for the test itself — but then the test will be less widely used. There is a similar incentive not to get FDA approval for 'esoteric' tests. As a result, companies developing new diagnostics (potentially based on pharmacogenetics and other novel therapeutic strategies) leading to alternative therapeutic plans might initially pursue non-Medicare payers

Box 3 | **Economic evaluation approaches**

Several methods of economic evaluation are available for determining the value of healthcare services and diagnostic tests. The main methods used include:

- Cost-minimization: used when effects are identical; compares costs only
- Cost–benefit: estimates the net social benefits of an intervention; values all costs and benefits in monetary terms
- Cost-effectiveness: estimates incremental costs and effects of an intervention and at least one alternative using a ratio; effects are health outcomes
- Cost–utility: estimates incremental costs and effects of an intervention and at least one alternative using a ratio; effects are quality-adjusted life years (QALYs)

For further details on conducting economic evaluations, see REFS 39,45–47.

Example: genetic testing for familial long QT syndrome. Genetic testing for familial long QT syndrome (LQTS) has been available in a research setting for the past decade, and a commercial test has recently become available. We examined the incremental cost-effectiveness of genetic testing compared with no genetic testing for symptomatic index cases and how this varied according to changes in assumptions and data inputs[48]. The study illustrates the importance of identifying and measuring how testing can change clinical practice and outcomes compared with standard practice, defining the population groups to be tested (for example, family members), and considering long-term costs and benefits.

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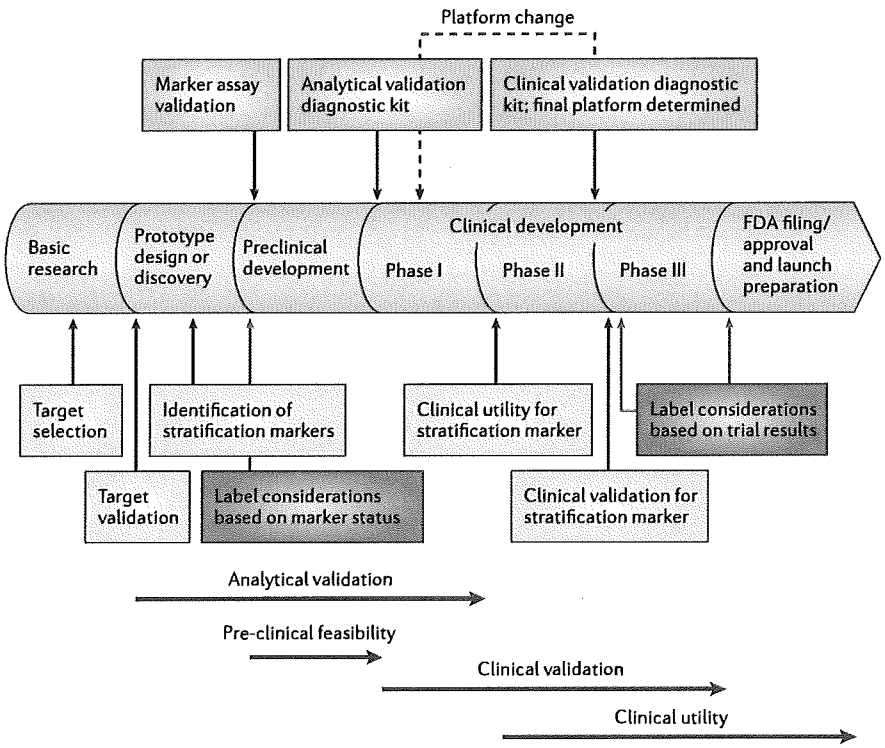

Figure 2 | **Prototype of possible approach to developing and regulating combined test–drug products.** One possible model for co-developed products is presented in the FDA Co-Developed Products document[23]. This figure shows a potential regulatory scenario for a single test that would be used in conjunction with a single drug in the clinical management of a patient. The figure highlights key events for both diagnostics and drug regulation but it is the overall coordination of the regulatory process so that the products launch together that is unique in the co-developed products model.

for reimbursement because these plans were more flexible and faster decision makers in the United States than the Centers for Medicare and Medicaid Services (CMS). However, such a strategy leaves coverage decisions fragmented and locally based, rather than national and standardized.

What are the roles of key stakeholders?

There are many stakeholders in the translation of diagnostics to clinical practice including patients, clinicians, industry (diagnostics, pharmaceutical, biotechnology and venture capital), laboratories, government, payers and academics. In this commentary, we focus on the role of industry, the FDA and payers.

Industry: the ascent of the diagnostic industry. The increasing focus on genetically based interventions is causing the role of diagnostics — and the diagnostic industry — to become more crucial to pharmaceutical development. Larger pharmaceutical firms have therefore engaged with diagnostics firms directly and developed internal diagnostics foci[16]. Pharmaceutical firms are increasingly embracing investment in genomics-based diagnostics as they use these diagnostics throughout the clinical development phases[17,18].

It might therefore be important for industry to embrace new models for diagnostics and drug development. Three key industry players — diagnostics, pharmaceuticals and biotechnology — are likely to shift towards more collaborative business models that focus on co-developed products. Research has shown that pharmaceutical products developed collaboratively have a higher probability of success[19] and at least one large pharmaceutical firm (Novartis) has advocated sharing biomarker data as one way to speed their translation to clinical practice[20]. The FDA's focus on voluntary genomic submissions (VGDS) is further evidence of a belief that sharing data is an opportunity to improve translation[21]. The FDA reports that a promising number of companies to date have submitted data under the VGDS guidance[22], but industry also remains sceptical of submissions.

What would a co-developed product model look like? One such model is presented in FIG. 2 (REF. 23).

FDA: the importance of a proactive regulatory approach. It has been suggested that early and frequent industry and FDA meetings can speed translation to clinical practice particularly if accompanied by clear expectations on deliverables and outcomes, as well as flexibility[24]. The importance of clarity is evidenced by the ongoing discussions on acceptable biomarkers for drug and diagnostics development and microarray experiments[25] (see also Minimum Information About a Microarray Experiment, Further information). Industry is encouraged by FDA's continuing efforts in producing guidance documents such as the Pharmacogenomic Data Submissions Guidance[21] and Co-developed Products Concept Paper[23].

A role for the FDA could also be to cultivate strong internal organization. Key FDA centres will need to work collaboratively with each other because novel products will increasingly require their collective expertise. However, some industry spokespersons remain sceptical that the FDA's organizational structure and resources are sufficient for improving translation, and wonder whether the CPI has the potential to increase regulatory burden[26]. There has been a perception that certain FDA centres are less rigorous than others in their evaluations, and because combination product sponsors recommend which centre should evaluate the application there is an incentive to recommend the 'easier' centre[27]. Some further argue that the current regulatory system, which focuses on definitive safety and effectiveness, is not well suited for probabilistic diagnostics or those aimed more specifically at subpopulations[26]. There is a more recent concern that the resources devoted to new safety initiatives in the wake of the COX2 debacle will further strain an already inadequately funded agency[28]. It will be especially important for the FDA to develop and foster adequate expertise (and funding) for future regulatory decisions about novel diagnostics.

The FDA might also have a role in working with industry to develop new evaluation methods and paradigms for data collection. There are opportunities for the FDA with respect to the collection and use of biological samples and the evaluation of data for regulatory purposes. The FDA could reconsider the use of stored samples for retrospective analysis and for uses not initially proposed, although this will require consideration of

ILLUM-0738

ethical and legal issues. It has been argued that genetic markers are not significantly different for regulatory purposes than other diagnostic tests[29], but the issue of whether genetic samples are unique is unresolved[30]. AdvaMed believes that the FDA could develop guidelines for waiving informed consent and Institutional Review Board (IRB) review for studies that use left-over or banked samples that are unlinked or unidentified[3].

The FDA could improve the pipeline problem for diagnostics and biomarkers through any action that would improve access to samples. Data such as the VGDS data from which industry and the FDA could identify promising drugs, diagnostics and biomarkers together also offer potential. A concern expressed was that the FDA was overly cautious on retrospective data analysis for regulatory purposes, yet as technology for data collection and data mining improve, retrospective analysis and models will increase in importance.

The FDA might also indirectly encourage investment in diagnostics through labelling changes. It is believed that including a diagnostic in the label increases the value of diagnostics, which creates an incentive for future diagnostics development. The FDA could require that test information appear in labelling, but for a test to be included in the label the test must be available (Lesko, L., personal communication). The FDA, the Centers for Medicare and Medicaid Services (CMS) and industry might have to work together to develop a publicly available comprehensive list of diagnostic tests. Nonetheless, whether labelling with biomarker and diagnostic test information actually influences clinical practice is uncertain. The potential influence a label has on encouraging the use of a diagnostic might more specifically relate to how the label describes the test, such as whether it is recommended or required. For example, the label for 6-mercaptopurine was recently amended to include information on recommended testing for thiopurine *S*-methyltransferase (TPMT) but it is believed that clinical practice has not significantly changed following the labelling revisions[31]. Other labels with pharmacogenetics-related information (for example, mentioning poor metabolizers) provide limited utility to the prescribing clinician or patient[32].

Finally, another role for the FDA is to encourage strong external relationships. The FDA has an important role to play that goes beyond their actual mandate because of their place in the pipeline. Labelling issues illustrate a broader concern about whether the current structure of the FDA and the Clinical Laboratory Improvement Amendments (CLIA) is adequate for the future[33–35]. Because tests are not typically subject to full review or tracking by either the FDA or the CMS, there is little information available on what tests are being performed by which laboratories, for what purposes and with what results[4]. This lack of information has been noted as a barrier to the development and approval of combination products. For example, the approval of pharmacogenetic drugs will often require the simultaneous review and approval of the appropriate test[36]. One issue is that the FDA has decided not to engage in more regulation of home-brew tests because of the large resources required and the lack of a mandate[37]. Similarly, although the FDA does not consider the cost or economic value of products, their decisions ultimately affect those outcomes and payers increasingly want such information.

Box 4 | **Recommendations to address the diagnostics and biomarkers pipeline problem**

- Generate better understanding of the use of diagnostics and contribution to patient outcomes
- Develop approaches to evaluating genetic tests, including advisory groups and economic analyses
- Facilitate the development of new co-development models by industry
- Facilitate the development of streamlined regulatory approaches by the FDA
- Facilitate collaboration across different sectors

Payers: the lynchpin. The role of valuing and paying for diagnostics is essential to translation. On the one hand, expensive, novel, high-tech diagnostics have the potential to increase costs to insurers. On the other hand, diagnostics could streamline expensive therapies based on efficacy and avoiding adverse events, and therefore *decrease* costs to payers. It is not surprising that some of our interviewees expressed the opinion that payers will not only support the implementation of diagnostics but also require them — although others are more sceptical that payers will be able to drive the agenda.

A role for payers will be developing new criteria for reimbursement that adequately values novel diagnostics. An Institute Of Medicine (IOM) report[13] in 2000 noted that the process for integrating new technologies into the payment system, including determinations of coverage, assignment of billing codes and development of appropriate prices, is slow, administratively inefficient and closed to stakeholder participation. The IOM also predicted exacerbation of the problem as laboratory medicine evolved, and concluded that there was insufficient means by which to determine the value of individual tests and services with respect to reimbursement rates. Final recommendations from the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) on coverage for genetic tests are expected in the near future[38], although the draft recommendations clearly indicate that there is some belief that reimbursement rates for genetic-based diagnostics are insufficient[14].

Payers are also crucial because they are in a position to encourage the analysis of the utility of new diagnostics and therapeutics. It is likely that payers will increasingly demand evidence that new products either improve care at a reasonable cost or decrease expenditures, and it is therefore likely that economic analyses of the value of such products will become increasingly important. Similarly, venture capital firms will only invest in companies that are developing products that have demonstrated value. Historically, venture capital firms have been more reluctant to invest in diagnostics companies, although this might change as the business model moves to co-developed products.

Conclusions

With the increasing emphasis on personalized medicine and targeted therapies, diagnostics and biomarkers will have an increasingly important role in drug development and healthcare delivery. It is therefore crucial to address the pipeline problem for diagnostics and biomarkers, and the unique aspects distinguishing the problems in diagnostic and drug development.

Several recommendations can be made to address the pipeline problem through both research and policy changes (BOX 4). A key recommendation is that more information must be made available on the use and value of diagnostics and biomarkers. One approach is being undertaken by the EGAPP Project (Evaluation of Genomic Applications in Practice and Prevention) (see Further information). EGAPP is a

ILLUM-0739

3-year model project sponsored by the Centers for Disease Control and Prevention (CDC) that began in 2005. The goal is to establish and evaluate a systematic, evidence-based process for assessing current and future genetic tests as they make the transition from research to practice. The 13 members of the Working Group have expertise in evidence-based review; health technology assessment; primary care, specialty care or nursing care; epidemiology; clinical genetics/genomics; economics and decision analysis; laboratory practice; and ethics, law and policy development. This Working Group is prioritizing and selecting topics, establishing methods and processes, overseeing expert and peer review of commissioned evidence reports, and developing conclusions or recommendations based on the evidence. Economic models and analyses can also be developed to help address the lack of demonstrated clinical utility and provide evidence for greater investment in diagnostics and for payers' reimbursement decisions[39,40].

An important role for industry will be to embrace new models for diagnostics and drug development. Three key industry players — diagnostics, pharmaceutical and genomics/biotech firms — must shift towards more collaborative business models that focus on co-developed products. The FDA also has the important role of facilitating a streamlined approval process that provides clarity; coordination across centres; cooperation and collaboration with other stakeholders outside the FDA; facilitating solutions to the sample problem; facilitating solutions for using data for approval, including standards development; and developing approaches for review of co-developed drugs/diagnostics. A role for payers will be developing new criteria for reimbursement that adequately value novel diagnostics.

Finally, it is clear that there must be collaboration across different sectors (such as the FDA, CMS, private insurers, industry and academia) in resolving the pipeline problem. The issues are complex and will require cooperative efforts, including efforts to educate the relevant stakeholders appropriately. Although not specifically discussed by our interviewees, the understanding and knowledge about the uses and benefits of new diagnostics and therapeutics is crucial to translation. There remains much scope for improving the knowledge of payers, providers, the FDA, CMS and patients through education and evaluation[41].

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ILLUM-0740

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Competing interests statement
The authors declare no competing financial interests.

FURTHER INFORMATION
Evaluation of Genomic Applications in Practice and Prevention: http://www.cdc.gov/genomics/gtesting/EGAPP/group.htm
Minimum Information About a Microarray Experiment: http://www.mged.org/Workgroups/MIAME/miame.html
National Institutes of Health: http://www.nih.gov/
NIH Roadmap: http://nihroadmap.nih.gov/
Access to this links box is available online.

ERRATUM

Insomnia market

Leland Gershell

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In this article, zolpidem, eszopiclone and indiplon were described as GABA-A agonists. All of these drugs bind to an allosteric site on GABA-A receptors (known as the benzodiazepine site, as it is where benzodiazepines such as triazolam bind), and potentiate GABA-A receptor function. Such drugs are therefore more precisely described as positive GABA-A receptor modulators. In contrast, gaboxadol is a selective extrasynaptic GABA-A receptor agonist. Unlike the GABA-A receptor modulators mentioned above, gaboxadol directly activates the extrasynaptic GABA-A receptors, which contain a delta subunit, rather than a gamma subunit, associated with the activity of the positive GABA-A receptor modulators.

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Reviews

Next-Generation Sequencing: From Basic Research to Diagnostics

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BACKGROUND: For the past 30 years, the Sanger method has been the dominant approach and gold standard for DNA sequencing. The commercial launch of the first massively parallel pyrosequencing platform in 2005 ushered in the new era of high-throughput genomic analysis now referred to as next-generation sequencing (NGS).

CONTENT: This review describes fundamental principles of commercially available NGS platforms. Although the platforms differ in their engineering configurations and sequencing chemistries, they share a technical paradigm in that sequencing of spatially separated, clonally amplified DNA templates or single DNA molecules is performed in a flow cell in a massively parallel manner. Through iterative cycles of polymerase-mediated nucleotide extensions or, in one approach, through successive oligonucleotide ligations, sequence outputs in the range of hundreds of megabases to gigabases are now obtained routinely. Highlighted in this review are the impact of NGS on basic research, bioinformatics considerations, and translation of this technology into clinical diagnostics. Also presented is a view into future technologies, including real-time single-molecule DNA sequencing and nanopore-based sequencing.

SUMMARY: In the relatively short time frame since 2005, NGS has fundamentally altered genomics research and allowed investigators to conduct experiments that were previously not technically feasible or affordable. The various technologies that constitute this new paradigm continue to evolve, and further improvements in technology robustness and process streamlining will pave the path for translation into clinical diagnostics.

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In 1977, 2 landmark articles describing methods for DNA sequencing were published. Allan Maxam and Walter Gilbert reported an approach in which terminally labeled DNA fragments were subjected to base-specific chemical cleavage and the reaction products were separated by gel electrophoresis *(1)*. In an alternative approach, Frederick Sanger and colleagues described the use of chain-terminating dideoxynucleotide analogs that caused base-specific termination of primed DNA synthesis *(2)*. Refinement and commercialization of the latter method led to its broad dissemination throughout the research community and, ultimately, into clinical diagnostics. In an industrial, high-throughput configuration, Sanger technology was used in the sequencing of the first human genome, which was completed in 2003 through the Human Genome Project, a 13-year effort with an estimated cost of $2.7 billion. In 2008, by comparison, a human genome was sequenced over a 5-month period for approximately $1.5 million *(3)*. The latter accomplishment highlights the capabilities of the rapidly evolving field of "next-generation" sequencing (NGS)[3] technologies that have emerged during the past 5 years. Currently, 5 NGS platforms are commercially available, with additional platforms on the horizon. To add to this pace, the US National Human Genome Research Institute (NHGRI) announced funding in August 2008 for a series of projects as part of its Revolutionary Genome Sequencing Technologies program, which has as its goal the sequencing of a human genome for $1000 or less (http://www.genome.gov/27527585). This review describes NGS technologies, reviews their impact on basic research, and explores how they have the translational potential to substantially impact molecular diagnostics.

Fundamentals of NGS Platforms

NGS platforms share a common technological feature—massively parallel sequencing of clonally amplified or single DNA molecules that are spatially separated in a flow cell. This design is a paradigm shift from that of

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[3] Nonstandard abbreviations: NGS, next-generation sequencing; NHGRI, National Human Genome Research Institute; dNTP, deoxynucleoside triphosphate; Mb, million base pairs; Gb, billion base pairs; miRNA, microRNA.

Sanger sequencing, which is based on the electrophoretic separation of chain-termination products produced in individual sequencing reactions. In NGS, sequencing is performed by repeated cycles of polymerase-mediated nucleotide extensions or, in one format, by iterative cycles of oligonucleotide ligation. As a massively parallel process, NGS generates hundreds of megabases to gigabases of nucleotide-sequence output in a single instrument run, depending on the platform. These platforms are reviewed next.

ROCHE/454 LIFE SCIENCES

The 454 technology (http://www.454.com) is derived from the technological convergence of pyrosequencing and emulsion PCR. In 1993, Nyren et al. described a sequencing approach based on chemiluminescent detection of pyrophosphate released during polymerase-mediated deoxynucleoside triphosphate (dNTP) incorporation *(4)*. Refinement by Ronaghi et al. served as the foundation for the commercial development of pyrosequencing *(5, 6)*. On a separate front, Tawfik and Griffiths described single-molecule PCR in microcompartments consisting of water-in-oil emulsions *(7)*. In 2000, Jonathan Rothberg founded 454 Life Sciences, which developed the first commercially available NGS platform, the GS 20, launched in 2005. Combining single-molecule emulsion PCR with pyrosequencing, Margulies and colleagues at 454 Life Sciences performed shotgun sequencing of the entire 580 069 bp of the *Mycoplasma genitalia* genome at 96% coverage and 99.96% accuracy in a single GS 20 run *(8)*. In 2007, Roche Applied Science acquired 454 Life Sciences and introduced the second version of the 454 instrument, the GS FLX. Sharing the same core technology as the GS 20, the GS FLX flow cell is referred to as a "picotiter well" plate, which is made from a fused fiber-optic bundle. In its newest configuration, approximately 3.4×10^6 picoliter-scale sequencing-reaction wells are etched into the plate surface, and the well walls have a metal coating to improve signal-to-noise discrimination. For sequencing (Fig. 1), a library of template DNA is prepared by fragmentation via nebulization or sonication. Fragments several hundred base pairs in length are end-repaired and ligated to adapter oligonucleotides. The library is then diluted to single-molecule concentration, denatured, and hybridized to individual beads containing sequences complementary to adapter oligonucleotides. The beads are compartmentalized into water-in-oil microvesicles, where clonal expansion of single DNA molecules bound to the beads occurs during emulsion PCR. After amplification, the emulsion is disrupted, and the beads containing clonally amplified template DNA are enriched. The beads are again separated by limiting dilution, deposited into individual picotiter-plate wells, and combined with sequencing enzymes. Loaded into the GS FLX, the picotiter plate functions as a flow cell wherein iterative pyrosequencing is performed by successive flow addition of the 4 dNTPs. A nucleotide-incorporation event in a well containing clonally amplified template produces pyrophosphate release and picotiter-plate well–localized luminescence, which is transmitted through the fiber-optic plate and recorded on a charge-coupled device camera. With the flow of each dNTP reagent, wells are imaged, analyzed for their signal-to-noise ratio, filtered according to quality criteria, and subsequently algorithmically translated into a linear sequence output. With the newest chemistry, termed "Titanium," a single GS FLX run generates approximately 1×10^6 sequence reads, with read lengths of $\geq$400 bases yielding up to 500 million base pairs (Mb) of sequence. A recognized strength of the 454 technology is the longer read length, which facilitates de novo assembly of genomes *(9)*. An outstanding concern has been the accurate determination of homopolymers >3–4 bases in length. A 6-base homopolymer should theoretically yield twice the luminescence of a 3-base homopolymer. Operationally, this luminescence yield varies, and estimates of homopolymer length are less accurate with increasing length *(8, 10)*. 454 has reported that the metal coating of the walls of picotiter wells mentioned above improves the accuracy of homopolymer determination. Sequence coverage depth and accuracy for the 454 technology is discussed below in the NGS Data Analysis section.

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In 1997, British chemists Shankar Balasubramanian and David Klenerman conceptualized an approach for sequencing single DNA molecules attached to microspheres. They founded Solexa in 1998, and their goal during early development of sequencing single DNA molecules was not achieved, requiring a shift toward sequencing clonally amplified templates. By 2006, the Solexa Genome Analyzer, the first "short read" sequencing platform, was commercially launched. Acquired by Illumina (http://www.Illumina.com) in 2006, the Genome Analyzer uses a flow cell consisting of an optically transparent slide with 8 individual lanes on the surfaces of which are bound oligonucleotide anchors (Fig. 2). Template DNA is fragmented into lengths of several hundred base pairs and end-repaired to generate 5′-phosphorylated blunt ends. The polymerase activity of Klenow fragment is used to add a single A base to the 3′ end of the blunt phosphorylated DNA fragments. This addition prepares the DNA fragments for ligation to oligonucleotide adapters, which have an overhang of a single T base at their 3′ end to increase ligation efficiency. The adapter oligonucleotides are complementary to the flow-cell anchors. Un-

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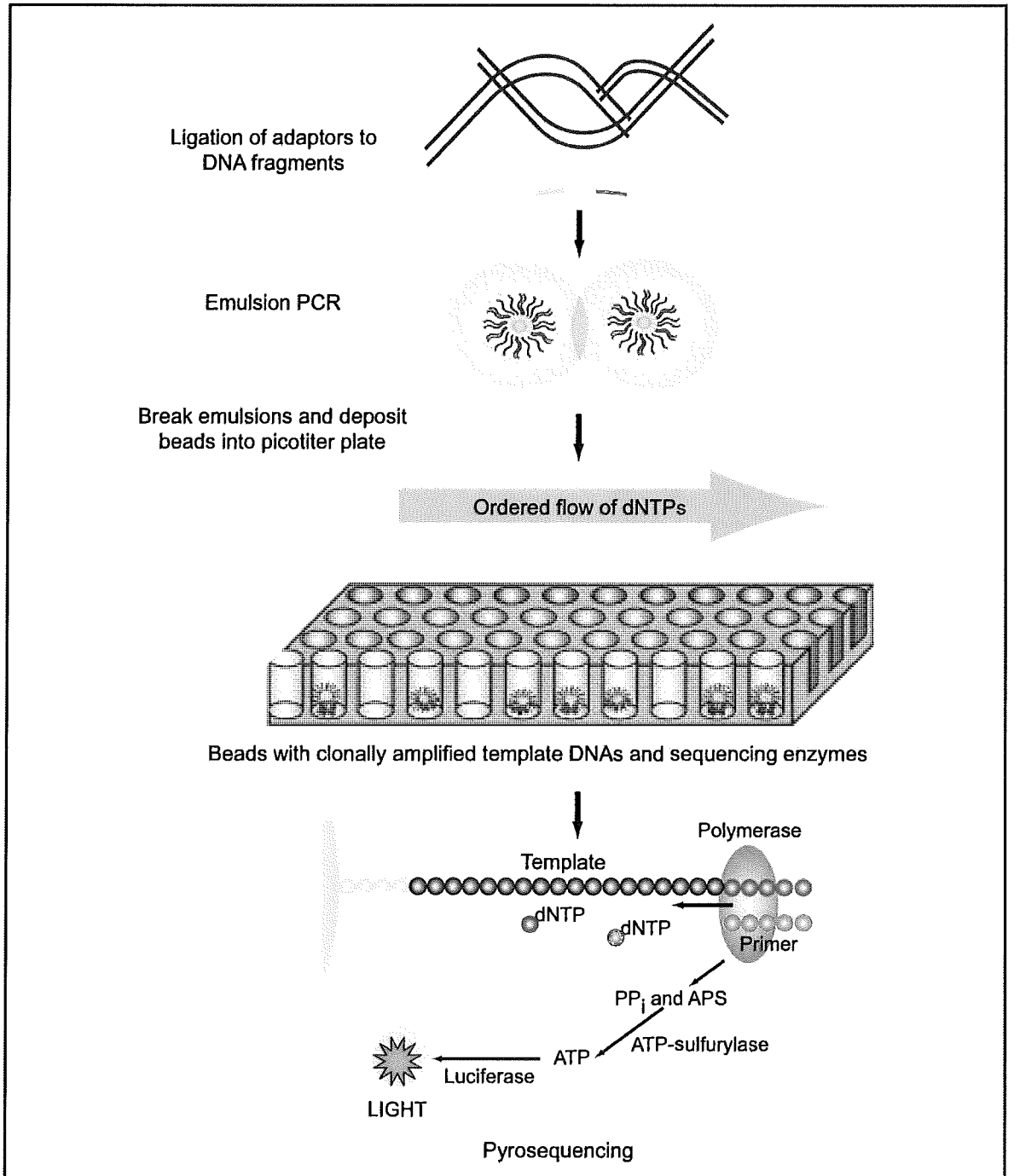

Fig. 1. Roche 454 GS FLX sequencing.

Template DNA is fragmented, end-repaired, ligated to adapters, and clonally amplified by emulsion PCR. After amplification, the beads are deposited into picotiter-plate wells with sequencing enzymes. The picotiter plate functions as a flow cell where iterative pyrosequencing is performed. A nucleotide-incorporation event results in pyrophosphate (PP_i) release and well-localized luminescence. APS, adenosine 5′-phosphosulfate.

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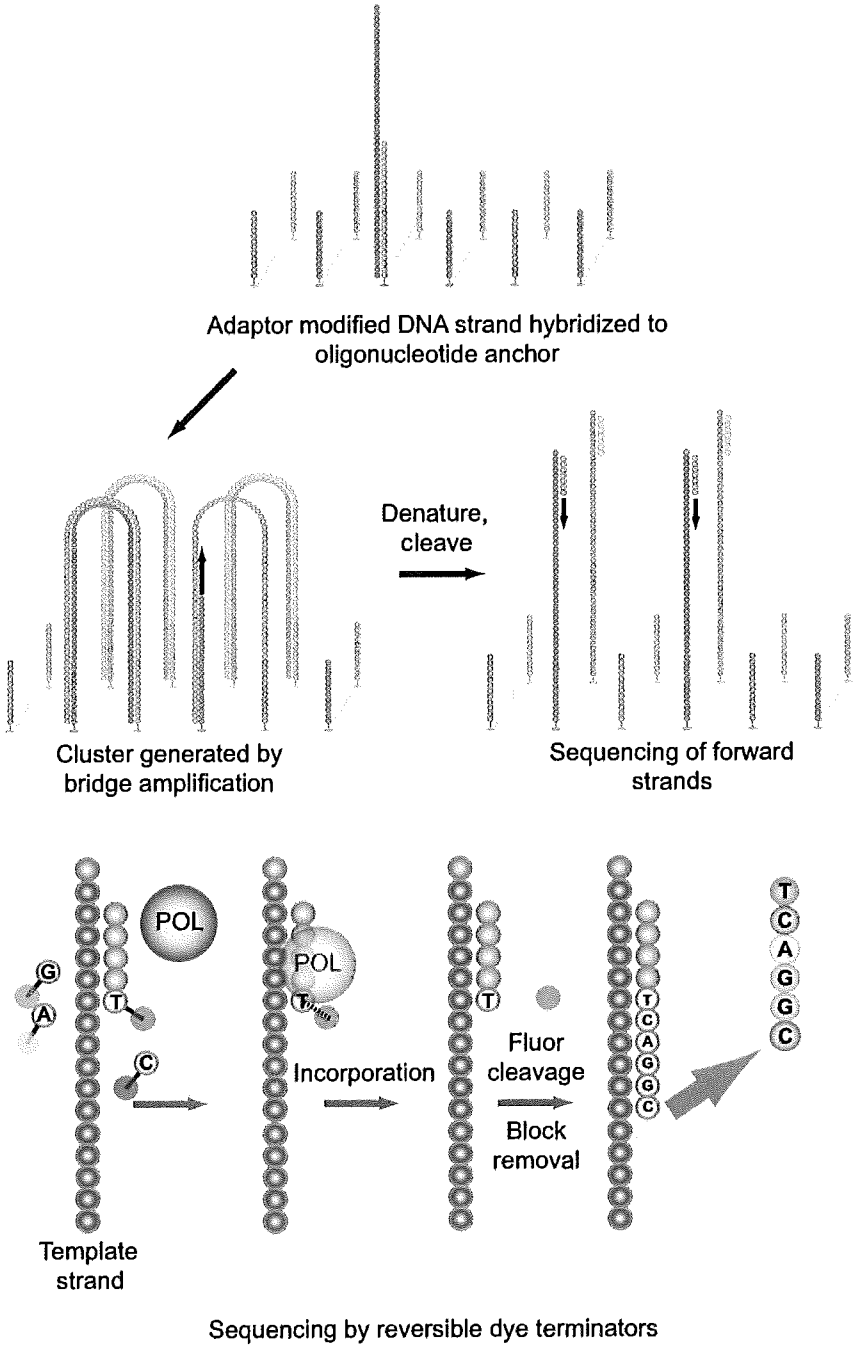

Fig. 2. Illumina Genome Analyzer sequencing.

Adapter-modified, single-stranded DNA is added to the flow cell and immobilized by hybridization. Bridge amplification generates clonally amplified clusters. Clusters are denatured and cleaved; sequencing is initiated with addition of primer, polymerase (POL) and 4 reversible dye terminators. Postincorporation fluorescence is recorded. The fluor and block are removed before the next synthesis cycle.

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der limiting-dilution conditions, adapter-modified, single-stranded template DNA is added to the flow cell and immobilized by hybridization to the anchors. In contrast to emulsion PCR, DNA templates are amplified in the flow cell by "bridge" amplification, which relies on captured DNA strands "arching" over and hybridizing to an adjacent anchor oligonucleotide. Multiple amplification cycles convert the single-molecule DNA template to a clonally amplified arching "cluster," with each cluster containing approximately 1000 clonal molecules. Approximately 50×10^6 separate clusters can be generated per flow cell. For sequencing, the clusters are denatured, and a subsequent chemical cleavage reaction and wash leave only forward strands for single-end sequencing. Sequencing of the forward strands is initiated by hybridizing a primer complementary to the adapter sequences, which is followed by addition of polymerase and a mixture of 4 differently colored fluorescent reversible dye terminators. The terminators are incorporated according to sequence complementarity in each strand in a clonal cluster. After incorporation, excess reagents are washed away, the clusters are optically interrogated, and the fluorescence is recorded. With successive chemical steps, the reversible dye terminators are unblocked, the fluorescent labels are cleaved and washed away, and the next sequencing cycle is performed. This iterative, sequencing-by-synthesis process requires approximately 2.5 days to generate read lengths of 36 bases. With 50×10^6 clusters per flow cell, the overall sequence output is >1 billion base pairs (Gb) per analytical run *(11)*. The newest platform, the Genome Analyzer II, has optical modifications enabling analysis of higher cluster densities. Coupled with ongoing improvements in sequencing chemistry and projected read lengths of 50-plus bases, further increases in output should be realized. Illumina and other NGS technologies have devised strategies to sequence both ends of template molecules. Such "paired-end" sequencing provides positional information that facilitates alignment and assembly, especially for short reads *(12, 13)*. A technical concern of Illumina sequencing is that base-call accuracy decreases with increasing read length *(14)*. This phenomenon is primarily due to "dephasing noise." During a given sequencing cycle, nucleotides can be under- or overincorporated, or block removal can fail. With successive cycles, these aberrations accumulate to produce a heterogeneous population in a cluster of strands of varying lengths. This heterogeneity decreases signal purity and reduces precision in base calling, especially at the 3′ ends of reads. Modifications in sequencing chemistry and algorithms for data-image analysis and interpretation are being pursued to mitigate dephasing *(15)*. Investigators at the Wellcome Trust Sanger Institute, who have extensive experience with the Illumina platform, have published a series of technical improvements for library preparation, including methods for increasing the reproducibility of fragmentation by adaptive focused acoustic wave sonication, enhanced efficiency of adapter ligation by use of an alternate ligase, and reducing the G+C bias that has been observed in Illumina reads via a modified gel-extraction protocol *(16)*.

APPLIED BIOSYSTEMS/SOLiD

The SOLiD (Supported Oligonucleotide Ligation and Detection) System 2.0 platform, which is distributed by Applied Biosystems (http://www.solid.appliedbiosystems.com), is a short-read sequencing technology based on ligation. This approach was developed in the laboratory of George Church and reported in 2005 along with the resequencing of the *Escherichia coli* genome *(17)*. Applied Biosystems refined the technology and released the SOLiD instrumentation in 2007. Sample preparation shares similarities with the 454 technology in that DNA fragments are ligated to oligonucleotide adapters, attached to beads, and clonally amplified by emulsion PCR. Beads with clonally amplified template are immobilized onto a derivitized-glass flow-cell surface, and sequencing is begun by annealing a primer oligonucleotide complementary to the adapter at the adapter–template junction (Fig. 3). Instead of providing a 3′ hydroxyl group for polymerase-mediated extension, the primer is oriented to provide a 5′ phosphate group for ligation to interrogation probes during the first "ligation sequencing" step. Each interrogation probe is an octamer, which consists of (in the 3′-to-5′ direction) 2 probe-specific bases followed by 6 degenerate bases with one of 4 fluorescent labels linked to the 5′ end. The 2 probe-specific bases consist of one of 16 possible 2-base combinations (for example TT, GT, and so forth). In the first ligation-sequencing step, thermostable ligase and interrogation probes representing the 16 possible 2-base combinations are present. The probes compete for annealing to the template sequences immediately adjacent to the primer. After annealing, a ligation step is performed, followed by wash removal of unbound probe. Fluorescence signals are optically collected before cleavage of the ligated probes, and a wash is performed to remove the fluor and regenerate the 5′ phosphate group. In the subsequent sequencing steps, interrogation probes are ligated to the 5′ phosphate group of the preceding pentamer. Seven cycles of ligation, referred to as a "round," are performed to extend the first primer. The synthesized strand is then denatured, and a new sequencing primer offset by 1 base in the adapter sequence (n − 1) is annealed. Five rounds total are performed, each time with a new primer with a successive offset (n − 2, n − 3, and so on). By this approach, each template nucleo-

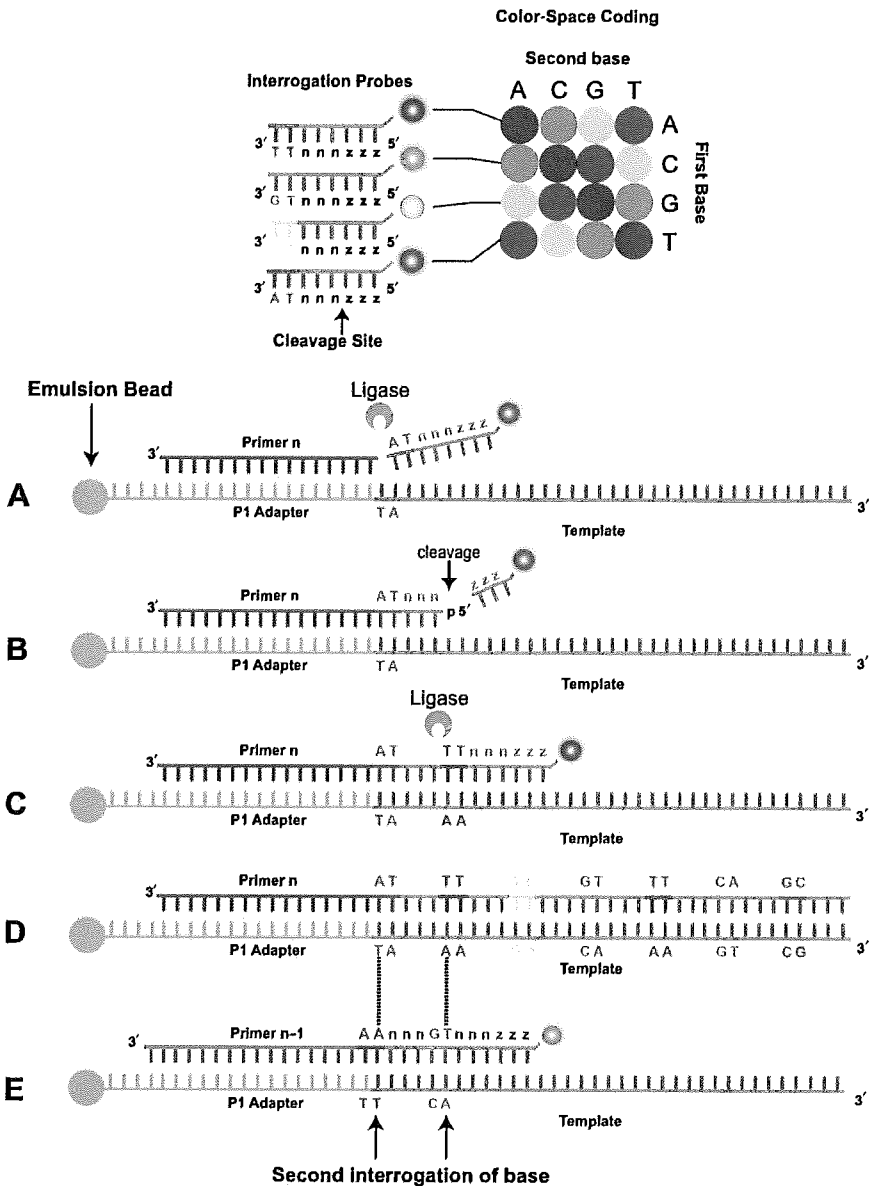

Fig. 3. Applied Biosystems SOLiD sequencing by ligation.

Top: SOLiD color-space coding. Each interrogation probe is an octamer, which consists of (3′-to-5′ direction) 2 probe-specific bases followed by 6 degenerate bases (nnnzzz) with one of 4 fluorescent labels linked to the 5′ end. The 2 probe-specific bases consist of one of 16 possible 2-base combinations. Bottom: (A), The P1 adapter and template with annealed primer (n) is interrogated by probes representing the 16 possible 2-base combinations. In this example, the 2 specific bases complementary to the template are AT. (B), After annealing and ligation of the probe, fluorescence is recorded before cleavage of the last 3 degenerate probe bases. The 5′ end of the cleaved probe is phosphorylated (not shown) before the second sequencing step. (C), Annealing and ligation of the next probe. (D), Complete extension of primer (n) through the first round consisting of 7 cycles of ligation. (E), The product extended from primer (n) is denatured from the adapter/template, and the second round of sequencing is performed with primer (n − 1). With the use of progressively offset primers, in this example (n − 1), adapter bases are sequenced, and this known sequence is used in conjunction with the color-space coding for determining the template sequence by deconvolution (see Fig. 1 in the online Data Supplement). In this technology, template bases are interrogated twice.

ILLUM-0747

Table 1. Comparison of NGS platforms.

	Roche 454 GS FLX	Illumina Genome Analyzer	Applied Biosystems SOLiD	Sanger
Sequencing method	Pyrosequencing	Reversible dye terminators	Sequencing by ligation	Dye terminators
Read lengths	400 bases	36 bases	35 bases	800 bp
Sequencing run time	10 h	2.5 days	6 days	3 h
Total bases per run	500 Mb	1.5 Gb	4 Gb	800 bp

tide is sequenced twice. A 6-day instrument run generates sequence read lengths of 35 bases. Sequence is inferred by interpreting the ligation results for the 16 possible 2 base–combination interrogation probes. With the use of offset primers, several bases of the adapter are sequenced. This information provides a sequence reference starting point that is used in conjunction with the color space–coding scheme to algorithmically deconvolute the downstream template sequence (see Fig. 1 in the Data Supplement that accompanies the online version of this review at http://www.clinchem.org/content/vol55/issue4). Placing 2 flow-cell slides in the instrument per analytical run produces a combined output of 4 Gb of sequence or greater. Unextended strands are capped before the ligation to mitigate signal deterioration due to dephasing. Capping coupled with high-fidelity ligation chemistry and interrogation of each nucleotide base twice during independent ligation cycles yields a company-reported sequence consensus accuracy of 99.9% for a known target at a 15-fold sequence coverage over sequence reads of 25 nucleotides. On an independent track, the Church laboratory has collaborated with Danaher Motion and Dover Systems to develop and introduce an alternative sequencing-by-ligation platform, the Polonator G.007 (http://www.polonator.org). Table 1 summarizes GS FLX, Genome Analyzer, and SOLiD platform features.

HELICOS BIOSCIENCES AND SINGLE-MOLECULE SEQUENCING

The first single-molecule sequencing platform, the HeliScope, is now available from Helicos BioSciences (http://www.helicosbio.com) with a company-reported sequence output of 1 Gb/day. This technology stems from the work of Braslavsky et al., published in 2003 *(18)*. Having obviated clonal amplification of template, the method involves fragmenting sample DNA and polyadenylation at the 3′ end, with the final adenosine fluorescently labeled. Denatured polyadenylated strands are hybridized to poly(dT) oligonucleotides immobilized on a flow-cell surface at a capture density of up to 100×10^6 template strands per square centimeter. After the positional coordinates of the captured strands are recorded by a charge-coupled device camera, the label is cleaved and washed away before sequencing. For sequencing, polymerase and one of 4 Cy5-labeled dNTPs are added to the flow cell, which is imaged to determine incorporation into individual strands. After label cleavage and washing, the process is repeated with the next Cy5-labeled dNTP. Each sequencing cycle, which consists of the successive addition of polymerase and each of the 4 labeled dNTPs, is termed a "quad." The number of sequencing quads performed is approximately 25–30, with read lengths of up to 45–50 bases having been achieved. The Helicos platform was used to sequence the 6407-base genome of bacteriophage M13 *(19)*. This study demonstrated both the potential and important technical issues that may be relevant to all single-molecule sequencing methods that are based on sequencing by synthesis. First, sequencing accuracy was appreciably improved when template molecules were sequenced twice ("2-pass" sequencing). Second, the accuracy of sequencing homopolymers was compromised by the polymerase adding additional bases of the same identity in a homopolymeric stretch in a given dNTP addition. Helicos has since developed proprietary labeled dNTPs, termed "virtual terminators," which the company reports reduce polymerase processivity so that only single bases are added, improving the accuracy of homopolymer sequencing. Interestingly, the percentage of strands in which longer read lengths can be achieved (e.g., 50 nucleotides) is substantially lower than that obtained with shorter (e.g., 25 nucleotides) read-length sequencing, possibly reflecting secondary structures (e.g., hairpins) assumed by the template molecules.

The Impact of NGS on Basic Research

In the short 4 years since the first commercial platform became available, NGS has markedly accelerated multiple areas of genomics research, enabling experiments that previously were not technically feasible or affordable. We describe major applications of NGS and then review the analysis of NGS data.

GENOMIC ANALYSIS

The high-throughput capacity of NGS has been leveraged to sequence entire genomes, from microbes to humans *(3, 8, 9, 11, 20–24)*, including the recent sequencing of the genome of cytogenetically normal acute myeloid leukemia cells, which identified novel, tumor-specific gene mutations *(25)*. The longer read lengths of the 454 technology, compared with the Illumina and SOLiD short-read technologies, facilitate the assembly of genomes in the absence of a reference genome (i.e., de novo assembly). For resequencing, both long- and short-read technologies have been used successfully. In one comparative study, the 454, Illumina, and SOLiD technologies all accurately detected single-nucleotide variations when coverage depth was ≥15-fold per allele *(20)* (the critical issue of coverage depth is discussed further in the NGS Data Analysis section). The 454 read lengths provide nucleotide haplotype information over a range of several hundred base pairs and are predicted to be better suited for detecting larger insertions and deletions and for producing alignments in areas containing repetitive sequences. Further studies are needed to compare technology performance for detecting insertions and deletions. Each platform has an optional strategy for sequencing both ends of DNA libraries (paired-end sequencing). In addition to effectively doubling sequence output, knowing that reads are associated with each other on a given fragment augments alignment and assembly, especially for short reads. Paired-end sequencing has been used to map genomic structural variation, including deletions, insertions, and rearrangements *(12, 13, 26, 27)*. The ability to sequence complete human genomes at a substantially reduced cost with NGS has energized an international effort to sequence thousands of human genomes over the next decade (http://www.1000genomes.org), which will lead to the characterization and cataloging of human genetic variation at an unprecedented level.

TARGETED GENOMIC RESEQUENCING

Sequencing of genomic subregions and gene sets is being used to identify polymorphisms and mutations in genes implicated in cancer and in regions of the human genome that linkage and whole-genome association studies have implicated in disease *(28, 29)*. Especially in the latter setting, regions of interest can be hundreds of kb's to several Mb in size. To best use NGS for sequencing such candidate regions, several genomic-enrichment steps, both traditional and novel, are being incorporated into overall experimental designs. Overlapping long-range PCR amplicons (approximately 5–10 kb) can be used for up to several hundred kb's, but this approach is not practical for larger genomic regions. More recently, enrichment has been achieved by hybridizing fragmented, denatured human genomic DNA to oligonucleotide capture probes complementary to the region of interest and subsequently eluting the enriched DNA *(30–33)*. Capture probes can be immobilized on a solid surface (Roche NimbleGen, http://www.nimblegen.com; Agilent Technologies, http://www.agilent.com; and Febit, http://www.febit.com) or used in solution (Agilent). Current NimbleGen arrays contain 350 000 oligonucleotides of 60–90 bp in length that are typically spaced 5–20 nucleotides apart, with oligonucleotides complementary to repetitive regions being excluded. For enrichment, 5–20 μg of genomic DNA is fragmented and ligated to oligonucleotide linkers containing universal PCR priming sites. This material is denatured, hybridized to an array for 3 days, and eluted, with the enriched DNA amplified by the PCR before NGS library preparation. In reported studies, up to 5 Mb of sequence has been captured on the 350K array, with 60%–75% of sequencing reads mapping to targeted regions; other reads mapping to nontargeted regions reflect nonspecific capture. In development by NimbleGen is the use of an array of 2.1×10^6 features for capturing larger genomic regions. Agilent's solution-based technology uses oligonucleotides up to 170 bases in length, with each end containing sequences for universal PCR priming and with primer sites containing a restriction endonuclease–recognition sequence. The oligonucleotide library is amplified by the PCR, digested with restriction enzymes, and ligated to adapters containing the T7 polymerase promoter site. In vitro transcription is performed with biotinylated UTP to generate single-stranded biotinylated cRNA capture sequences. For capture, 3 μg of fragmented, denatured genomic DNA is hybridized with cRNA sequences for 24 h in solution. After hybridization, duplexes consisting of single-stranded DNA and cRNA are bound to streptavidin-coated magnetic beads; the cRNA is then enzymatically digested, leaving enriched single-stranded DNA that is subsequently processed for NGS. An alternative enrichment approach developed by RainDance Technologies (http://www.raindancetechnologies.com) uses a novel microfluidics technology in which individual pairs of PCR primers for the genomic regions of interest are segregated in water in emulsion droplets and then pooled to create a "primer library." Separately, emulsion droplets containing genomic DNA and PCR reagents are prepared. Two separate droplet streams are created, one with primer-library droplets and the other with droplets containing genomic DNA/PCR reagents. The 2 streams are merged and primer-library droplets and genomic DNA/PCR reagent droplets are paired in a 1:1 ratio. As paired droplets proceed through the microfluidic channel, they pass an electrical impulse that causes them to physically coalesce. The

ILLUM-0749

coalesced droplets containing individual primer pairs and genomic DNA/PCR reagents are deposited in a 96-well plate and amplified by the PCR. After amplification, the emulsions are disrupted, and the amplicons are pooled and processed for NGS.

METAGENOMICS

NGS has had a tremendous impact on the study of microbial diversity in environmental and clinical samples. Operationally, genomic DNA is extracted from the sample of interest, converted to an NGS library and sequenced. The sequence output is aligned to known reference sequences for microorganisms that are predicted to be present in the sample. Closely related species can be discerned, and more distantly related species can be inferred. In addition, de novo assembly of the data set can yield information to support the presence of known and potentially new species. Qualitative genomic information is obtained, and analysis of the relative abundance of the sequence reads can be used to derive quantitative information on individual microbial species. To date, most NGS-based metagenomic analyses have used the 454 technology and its associated longer read lengths to facilitate alignment to microbial reference genomes and for de novo assembly of previously uncharacterized microbial genomes. Examples of metagenomic studies include the analysis of microbial populations in the ocean *(34, 35)* and soil *(36)*, the identification of a novel arenavirus in transplantation patients *(37)*, and the characterization of microflora present in the human oral cavity *(38)* and the guts of obese and lean twins *(39)*.

TRANSCRIPTOME SEQUENCING

NGS has provided a powerful new approach, termed "RNA-Seq," for mapping and quantifying transcripts in biological samples. Total, ribosomal RNA–depleted, or poly(A)$^+$ RNA is isolated and converted to cDNA. A typical protocol would involve the generation of first-strand cDNA via random hexamer–primed reverse transcription and subsequent generation of second-strand cDNA with RNase H and DNA polymerase. The cDNA is then fragmented and ligated to NGS adapters. For small RNAs such as microRNAs (miRNAs) and short interfering RNAs, preferential isolation via a small RNA–enrichment method, size selection on an electrophoresis gel, or a combination of these approaches is commonly used. RNA ligase is used to join adapter sequences to the RNA; this step is often followed by a PCR amplification step before NGS processing. After sequencing, reads are aligned to a reference genome, compared with known transcript sequences, or assembled de novo to construct a genome-scale transcription map. Although RNA-Seq is in its early stages as a technology, it has already shown some advantages over gene expression arrays *(40)*. First, arrays depend on tiling existing genomic sequences, whereas RNA-Seq is not constrained by this limitation, allowing characterization of transcription without prior knowledge of the genomic sites of transcription origin. RNA-Seq is capable of single-base resolution and, compared with arrays, demonstrates a greater ability to distinguish RNA isoforms, determine allelic expression, and reveal sequence variants. Expression levels are deduced from the total number of reads that map to the exons of a gene, normalized by the length of exons that can be uniquely mapped. Results obtained with this approach have shown close correlation with those of quantitative PCR and RNA-spiking experiments. The dynamic range of RNA-Seq for determining expression levels is 3–4 orders of magnitude, compared with 2 orders of magnitude for expression arrays. In this context, RNA-Seq has shown improved performance for the quantitative detection of both highly produced transcripts and transcripts produced at low levels. RNA-Seq is being used to confirm and revise gene annotation, including 5′ and 3′, and exon/intron boundaries; the latter is achieved by mapping reads to exon junctions defined by GT-AG splicing consensus sites. Both qualitative and quantitative information regarding splicing diversity can be deduced. RNA-Seq has been applied to a variety of organisms, including *Saccharomyces cerevisiae*, *Arabidopsis thaliana*, mice, and human cells *(40–51)*.

MAPPING OF DNA-BINDING PROTEINS AND CHROMATIN ANALYSIS

The delineation of regulatory proteins associated with genomes was substantially accelerated by the introduction of chromatin immunoprecipitation and microarray hybridization (ChIP-on-chip) technology *(52)*. In this approach, proteins in contact with genomic DNA are chemically cross-linked (typically with mild formaldehyde treatment) to their binding sites, and the DNA is fragmented by sonication or digestion with micrococcal nuclease. The proteins cross-linked with DNA are immunoprecipitated with antibodies specific for the proteins of interest. The DNA in the immunoprecipitate is purified and hybridized to an oligonucleotide array consisting of sequences from the genome, allowing identification of the protein-binding sites. This approach has been successfully used to identify binding sites for transcription factors and histone proteins. ChIP-on-chip technology is now being supplanted in a variety of experimental settings with ChIP-Seq, in which the DNA harvested from the immunoprecipitate is converted into a library for NGS. The obtained reads are mapped to the reference genome of interest to generate a genome-wide protein-binding map *(53–55)*. Studies to date that have exam-

ILLUM-0750

ined the genomic-binding sites of the human NRSF (neuron restrictive silencer factor) and STAT1 (signal transducer and activator of transcription 1) proteins indicate the resolution of ChIP-Seq to be greater than for ChIP-on-chip, as evidenced by confirmation of previously identified binding sites and identification of novel binding sites *(56, 57)*. Analogous to RNA-Seq, ChIP-Seq has the important advantage of not requiring prior knowledge of genomic locations of protein binding. In addition to the study of transcription factors, NGS is being used to map genomic methylation. One approach involves traditional bisulfite conversion of DNA followed by NGS, which has been applied to the study of entire genomes or genomic subregions *(58, 59)*. Ongoing studies are attempting to develop a variant of ChIP-Seq in which genomic methylation is assayed by coupling immunoprecipitation with a monoclonal antibody directed against methylated cytosine and subsequent NGS *(60)*.

NGS Data Analysis

NGS experiments generate unprecedented volumes of data, which present challenges and opportunities for data management, storage, and, most importantly, analysis *(61)*. NGS data begin as large sets of tiled fluorescence or luminescence images of the flow-cell surface recorded after each iterative sequencing step (Fig. 4). This volume of data requires a resource-intensive data-pipeline system for data storage, management, and processing. Data volumes generated during single runs of the 454 GS FLX, Illumina, and SOLiD instruments are approximately 15 GB, 1 TB, and 15 TB, respectively. The main processing feature of the data pipeline is the computationally intensive conversion of image data into sequence reads, known as base calling. First, individual beads or clusters are identified and localized in an image series. Image parameters such as intensity, background, and noise are then used in a platform-dependant algorithm to generate read sequences and error probability–related quality scores for each base. Although many researchers use the base calls generated by the platform-specific data-pipeline software, alternative base-calling programs that use more advanced software and statistical techniques have been developed. Features of these alternative programs include the incorporation of ambiguous bases into reads, improved removal of poor-quality bases from read ends *(62)*, and the use of data sets for software training *(15)*. Incorporation of these features has been shown to reduce read error and improve alignment, especially as platforms are pushed to generate longer reads. These advantages, however, must be weighed against the substantial computer resources required by the large volumes of image data.

The quality values calculated during NGS base calling provide important information for alignment, assembly, and variant analysis. Although the calculation of quality varies between platforms, the calculations are all related to the historically relevant phred score, introduced in 1998 for Sanger sequence data *(63, 64)*. The phred score quality value, q, uses a mathematical scale to convert the estimated probability of an incorrect call, e, to a log scale:

$$q = -10 \cdot \log_{10}(e).$$

Miscall probabilities of 0.1 (10%), 0.01 (1%), and 0.001 (0.1%) yield phred scores of 10, 20, and 30, respectively. The NGS error rates estimated by quality values depend on several factors, including signal-to-noise levels, cross talk from nearby beads or clusters, and dephasing. Substantial effort has been made to understand and improve the accuracy of quality scores and the underlying error sources *(10, 14)*, including inaccuracies in homopolymer run lengths on the 454 platform and base-substitution error biases with the Illumina format. Study of these error traits has led to examples of software that require no additional base calling but that improve quality-score accuracies and thus improve sequencing accuracy *(65, 66)*. Quality values are an important tool for rejecting low-quality reads, trimming low-quality bases, improving alignment accuracy, and determining consensus-sequence and variant calls *(67)*.

Alignment and assembly are substantially more difficult for NGS data than for Sanger data because of the shorter reads lengths in the former. One limitation of short-read alignment and assembly is the inability to uniquely align large portions of a read set when the read length becomes too short. Similarly, the number of uniquely aligned reads is reduced when aligning to larger, more complex genomes or reference sequences because of their having a higher probability of repetitive sequences. A case in point is a modeling study that indicated that 97% of the *E. coli* genome can be uniquely aligned with 18-bp reads but that only 90% of the human genome can be uniquely aligned with 30-bp reads *(68, 69)*. Unique alignment or assembly is reduced not only by the presence of repeat sequences but also by shared homologies within closely related gene families and pseudogenes. Nonunique read alignment is handled in software by read distribution between multiple alignment positions or leaving alignment gaps. De novo assembly will reject these reads, leading to shorter and more numerous assembled contigs. These factors are relevant when choosing an appropriate sequencing platform with its associated read length, particularly for de novo assembly *(9)*.

Error rates for individual NGS reads are higher than for Sanger sequencing. The higher accuracy of

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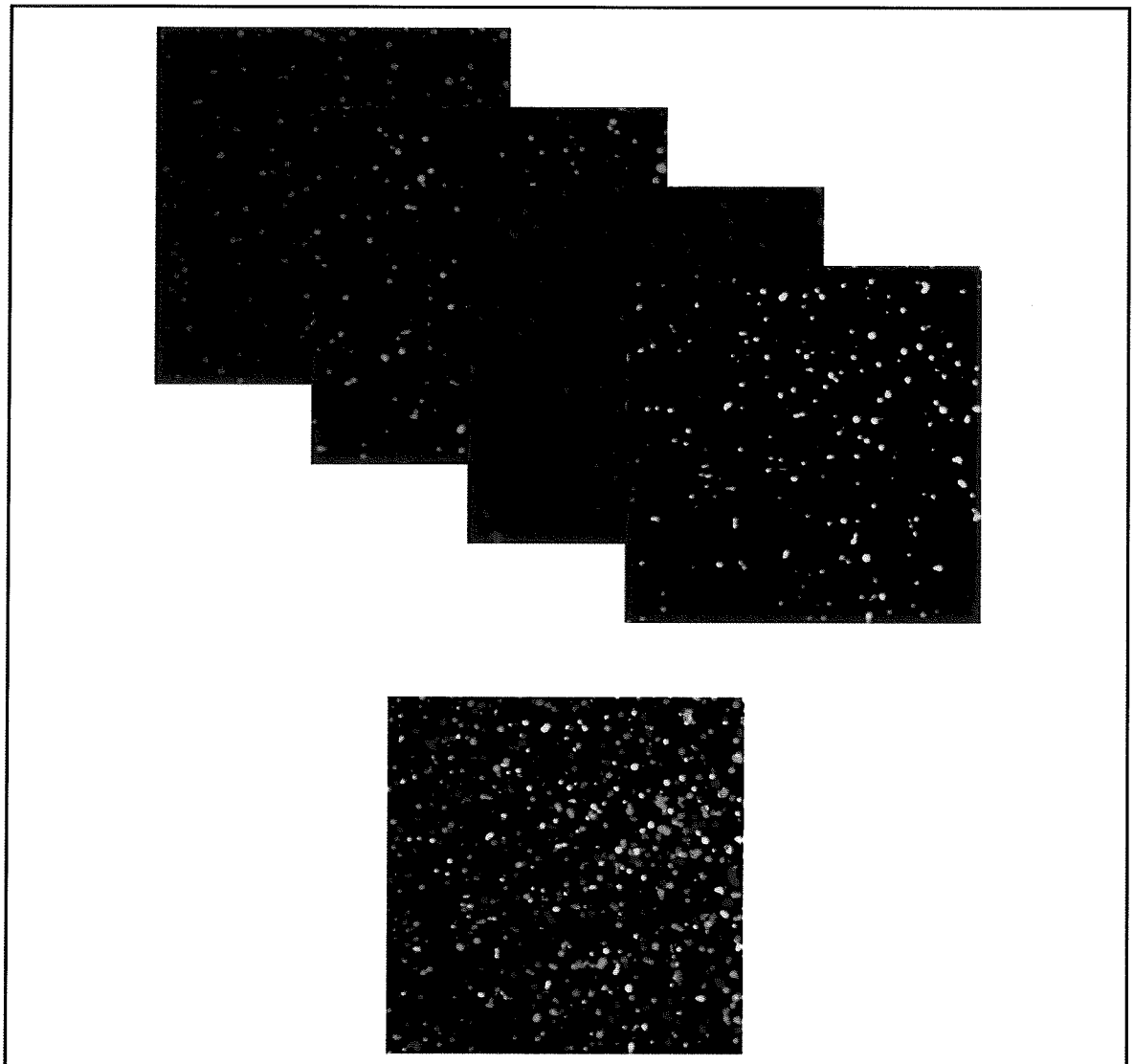

Fig. 4. Pseudocolor image from the Illumina flow cell.

Each fluorescence signal originates from a clonally amplified template cluster. Top panel illustrates 4 emission wavelengths of fluorescent labels depicted in red, green, blue, and yellow. Images are processed to identify individual clusters and to remove noise or interference. The lower panel is a composite image of the 4 fluorescence channels.

Sanger sequencing reflects not only the maturity of the chemistry but also the fact that a Sanger trace peak represents highly redundant, multiple terminated extension reactions. Accuracy in NGS is achieved by sequencing a given region multiple times, enabled by the massively parallel process, with each sequence contributing to "coverage" depth. Through this process, a "consensus" sequence is derived. To assemble, align, and analyze NGS data requires an adequate number of overlapping reads, or coverage. In practice, coverage across a sequenced region is variable, and factors other than the Poisson-like randomness of library preparation that may contribute to this variability include differential ligation of adapters to template sequences and differential amplification during clonal template generation *(11, 70)*. Beyond sequence errors, inadequate coverage can cause failure to detect actual nucleotide variation, leading to false-negative results for heterozygotes *(3, 11)*. Studies have shown that coverages of less than 20- to 30-fold begin to reduce the accuracy of single-nucleotide polymorphism calls in data on the 454 platform *(65)*. For the Illumina system, higher

coverage depths (50- to 60-fold) have been used in an effort to improve short-read alignment, assembly, and accuracy, although coverage in the 20- to 30-fold range may be sufficient for certain resequencing applications *(14)*. As noted above, one comparative study of a yeast genome showed that the 454, Illumina, and SOLiD technologies all accurately detected single-nucleotide variations when the coverage depth was ≥15-fold per allele *(20)*. Coverage gaps can occur when sequences are not aligned because of substantial variance from a reference. Alignment of repetitive sequences in repeat regions of a target sequence can also affect the apparent coverage. Reads that align equally well at multiple sites can be randomly distributed to the sites or in some cases discarded, depending on the alignment software. In de novo–assembly software, reads with ambiguous alignments are typically discarded, yielding multiple aligned read groups, or contigs, with no information regarding relative order.

A large variety of software programs for alignment and assembly have been developed and made available to the research community (see Table 1 in the online Data Supplement). Most use the Linux operating system, and a few are available for Windows. Many require a 64-bit operating system and can use ≥16 MB of RAM and multiple central-processing unit cores. The range of data volumes, hardware, software packages, and settings leads to processing times from a few minutes to multiple hours, emphasizing the need for sufficient computational power. Although a growing set of variations in alignment and assembly algorithms are available, there remains the trade-off between speed and accuracy in which many but not all possible alignments are evaluated, with a balance having to be struck between ideal alignment and computational efficiency.

NGS software features vary with the application and in general may include alignment, de novo assembly, alignment viewing, and variant-discovery programs. In addition some NGS statistical data-analysis tools are being developed (such as JMP Genomics; SAS Institute). Software packages available for alignment and assembly to a reference sequence include Zoom *(71)*, MAQ *(67)*, Mosaik *(72)*, SOAP *(73)*, and SHRiMP (http://compbio.cs.toronto.edu/shrimp/), which supports SOLiD color-space analysis. Software for de novo assembly includes Edina *(70)*, EULER-SR *(74)*, SHARCGS *(75)*, SSAKE *(69)*, Velvet *(76)*, and SOAPdenovo (http://soap.genomics.org.cn/). Recently released commercial software for alignment and de novo assembly includes packages from DNAStar (www.dnastar.com), SoftGenetics (www.softgenetics.com), and CLC bio (www.clcbio.com) that feature data viewers that allow the user to see read alignments, coverage depth, genome annotations, and variant analysis. Fig. 5 presents some examples of NGS data viewed in 2 different software systems.

RNA-Seq data analysis poses unique challenges and requires sequence alignment across spliced regions of transcripts as well as poly(A) tails. Current software has made strong inroads, however, with incorporation of motif recognition at splice junctions and identification of intron–exon borders through regions of low alignment coverage *(41)*. Deciphering multiple transcript isoforms involves mapping reads to known and putative splicing junctions and, in one approach, requires that each isoform be supported by multiple independent splice-junction reads with independent start sites *(51)*. ERANGE software has been used in the analysis of the mouse transcriptome *(43)*. ERANGE maps unique reads to their genomic site of origin and maps reads that match to several sites, or multireads, to a most likely site of origin. Reads that do not map to a known exon are grouped together by homology into candidate exons or parts of exons. The near proportional nature of NGS transcriptome data allows quantification of RNA production from the coverage of the assembled or aligned data. ERANGE uses normalized counts of unique reads, spliced reads, and multireads to quantify transcripts. Additional analytical considerations are needed for miRNA studies, including RNA secondary-structure analysis for hairpins, alignment to known miRNA databases, and searches within the NGS data set for complementary miRNA strands, as described in studies of developing rice grains *(77)* and chicken embryos *(78)*.

Research with ChIP-Seq has led to analysis methods and software that exploit the advantages over ChIP-in-chip, namely a larger, more information-rich data set. The single-base resolution of the data allows improved estimation of binding-site positions in the programs QuEST *(79)* and MACS *(80)*. Aligned data at the protein-binding regions typically have 2 characteristic offset peaks, each of which is populated by only forward or only reverse reads. These peaks are hallmarks of the immunoprecipitated short ChIP-Seq DNA fragments with a binding site near the center and are used by the software to estimate binding-site location near the mean peak position. Additional program features include advancements in statistical analysis to minimize miscalled binding sites, error probability estimation, and motif analysis (see Table 1 in the online Data Supplement).

A Clinical Future for NGS

From the impact that NGS has made at the basic-research level, we can anticipate its translation into molecular diagnostics. Key issues that will need to be addressed in this transition will include complexity of

ILLUM-0753

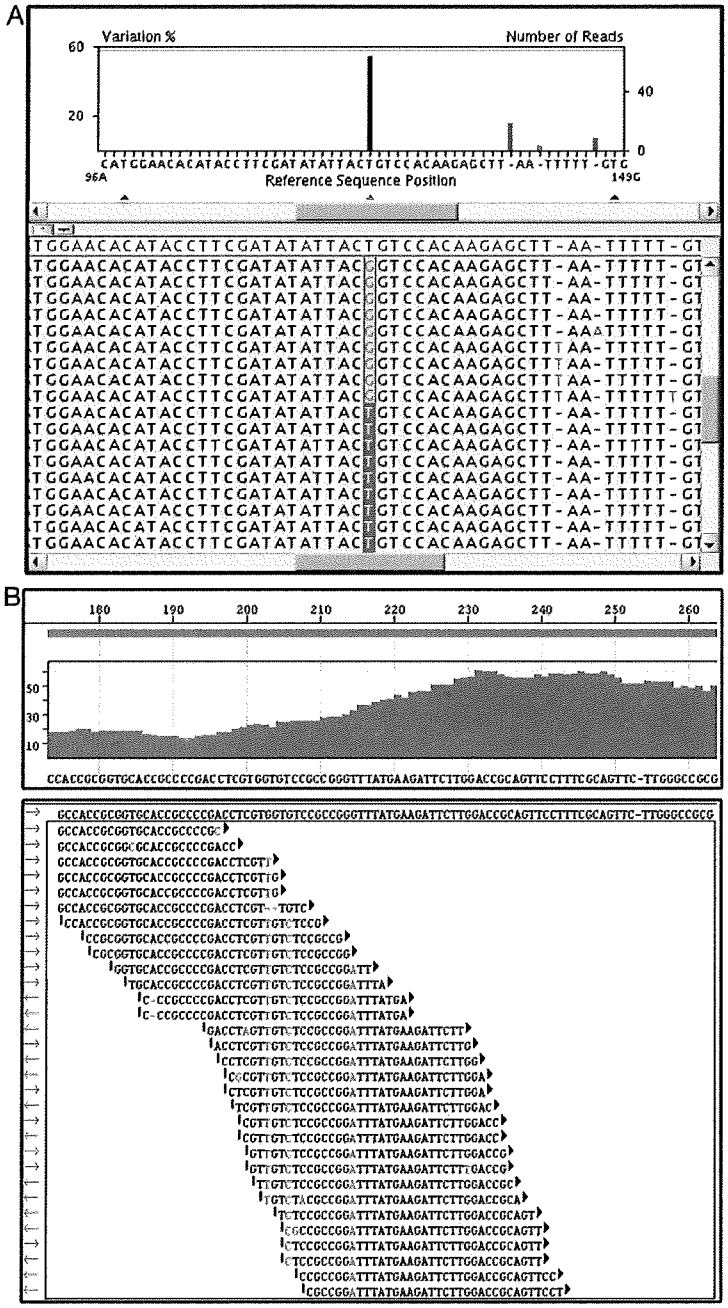

Fig. 5. Examples of NGS data viewed in 2 different software systems.

(A), Roche Amplicon Variant Analyzer software displaying GS FLX data from the CFTR gene [cystic fibrosis transmembrane conductance regulator (ATP-binding cassette sub-family C, member 7)]. Lower pane shows reference sequence (green) above 18 of 68 aligned reads. Column highlighted in yellow and blue shows a heterozygous single-nucleotide polymorphism (SNP). Single T/A insertions (red) may represent errors. Upper pane shows percent variation from reference (vertical bars) and coverage (pale blue line). (B), DNAStar SeqMan Pro software displaying Illumina data from Mycobacterium massiliense. Lower pane shows reference sequence above aligned reads. Green and red arrows show direction of sequencing; base calls at variance with reference are indicated (red). Three columns in agreement (red) indicate presumptive SNPs. Other bases in red may be errors. Upper pane shows read coverage, with relative alignment positions above the graph. See the Acknowledgments for disclosure information on the CFTR-gene analysis performed on residual, deidentified DNA.

ILLUM-0754

technical procedures, robustness, accuracy, and cost. By all these measures, NGS platforms will benefit from continued process streamlining, automation, chemistry refinements, cost reductions, and improved data handling. The cost of NGS is currently substantial in terms of the investment in capital equipment (from approximately $600 000 for the Roche/454 Life Science, Illumina, and Applied Biosystems SOLiD platforms to $1.35 million for the HeliScope platform) and costs of sequencing reagents (from approximately $3500–$4500 for the Illumina, Applied Biosystems, and Roche/454 platforms to $18 000 for the HeliScope platform). Nonetheless, the cost per base is substantially lower than for Sanger sequencing, and combined with the tremendous output, it is straightforward to see why genome centers, core facilities, and commercial contract-sequencing enterprises have readily adopted this new technology. Work flow considerations include the fact that preparation of a sample library requires multiple molecular biology steps and 2–4 days to complete, depending on the platform. In addition to the required molecular biology expertise, data analysis requires expertise in bioinformatics facilitated by a knowledge of Linux operating systems. Leveraging the high-throughput capacity of NGS platforms can be facilitated by analyzing multiple samples with separate flow-cell lanes or compartments. In addition, unique identifier sequences or "bar codes" can be ligated to individual samples, which can subsequently be pooled and sequenced. After sequencing, sequences of individual samples are derived by data deconvolution *(81–83)*.

The transition of NGS into clinical diagnostics is in the early stages of development in large reference laboratories and is being leveraged for applications that require large amounts of sequence information, relative quantification, and high-sensitivity detection. Examples that meet these criteria include the aforementioned detection of mutations in tumor cells from biopsies or in the circulation. In the area of mitochondrial disorders, NGS can be used to sequence the entire 16.5-kb mitochondrial genome, determine mutation heteroplasmy percentage, and analyze nuclear genes whose protein products affect mitochondrial metabolism—all in a single analytical run. In the authors' laboratory, sequencing of mycobacterial genomes is ongoing as an approach to refine organism identification and support clinical epidemiologic investigations. HIV quasi-species detection and relative quantification have been demonstrated and can be used to monitor emerging drug resistance *(84)*. For human genetics, there is an increasing need to analyze multiple genes that, when mutated, lead to overlapping physical findings and clinical phenotypes. For example, 16 different genes are implicated in the pathogenesis of hypertrophic cardiomyopathy *(85, 86)*. For a comprehensive diagnostic evaluation in such settings, it will be necessary to sequence upwards of 100 000 to 200 000 bp. The coupling of NGS with the genomic-enrichment techniques described above offers a promising approach to this technical challenge.

Recently, investigative groups led by Y.M. Dennis Lo and Stephen Quake have applied NGS to the detection of fetal chromosomal aneuploidy *(87, 88)*. Prior work had demonstrated that cell-free fetal nucleic acids (DNA and RNA) are present in maternal blood during pregnancy, along with maternally derived cell-free nucleic acids. Several analytical approaches that use cell-free fetal nucleic acids have been developed to determine fetal aneuploidy, including the analysis of placental mRNA derived from the chromosomes of interest (e.g., chromosome 21) and the determination of relative chromosomal dosage via digital PCR analysis of a large number of target chromosomal loci compared with reference chromosomal loci *(89–91)*. Building on the concept of relative chromosome dosage, the Lo and Quake groups have independently shown the feasibility of converting cell-free DNA from maternal blood into an Illumina library, followed by sequencing and mapping the reads to the reference human genome. Counting the number of reads that map to each chromosome allows the relative dosage of each chromosome to be ascertained. If fetal aneuploidy is present, the number of sequence reads mapping to the affected chromosome would be expected to be statistically overrepresented in the data set. This expectation was confirmed in trisomy 21 pregnancies, with additional supporting evidence obtained for trisomy 18 and 13 pregnancies. These studies open a new avenue for assessing fetal aneuploidy and provide a foundation for NGS-based analysis of cell-free DNA in both nonpathologic and pathophysiological states.

Technologies on the Horizon

New single-molecule sequencing technologies in development may decrease sequencing time, reduce costs, and streamline sample preparation. Real-time sequencing by synthesis is being developed by VisiGen (http://www.visigenbio.com) and Pacific Biosciences (http://www.pacificbiosciences.com). VisiGen's approach uses DNA polymerase modified with a fluorescent donor molecule. Attached to a glass slide surface, the polymerase directs strand extension from primed DNA templates. Nucleotides are modified with fluorescent acceptor molecules, and light energy is used during incorporation to invoke fluorescence resonance energy transfer between polymerase and nucleotide fluorescent moieties, the latter being in the

ILLUM-0755

γ-phosphate position and cleaved away during incorporation. The company envisions its platform will consist of a massively parallel array of tethered DNA polymerases that will generate 1×10^6 bp of sequence per second.

Pacific Biosciences performs single-molecule real-time sequencing and uses phospholinked fluorescently labeled dNTPs. DNA sequencing is performed in thousands of reaction wells 50–100 nm in diameter that are fabricated with a thin metal cladding film deposited on an optical waveguide consisting of a solid, transparent silicon dioxide substrate. Each reaction well is a nanophotonic chamber in which only the bottom third is visualized, producing a detection volume of approximately 20 zL (20×10^{-21} L). DNA polymerase/template complexes are immobilized to the well bottoms, and 4 differently labeled dNTPs are added. As the DNA polymerase incorporates complementary nucleotides, each base is held within the detection volume for tens of milliseconds, orders of magnitude longer than the amount of time it takes for a nucleotide to diffuse in and out of the detection volume. Laser excitation enables the incorporation events in individual wells to be captured through the optical waveguide, with the fluorescent color detected reflecting the identity of the dNTP incorporated. For sequencing, Pacific Biosciences uses a modified phi29 DNA polymerase that has enhanced kinetic properties for incorporating the system's phospholinked fluorescently labeled dNTPs. In addition, phi29 DNA polymerase is highly processive, with strand-displacement activity. By taking advantage of these properties, Pacific Biosciences has demonstrated sequencing reads exceeding 4000 bases when a circularized single-stranded DNA molecule is used as template. In this configuration, the phi29 DNA polymerase carries out multiple laps of DNA strand-displacement synthesis around the circular template. The mean DNA-synthesis rate was determined to be approximately 4 bases/s. The observed errors, including deletions, insertions, and mismatches can be addressed by developing a consensus sequence read derived from the multiple rounds of template sequencing. Further refinement of the chemistries and platform instrumentation are ongoing, with a 2010 target date for commercial launch *(92–94)*.

Farther out toward the horizon is sequencing based on monitoring the passage of DNA molecules through nanopores 2–5 nm or greater in diameter. Nanopores are being fabricated in inorganic membranes (solid-state nanopores), assembled from protein channels in lipid membranes, or configured in polymer-based nanofluidic channels. In some configurations, current is applied across nanopore membranes to drive the translocation of negatively charged DNA molecules through pores while monitoring changes in membrane electrical conductance measured in the picoampere range. NABsys (http://www.nabsys.com) is pursuing a combination of nanopores with sequencing by hybridization in which single-stranded DNA molecules are hybridized with a library of hexamers of known sequence. The hybridized DNA is interrogated through a nanopore, with the current changes being different in regions of hexamer hybridization. The patterns of hybridization are used to map annealing regions and determine sequence. Oxford Nanopore Technologies (http://www.nanoporetech.com) is developing nanopore-based sequencing that uses an α-hemolysin protein channel in reconstituted lipid bilayers. The nanopores are situated in individual array wells, and single DNA molecules are introduced into the wells and progressively digested by exonuclease. The released single-nucleotide bases enter the nanopore and alter the electrical current, creating a characteristic current change for each individual base *(95, 96)*. Although the technology is seemingly futuristic, considerable NHGRI funding is being directed toward a variety of nanopore technologies under development as part of the goal of achieving the $1000 genome. For further descriptions of nanopore technologies, the reader is referred to recent reviews *(97, 98)*.

Conclusions

The past few years have witnessed the emergence of NGS technologies that share a common basis, massively parallel sequencing of clonally amplified DNA molecules. In 2008, the first NGS platform based on single-molecule DNA sequencing was launched. On the horizon are real-time single-molecule DNA-sequencing technologies and approaches based on nanopores. NGS has had a substantial impact on basic genomics research in terms of scale and feasibility. Over the next several years, NGS is anticipated to transition into clinical-diagnostics use. Essential elements to make this transition successful will be the requirement of streamlining the processes, especially sample preparation, coupled with improvements in technology robustness and characterization of accuracy through validation studies. The large amounts of sequence-data output will pose a bioinformatics challenge for the clinical laboratory. In addition to data processing, the interpretation of sequencing results will require further characterization of the genomic variation present in the regions analyzed. Although considerable work lies ahead to implement NGS into clinical diagnostics, the potential applications are exciting and numerous.

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ILLUM-0757

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ILLUM-0758

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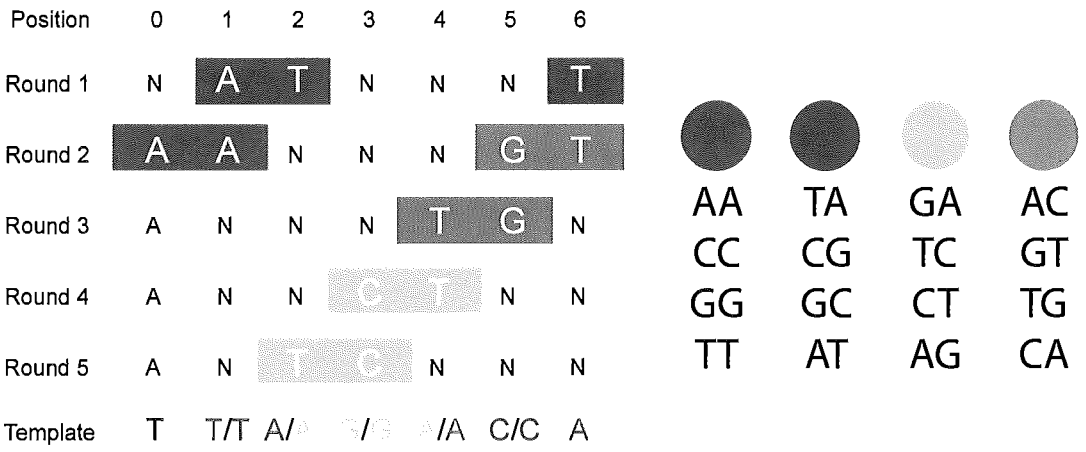
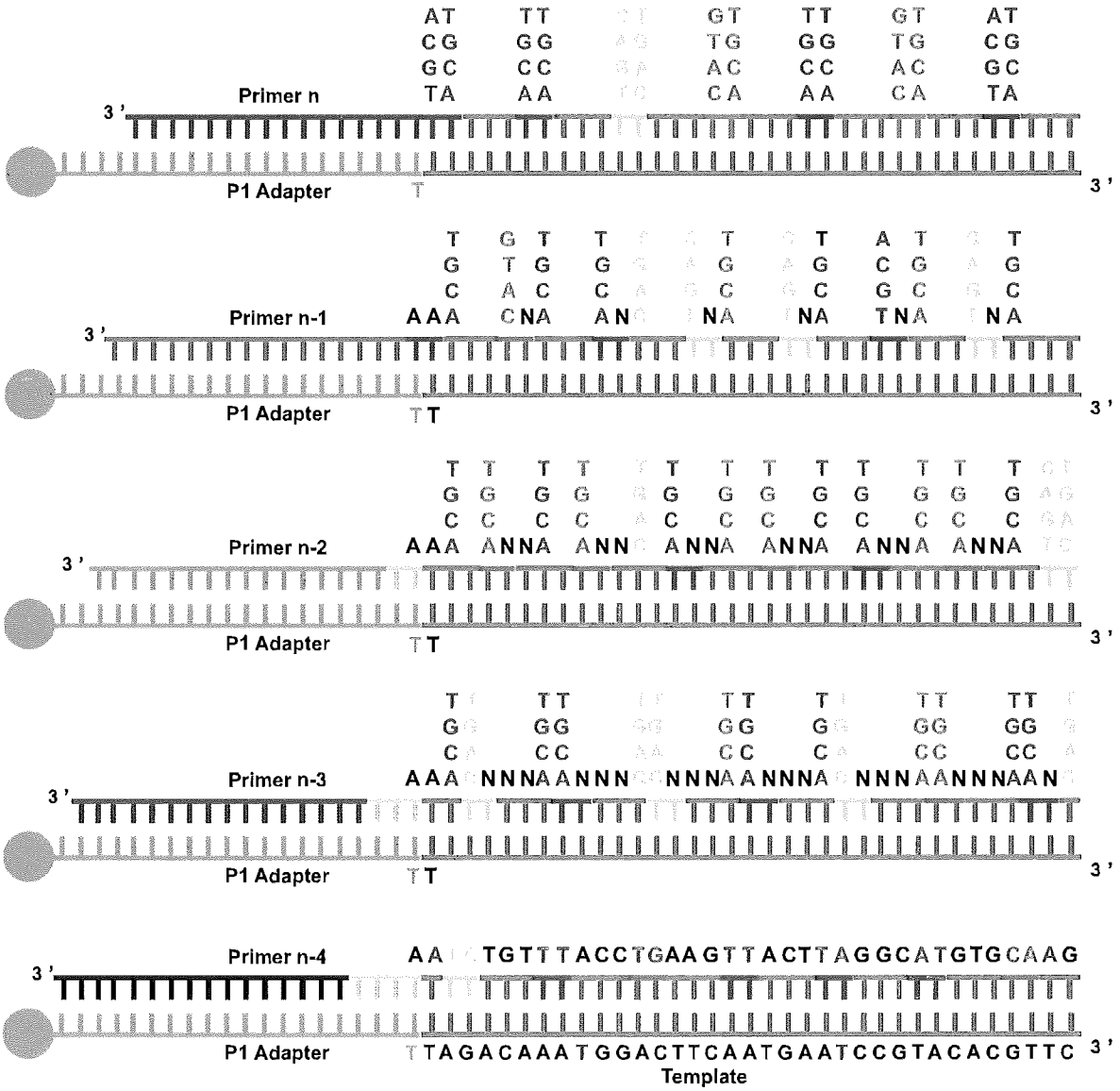
Supplemental Text Voelkerding, Dames, and Durtschi

Supplemental Data Figure 1.





Supplemental Figure 1. SOLiD Color Space Coding and Sequence Deconvolution. Top. Left) Interrogation of a template with sequence TAGACA (positions 1-6 with adapter sequence T at position 0). Right) Color space coding is reshown as reference. Bottom. Sequencing by ligation and deconvolution of template sequence. Extension of primer (n) interrogates template positions 1 and 2, 6 and 7, 11 and 12, and so forth. No sequence information can be determined during the first round since each fluor represents four two base possible combinations. The extension of primer (n-1) allows for the deconvolution of the base at position 1 with the knowledge of the P1 adapter base "T" at position 0. The extension of primers (n-2) and (n-3) provide additional positional color space information prior to deconvolution of the template performed after round 5 (primer n-4). The "N" bases show the positions along the template that have been sequenced twice prior to deconvolution.

Supplementary Data Table 1 Next Generation Sequencing Software Summary

Program Name	Alignment to Reference	De Novo Assembly	SNP Indel Discovery	CHiP/ Bisulphite -Seq	RNA-Seq	Alternate Base Caller	Alignment Viewer	Statistical Analysis	Primary Operating Environments	References	Authors	Web Site
ALLPATHS		X								(1)	Jonathan Butler et al.	
Alta-cyclic						X			Linux, SGE cluster environment	(2)	Yaniv Erlich et al.	hannonlab.cshl.edu/Alta-Cyclic/main.html
Bowtie	X								Linux, Windows, Mac		Ben Langmead and Cole Trapnell	bowtie-bio.sourceforge.net
BS-Seq				X					POSIX OS	(3)	S.J. Cokus et al	epigenomics.mcdb.ucla.edu/BS-Seq/download.html
CHiPSeq				X					Linux, Mac	(4)	D.S. Johnson et al.	woldlab.caltech.edu/html/chipseq_peak_finder
CLCbio Genomics Workbench	X	X	X				X		Windows		CLCbio	www.clcbio.com
EagleView							X		Linux, Windows, Mac	(5)	W. Huang, G. Marth	bioinformatics.bc.edu/marthlab/EagleView
Edena		X							Linux, Windows	(6)		www.genomic.ch/edena.php
ELAND	X								Linux		Anthony J. Cox	bioinfo.cgrb.oregonstate.edu/docs/solexa
Erange				X	X				Linux, Mac	(7)	Ali Mortazavi et al.	woldlab.caltech.edu/rnaseq
Euler-SR		X								(8, 9)	Mark J. Chaisson and Pavel A. Pevzner	
Exonerate	X								Linux	(10)	Guy St, C Slater and Ewan Birney	www.ebi.ac.uk/~guy/exonerate
FindPeaks				X					Java	(11)	Anthony Fejes	vancouvershortr.sourceforge.net
GMAP	X								Unix	(12)	Thomas Wu and Colin Watanabe	
JMP Genomics							X	X	Linux, Win, Mac		SAS Institue Inc.	www.jmp.com/software/genomics
MAQ	X								Linux, Mac	(13)	Heng Li	maq.sourceforge.net/index.shtml
MIRA2	X	X							Linux	(14)	Bastien Chevreux	chevreux.org/projects_mira.html
MOSAIK	X										Michael Strömberg and Gabor Marth	
MUMmer	X								POSIX OS	(15)	Stefan Kurtz, Adam Phillippy, Arthur L Delcher, Michael Smoot, Martin Shumway, Corina Antonescu and Steven L. Salzberg	http://mummer.sourceforge.net
NextGENe	X	X	X				X		Windows		SoftGenetics	www.softgenetics.com
NOVOALIGN	X								Linux, Mac OS X		Novocraft Technologies	www.novocraft.com/products.html
PBShort			X						Linux		Gabor Marth	bioinformatics.bc.edu/marthlab/PbShort
PyroBayes			X						Linux	(16)	A.R. Quinlan, D.A. Stewart, M.P. Strömberg, G.T. Marth	http://bioinformatics.bc.edu/marthlab/PyroBayes

ILLUM-0762

Program Name	Alignment to Reference	De Novo Assembly	SNP Indel Discovery	CHiP/ Bisulphite -Seq	RNA-Seq	Alternate Base Caller	Alignment Viewer	Statistical Analysis	Primary Operating Environments	References	Authors	Web Site
QuEST				X					Linux	(17)	Anton Valouev	mendel.stanford.edu/sidowlab/downloads/quest
RMAP	X								POSIX OS	(18)	Andrew D. Smith and Zhenyu Xuan	http://rulai.cshl.edu/rmap
Roche 454 analysis tools	X	X	X				X		Linux		Roche	www.454.com/products-solutions/analysis-tools/index.asp
Rolexa						X			R	(19)	Jacques Rougemont	svitsrv25.epfl.ch/R-doc/library/Rolexa/html/00Index.html
SAM							X		Linux		Rene Warren, Yaron Butterfield, Asim Siddiqui and Steven Jones	www.bcgsc.ca/platform/bioinfo/software/sam
SeqMan Ngen with SeqMan Pro	X	X	X				X		Windows	(20)	DNAStar	www.dnastar.com
SeqMap	X								Linux, Windows, Mac	(21)	H. Jiang and W.H. Wong	biogibbs.stanford.edu/~jiangh/SeqMap
SHARCGS		X							Perl	(22)	Juliane C. Dohm, Claudio Lottaz, and Heinz Himmelbauer	sharcgs.molgen.mpg.de
SHRAP		X								(23)	Andreas Sundquist et al.	
SHRiMP	X								Linux, Mac		Michael Brudno and Stephen Rumble	http://compbio.cs.toronto.edu/shrimp
SISSRs				X					Perl		Raja Jothi	dir.nhlbi.nih.gov/papers/lmi/epigenomes/sissrs
Slider	X								Java	(24)	N. Malhis, Y. Butterfield, M. Ester, S.J. Jones	http://www.bcgsc.ca/platform/bioinfo/software/slider
SOAPaligner/ soap2	X								Linux	(25)	T.W. Lam, Alan Tam, Simon Wong, Edward Wu and S.M. Yiu, Ruiqiang Li	soap.genomics.org.cn/soapaligner.html
SOAPdenovo		X							Linux		T.W. Lam, Alan Tam, Simon Wong, Edward Wu and S.M. Yiu, Ruiqiang Li	soap.genomics.org.cn/#
SSAHA2	X								Linux	(26)	Zemin Ning, Anthony Cox and James Mullikin	www.sanger.ac.uk/Software/analysis/SSAHA
ssahaSNP			X						Linux, Solaris, Mac		Adam Spargo and Zemin Ning	www.sanger.ac.uk/Software/analysis/ssahaSNP
SSAKE		X							Linux	(27)	René Warren, Granger Sutton, Steven Jones and Robert Holt	http://www.bcgsc.ca/platform/bioinfo/software/ssake
SXOligoSearch	X								Web Based		Synamatix	http://synasite.mgrc.com.my:8080/sxog/NewSXOligoSearch.php
VCAKE		X							Perl	(28)	W. Jeck	http://sourceforge.net/projects/vcake
Velvet		X							Linux, Mac	(29)	Daniel Zerbino and Ewan Birney	http://www.ebi.ac.uk/~zerbino/velvet/
XMatchView							X		Linux, Windows		Rene Warren and Steven Jones	http://www.bcgsc.ca/platform/bioinfo/software/xmatchview

ILLUM-0763

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EXHIBIT 5

(Part I of VII)

OF

DECLARATION OF GREGORY F. HEATH

ILLUM-0065

AACC 2006 ANNUAL MEETING

Annual Meeting

July 23 - 27, 2006
McCormick Place Convention Center
Chicago, Illinois

EDUCATION NETWORKING EXPOSITION

Individual Annual Meeting sessions have been developed in cooperation with: American Diabetes Association, American Society for Clinical Laboratory Science, Association for Clinical Biochemistry, Association for Molecular Pathology, Institute for Quality in Laboratory Medicine, National Academy for Clinical Biochemistry, United Kingdom National External Quality Assurance Immunochemistry Group

JOIN US IN CHICAGO FOR THE AACC ANNUAL MEETING:

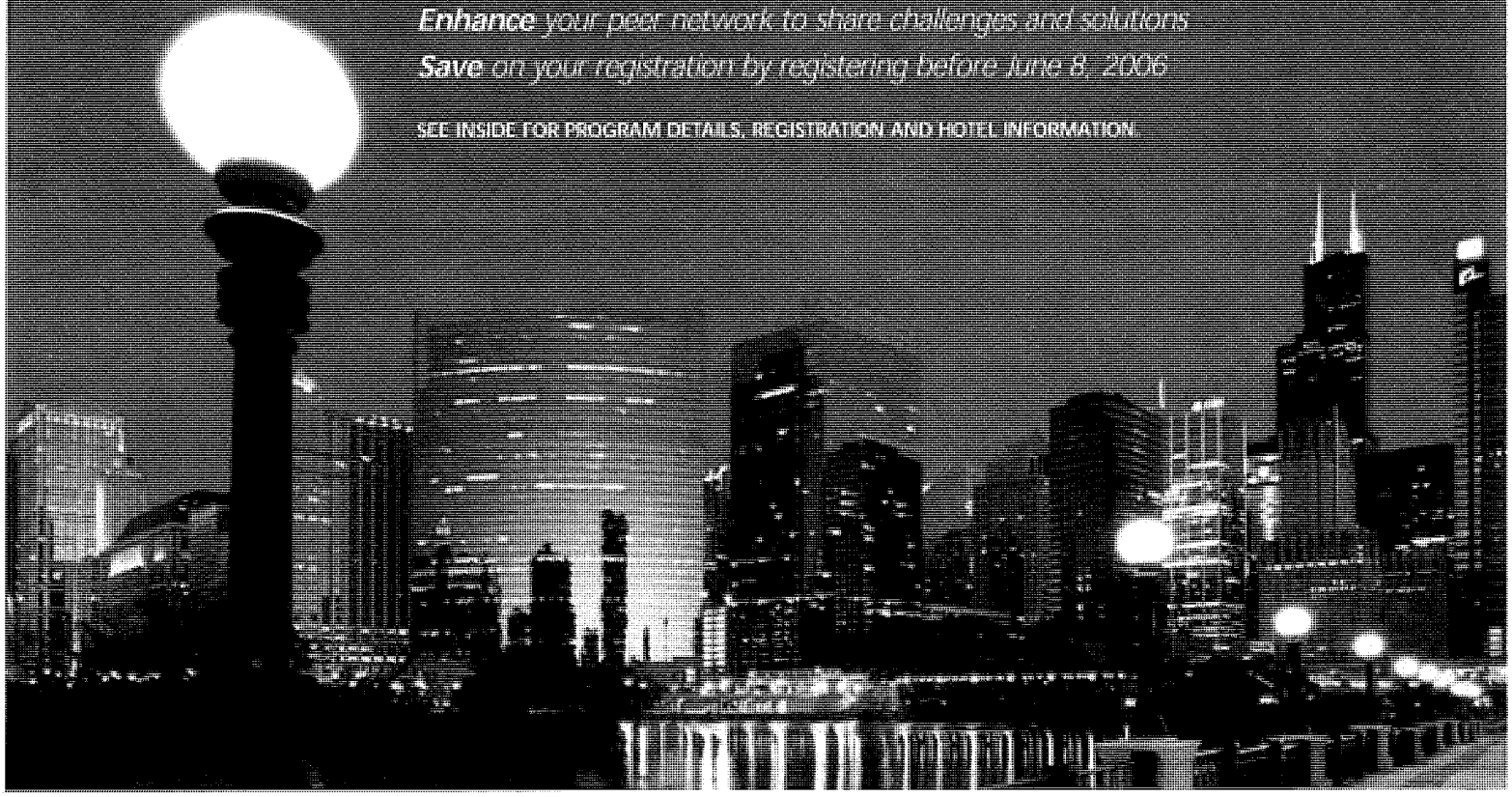
Learn *leading edge science, clinical applications of lab tests plus ways of improving your operations today*

Evaluate *new technologies in the world's largest clinical lab exposition*

Enhance *your peer network to share challenges and solutions*

Save *on your registration by registering before June 8, 2006*

SEE INSIDE FOR PROGRAM DETAILS, REGISTRATION AND HOTEL INFORMATION.



Ad goes here

AACC 2006 ANNUAL MEETING

Dear Colleague:

We hope you'll join us in Chicago—July 23-27, 2006—at the American Association for Clinical Chemistry's 2006 Annual Meeting.

This year's program is more dynamic than ever. We have added new types of sessions to the Program. On Sunday, you can register for Short Courses and Interactive Workshops at AACC University—without paying the general registration fee. For specifics, see page 3. During the week, we have added "Meet the Experts" sessions—a chance to meet with Plenary speakers and other experts in small groups for interactive discussions. And you can hear presentations by the authors of the most outstanding poster abstracts at special presentations on Tuesday and Wednesday.

Flip through the pages of this brochure to plan your meeting schedule.This year, there are five outstanding Plenary sessions and 30 Symposia. You can also enroll for Short Courses, Interactive Workshops, Meet the Experts sessions and Brown Bag sessions—for all of which advance registration is suggested as attendance is limited.

You'll get a first-hand preview of breakthrough science and technology at our Clinical Lab Expo. Bolster your operational decisions and plan for future acquisitions as you evaluate products for point-of-care, clinical, molecular and genetic diagnostics, OEM, automation and information systems, biotech and more.

The clinical and management information you'll take home from the AACC Annual Meeting will be worth much more than the cost of your registration. Even more valuable are the opportunities you'll have to network with your peers during the mixers, breaks, and interactive sessions. You'll form relationships that will continue after the Annual Meeting ends.

All this, and you can earn CEUs as well.

We look forward to seeing you in Chicago this summer.

Sincerely,

John E. Sherwin, PhD
AACC President

P.S. Register by June 8 and save $125 on your registration.
See page 81 to register or sign up online at: www.aacc.org/2006am.

ILLUM-0067

Table of Contents

New for 2006 3
AACC University
Meet the Experts
Chair's Invited Sessions
How to Use the Brochure/Session Descriptions 4
2006 Annual Meeting Organizing Committee 6
Continuing Education Credit Information 6
Clinical Lab Expo 7
Exhibitors 8
Plenary Overview 10
Case Studies 71
Governance and Special Events Schedule 72
AACC Special Events 74
Van Slyke Foundation 76
NACB and ABCC 77
Registration Policies and Procedures 78
What's Included
Registration Fees
How to Register
Cancellation Policy
AACC Booth and Bookstore 80
Meeting Registration Form 81
Membership Information 85
Membership Form 86
Hotel Information 87
Hotel Amenities Chart 88
Hotel Map 90
Hotel Reservation Form 91
Tour Program 92
Tour Reservation Form 94
General Annual Meeting Information 95
Registration Hours
Activity Locations
Travel and Transportation
Housing Information
Messages/Product Locator
Email Stations - Cyberlink

SESSIONS BY DAY

Sunday, July 23 12
Monday, July 24 22
Tuesday, July 25 38
Wednesday, July 26 52
Thursday, July 27 66

AACC ANNUAL MEETING HOT TOPICS

Patient Safety/Lab Errors 14
Evidence Based Medicine 16
Personalized Medicine/Pharmacogenomics 19
Test Utility/Outcomes 21
Analytical Systems/Automation/Instrumentation .28
Cardiac Markers, Cardiovascular Disease 30
POCT 33
Regulation/QA/QC Standards 37
Genomics/Proteomics 43
Mass Spec 48
TDM/Tox 51
Cancer/Tumor Markers 57
Molecular Diagnostics/Genomics 59
Management/Financial/Outreach 65

See inside spread for Annual Meeting-At-A-Glance Schedule and Personal Meeting Planner

ILLUM-0068

AACC UNIVERSITY

Sunday, July 23, 2006

THE CONFERENCE BEFORE THE CONFERENCE!

AACC University includes 15 Short Courses and Interactive Workshops that you can attend without paying the general registration fee. Don't have the time or budget to attend the full Conference? Are you too busy during the week to go to educational sessions? This is your chance to participate in educational sessions at lower cost and on your schedule.

Learn about recent scientific breakthroughs and innovative techniques

Evaluate new technologies to improve organizational performance

Enhance your peer network to share challenges and solutions

AACC University offers a wide variety of topics, so you are sure to find something of interest. See pages 14-21 for descriptions of these sessions.

Alphabet Soup - The Hepatitis Viruses 191001

Perspective and Tools: How to Interpret Pharmacogenetics Testing 191003

The Art of Evidence Based Medicine: Approaches to Question Formulation and Study Design 191004

Tumor Markers: How We Use Them in the Clinic and New Developments 191008

LC/MS/MS Instrumentation Applications in Clinical Laboratory Medicine 191010

Blood Gas, Calcium, Magnesium, and Lactate Testing: Interpretation, Sample Handling, and Point-of-Care Applications 191011

Concepts and Practices in the Evaluation of Laboratory Methods 191012

Principles of Molecular Diagnostics 191014

Biomarkers for Detection of Myocardial Injury, Risk Stratification and Heart Failure 191016

Autoverification in the Clinical Laboratory - It's More Than Meets the Eye! 191009

Hemoglobinopathies and Thalassemias: A Case Study Approach 191002

Hot Topics in Point-of-Care Testing 191005

Solving Day-To-Day Management Challenges: Case Histories & Applications 191007

Service Excellence Is Sweeping Through Healthcare: Applying These Principles In Laboratory Management 191013

How Laboratorians Can Gain Hospital Executives' Support for Implementing Laboratory Automation Technology 191015

MEET THE EXPERTS

Want to talk one-on-one with any of the Plenary speakers or other leaders in the field? Sign up for a Meet the Experts session, where you'll take part in an extended Q&A exchange. Attendance at the sessions will be strictly limited, and advance registration is highly encouraged. See page 5 for scheduled days and times of these invaluable sessions.

CHAIR'S INVITED SESSIONS

The Chair of the 2006 Annual Meeting Organizing Committee created these two special sessions of particular importance to annual meeting attendees. This is an opportunity to hear about lab staffing issues as well as educating consumers about lab testing. These sessions are included in the general conference registration fee. See pages 56 and 61 for details.

MAKE THE MOST OUT OF YOUR VISIT TO CHICAGO DURING THE AACC ANNUAL MEETING.

>Benefit from the multiple scientific sessions.

>Develop and expand on professional and personal relationships that will go on long after the meeting concludes.

>Take the opportunity to evaluate new technology in our Clinical Lab Expo.

The information is all right here at your fingertips.

Use this brochure to help create your personal agenda for the meeting. To simplify the process, we've divided it into easy-to-use sections. You can:

Choose your sessions by topic.
Are there "can't miss" sessions you want to attend? For cutting-edge information on such issues as pharmacogenomics, immunology, cardiac markers, cancer, diabetes, information management, instrumentation and analytical methods and more, turn to the table of contents on page 2 for a listing of hot topic sessions. Be sure to mark the sessions that interest you.

Choose your sessions by type of program.
While many sessions are open to all Annual Meeting conference registrants, others require advance registration and/or additional fees. Special icons in the center Meeting-At-A-Glance will guide you to the various session selections, so that you can evaluate formats and select choices that make sense for your budget and learning style.

Choose your sessions by date and time.
Plan your time in Chicago by reviewing the Sessions-by-Day (beginning on page 12) or Meeting-At-A-Glance in the center of this brochure. We've also included information on the Clinical Lab Expo, networking opportunities and committee meetings.

SIMPLIFY YOUR ANNUAL MEETING PLANNING – ONLINE.

Go to www.aacc.org/2006am to search for sessions by: topic, keyword, speaker, date, time or type of session.

Register by June 8 and save! Turn to page 81 or go to: www.aacc.org/2006am

SESSION DESCRIPTIONS

These brief descriptions will help you in planning your meeting agenda:

PLENARY

Open to all conference registrants.

Plenary sessions feature speakers with different perspectives on the future of healthcare. Plenary speakers are nationally recognized leaders from clinical practice, research, business and policy. The sessions are designed for registrants at all levels of experience.

Plenary Sessions Times

Sunday	5:00pm - 6:30pm
Monday, Tuesday, Wednesday	8:45am - 10:15am
Thursday	12:30pm - 2:00pm

SYMPOSIA

Open to all conference registrants.

These educational sessions are presented by experts actively involved in the field. The educational mode is lecture and rooms are arranged theater style. By attending any of the Symposia, you'll gain an overview of a subject. Question and answer sessions are generally short and saved for the end of each lecture. Symposia are designed for basic, intermediate or advanced audiences as indicated. Select specific symposia based upon your interests and level of experience.

Symposia Sessions Times

Monday, Tuesday, Wednesday	
Full Day Symposia	10:30am - 12noon and 2:30pm - 5:00pm
Morning Symposium	10:30am - 12noon
Afternoon Symposia	2:30pm - 5:00pm
Thursday	9:30am - 12noon

SHORT COURSES

Attendance is limited. Session fees are required at time of registration.

Short Courses offer intensive treatment of a particular subject. While the teaching method is traditional didactic lecture, these sessions are presented to smaller audiences of approximately 50-100 participants. Expect to take home valuable handouts from any Short Courses you attend. Short Courses are designed for basic, intermediate or advanced levels.

Short Course Sessions Times

Sunday	
Full Day Short Course	10:30am - 12noon and 1:30pm - 4:00pm
Morning Short Courses	10:30am - 12noon
Afternoon Short Courses	1:30pm - 4:00pm
Monday, Tuesday, Wednesday	
Full Day Short Course	10:30am - 12noon and 2:30pm - 5:00pm
Morning Short Courses	10:30am - 12noon
Afternoon Short Courses	2:30pm - 5:00pm

INTERACTIVE WORKSHOPS

Attendance is limited. Session fees are required at time of registration.

As you might expect from the name, Interactive Workshops promote active participant involvement in the learning process. Expect frequent exchanges of information between speakers and audience. Intensive treatment of a subject is presented in a context of dialogue and discussion. Think "audience participation," not lecture. Teaching strategies include: problems (problem-based learning); case studies; examples; group discussion; debate; learning exercises; and Q & A. Material covered or introduced during Interactive Workshops may be basic, intermediate or advanced.

Interactive Workshop Sessions Times

Sunday	
Full Day Interactive Workshop	10:30am - 12noon and 1:30pm - 4:00pm
Afternoon Interactive Workshop	1:30pm - 4:00pm
Monday, Tuesday	
Morning Interactive Workshop	10:30am - 12noon
Afternoon Interactive Workshop	2:30pm - 5:00pm
Wednesday	
Afternoon Interactive Workshop	2:30pm - 5:00pm

BROWN BAG SESSIONS

Limited to 10 participants per session. Advance registration and session fees are required at time of registration.

These small discussion groups provide an opportunity for intimate and active exchange among participants and noted experts in the field. Expect lively discussion, dialogue and debate, as well as frequent Q&As. Brown Bag sessions repeat twice daily. AACC does not provide meals for these sessions. You can purchase your own food in the Convention Center.

Brown Bag Sessions Times

Monday, Tuesday, Wednesday	7:30am - 8:30am and 12:30pm - 1:30pm

MEET THE EXPERTS NEW FOR 2006

Attendance is limited. Session fees are required at time of registration.

This is your opportunity to join a small group of interested colleagues for intense discussions with Plenary speakers and other invited experts. These sessions provide the chance for in-depth, interactive discussion. Attendance in these sessions will be strictly limited, and advance registration is highly encouraged.

Meet the Experts Sessions Times

Monday	10:30am - 11:30am and 2:00pm - 3:00pm
Tuesday, Wednesday	10:30am - 11:30am

CHAIRS INVITED SESSIONS NEW FOR 2006

Open to all conference registrants.

The Chair of the 2006 Annual Meeting Organizing Committee created these two special sessions of particular importance to annual meeting attendees. This is an opportunity to hear about lab staffing issues and educating consumers about lab testing.

Chairs Invited Sessions Times

Wednesday	10:30am - 12noon and 2:30pm - 4:00pm

POSTER SESSIONS

Posters are presented by your colleagues to showcase their latest research. Check the June Abstracts issue of *Clinical Chemistry* for a schedule of poster topics. Each year, NACB reviews all the accepted abstracts and selects those deserving special recognition for the quality and importance of the research they are reporting. These posters will be recognized in the Poster Sessions by the NACB Exceptional Poster ribbon.

Poster sessions are held during exhibit hours

Tuesday and Wednesday	9:30am - 5:00pm
Thursday	8:30am - 2:00pm

SPECIAL POSTER PRESENTATIONS

The Abstracts Review Committee and the Organizing Committee evaluate all the accepted abstracts and select exceptional ones for special presentations. You are invited to these special presentations on Tuesday and Wednesday afternoon in the McCormick Place Convention Center.

Want to know what our younger colleagues are up to? Join AACC leadership at the Student Poster Award Presentations on Monday afternoon in the McCormick Place Convention Center. Listen to tomorrow's leaders present their research.

AACC UNIVERSITY NEW FOR 2006

Registration fees apply for each session attended. General Conference registration is waived for Sunday only.

Attend Sunday Interactive Workshops or Short Courses without paying the general Annual Meeting registration fee. This is ideal if the rest of your week is filled with non-Conference activities such as the Expo or committee meetings.

AACC University Times

Sunday	10:30am – 4:00pm

2006 AACC ANNUAL MEETING ORGANIZING COMMITTEE

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Deanna Klosinski, PhD
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HOW TO EARN CONTINUING EDUCATION CREDIT

AACC is accredited to sponsor continuing medical education (CME) activities for physicians by the Accreditation Council for Continuing Medical Education. AACC designates these Continuing Education activities for Category 1 credit towards the AMA Physician's Recognition Award (AMA PRA Category 1 Credit™). Physicians should only claim credit commensurate with the extent of their participation in the activity.

AACC also designates these Continuing Education activities for Category 1 ACCENT® credit towards the Clinical Chemist's Recognition Award. AACC is an approved provider for the states of California, Florida, Louisiana, Montana, Nevada, North Dakota, Rhode Island, and West Virginia.

All of the scientific sessions, except the Poster Sessions, are approved for both AMA PRA Category 1 Credit™ and ACCENT® credit unless otherwise noted.

Eligibility to Earn Continuing Education Credit

To be eligible to earn Continuing Education credit (AMA PRA Category 1 Credit™ or ACCENT®) for the scientific sessions, you must be registered for the Annual Meeting. To obtain your Verification of Participation certificate, after attending scientific sessions, you may download and print your certificate on-site or from the convenience of your home or office computer.

All attendees, including Expo-Only attendees, are eligible to earn ACCENT® credit for attending the Poster Sessions and the Lab Expo. To obtain ACCENT® credit for these activities, you will need to complete the special forms provided on-site.

If you are planning to participate in both the AACC and the ASCLS Annual Meeting scientific sessions, one ACCENT® credit equals one P.A.C.E.® contact hour. Further instructions about how to claim Continuing Education credit will be detailed in the Program Guide provided on-site at the AACC Annual Meeting.

JULY 25 – 27, CHICAGO, IL

See new science and new technology in all areas of clinical diagnostics, automation, information systems, point-of-care, OEM and biotech.

More Exhibitors and More Products

Plan NOW to attend the Clinical Lab Expo. Last year, the Expo included more than 600 organizations occupying more than 1,600 booths. Come to Chicago in July to visit even more exhibitors in more booths than ever before. You will see more products in every clinical lab discipline than at any other conference and expo:

- > Abused drugs
- > Allergy
- > Autoimmune disease
- > Automation and Robotics
- > Blood gas/Electrolytes
- > Bone markers
- > Cancer diagnostics and markers
- > Cardiac diagnostics and markers
- > Cholesterol testing
- > Clinical decision systems
- > Cytology/Histology
- > DNA/RNA testing
- > Endocrine testing
- > Flow cytometry
- > Genetic testing/Genotyping
- > Genomics, Proteomics
- > Glucose
- > Glycohemoglobin
- > Hematology
- > Hemostasis/Coagulation
- > Immunoassay
- > Infectious diseases
- > InformationSystems/ Informatics
- > Microbiology
- > Nutrition
- > OEM and research products
- > Osteoporosis
- > Patient self-testing
- > Pharmacogenomics
- > Point-of-care and POL testing
- > TDM/Toxicology
- > Thyroid testing
- > Urinalysis
- > Viral genotyping

...and much more.

More International Exhibitors

As the international attendance of the meeting grows, so does the number of international exhibitors. This gives you a chance to see what products are available to labs around the world. The Clinical Lab Expo will be the largest international marketplace for the clinical laboratory community this year.

Special Sections for Special Products

Visit the special sections for Point-of-Care Testing and Lab Automation/Robotics/Informatics exhibitors. In these concentrated areas you will find a number of exhibitors offering specialized products and services. Not all exhibitors demonstrating these products choose to be in these sections so make sure you check the Exhibit Guide and the computerized Product Locator System onsite to find all the exhibitors offering products you need. Or go to www.aacc.org/2006am/exhibitors where you can search the list by company name or by 200+ product categories.

More Products for OEM, Biotech and Research

This section of the expo has been created to make it easy for product designers and development scientists to find the products and services they need for the new products their companies are developing as well as their research efforts. Come to this area to find novel technologies and products!

More Hours and More Exhibitor Personnel

The exposition is open:

Tues, July 25	**9:30am – 5:00pm**
Wed, July 26	**9:30am – 5:00pm**
Thurs, July 27	**8:30am – 2:00pm** New Hours!

If you are a serious shopper, you need this time to check out the new workstations, new applications, and the new opportunities for your lab to expand the services you provide. Exhibitors bring their top technical staff as well as sales representatives because they know that the attendees at the Clinical Lab Expo ask the tough questions and make tough purchasing decisions.

Free Expo Only Admissions Available

The Clinical Lab Expo offers more of everything you need to make decisions about the future of your laboratory. If you want to visit the exhibits only and not participate in any of the outstanding conference programs, please visit www.aacc.org/2006am.

We'll see you in Chicago!

2006 Clinical Lab Expo Exhibitors As of March 8, 2006

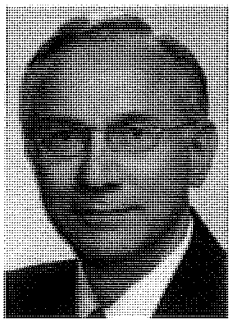
AACC
A/C Diagnostics LLC
AAFP-Laboratory Proficiency Testing
Abaxis
Abbott Diagnostics
Abbott Point of Care
Accumetrics, Inc
Acro Biotech, LLC.
Adaltis
ADEMTECH
Adeza Biomedical
Adhesives Research, Inc.
Advanced Instruments, Inc.
Advanced Microdevices Pvt. Ltd.
Aesku Diagnostics
Affymetrix, Inc.
Air Sea Atlanta, Inc.
Alfa Scientific Designs, Inc.
ALIFAX SPA
Aloka Co., Ltd.
ALPCO Diagnostics
Amano Enzyme USA Co., Ltd.
Amedica Biotech, Inc.
Ameditech, Inc.
American Bio Medica Corporation
American Biological Technologies, Inc.
American Board of Clinical Chemistry
American Diagnostica Inc.
American Medical Technologists
American Proficiency Institute
American Society for Clinical Pathology/Board of Registry
Ameritek USA
Amic AB
AnaSpec, Inc.
Antek HealthWare
Antibodies by Design
Aries Filterworks, Division of ResinTech, Inc.
Arista Biologicals Inc
Arlington Scientific - ASI
Artel
ARUP Laboratories
Asahi Kasei Pharma Corporation
ASCLS
Astech Corporation
Asymtek
Audit MicroControls, Inc.
AutoGenomics Inc.
AutoImmun Diagnostika GmbH/Cell Technology, Inc.
Awareness Technology, Inc.
AWEX (Wallonia Export Agency)
Axis-Shield plc
Bayer HealthCare, Diagnostics Division
Baytree Leasing
BBI Diagnostics (A SeraCare Company)
BBInternational
BD
BD Lee Laboratories
Beckman Coulter, Inc.
Berthold Detection Systems GmbH
BERTHOLD TECHNOLOGIES GmbH & Co. KG
Binding Site Inc., The
Bio Processing, Inc
BioCheck, Inc.
Bio-Chem Valve and Omnifit
Biochemed Corporation
BIODESIGN International
BioDot, Inc.
BioFX Laboratories, Inc.
Biogenesis
BIOHIT, Inc.
BioKit SA
Biological Specialty Corporation
BIOLYPH, LLC
BioMed Resource Inc.
Biomerica, Inc.
Bio-Rad Laboratories
Biosigma S.R.L.
Biosite Incorporated
BIOSPACIFIC / FORTRON
BioTek Instruments, Inc.
BIOTRON DIAGNOSTICS USA
Biozyme Laboratories
BIVDA / GAMBICA
Blackhawk BioSystems, Inc.
Block Scientific, Inc.
Blood Center of Wisconsin
BMD SA
Boval Company, L.P.
Bruker Daltonics Inc.
Burkert
Calbiotech Inc
Calzyme Laboratories, Inc.
Cambridge Consultants Ltd
CanAg Diagnostics
Capricorn Products LLC
Cardinal Health
Carolina Liquid Chemistries
CaseBauer
CellaVision
Cellestis, Inc.
Celliance
Centerchem Inc.
Centers for Medicare & Medicaid Svcs-CLIA
Cepheid
Chromsystems GmbH
Ciphergen Biosystems, Inc.
CITOTEST LABWARE MANUFACTURING CO., LTD.
Clinical & Laboratory Standards Institute
Clinical Analysis Corporation
Clinical Diagnostic Solutions, Inc.
Clinical Ligand Assay Society
CLINIQA Corporation
Cohesive Technologies Inc.
COLA
College of American Pathologists
Computype, Inc.
Conductive Technologies Inc.
Copan Diagnostics, Inc.
Corgenix, Inc.
CORTEX BIOCHEM
CTK Biotech, Inc.
Custom Pack, Inc.
Dade Behring, Inc.
Daiichi Pure Chemicals
DakoCytomation
DAS Srl
Data Innovations, Inc.
Davco Resources LLC
David G. Rhoads Associates, Inc.
Dawning Technologies, Inc.
DCM Diagnostics LLC
Denka Seiken Co., Ltd
DenLine Uniforms, Inc.
Desert Biologicals/Omega Biologicals
Diagnostic Automation /Cortez Diagnostic, Inc.
Diagnostic Chemicals Limited
Diagnostic Laminations Engineering
Diagnostic Products Corp.
Diagnostica Stago, Inc.
DIALAB G.m.b.H
Diamedix Corporation
DiaSorin
DiaSys Diagnostic Systems GmbH
DIBA Industries, Inc.
Diesse Diagnostica Senex S.p.A.
DOCRO, Inc.
Drew Scientific
DRG International, Inc.
Drucker Company, The
Drummond Scientific
Duke Scientific Corporation
DXS LIMITED
DYNEX Technologies Inc.
Ease Labs, Inc.
EastCoastBio, Inc.
Eastern Plastics, Inc.
Egemin Automation Inc
Ekips Technologies, Inc.
Elsevier
EMD Biosciences
EMD Chemicals, Inc.
Epocal Inc
Eppendorf AG
EPS Bio Technology Corp.
EQUITECH-BIO, Inc.
ERBA Diagnostics Mannheim GmbH
ESA Biosciences, Inc.
Eurotrol
EVERGREEN SCIENTIFIC
Excel Scientific, Inc.
Express Diagnostics Int'l, Inc.
Ferrotec (USA) Corporation
Filtrona Fibertec
Fisher HealthCare
Fluid Metering, Inc.
Focus Diagnostics
Foliage Software Systems
Fujirebio Diagnostics, Inc.
Furuno Electric Co., Ltd.
G&L Precision Die Cutting, Inc.
Gems Sensors Inc.
Genisphere, Inc.
Gen-Probe
Genzyme Diagnostics
Globe Scientific Inc.
GML
Golden West Biologicals, Inc.
GONOTEC GmbH
Greiner Bio-One, Inc.
Grifols USA, Inc.
Guangzhou Improve Medical Instruments Co., Ltd.
Hamamatsu Corporation
Handy Lab, Inc.
Hardy Diagnostics
Harlan Bioproducts for Science
Haydon Switch & Instrument, Inc.
Helena Laboratories
Helena Laboratories - POC
HELMER
Hema Diagnostic Systems
Hemagen Diagnostics, Inc.
Hematechnologies, Inc.
HemoCue Inc.
Hemosure Inc
HIMEDIA LABORATORIES PVT. LTD
HOLTSCH Corporation
Hoover Precision Products, LLC
HORIBAABX Diagnostics
HRA Research
Huayang Analyse Instrument Co., Ltd.
Hycor Biomedical Inc.
HyTest Ltd.
Idaho Technology Inc.
Illumina, Inc.
ILS Innovative Laborsysteme GmbH
Imagene Technology Inc.
IMMCO Diagnostics
Immucor, Inc.
Immuno - Biological Laboratories, Inc. (IBL-America)
Immuno Concepts
Immunodiagnostic Systems (IDS)
Immunology Consultants Laboratory, Inc.
IMPAC Medical Systems, Inc.
InBios International, Inc.
IND Diagnostic Inc.
Indiana Pathology Images
Industrial Test Systems
INOVA Diagnostics, Inc.
Instrumentation Laboratory
International Immunology Corporation
Inverness Medical Professional Diagnostics
Invetech
IQuum, Inc.

IRIS Diagnostics
ITC
IVD Research, Inc.
IVD Technology Magazine
IVEK Corporation
Iwaki America Inc.
Jackson ImmunoResearch Laboratories, Inc
JAJ International
Japan Association for Clinical Laboratory Automation
JAS Diagnostics, Inc.
Joint Commission
Jokoh Co., Ltd
Kamiya Biomedical Company
Kelly Scientific Resources
Kem-En-Tec Diagnostics
KIKKOMAN CORPORATION
Kinematic Automation Inc.
Kloehn Co. Ltd.
KMC Systems, Inc.
KRONUS, Inc.
LabCorp-Esoterix
LabiTec GmbH, Germany
Lampire Biological Laboratories
Lathrop Engineering, Inc.
Lattice Inc
Lee Company, The
LifeScan Inc., a Johnson & Johnson Company
LifeSign LLC
LINCO Research, Inc.
LipoScience, Inc.
LPS Industries
LRE Medical, an Esterline Company
Luminex Corporation
m.u.t GmbH
Magellan Biosciences, Inc.
Magna Bio Sciences
Magsphere Inc.
Maine Biotechnology Services
March Plasma Systems
Market Research.com
Mayo Medical Laboratories
MBL International Corp.
McKesson
MDSS - Medical Device Safety Service
Medcompare
Medica 2006/ Messe Duesseldorf North America
Medica Corporation
Medical Automation Systems
Medical Device Consultants, Inc.
Medical Laboratory Evaluation
Medical Learning, Inc.
Medical Staffing Network Inc.
MEDIPAN GmbH
Medivative Technologies LLC
Medix Biochemica
MEDTOX Laboratories, Inc.
Medtronic Inc.
Melcor Corporation
Mercodia Inc.
Meridian Bioscience, Inc.
Metro Mold & Design, Inc.
Michigan Diagnostics, LLC
MICROGENICS
Microsens Iseao
Midland BioProducts Corp
Millenia Diagnostics, Inc.
Millipore Corporation
Mindray Co., Ltd.
Moss, Inc.
MT Promedt Consulting GmbH
Multisorb Technologies, Inc.
Nalge Nunc International
Nano-Ditech Corporation
Nanogen, Inc.
Nanosphere, Inc.
National Academy
National Jewish Medical & Research Ctr.
National Registry of Certified Chemists
NCA -National Credentialing Agency for Laboratory Personnel, Inc.
Neogen Corporation
NERL Diagnostics
New England Small Tube
NICHIREI BIOSCIENCES, INC.
Nichols Institute Diagnostics
NIKON Instruments Inc.
NIST
Noble Medical, Inc.
Norgren Inc.
Nova Biomedical
NuAire Inc.
OEM Concepts Inc.
Olympus America, Inc.
OraSure Technologies, Inc.
Orchard Software Corp
Ortho-Clinical Diagnostics
Osmetech Inc.
Owen Mumford Inc.
Oyster Bay Pump Works, Inc.
Parter Medical Products, Inc.
PBM-Princeton BioMeditech Corporation
PerkinElmer Life and Analytical Sciences
Pierce
Pointe Scientific, Inc.
Polymedco, Inc.
Polymer Laboratories, A Varian, Inc. Company
POLYMICROSPHERES
Porex Technologies
Precision Systems Inc.
PRIMUS Corporation
Prodesse, Inc
Proliant Health and Biologicals
Promega Corporation
Protedyne Corporation
Puritan Medical Products Co. LLC
PVT LabSystems LLC
QAS
QIAGEN Inc.
Quad Five
Quantimetrix Corporation
Quantum Analytics
Quest Diagnostics Incorporated
Quidel Corporation
R&D Systems, Inc.
R2 Diagnostics
Radim SpA
Radiometer America Inc.
Radiometer America Inc.
RAM Scientific, Inc.
RANDOX LABORATORIES LTD
Rayto Life & Analytical Sciences Co, Ltd
RD Plastics Company
Rees Scientific Corporation
Reference Diagnostics, Inc.
Remel Inc.
Research Organics, Inc.
Response Biomedical Corp
Rheodyne, LLC
RNA Medical
RND Group, Inc., The
Roche Diagnostics
Roche Diagnostics Corporation
Rocky Mountain Diagnostics, Inc.
Rotek Industries
SA Scientific
SaatiTech
Safe-Tec Clinical Products, Inc.
Saladax Biomedical, Inc.
Salimetrics LLC
Sapphire Engineering, Inc.
Sarstedt, Inc.
Sartorius Corporation
Scantibodies Laboratory Inc.
SCC Soft Computer
SCIMEDX Corporation
SCIPAC Ltd.
Scripps Laboratories
SDI Biomed, Inc.
Sebia Electrophoresis
Selective Micro Technologies LLC
SENTINEL Diagnostics
Separation Technology, Inc. (STI)
SEPPIM - ELITECH
SeraCare Life Sciences
Seradyn, Inc.
Serotec
SFRI Diagnostics
Shamrock Scientific Specialty
Shanghai Fosun Med-Tech Development co., Ltd
Shanghai SIIC Kehua Biotech Co., Ltd.
Sifin GmbH
SimPort Plastics Ltd
SKF USA Inc.
SMC Corporation of America
Source Scientific, LLC
Specialty Laboratories
Spherotech Inc.
STANBIO LABORATORY
Standard Diagnostics, Inc.
STRATEC Biomedical Systems AG
Strategic Diagnostics/Strategic BioSolutions
Streck
Sud-Chemie Performance Packaging
SurModics, Inc.
Sutter Health
Symbol Technologies
Symprotek Corporation
Syntron Bioresearch, Inc.
Sysmex
Taigen Bioscience Corporation
Technidata America Medical Software, LLC
Teknova, Inc.
TELCOR
Tennant Packaging Corp.
Thermo Electron Corporation
Third Wave Technologies
Tm Bioscience Corporation
Tosoh Bioscience, Inc.
Toyobo Co., Ltd. c/o Shinko American Inc
Trinity Biotech
UNC Hospitals
Uniflex
United Biotech, Inc.
Upchurch Scientific
Upstate / Chemicon
US Diagnostics
US Filter, a Siemens Business
UTAK Laboratories, Inc.
ValuMax Protective Apparel Inc.
VEDALAB
Viral Antigens, Inc.
ViroStat, Inc.
Vista Technology Inc.
Vital Diagnostics
Vivaproducts, Inc.
Wako Diagnostics
Warde Medical Laboratory
Waters Corporation
Web Converting, Inc.
Wescor, Inc.
WesTgard QC, Inc.
Whatman
Wheaton Science Products
Wiener Laboratorios SAIC
Wolters Kluwer Health - Lippincott Williams & Wilkins
Worthington Biochemical Corporation
WSLH Proficiency Testing
XDX
YD Diagnostics
ZeptoMetrix Corporation
Zeta Corporation
ZheJiang Gongdong Medical Plastic Factory

SUNDAY, JULY 23
5:00pm - 6:30pm

Crossing the Quality Chasm: The Role of Laboratory Medicine
11001

Harvey Fineberg, MD, PhD,
Institute of Medicine, Washington, DC



Level: Intermediate
CE Credit: 1

Laboratory medicine must play a key role in bridging the quality chasm — the gap between the desired and actual levels of quality in the U.S. healthcare system. In this session, you'll learn about initiatives and activities laboratories are already involved in related to narrowing the quality chasm, identify key obstacles which must be overcome to bridge the gap and understand the opportunities for laboratorians to provide future aid in eliminating this area of differentiation.

MONDAY, JULY 24
8:45am - 10:15am

Computing in the Age of the Genome
12001

Carolyn Kovac, PhD,
IBM Life Sciences, Somers, NY

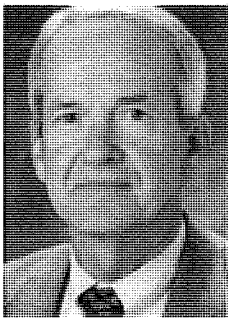
Level: Intermediate
CE Credit: 1

The convergence of life sciences, healthcare and information technology is revolutionizing the discovery of new treatments and the practice of medicine. The integration of diverse clinical and biomedical data has improved existing pharmaceutical and medical practices. Learn from Dr. Kovac how this new paradigm of information-based medicine may very well act as the catalyst that transforms healthcare into a more personalized model.

TUESDAY, JULY 25
8:45am - 10:15am

Employer Managed Healthcare: Corporations Get Back into the Healthcare Business
13001

Leonard Quadracci, MD,
Quad/Graphics, Inc, West Allis, WI



Level: Basic
CE Credit: 1

The phrase "employer-managed healthcare" once conjured up images of a company clinic staffed with a nurse and maybe a physician, or a program to minimize costs by denying services. Today's reality can be quite different from this image, especially at Wisconsin-based Quad/Graphics, Inc. Learn how this innovative company has increased employee wellness and reduced morbidity via a model of care that's fully self-insured, includes self-delivered primary and specialty care and incorporates onsite laboratory services.

For a complete description of each of the Plenary Sessions, turn to the Sessions-By-Day sections. Plenary session descriptions are at the beginning of each day's pages.

ILLUM-0076

WEDNESDAY, JULY 26
8:45am - 10:15am

The Convergence of Diagnostics and the Transformation of Medicine
14001

William Clarke, MD, MSc,
GE Healthcare, Waukesha, WI

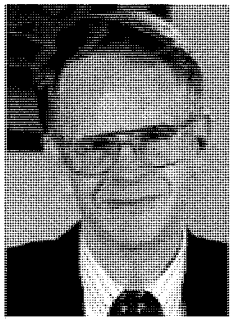
Level:
Intermediate
CE Credit: 1

Are new targeted therapies emerging from the convergence of molecular *in-vitro* diagnostics and molecular *in-vivo* imaging? Dr. Clarke, GE Healthcare's Chief Technology and Medical Officer, will share his views on the role that molecular diagnostics will play in directing clinicians towards highly specific molecular imaging diagnostics. You can benefit from his insights on the synergy between *in-vitro* molecular diagnostics tests and molecular *in-vivo* imaging in selected disease states, and gain guidance on clinical scenarios of predisposition testing for at-risk populations.

THURSDAY, JULY 27
12:30pm - 2:00pm

MITOCHONDRIA:
The Missing Link among Degenerative Diseases, Cancer and Aging, and the Next Molecular Diagnostics Frontier
15001

Douglas Wallace, PhD,
MAMMAG, Univ. of California, Irvine



Level:
Basic
CE Credit: 1

Mitochondrial analysis has allowed the exploration of the relationship between human evolution and some of the most common and disabling diseases, including diabetes, Alzheimer's disease, seizure disorders and Parkinson's disease. You'll hear about mtDNA malfunctions that may have their roots in evolutionary adaptations, and gain better understanding of the relationship between mitochondrial function, mitochondrial mutations and the likelihood of specific disorders.

DON'T MISS YOUR CHANCE TO MEET THE EXPERTS

Most Plenary speakers — along with several other experts — have agreed to join a limited number of conference participants in an extended Q&A session. Attendance in these sessions will be strictly limited, and advance registration is highly encouraged.

To sign up for Meet the Expert sessions, where you'll be part of in-depth, interactive discussions with industry leaders, see the registration form beginning on page 81.

REGISTER FOR THE AACC ANNUAL MEETING TODAY

www.aacc.org/2006am

SUNDAY'S SCHEDULE

9:00am – 10:30am
Clinical Chemistry Journal Board of Editors Meeting
Hyatt Regency Chicago

10:30am – 12noon
Interactive Workshops: AACC University

10:30am – 12noon
Short Courses: AACC University

1:30pm – 3:00pm
Division Awards and Networking Session
Hyatt Regency Chicago

1:30pm – 4:00pm
Interactive Workshops: AACC University

1:30pm – 4:00pm
Short Courses: AACC University

2:00pm – 4:00pm
NGSP Steering Committee Meeting
Hyatt Regency Chicago

5:00pm – 6:30pm
Opening Plenary Session

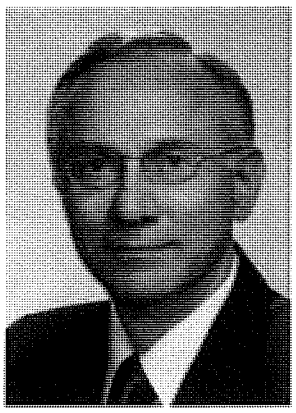
6:30pm – 7:30pm
AACC Annual Meeting Opening Mixer
Hyatt Regency McCormick Place

7:30pm – 8:30pm
Joint Reception of the TDM/Tox and the Molecular Pathology Divisions
Hyatt Regency Chicago

PLENARY SESSION
5:00pm - 6:30pm

Crossing the Quality Chasm: The Role of Laboratory Medicine 11001

Harvey Fineberg, MD, PhD, Institute of Medicine, Washington, DC



Level: Intermediate

CE Credit: 1

Session Overview: This plenary session will educate and inform attendees about initiatives and activities in the U.S. healthcare system that focus on the role of laboratory medicine in bridging the quality chasm (i.e., the gap which exists between the desired and actual levels of quality in the U.S. healthcare system). This session will also identify the key obstacles which must be overcome, and the opportunities available for those in laboratory medicine to contribute to further narrowing of the quality chasm.

Expected Outcomes: After attending this session, participants will be able to: 1) identify three key factors, publications, or initiatives that have resulted in a renewed demand for increased quality in the delivery of healthcare, particularly with regards to patient safety and medical errors; 2) list three ways in which specific applications of laboratory medicine have contributed to improving the quality of healthcare; 3) describe three key opportunities for laboratory medicine to make an even greater contribution to improving the quality of healthcare; and 4) list three obstacles that prevent laboratory medicine from making a greater contribution in improving the quality of healthcare delivery.

This session is open to conference registrants only.

2006 AACC Awards to be presented during the Opening Plenary Session

Mitchell G. Scott, PhD, DABCC, FACB
Washington University School of Medicine
Past President's Award
Sponsored by Cardinal Health, Scientific Products Distribution McGaw Park, IL

Harvey V. Fineberg, MD, PhD
Institute of Medicine
The AACC Lectureship Award
Sponsored by an educational grant from Bayer HealthCare Diagnostics Division Tarrytown, NY

FULL DAY INTERACTIVE WORKSHOPS: AACC UNIVERSITY

10:30am - 12noon and 1:30pm - 4:00pm

Alphabet Soup - The Hepatitis Viruses 191001
Moderator/Speaker: D. Robert Dufour, MD, VA Medical Center, Washington, DC
Level: Intermediate
CE Credit: 1.5 & 2.5

Session Overview: With changing prevalence, acute viral hepatitis has become less common and chronic viral hepatitis is increasingly recognized. This interactive workshop will review serologic and virologic tests for the major hepatitis viruses and, through engaging case studies, discuss application of test results to the diagnosis and management of patients.

Expected Outcomes: After attending this session, participants will be able to: 1) determine appropriate use of follow-up serologic tests for hepatitis B and C; 2) describe advantages and limitations of differing nucleic acid tests for hepatitis B and C; and 3) describe the uses of nucleic acid and other tests for monitoring treatment of hepatitis B and C.

HOT TOPIC – PATIENT SAFETY/LAB ERRORS

MONDAY MORNING SHORT COURSE 72108
An Integrated Incident Reporting System to Reduce Medical Errors and Improve Patient Safety

MONDAY MORNING SYMPOSIUM 32105
The Opportunities and Pitfalls of Using Information Technology to Decrease Postanalytic Errors

MONDAY BROWN BAG SESSION 42105/52205
Impact of Analyte Heterogeneity in Clinical Analysis

TUESDAY AFTERNOON SHORT COURSE 73209
Laboratory Ambassadors: Agents of Change for Improved Service, Patient Safety, and Morale

TUESDAY FULL DAY SYMPOSIUM 33302
Improving the Total Testing Cycle Through Partnerships - The New IQLM

TUESDAY BROWN BAG SESSION 43102/53202
Drug Interference - The Unsolved Problem

TUESDAY AFTERNOON SHORT COURSE 73213
How to Minimize Personal and Laboratory Litigation Risk

TUESDAY BROWN BAG SESSION 43113/53213
Laboratory Interference Issues with Lipemia

WEDNESDAY BROWN BAG SESSION 44118/54218
Error Proofing and Process Improvement Techniques for Laboratory and IVD Industry Scientists

WEDNESDAY MORNING SYMPOSIUM 34106
Extending Traceability to the Laboratory, EQAS and Proficiency Systems - Advantages, Obstacles and Issues

WEDNESDAY BROWN BAG SESSION 44112/54212
Strategies to Reduce Medical Error: A Clinical Laboratory Model

Perspective and Tools: How to Interpret PGx Testing 191003
Moderator: Bonny Bukaveckas, PhD, Virginia Commonwealth Univ., Richmond
Level: Intermediate
CE Credit: 1.5 & 2.5
Developed in cooperation with AACC PGx Committee and Molecular Pathology Division

Session Overview: This interactive workshop will address the challenges of pharmacogenomic (PGx) test clinical interpretation in three sessions: 1) open interactive dialogue, including small breakout groups, on how leaders in PGx from several practice settings are handling the task of test interpretation; 2) solutions and technology for test interpretation, along with a composite clinical case for discussion; and 3) moderated panel discussion among all presenters and participants.

Expected Outcomes: After attending this session, participants will be able to: 1) contrast and compare PGx test interpretation strategies from different practice settings; 2) develop a reference list of technologies, approaches and guidelines to facilitate test interpretation; 3) discuss the role that automated clinical decision support systems can play in promoting the adoption and appropriate interpretation of pharmacogenetic testing; and 4) plan and justify the resources required to interpret PGx test results.

MORNING SPEAKERS

It Takes a Village: PGx in an Academic Medical Center
Bonny Bukaveckas, PhD, Virginia Commonwealth University, Richmond

Design of a PGx Clinical Service Laboratory: From SNP Selection to Genotype Interpretation
Kristen Reynolds, PhD, PGx Laboratories, LLC, Louisville, KY

AFTERNOON SPEAKERS

Interpretation and Utility of Clinical Pharmacogenomic Data Obtained During Clinical Drug Development
Michael Murphy, PhD, Gentris Corporation, Morrisville, NC

The Electronic Medical Record and Automated Clinical Decision Support as Key Factors in the Personalization of Medicine
Mark Hoffman, Cerner Corporation, Kansas City, MO

Lessons Learned from HIV Testing Applied to PGx
David Hillyard, MD, ARUP Laboratories, Salt Lake City, UT

The Art of Evidence Based Medicine: Approaches to Question Formulation and Study Design 191004
Moderator: Robert Christenson, PhD, DABCC, FACB, Univ. of Maryland Medical Center, Baltimore
Level: Intermediate
CE Credit: 1.5 & 2.5
Developed in cooperation with Evidence Based Medicine Committee

Session Overview: This will be an interactive session on "how to do" Evidence Based Medicine (EBM). The first part of the session will be didactic and is designed to provide participants with background knowledge on question formulation, study design and how to use EBM tools. The second part of the workshop will consist of a small group activity; a facilitator will lead each group and focus on the art of practical question formulation for cases involving laboratory medicine where diagnostic performance, screening, monitoring, prognosis, risk stratification, intervention and outcomes are the central issues. Participants will use the structured "PICO" method to aid question formulation, and will apply appropriate models of study design to answer the clinically relevant questions developed. The pitfalls of design-related and other biases and their effects on estimates of diagnostic accuracy will be discussed, and the take home message will be a better practice of laboratory medicine through EBM.

Expected Outcomes: After attending this session, participants will be able to: 1) explain how to formulate relevant questions on important laboratory medicine topics; 2) list sources of bias in clinical studies, and how these biases can be minimized or avoided; and 3) discuss the pros and cons of various study design strategies for addressing specific clinically relevant questions.

MORNING SPEAKER

Introduction to Evidence-Based Laboratory Medicine
Robert Christenson, PhD, DABCC, FACB, Univ. of Maryland Medical Center, Baltimore

AFTERNOON SPEAKERS

The Art of Question Formulation
Christopher Price, PhD, Diagnostics Outcomes, Newbury, United Kingdom

How to Design Diagnostic Studies: a Query Oriented Approach
Andrea Horvath, MD, PhD, EurClinChem, FRCPath, Univ. of Szeged, Hungary

FULL DAY SHORT COURSES: AACC UNIVERSITY

10:30am - 12noon and 1:30pm - 4:00pm

Tumor Markers: How We Use Them in the Clinic and New Developments 191008
Moderator: Eleftherios Diamandis, MD, PhD, FRCPC, Mount Sinai Hospital, Toronto, Canada
Level: Intermediate
CE Credit: 1.5 & 2.5
This Short Course is supported by an educational grant from Abbot Diagnostics.

Session Overview: This session will explain how tumor markers are used today, and project what kind of tumor markers will be used over the next 10-20 years. The presenters will describe the new recommendations of the National Academy of Clinical Biochemistry for using tumor markers and compare them with recommendations from other bodies. Speakers will address the issue of appropriate use of tumor markers by presenting clinical cases, and will further describe how this field is changing as the result of technological advances. New developments coming from proteomic, genomic and microarray technologies will be described in detail.

Expected Outcomes: After attending this session, participants will be able to: 1) facilitate the evidence-based use of tumor markers at the clinic, as recommended by the National Academy of Clinical Biochemistry, the American Society for Clinical Oncology and other bodies; 2) interpret tumor marker values in combination with the clinical picture and use tumor markers for evaluating cancer patients; and 3) describe which new technological advances are coming to the clinic in the area of tumor markers over the next 10 years.

MORNING SPEAKERS

Tumor Markers: How We Use Them in the Clinic and New Developments
Eleftherios Diamandis, MD, PhD, FRCPC, Mount Sinai Hospital, Toronto, Canada

Clinical Cases Presentation on Tumor Markers
Daniel Chan, PhD, DABCC, FACB, Johns Hopkins Medical Institutions, Baltimore, MD

AFTERNOON SPEAKER

National Academy of Clinical Biochemistry Recommendations for Use of Tumor Markers in the Clinic
Martin Fleisher, PhD, Memorial-Sloan Kettering Cancer Center, New York, NY

LC/MS/MS Instrumentation Applications in Clinical Laboratory Medicine 191010
Moderator: Peter Chou, PhD, DABCC, Quest Diagnostics Nichols Institute, Chantilly, VA
Level: Intermediate
CE Credit: 1.5 & 2.5

Session Overview: This session will cover instrumentation for LC/MS/MS analyses as well as applications used in clinical laboratories. Uses of LC/MS/MS in areas such as therapeutic drug monitoring, thyroid testing, steroids, vitamins and proteomics will be addressed by experts in these fields.

Expected Outcomes: After attending this session, participants will be able to: 1) compare the various LC/MS/MS systems currently available on the market; 2) analyze costs/benefits and pros/cons of this instrumentation as compared to other more conventional methods; and 3) evaluate the potential applications of LC/MS/MS in specific areas of their laboratories, including TDM, steroids, thyroid, vitamins, proteomics and peptidomics.

MORNING SPEAKERS

LC/MS/MS Instrumentation
Fred Banks, PhD, Quest Diagnostics Nichols Institute, Chantilly, VA

Using LCMSMS for Therapeutic Drug Monitoring and Thyroid Testing
Steven Soldin, PhD, Georgetown Clinical Research Center, Washington, DC

AFTERNOON SPEAKERS

Determination of Various Steroids Using LC/MS/MS
Nigel Clarke, PhD, Quest Diagnostics Nichols Institute, San Juan Capistrano, CA

Determination of 25 Hydroxyvitamin D Using LC/MS/MS
Brett Holmquist, Quest Diagnostics Nichols Institute, San Juan Capistrano, CA

Proteomics/Peptidomics by LC/MS/MS
Glen Hortin, PhD, MD, National Institutes of Health, Bethesda, MD

Blood Gas, Calcium, Magnesium and Lactate Testing: Interpretation, Sample Handling, and Point-of-Care Applications 191011
Moderator/Speaker: John Toffaletti, PhD, DABCC, Duke Univ. Health System, Durham, NC
Level: Intermediate
CE Credit: 1.5 & 2.5
Developed in cooperation with Critical and Point-of-Care Testing Division

Session Overview: This workshop will provide clinical, pathophysiological, and practical information that will allow the participant to interpret blood gas, Ca, Mg, and lactate results, apply proper sample handling techniques, and understand the benefits, challenges, and limitations of point-of-care testing.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the factors that alter pH, PCO2, PO2; 2) interpret blood gas results to evaluate the ventilatory, metabolic, and oxygenation status; 3) Describe the metabolism of lactate and how it serves as a marker for altered cellular metabolism; 4) describe the biochemical regulation and functions of calcium and magnesium; 5) diagram the differential diagnosis of calcium and magnesium disorders; and 6) set up appropriate point-of-care systems for various critical care settings.

HOT TOPIC – EVIDENCE BASED MEDICINE

SUNDAY FULL DAY INTERACTIVE WORKSHOP 191004
The Art of Evidence Based Medicine: Approaches to Question Formulation and Study Design

MONDAY MORNING SHORT COURSE 72107
The Value of Laboratory Diagnostics in Healthcare

MONDAY MORNING SHORT COURSE 72106
Computer Models in Medicine

MONDAY FULL DAY SYMPOSIUM 32302
Improving Clinical Utilization of Laboratory Data

MONDAY FULL DAY SYMPOSIUM 32303
Health Issues After 40: Preparing the Laboratory to Meet the Demand

MONDAY MORNING SYMPOSIUM 32106
Estimating GFR: Improving Early Detection of Kidney Disease

TUESDAY MORNING SYMPOSIUM 33105
Menopause: Diagnosis, Symptoms and Clinical Management

TUESDAY FULL DAY SYMPOSIUM 33301
Pharmacogenetics Practice Guidelines I: Establishing Clinical Applications

WEDNESDAY AFTERNOON SYMPOSIUM 34208
Acute Coronary Syndromes: The Complete Story

WEDNESDAY FULL DAY SYMPOSIUM 34303
Best Practices in Molecular Pathology

Concepts and Practices in the Evaluation of Laboratory Methods 191012
Moderator: David Koch, PhD, DABCC, Grady Memorial Hospital & Emory Univ., Atlanta, GA
Level: Intermediate
CE Credit: 1.5 & 2.5
Developed in cooperation with Clinical and Laboratory Standards Institute (CLSI) and Management Sciences Division

Session Overview: This short course will discuss the process of selecting and evaluating clinical laboratory methods and develop an understanding of the correct approach to this key clinical laboratory task. Through the use of a series of clinical laboratory evaluation examples, attention will be placed on the critical aspects of the method evaluation process.

Expected Outcomes: After attending this session, participants will be able to: 1) evaluate the claims of manufacturers and determine whether these claims are well-grounded and pertinent; 2) evaluate validation studies published in the literature and presented at meetings; 3) perform evaluation experiments designed to verify claims, confirm literature reports, and compare achieved performance with desired performance; and 4) state justifiable decisions about the method being tested.

MORNING SPEAKERS

Concepts and Practices in the Evaluation of Laboratory Methods
David Koch, PhD, DABCC, Grady Memorial Hospital & Emory Univ., Atlanta, GA

Performance Standards
James Westgard, PhD, Univ. of Wisconsin Hospital, Madison

AFTERNOON SPEAKERS

Concepts and Practices in the Evaluation of Laboratory Methods
Carl Garber, PhD, Quest Diagnostics, Incorporated, Lyndhurst, NJ

Concepts and Practices in the Evaluation of Laboratory Methods
R. Neill Carey, PhD, Peninsula Regional Medical Center, Salisbury, MD

Principles of Molecular Diagnostics 191014
Moderator: Steven Wong, PhD, DABCC (TC), FACB, Medical College of Wisconsin, Milwaukee
Level: Basic
CE Credit: 1.5 & 2.5
Developed in cooperation with The Association for Molecular Pathology, AACC's Pharmacogenomics Committee and Molecular Pathology Division

Session Overview: Clinical molecular diagnostics focuses on the detection of genomes or mutations associated with disease diagnosis, therapeutic management and other patient management information. This course will provide an introduction to the basic principles of molecular diagnostic methods, detailed descriptions of several common test categories, and consideration of regulatory issues which influence molecular diagnostics.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the basic principles of molecular biology underlying molecular pathology applications; 2) recognize the distinctions between research and clinical molecular pathology applications; 3) describe how the molecular basis of genetic variation determines the selection of the diagnostic methodology; and 4) demonstrate the clinical utility of the molecular pathology results in directing patient care decisions.

MORNING SPEAKERS

Molecular Pathology Methods
Gregory Tsongalis, PhD, ABB, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Infectious Disease - Viral Genome Detection
John Howe, Yale Univ. School of Medicine, New Haven, CT

AFTERNOON SPEAKERS

Cancer - BCR-ABL (CML) and Clonal Gene Rearrangements
Barbara Zehnbauer, PhD, FACMG, Washington Univ. School of Medicine, St. Louis, MO

Genetics of Cystic Fibrosis
Vicky Pratt, PhD, FACMG, Quest Diagnostics Nichols Institute, Chantilly, VA

Lab Organization, Regulation, and Reimbursement in Molecular Pathology
Andrea Ferreira-Gonzalez, PhD, Medical College of Virginia Hospital, Richmond

Biomarkers for Detection of Myocardial Injury, Risk Stratification and Heart Failure 191016
Moderator: Fred Apple, PhD, Hennepin County Medical Center, Minneapolis, MN
Level: Advanced
CE Credit: 1.5 & 2.5
This Short Course is supported by an educational grant from Abbott Diagnostics.

Session Overview: This course will address: 1) guidelines for redefinition of myocardial infarction; 2) analytical issues of cardiac troponin assays; 3) pathophysiology of cell death and biomarker release; 4) diagnostic and risk assessment of cardiac troponins in acute coronary syndrome patients and non-ischemic patients; 5) role of natriuretic peptides (including assay considerations) in diagnosis, triage, management and risk assessment of congestive heart failure patients; 6) role of high sensitivity CRP as a marker for cardiovascular disease; 7) role of future markers of ischemia; and 8) future role of proteomics in detection and risk stratification. Attendees will participate in a discussion and point-counter-point of case studies.

Expected Outcomes: After attending this session, participants will be able to understand and describe the laboratory's role for: 1) monitoring cardiac troponin for diagnosis of myocardial infarction and risk stratification in patients presenting with and without myocardial ischemia; 2) monitoring B-type natriuretic peptides for patient triage, diagnosis, management and risk assessment for congestive heart failure; 3) assessing which cardiac troponin and B-type natriuretic peptide assays should be utilized for clinical practice based on quality specifications; 4) monitoring hs-CRP use in cardiac risk assessment; 5) future role of proteomics; and 6) implementation of markers of myocardial ischemia, and implications (financial and administrative) for implementation of POC testing.

MORNING SPEAKER

Cardiac Biomarkers: Analytical Issues
Fred Apple, PhD, Hennepin County Medical Center, Minneapolis, MN

AFTERNOON SPEAKERS

Cardiac Troponin: Triage, Diagnostic and Risk Assessment in ACS/Non-ACS Patients
Allan Jaffe, MD, Mayo Clinic, Rochester, MN

Natriuretic Peptides: Triage Diagnostic and Risk Assessment in Heart Failure/Non-Heart Failure Patients
Johannes Mair, MD, Univ. of Innsbruck, Austria

Emerging Biomarkers — Clinical Potential
Fred Apple, PhD, Hennepin County Medical Center, Minneapolis, MN

MORNING SHORT COURSE: AACC UNIVERSITY
10:30am - 12noon

Autoverification in the Clinical Laboratory - It's More Than Meets the Eye! 191009
Moderator: Judy Johnson, BS, MT(ASCP)SH, Bon Secours HealthPartners Laboratories, Richmond, VA
Level: Basic
CE Credit: 2.5

Session Overview: This short course will show how one laboratory set a strategic goal to autoverify results on all newly acquired instrumentation, accomplished that goal and also was able to include existing instrumentation. Lessons learned were: where to begin; how to assess which methods lend themselves to autoverification; and how to address technologist resistance. Using laboratory examples and sample documents, this session will address implementation, testing, CAP verification and technologist attitude.

Expected Outcomes: After attending this session, participants will be able to: 1) create a plan for implementation of autoverification; 2) obtain the tools to work through the process; 3) utilize lessons learned for achieving acceptance from their technologists; and 4) select appropriate criteria for autoverification.

SPEAKERS

Autoverification from the Hematology View
Judy Johnson, BS, MT(ASCP)SH, Bon Secours HealthPartners Laboratories, Richmond, VA

Autoverification from the Chemistry View
Deborah Stelmach, BS, MS, MT(ASCP), Bon Secours HealthPartners Laboratories, Richmond, VA

AFTERNOON INTERACTIVE WORKSHOPS: AACC UNIVERSITY

1:30pm - 4:00pm

Hemoglobinopathies and Thalassemias: A Case Study Approach 191002

Moderator/Speaker: Shirley Welch, PhD, DABCC, FACB, Kaiser Permanente Regional Lab, Portland, OR
Level: Intermediate
CE Credit: 2.5

Session Overview: This workshop is designed to be an interactive session on the "how-tos" of interpreting hemoglobinopathy workups. After an initial discussion of hemoglobin genetics and methods for qualitative and quantitative evaluation of hemoglobin variants, case studies will be presented for group discussion and interpretation. Information used in interpretation will include CBC and other hematologic and iron studies, in addition to hemoglobin HPLC and electrophoresis. In the second half of the session, participants will apply their knowledge to more complex cases of patients with hemoglobinopathies and/or thalassemias. Participants will also be encouraged to bring their own case studies for presentation and discussion.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the most common analytical techniques for identifying hemoglobin variants and some advantages and disadvantages of each; 2) list four of the most common hemoglobin variants and their clinical consequences; and 3) interpret hemoglobin HPLC or electrophoresis along with other clinical information.

Hot Topics in Point-of-Care Testing 191005

Moderator: Paula Santrach, MD, Mayo Clinic, Rochester, MN
Level: Intermediate
CE Credit: 2.5
Developed in cooperation with Critical and Point-of-Care Testing Division

Session Overview: This session will provide information on the latest developments in POCT related to accreditation requirements, clinical utility/effectiveness, and infectious disease-related testing. Audience participation in case studies and associated exercises will help to demonstrate practical approaches to these challenging issues.

Expected Outcomes: After attending this session, participants will be able to: 1) respond effectively to JCAHO and CAP inspection checklists and questions related to POCT; 2) assess the clinical justification for POCT in a systematic manner to prove if faster is better; and 3) decide on the appropriateness of POCT for infectious disease for their facility.

SPEAKERS

Requests for POCT: Is Faster Always Better?
James Nichols, PhD, FACB, Baystate Health System, Springfield, MA

Infectious Disease POCT: Is It Right for Your Program?
Sheldon Campbell, MD, PhD, FCAP, Yale Univ. School of Medicine, West Haven, CT

Accreditation Inspection Strategies
Paula Santrach, MD, Mayo Clinic, Rochester, MN

HOT TOPIC – PERSONALIZED MEDICINE/PHARMACOGENOMICS

SATURDAY SPECIAL EVENT
Issues in Immunodiagnostics Symposium: Organ Transplantation and the Clinical Laboratory – What's on the Horizon

SUNDAY FULL DAY INTERACTIVE WORKSHOP 191003
Perspective and Tools: How to Interpret PGx Testing

MONDAY AFTERNOON SYMPOSIUM 32207
Challenges in Biomarker and Drug Co-Development and Regulation

MONDAY FULL DAY SYMPOSIUM 32302
Improving Clinical Utilization of Laboratory Data

MONDAY BROWN BAG SESSION 42108/52208
Pharmacogenomics - The Practical Challenges

MONDAY PLENARY 12001
Computing in the Age of the Genome

TUESDAY BROWN BAG SESSION 43111/53211
New Pharmacogenomic Tests: Coming to a Lab near You.

TUESDAY FULL DAY SHORT COURSE 73303
Business Opportunities for Clinical Labs in Pharmaceutical Discovery and Development

TUESDAY FULL DAY SYMPOSIUM 33301
Pharmacogenetics Practice Guidelines I: Establishing Clinical Applications

WEDNESDAY AFTERNOON SHORT COURSE 74209
Pharmacogenetics and Cancer Treatment Efficacy

WEDNESDAY BROWN BAG SESSION 44101/54201
The Application of Pharmacogenetics in Personalized Treatment: New Roles for Laboratory Medicine and Clinicians

WEDNESDAY BROWN BAG SESSION 44107/54207
Personalized Medicine: What does it Mean for the Laboratory?

WEDNESDAY PLENARY 14001
The Convergence of Diagnostics and the Transformation of Medicine

WEDNESDAY FULL DAY SYMPOSIUM 34301
Pharmacogenetics Practice Guidelines II: Clinical Utilization of Pharmacogenetics

THURSDAY SYMPOSIUM 35105
Contemporary Therapeutic Drug Management: Merging Pharmacogenomics, Biomarkers, Drug Concentrations, and Informatics to Improve Patient Care

Solving Day-To-Day Management Challenges: Case Histories & Applications 191007
Moderator/Speaker: Christopher Frings, PhD, CSP, Chris Frings & Associates, Birmingham, AL
Level: Intermediate
CE Credit: 2.5
Developed in cooperation with Management Sciences Division

Session Overview: Through the use of case studies, examples, and group discussions, practical strategies will be explored for the following management challenges: managing matures vs. boomers vs. generation Xers vs. generation Yers; managing change after lab mergers; sexual harassment; adding new lab tests; vendor bias; scheduling vacation and holiday requests; conflicts within and outside the department; getting staff cooperation; and too much work.

Expected Outcomes: After attending this session, participants will be able to: 1) compare their approaches to management challenges to those of the other participants; 2) identify alternative approaches to day-to-day management issues; and 3) implement strategies in their laboratories to be a more effective manager and leader.

AFTERNOON SHORT COURSES: AACC UNIVERSITY
1:30pm - 4:00pm

Service Excellence Is Sweeping Through Healthcare: Applying These Principles In Laboratory Management 191013
Moderator/Speaker: Cherie Petersen, ARUP Laboratories, Salt Lake City, UT
Level: Basic
CE Credit: 2.5

Session Overview: With the onset of consumerism, service excellence initiatives have been spreading throughout healthcare organizations. The primary focus has been on patient care; however 95% of laboratory employees don't directly interact with patients. This course will provide laboratory leaders with tools for integrating these concepts into the laboratory paradigm. Management techniques relating to accountability, measurement, communication, reward and recognition, and celebration will be discussed in ways that will provide guidelines for the specific application of principles that foster a culture of service excellence within the laboratory.

Expected Outcomes: After attending this session, participants will be able to: 1) validate the positive financial impact of implementing service excellence strategies by using the statistical findings presented during the course; 2) recognize ambiguities in their own currently stated expectations related to service excellence; 3) develop a more clearly focused and defined standard that can be communicated to their employees as a starting point for aligning expectations and behaviors; and 4) select the most valuable service excellence strategies for implementation within their laboratory to create a culture focused on service excellence.

ILLUM-0086

How Laboratorians Can Gain Hospital Executives' Support for Implementing Laboratory Automation Technology 191015

Moderator: Denise Uettwiller-Geiger, John T. Mather Hospital, Port Jefferson, NY

Level: Intermediate

CE Credit: 2.5

Developed in cooperation with Management Sciences Division

Session Overview: A hospital executive and laboratory administrative director will describe the comprehensive benefits that laboratory automation systems and advanced data management software produce for hospitals. Participants will learn how laboratorians can best communicate the benefits to hospital executives to gain their support for acquiring automation/data management systems.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the criteria by which executives value a capital investment; 2) enumerate the many advantages of automation in terms that speak to executives' priorities; and 3) explain metrics and other documentation that establish the value and cost-effectiveness of automation systems.

SPEAKERS

How Laboratorians Can Gain Hospital Executives' Support for Implementing Laboratory Automation Technology
Denise Uettwiller-Geiger, John T. Mather Hospital, Port Jefferson, NY

How Laboratorians Can Gain Hospital Executives' Support for Implementing Laboratory Automation Technology
Wayne Shattes, Port Jefferson, NY

HOT TOPIC – TEST UTILITY/OUTCOMES

SUNDAY FULL DAY INTERACTIVE WORKSHOP 191004
The Art of Evidence Based Medicine: Approaches to Question Formulation and Study Design

SUNDAY FULL DAY INTERACTIVE WORKSHOP 191003
Perspective and Tools: How to Interpret PGx Testing

SUNDAY PLENARY 11001
The Vital Role of the Clinical Diagnostic Laboratory in Medical Decision Making

SUNDAY AFTERNOON INTERACTIVE WORKSHOP 191002
Hemoglobinopathies and Thalassemias: A Case Study Approach

SUNDAY FULL DAY SHORT COURSE 191016
Biomarkers for Detection of Myocardial Injury, Risk Stratification and Heart Failure

MONDAY MORNING INTERACTIVE WORKSHOP 22102
Clinical Toxicology Cases

MONDAY BROWN BAG SESSION 42101/52201
Implementing Estimated GFR in your Laboratory using the Modification of Diet Renal Disease (MDRD) Equations

MONDAY BROWN BAG SESSION 42102/52202
How Statistics Influence Our Clinical Decisions

MONDAY BROWN BAG SESSION 42104/52204
Interpretation of Glycohemoglobin Results

MONDAY MORNING SHORT COURSE 72107
The Value of Laboratory Diagnostics in Healthcare

MONDAY FULL DAY SYMPOSIUM 32302
Improving Clinical Utilization of Laboratory Data

TUESDAY AFTERNOON SYMPOSIUM 33207
New Developments in Diabetes Testing and Management

TUESDAY MORNING SYMPOSIUM 33105
Menopause: Diagnosis, Symptoms and Clinical Management

TUESDAY BROWN BAG SESSION 43113/53213
Laboratory Interference Issues with Lipemia

TUESDAY BROWN BAG SESSION 43121/53221
Prenatal Screening for Fetal Down Syndrome

TUESDAY BROWN BAG SESSION 43112/53212
Antioxidant Supplementation and Its Effect on Clinical Outcome in Critical Illness

WEDNESDAY BROWN BAG SESSION 44110/54210
Clinical Value of Very Sensitive PSA Measurements Following Prostatectomy

WEDNESDAY AFTERNOON SYMPOSIUM 34208
Acute Coronary Syndromes: The Complete Story

WEDNESDAY BROWN BAG SESSION 44121/54221
Prealbumin as a Nutritional Marker: Its Financial Impact and Positive Patient Outcome

WEDNESDAY AFTERNOON SYMPOSIUM 34208
Acute Coronary Syndromes: The Complete Story

WEDNESDAY PLENARY 13001
Employer Managed Healthcare: Corporations Get Back into the Healthcare Business

WEDNESDAY MORNING SYMPOSIUM 34104
Clinician's Perceptions of Waived Testing: Is There an Impact on Patient Safety?

WEDNESDAY AFTERNOON SHORT COURSE 74207
Clinical Utilization of Laboratory Data: Using POC Glucose Data to Support Tight Glycemic Control

THURSDAY SYMPOSIUM 35105
Contemporary Therapeutic Drug Management: Merging Pharmacogenomics, Biomarkers, Drug Concentrations, and Informatics to Improve Patient Care

MONDAY'S SCHEDULE

7:00am – 9:00am
University HealthSystem Consortium Lab Council Steering Committee Meeting
Hyatt Regency Chicago

7:30am – 8:30am
Brown Bag Sessions

8:00am – 12:00noon
NRCC Certification Exams
Hyatt Regency Chicago

8:00am – 12:00noon
ABCC Board of Directors Meeting
Hyatt Regency Chicago

8:00am – 5:00pm
University HealthSystem Consortium Lab Council Meeting
Hyatt Regency Chicago

8:30am – 10:00am
International Advisory Group
Hyatt Regency Chicago

8:45am – 10:15am
Plenary Session

10:30am – 11:30am
Meet the Experts

10:30am – 12:00noon
CLSI's Commitment to Quality: Progress on Alternative Quality Control
Hyatt Regency McCormick

10:30am – 12:00noon
Symposia

10:30am – 12:00noon
Short Courses

10:30am – 12:00noon
Interactive Workshops

12:00noon – 1:00pm
CPOCT Industry Liaison Committee Meeting
Hyatt Regency Chicago

12:00noon – 1:30pm
AACC Annual Meeting of the Membership
McCormick Place Convention Center

12:00noon – 4:00pm
LISMI Membership Meeting
Hyatt Regency Chicago

12:30pm – 1:30pm
Brown Bag Sessions

1:30pm – 3:00pm
NACB Board Meeting
Hyatt Regency Chicago

2:00pm – 3:00pm
Meet the Experts

2:00pm – 4:30pm
Student Oral Presentations and Poster Contest
McCormick Place Convention Center

2:30pm – 4:30pm
NGSP Manufacturer Forum
Hyatt Regency Chicago

2:30pm – 5:00pm
Symposia

2:30pm – 5:00pm
Short Courses

2:30pm – 5:00pm
Interactive Workshops

3:00pm – 5:30pm
NRCC Board of Directors Meeting
Hyatt Regency Chicago

3:00pm – 6:00pm
IFCC Working Group on Standardization of Thyroid Function Tests
Hyatt Regency Chicago

4:30pm – 6:30pm
California Local Sections Mixer Networks Bar & Lounge
Hyatt Regency McCormick Place

5:00pm – 5:30pm
ABCC Forum: What Are the Benefits of ABCC Certification?
Hyatt Regency Chicago

5:30pm – 6:30pm
SYCL Networking Reception
Hyatt Regency Chicago

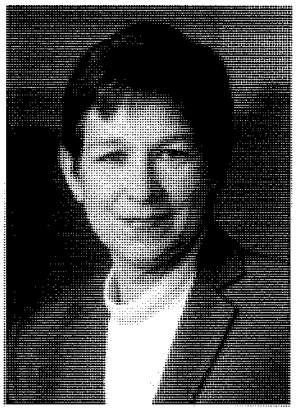
5:30pm – 9:30pm
Annual LVD Annual Dinner Meeting and Mixer: Current Topics in Cardiovascular Disease and Stroke
Hyatt Regency Chicago

6:00pm – 7:00pm
International Reception
Hyatt Regency Chicago

6:00pm – 7:30pm
ABCC Reception
Hyatt Regency Chicago

PLENARY SESSION
8:45am - 10:15am

Computing in the Age of the Genome 12001
Carolyn Kovac, PhD, IBM Life Sciences, Somers, NY



Level: Intermediate
CE Credit: 1
Session Overview: The convergence of life sciences, healthcare and information technology is revolutionizing the discovery of new treatments and the practice of medicine. The new paradigm of information based medicine serves to improve existing pharmaceutical and medical practices with the knowledge that is generated by integration of diverse clinical and biomedical data. Application of information based medicine will, in turn, also help to catalyze the transformation of healthcare into a new model with a greater focus on personalized care.
Expected Outcomes: After attending this session, participants will be able to: 1) explain how use of informatics accelerates the molecular understanding of disease by enabling greater collaboration of stakeholders in both clinical and pharmaceutical research activities; 2) describe how information technology can be optimally used to aid in the collection, integration, analysis and dissemination of critical molecular and clinical data; and 3) discuss the significance in delivery of clinical information in near real time — when and where it is most needed — to research investigators and physicians.

2006 AACC Awards to be presented during this Plenary Session

Helen M. Free, DSc
Bayer Healthcare
Outstanding Contributions to Clinical Chemistry
Sponsored by Bayer HealthCare Diagnostics Division
Tarrytown, NY

Herbert A. Fritsche, PhD, FACB
MD Anderson Cancer Center
The Morton K. Schwartz Award for Significant Contributions in Cancer Research Diagnostics
Sponsored by Bayer HealthCare Diagnostics Division
Tarrytown, NY

Gary L. Myers, PhD, FACB
Centers for Disease Control & Prevention
Outstanding Contributions through Service to the Profession of Clinical Chemistry
Sponsored by Beckman Coulter, Inc.
Brea, CA

Catherine A. Hammett-Stabler, PhD, DABCC, FACB
University of North Carolina, Chapel Hill
Outstanding Contributions in Education
Sponsored by Quest Diagnostics Nichols Institute
Chantilly, VA

Hugo Katus, MD
University of Heidelberg
Outstanding Contributions to Clinical Chemistry in a Selected Area of Research
Sponsored by Olympus America Inc., Diagnostic Systems Group
Center Valley, PA

Michael L. Astion, MD, PhD
University of Washington Medical Center
Outstanding Clinical Laboratory Contributions to Patient Safety
Sponsored by Ortho-Clinical Diagnostics
Raritan, NJ

Roshini S. Abraham, PhD
Mayo Clinic
Outstanding Scientific Achievements by a Young Investigator
Sponsored by Roche Diagnostics
Indianapolis, IN

Sarfraz Ahmad, PhD
Florida Hospital Cancer Institute
International Travel Fellowship
*Sponsored by **BD Diagnostics** - Preanalytical Systems*
Franklin Lakes, NJ

David J. Warren, PhD
The Norwegian Radium Hospital
The Sigi Ziering Award for Outstanding Contribution for a Publication in the Journal *Clinical Chemistry*
Sponsored by Diagnostic Products Corporation (DPC)
Los Angeles, CA

Larry J. Kricka, PhD, FACB
Hospital of the University of Pennsylvania
The Edwin F. Ullman Award
Sponsored by Dade Behring, Inc.
Deerfield, IL

BROWN BAG SESSIONS

7:30am - 8:30am and 12:30pm - 1:30pm

Brown Bag Sessions are repeated twice daily. Attendance is limited to 10 participants per session. AACC does not provide meals for these sessions. You will be able to purchase your own food in the Convention Center prior to the session.

Session numbers beginning with a "4" are morning sessions. Those beginning with a "5" are noon-time sessions.

CE Credit: Each Brown Bag session is eligible for one hour

Implementing Estimated GFR in Your Laboratory Using the Modification of Diet in Renal Disease (MDRD) Equations 42101 or 52201
Ronald Haas, PhD, Marshfield Clinic/St. Joseph's Hospital, Marshfield, WI
Level: Intermediate

How Statistics Influence Our Clinical Decisions 42102 or 52202
Oswald Sonntag, Ortho-Clinical Diagnostics Gmbh, Eichenau, Germany
Level: Basic

Testing for Hepatitis C Virus Infection 42103 or 52203
Mark Jandreski, PhD, DABCC, FACB, Bayer HealthCare, LLC, East Walpole, MA
Level: Intermediate

Interpretation of Glycohemoglobin Results 42104 or 52204
William Roberts, MD, PhD, Univ. of Utah, Salt Lake City
Level: Intermediate

Impact of Analyte Heterogeneity in Clinical Analysis 42105 or 52205
Pradip Datta, PhD, DABCC, Bayer Healthcare LLC-Diagnostics, Tarrytown, NY
Level: Basic
Developed in cooperation with TDM & Toxicology Division

An Introductory Overview of Technologies in Molecular Diagnostics 42106 or 52206
Shu-Ling Liang, Johns Hopkins Univ. School of Medicine, Baltimore, MD
Level: Basic
Developed in cooperation with Molecular Pathology Division

ROC Curves: How, Why and Always — 2006 42107 or 52207
David Plaut, Plano, TX
Level: Intermediate
Developed in cooperation with Management Sciences Division

Pharmacogenomics — The Practical Challenges 42108 or 52208
Hong Lee, PhD, Dartmouth Medical School, Lebanon, NH
Level: Intermediate
Developed in cooperation with Molecular Pathology Division

Serum vs. Plasma: Which Specimen Should You Use? 42109 or 52209
Jeffrey Chance, PhD, BD Diagnostics-Preanalytical Systems, Franklin Lakes, NJ
Level: Basic

The "Value Added" Surgical Pathology Report: Integrating Serum Tumor Markers with Histopathology 42110 or 52210
Robert McCord, Lake Mary, FL
Level: Basic

Communicating for Success 42111 or 52211
Helen Free, DSc, Bayer HealthCare, Diabetes Care Division, Elkhart, IN
Level: Intermediate
Developed in cooperation with Management Sciences Division

Diagnosis of Hemoglobinopathies by HPLC 42112 or 52212
Ching-Nan Ou, PhD, FACB, Texas Children's Hospital, Houston
Level: Intermediate
Developed in cooperation with Pediatric and Maternal-Fetal Division

An Introduction to Crystal "Meth" - The Lab's Perspective 42113 or 52213
Donald LeGatt, PhD, FCACB, Univ. of Alberta Hospital, Edmonton, Canada
Level: Intermediate

Tandem Mass Spectrometry Assay Development: What it Takes to Bring and Keep an Assay Successfully On-Line 42114 or 52214
Elizabeth Pattison, BS, C(ASCP), ARUP Laboratories, Salt Lake City, UT
Level: Basic

Human Erythrocyte Carbonic Anhydrase and Its Isoenzyme-1 as a Potential Marker of Prediabetic State 42115 or 52215
Kanwal Gambhir, PhD, ABCC & SC(ASCP), Howard Univ. College of Medicine, Washington, DC
Level: Intermediate
Developed in cooperation with Clinical & Diagnostic Immunology Division

ILLUM-0090

Assuring the Reliability of Manufacturers' QC Recommendations 42116 or 52216
Greg Cooper, CLS, MHA, Bio-Rad Laboratories, Irvine, CA
Level: Intermediate
Developed in cooperation with Industry Division

Laboratory Outreach Programs: Competing on Service 42117 or 52217
Cherie Petersen, ARUP Laboratories, Salt Lake City, UT
Level: Intermediate

Therapeutic Drug Management in the Pain Clinic Setting 42118 or 52218
Andrea Terrell, AIT Laboratories, Indianapolis, IN
Level: Intermediate
Developed in cooperation with TDM & Toxicology Division

Alternative Medicinals: Impact on Clinical Laboratory Medicine 42119 or 52219
Donald Cannon, PhD, FACB, Univ. of Tampa, FL
Level: Basic
Developed in cooperation with Management Sciences Division

Ensuring Quality in a Multi-Hospital Point-of-Care Program: One System's Approach 42121 or 52221
Barbara Goldsmith, PhD, St. Elizabeth's Medical Center, Boston, MA
Level: Basic
Developed in cooperation with Critical and Point-of-Care Testing Division

Pharmacogenetics in Oncology 42122 or 52222
Dennis O'Kane, PhD, DABCC, FACB, Mayo Clinic, Rochester, MN
Level: Basic

Laboratorian and Clinician Partnership in Near Patient Testing (NPT) and Point-of-Care Testing (POCT) 42123 or 52223
Frank LaDuca, PhD, Bayer Healthcare, Tarrytown, NY
Level: Intermediate
Developed in cooperation with Critical and Point-of-Care Testing Division

Development of Quantitative Real-Time PCR Tests 42124 or 52224
Fernando Alberto, MD, PhD, Fleury Diagnostics, São Paulo, Brazil
Level: Intermediate

The Design and Validation of Autoverification Rules 42127 or 52227
William Coughlin, BS, MBA, Data Innovations North America, South Burlington, VT
Level: Intermediate
Developed in cooperation with Laboratory Information Systems and Medical Informatics Divisions

MEET THE EXPERTS

10:30am - 11:30am

Attendance in these sessions is strictly limited. Advance registration is highly encouraged.

Information Based Medicine 62001
Carolyn Kovac, PhD, IBM Life Sciences, Somers, NY
Level: Intermediate
CE Credit: 1

Session Overview: The convergence of life sciences, healthcare and information technology is revolutionizing the discovery of new treatments and the practice of medicine. Dr. Kovac will present this new paradigm — information based medicine — and discuss briefly how it improves existing pharmaceutical and medical practices with the knowledge generated from the integration of diverse clinical and biomedical data. This will, in turn, help to catalyze the transformation of healthcare to a model of more personalized care. This session will provide a more in-depth and intimate discussion of the topics raised in the accompanying plenary session and is designed for enhanced audience participation.

Expected Outcomes: After attending this session, participants will be able to: 1) have a greater knowledge of how informatics is accelerating the molecular understanding of disease by enabling greater collaboration in both clinical and pharmaceutical research; 2) understand how information technology is used to aid in the collection, integration, analysis and dissemination of critical molecular and clinical data; and 3) evaluate the significance of clinical information delivery in near real time to researchers and physicians when and where it's most needed.

ILLUM-0091

Transforming the Changing Landscape of Healthcare: Current and Future Initiatives of the Institute of Medicine 62002
Harvey Fineberg, MD, PhD, Institute of Medicine, Washington, DC
Level: Intermediate
CE Credit: 1

Session Overview: Harvey V. Fineberg, MD, PhD, is the President of the Institute of Medicine (IOM), former Provost of Harvard University and Dean of the Harvard School of Public Health. He has devoted most of his academic career to the fields of health policy and medical decision-making. At the IOM, he has chaired and served on a number of panels dealing with health policy issues, ranging from AIDS to vaccine safety. As AACC's 2006 National Lectureship Award Recipient, Dr. Fineberg will give the opening plenary keynote presentation on "Crossing the Quality Chasm: The Role of Laboratory Medicine." In this session, Dr. Fineberg will provide introductory remarks on the key healthcare challenges of current focus in the IOM's initiatives including areas of opportunity for laboratory medicine. The remainder of the session will be a question and answer discussion with the audience focusing on these issues.

Expected Outcomes: After attending this session, participants will be able to: 1) describe recent initiatives of the IOM that focus on improving the quality of patient care and reducing medical errors; 2) identify two new areas of focus on the IOM's prioritized agenda; and 3) explain the opportunities for laboratory medicine to broaden its impact in improving the quality of healthcare.

FULL DAY SYMPOSIA
10:30am - 12noon and 2:30pm - 5:00pm

Novel Applications of Genomic Profiling 32301
Moderator: Gregory Tsongalis, PhD, ABB, Dartmouth-Hitchcock Medical Center, Lebanon, NH
Level: Intermediate
CE Credit: 1.5 & 2.5
Developed in cooperation with Molecular Pathology Division

Session Overview: This symposium will provide an overview of novel uses of genomic profiling in the growing field of molecular diagnostics. Applications for oncology, genetics, pharmacogenomics, toxicogenomics and infectious disease testing will be presented.

Expected Outcomes: After attending this session, participants will be able to: 1) describe clinical molecular profiling techniques; 2) list applications of molecular profiling for various clinical scenarios; and 3) identify situations where molecular profiling may be most useful in patient management.

MORNING SPEAKERS

Oncology: miRNA Profiling in Human Cancers
Gregory Tsongalis, PhD, ABB, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Genomic Profiling in Genetic Disease Testing
William Highsmith, PhD, Mayo Clinic, Rochester, MN

AFTERNOON SPEAKERS

Pharmacogenomic Profiling in a Clinical Setting
KT Jerry Yeo, PhD, DABCC, FACB, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Toxicogenomic Profiling
Brian Spear, Abbott Laboratories, North Chicago, IL

Applications of Genomic Profiling to Infectious Disease Testing
David Persing, MD, Cepheid, Sunnyvale, CA

ILLUM-0092

Improving Clinical Utilization of Laboratory Data 32302

Moderator: Stuart Smellie, MA, DM, MRCP, FRCPath, County Durham and Darlington Acute NHS Trust, Bishop Auckland, United Kingdom
Level: Intermediate
CE Credit: 1.5 & 2.5
Developed in cooperation with Association for Clinical Biochemistry

Session Overview: This symposium will highlight methods for improved use of laboratory testing through the application of a more robust evidence-based approach which effectively integrates knowledge acquisition, guideline authorship and a range of knowledge dissemination mechanisms. In addition, the session will explore selected technological solutions for implementing these initiatives into routine clinical practice with a special emphasis on their extension to telehealthcare.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the applications for and limitations of evidence-based laboratory medicine; 2) explain how to establish and support a knowledge management network for the clinical users in the participant's country or state; 3) list key options available to turn knowledge into changes in practice; and 4) identify the optimal technologies to use for achieving these objectives.

MORNING SPEAKERS

Better Testing — Changing the Test Requesting Culture and the Clinical Benefit
Stuart Smellie, MA, DM, MRCP, FRCPath, County Durham and Darlington Acute NHS Trust, Bishop Auckland, United Kingdom

Providing IT Decision Aids for Test Ordering in Primary Care
Sharon Smart, MBBS, MRCGP, DCH, DRCOG, Dip Ther, Sowerby Centre for Health Informatics, Newcastle, United Kingdom

AFTERNOON SPEAKERS

Using Laboratory Informatics to Improve Test Use
Patrick Twomey, BSc, MB, BAO, BCh, MRCPath, Ipswich Hospital, United Kingdom

Latest Technological Solutions at the Bedside for Safe Ordering: Building on a National IT Infrastructure in the US and the UK
Richard Jones, Univ. of Leeds, United Kingdom

Test Utilization Extended to Telehealthcare
Craig Lehmann, PhD, C(NRCC), FACB, State Univ. of New York at Stony Brook

Health Issues After 40: Preparing the Laboratory to Meet the Demand 32303

Moderator: Linda Rogers, PhD, DABCC, FACB, Laguna Hills, CA
Level: Intermediate
CE Credit: 1.5 & 2.5

Session Overview: This symposium will address the utilization of laboratory tests critical to the health and well-being of the over-40 patient population. The session will focus on gender related health issues in the male (morning speakers) and female (afternoon speakers). Topics will include the management of hormone replacement, screening for cancer and the determination of cardiovascular risk.

Expected Outcomes: After attending this session, participants will be able to: 1) explain the management of hormone replacement therapy in men and women, by utilizing the appropriate hormone measurements; 2) describe the diagnosis and management of prostate disease using PSA and its isoforms; 3) summarize the most common cancers and tumor markers used in the management of cancer in women; 4) list the most critical assays required of the laboratory for servicing the over-40 population; and 5) justify the role of gender-specific reference ranges for relevant risk assessment tests.

MORNING SPEAKERS

Hormone Replacement, Not Just for Women Anymore
Leonard Marks, MD, Culver City, CA

Advances in the Management of Prostate Disease
George Klee, MD, PhD, Mayo Clinic, Rochester, MN

AFTERNOON SPEAKERS

The Controversy of Screening for Organ-Specific Cancer in Women
A. Michael Spiekerman, PhD, DABCC, Scott & White Memorial Hospital, Temple, TX

Keeping Women Hormonally Balanced After Age 40
Nisha Jackson, PhD, S. Oregon Health and Wellness, PC, Medford

Cardiovascular Disease: Women are Different!
Allan Jaffe, MD, Mayo Clinic, Rochester, MN

EXHIBIT 5

(Part II of VII)

OF

DECLARATION OF GREGORY F. HEATH

FULL DAY SHORT COURSE
10:30am - 12noon and 2:30pm - 5:00pm

Advances in Prenatal Screening for Fetal Chromosome Disorders 72304
Moderator: Andrew MacRae, PhD, FCACB, Univ. of Toronto, Canada
Level: Intermediate
CE Credit: 1.5 & 2.5

Session Overview: Prenatal screening for fetal chromosome disorders continues to grow in complexity and in the nature of disorders detected. New biochemical markers in maternal serum and urine, and ultrasound biometry can be combined to estimate a risk of targeted disorders in the first or second trimester, or across both trimesters.

Expected Outcomes: After this session, participants will be able to: 1) explain the principles of screening; 2) define at least three different modes of prenatal screening, comparing their strengths and limitations; 3) summarize recent literature that supports each screening modality; and 4) interpret examples of abnormal marker patterns.

MORNING SPEAKERS

Second Trimester Screening, Marker Choices and Laboratory Performance Validation
Andrew MacRae, PhD, FCACB, Univ. of Toronto, Canada

Introduction to Screening and Results of Recent Trials of First Trimester and Integrated Screening
Jacob Canick, PhD, Women & Infants Hospital, Providence, RI

AFTERNOON SPEAKER

Principles of Screening Including Contingency, Sequential and Repetitive Screening
Glenn Palomaki, BS, BA, Women & Infants Hospital, Providence, RI

MORNING SYMPOSIA
10:30am - 12noon

Autoimmune Disease Testing 32104
Moderator: Luis Andrade, MD, PhD, Fleury Diagnostics, São Paulo, Brazil
Level: Intermediate
CE Credit: 1.5

Session Overview: This symposium will present an overview of techniques used for autoantibody detection emphasizing how these techniques can aid in diagnosis in patients without apparent autoimmune disease. This session will also highlight a novel paradigm in autoantibody interpretation — consideration of the conjugated autoimmune response to different autoantigens — as well as offer a critical analysis of selected multiplex assays employed for autoantibody detection.

Expected Outcomes: After attending this session, participants will be able to: 1) list key factors in the use of the ANA-IIF test on HEP-2 cells; 2) recognize distinctive features of autoantibodies observed in patients without apparent autoimmune disease and their impact on test result interpretation; 3) describe the methodologies of multiplex assays which are used for autoantibody detection; and 4) explain the concept of autoantibody profiling.

SPEAKERS

Autoantibody Integrated Profiles as Potential Indicators of Clinical Phenotypes
Marvin Fritzler, MD, Univ. of Calgary, Canada

How to Interpret a Positive Autoantibody Test in an Apparently Healthy Individual
Luis Andrade, MD, PhD, Fleury Diagnostics, São Paulo, Brazil

HOT TOPIC – ANALYTICAL SYSTEMS/AUTOMATION/INSTRUMENTATION

SUNDAY FULL DAY SHORT COURSE 191012
Concepts and Practices in the Evaluation of Laboratory Methods

SUNDAY FULL DAY SHORT COURSE 191010
LC/MS/MS Instrumentation and Its Applications in Clinical Laboratory

MONDAY MORNING SHORT COURSE 72105
Automated Immunoassay: Past, Present and Future Trends

MONDAY BROWN BAG SESSION 42114/52214
Tandem Mass Spectrometry Assay Development: What it Takes to Bring and Keep an Assay Successfully On-Line

TUESDAY AFTERNOON SHORT COURSE 73210
Proteomics: Introduction to Mass Spectrometric Analysis of Proteins

TUESDAY AFTERNOON INTERACTIVE WORKSHOP 23202
High-Resolution DNA Melting Analysis

TUESDAY FULL DAY SYMPOSIUM 33303
Nanotechnology: Clinical Applications, Diagnostics and Therapeutics

WEDNESDAY BROWN BAG SESSION 44108/54208
Laboratory Automation, If I Knew Then What I Know Now

WEDNESDAY AFTERNOON SHORT COURSE 74206
The New Tools of Proteomics: Mass Spectrometry and Protein Microarrays

THURSDAY SYMPOSIUM 35101
Clinical Applications of Liquid Chromatography/Mass Spectrometry

ILLUM-0094

The Opportunities and Pitfalls of Using Information Technology to Decrease Postanalytic Errors 32105

Moderator: Michael Astion, MD, PhD, Univ. of Washington School of Medicine, Seattle
Level: Intermediate
CE Credit: 1.5
Developed in cooperation with AACC Patient Safety Taskforce

Session Overview: This symposium will focus on the use of information technology (IT) to reduce clinically significant postanalytic errors. Specifically, two aspects of IT will be addressed: 1) interfacing laboratory information systems to electronic medical records; and 2) use of automated paging systems in which the laboratory information system (LIS) or hospital information system (HIS) directly calls critical laboratory values to physicians and nurses caring for the patient. Presentations will focus on actual cases, and emphasize how to overcome the significant obstacles encountered when implementing these complex systems.

Expected Outcomes: After attending this session, participants will be able to: 1) cite two barriers to implementing a real-time interface between the laboratory information system (LIS) and electronic medical record (EMR) as well as describe how to overcome each barrier; 2) list two errors that occur in LIS-EMR interfaces and describe how these errors can harm patients; 3) describe the key features of a paging system in which the LIS or HIS automatically pages direct care providers with critical laboratory results; and 4) identify two barriers to successful implementation of an automated paging system for critical values and how to overcome them.

SPEAKERS

Triumphs and Tragedies in Interfacing Laboratory Information Systems to Electronic Medical Records
David Chou, MD, Univ. of Washington School of Medicine, Seattle

Real-time Notification of Critical Laboratory Data to Direct Care Providers
Gilad Kuperman, MD, PhD, New York Presbyterian Hospital, NY

Estimating GFR: Improving Early Detection of Kidney Disease 32106

Moderator: Elisa Gladstone, MPH, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD
Level: Intermediate
CE Credit: 1.5

Session Overview: This symposium is designed to inform laboratory professionals about important developments related to using estimated GFR for early detection of kidney disease. These developments include serum creatinine standardization, use of a revised Modification of Diet in Renal Disease (MDRD) equation, and automatic reporting of estimated Glomerular Filtration Rate (GFR).

Expected Outcomes: After attending this session, participants will be able to: 1) explain the importance of estimated GFR (eGFR) in early detection of kidney disease; 2) describe the rationale for, and progress in, the creatinine standardization program; 3) define the revised MDRD equation used to estimate GFR; and 4) cite key issues associated with instituting of routine and automatic reporting of eGFR to healthcare providers.

SPEAKERS

Estimating GFR from Serum Creatinine: Issues and Recommendations for Reporting
Greg Miller, PhD, Virginia Commonwealth Univ., Richmond

Improving GFR Estimation: The NKDEP Program to Standardize Serum Creatinine Measurement
Gary Myers, PhD, FACB, Centers for Disease Control & Prevention, Atlanta, GA

ILLUM-0095

MORNING INTERACTIVE WORKSHOPS
10:30am - 12noon

Veterinary Hematology: The Diagnostic Power of Peripheral Blood and Bone Marrow Evaluation 22101
Moderator/Speaker: Kay Criswell, Pfizer Global Research & Development, Ann Arbor, MI
Level: Intermediate
CE Credit: 1.5
Developed in cooperation with Animal Clinical Chemistry Division

Session Overview: This session will be conducted as a series of interactive case studies, examples, and audience/presenter discussion. Through these case studies the audience will gain insight into the differences of hematologic cell counts, peripheral blood erythrocyte and WBC morphology, and bone marrow morphology among several species. Cases will be presented in a manner that allows audience participation in the disease diagnosis of the animal, or in evaluation of the risk associated with administration of new drugs under development.

Expected Outcomes: After attending this session, participants will be able to: 1) distinguish differences between cell counts and peripheral blood morphology in mice, rats, rabbits, dogs cats, monkeys and some exotic species; 2) distinguish differences in bone marrow composition in mice, rats, dogs, and monkeys; 3) define hematologic criteria essential in the diagnosis of nutritional deficiencies, intravascular and extravascular hemolytic processes, blood loss and platelet abnormalities; and 4) display familiarity with typical sources of artifact and species-specific phenomenon that interfere with hematologic testing in animals.

Clinical Toxicology Cases 22102
Moderator: Ian Watson, PhD, FRCPath, Univ. Hospital Aintree, Liverpool, United Kingdom
Level: Intermediate
CE Credit: 1.5
Developed in cooperation with Association of Clinical Biochemists

Session Overview: In this workshop the investigation and treatment of a variety of different poisonings will be explored interactively with the audience. Cases with a series of options at different stages of the case scenario will let the audience consider appropriate differential diagnoses, investigations and interventions. The presenter will dynamically interact with the audience to highlight useful clinical and laboratory information. Speakers will make use of their respective national guidelines on the role of the laboratory in clinical toxicology.

Expected Outcomes: After attending this session, participants will be able to: 1) develop differential diagnoses for different poisonings; 2) select the most appropriate laboratory and toxicology investigations; 3) describe the most appropriate treatment options for different poisonings; and 4) identify and access authoritative guidance on these issues.

SPEAKERS

Acute Clinical Toxicology Case Presentations
Ian Watson, PhD, FRCPath, Univ. Hospital Aintree, Liverpool, United Kingdom

Chronic Clinical Toxicology Poisoning Cases
Tai Kwong, PhD, Univ. of Rochester Medical Center, NY

HOT TOPIC – CARDIAC MARKERS, CARDIOVASCULAR DISEASE

SUNDAY FULL DAY SHORT COURSE 191016
Biomarkers for Detection of Myocardial Injury, Risk Stratification and Heart Failure

MONDAY SPECIAL EVENT
Current Topics in Cardiovascular Disease and Stroke
AACC LVD Division Annual Dinner Meeting and Mixer

MONDAY FULL DAY SYMPOSIUM 32303
Health Issues after 40: Preparing the Laboratory to Meet the Demand

MONDAY AFTERNOON SHORT COURSE 72212
Coronary Heart Disease Risk Factors: What and How to Measure

TUESDAY BROWN BAG SESSION 43107/53207
D-dimer Assays and Rapid Emergency Department Triage of Patients Suspected of Thrombotic Disease

TUESDAY BROWN BAG SESSION 43106/53206
Coagulation Proteins as Biomarkers in Cardiovascular Diseases

TUESDAY BROWN BAG SESSION 43103/53203
Evaluation of High Sensitivity C-Reactive Protein Methods

TUESDAY BROWN BAG SESSION 43116/53216
Lipoprotein Subfractions and their Significance in Healthcare

WEDNESDAY BROWN BAG SESSION 44106/54206
Core Profile Testing During Cardiac Crises

WEDNESDAY BROWN BAG SESSION 44105/54205
Standardization of High-Sensitivity C-Reactive Protein Assays

WEDNESDAY AFTERNOON SYMPOSIUM 34208
Acute Coronary Syndromes: The Complete Story

WEDNESDAY BROWN BAG SESSION 44115/54215
C-Reactive Protein: A New Inflammatory Risk Factor for Cardiovascular Disease and Diabetes.

WEDNESDAY BROWN BAG SESSION 44111/54211
Lipid and Cardiac Profiling In Laboratory Animals

WEDNESDAY BROWN BAG SESSION 44114/54214
Challenges in Drug Development - Assessment of In Vitro Hemolysis: Study Design and Interpretation

MORNING SHORT COURSES
10:30am - 12noon

Automated Immunoassay: Past, Present and Future Trends 72105
Moderator/Speaker: Kenneth Blick, PhD, DABCC, ACS, FACB, Univ. of Oklahoma Health Sciences Center, Oklahoma City
Level: Intermediate
CE Credit: 1.5
Developed in cooperation with Clinical & Diagnostic Immunology Division

Session Overview: This program will review immunoassay techniques and steps required to automate immunoassays. Also covered during this session: required features of automated immunoassays; a review of current instruments and how well they address these requirements; integration of automated immunoassay instruments with total laboratory automation systems; automation approaches for stand alone systems; heterogeneous modules on chemistry analyzers; total automation with track system connections; and recent advances in point-of-care immunoassay testing and automation.

Expected Outcomes: After attending this session, participants will be able to: 1) list desirable and essential features of automated immunoassay instruments and methods; 2) evaluate automated immunoassay instruments and how well they achieve partial or total automation; 3) list three essential steps required to automate a method; and 4) describe how some approaches may be superior to others.

Computer Models in Medicine 72106
Moderator/Speaker: Martin Kroll, MD, Univ. of Texas Southwestern School of Medicine, Dallas
Level: Advanced
CE Credit: 1.5

Session Overview: This session will discuss ways in which computer models may be incorporated into test evaluation of outcome studies and test interpretation. Examples will be provided where the model chosen for the physiologic system alters interpretation of data, especially laboratory data such as PSA, glucose, and BNP.

Expected Outcomes: After attending this session, participants will be able to: 1) list the different types of models; 2) explain the compartmental model for analyte concentration; 3) show how kinetics imply cell growth; and 4) demonstrate the results for different sources of biological variation.

The Value of Laboratory Diagnostics in Healthcare 72107
Moderator: Roberta Madej, Roche Molecular Systems, Pleasanton, CA
Level: Intermediate
CE Credit: 1.5

Session Overview: The presentation will include: Integrating laboratory tests in clinical practice guidelines, using them as metrics for medical practice performance and establishing their value in different segments of healthcare. We will also discuss efforts to increase awareness of the value of laboratory medicine by professional organizations examining reimbursement, industry-supported reports, and government policy committees.

Expected Outcomes: After attending this session, participants will be able to: 1) discuss the integral role of laboratory testing in clinical practice guidelines, clinical studies and medical decision-making; 2) explain how the focus in "personalized" medicine and pharmacogenomics will increase reliance on new technologies and tests; and 3) analyze ways to determine and present the economic value of laboratory testing to medical and political communities.

SPEAKERS

Value of Diagnostic Medicine: The Lewin Report
Eric Faulkner, MPH, The Lewin Group, Falls Church, VA

ASCLS, CLMA and Other Professional Organizations Activities Regarding Revisions to the Lab Fee Schedule
Elissa Passiment, EdM, CLS (NCA), ASCLS, Bethesda, MD

Activities of the SACGHS
Emily Winn-Deen, PhD, Cepheid, Sunnyvale, CA

An Integrated Incident Reporting System to Reduce Medical Errors and Improve Patient Safety 72108
Moderator/Speaker: Leroy Mell, Jr., PhD, MBA, HCLD(ABB), Anne Arundel Medical Center, Annapolis, MD
Level: Intermediate
CE Credit: 1.5
Developed in cooperation with Management Sciences Division

Session Overview: A laboratory integrated, automated system for reporting, documenting, analyzing, trending and managing incidents related to patient safety will be presented. The automated Incident Reporting System (IRS) provides a real-time mechanism to integrate incident reports, patient records, responses and follow-up, incident report tracking, and data collection and analyses. Utilization of this procedure has significantly reduced laboratory-related errors.

Expected Outcomes: After attending this session, participants will be able to: 1) develop a no-blame culture that identifies opportunities for learning and change across the organization; 2) use trending and analysis of adverse incidents to enable change and reduce medical errors; and 3) identify areas for investigation to improve patient safety through analysis of incident trend data, e.g. labeling errors, blood culture contamination rate.

ILLUM-0097

MEET THE EXPERTS

2:00pm - 3:00pm

Attendance in this session is strictly limited. Advance registration is highly encouraged.

The Battle Against MRSA - We Can Win the War! 62003

Lance Peterson, MD, Evanston Northwestern Healthcare, Evanston, IL

Level: Intermediate

CE Credit: 1

Session Overview: This interactive session will address hospital-based screening of newly admitted patients for methicillin resistant Staphylococcus aureus (MRSA) colonization or infection to reduce hospital acquired MRSA acquisition and disease. The session will begin with an overview from Dr. Peterson on the benefits and challenges of this practice. The remainder of the session will be a question and answer discussion with the audience focusing on significant clinical issues with this practice, the roles of conventional and molecular MRSA testing, as well as the financial and operational factors to be considered.

Expected Outcomes: After attending this session, participants will be able to: 1) understand the need for better management of MRSA exposure risk; 2) learn how to develop the data to determine that a local MRSA problem exists; and 3) discuss how to develop a MRSA surveillance program.

AFTERNOON SYMPOSIA

2:30pm - 5:00pm

Challenges in Biomarker and Drug Co-Development and Regulation 32207

Moderator/Speaker: Carolyn Jones, AdvaMed, Washington, DC

Level: Intermediate

CE Credit: 2.5

Developed in cooperation with Industry Division

Session Overview: The advantages of *in-vitro* diagnostic devices designed to enhance the efficacy of drugs and other therapeutic agents are now well-established. To fully realize the potential benefits for patients and physicians, the processes of biomarker and drug co-development, particularly including regulatory approval, will require stakeholder cooperation as well as clarification of key areas of concern. Pharmaceutical companies are learning to redefine patient populations based on the genetic or molecular characteristics of the disease to simplify clinical trial cohorts and raise the efficacy rate of the drug by including only a pre-defined population in the clinical trial. The significant issues in biomarker and drug co-development and their regulation as well as possible solutions to the challenges encountered will be explored in this symposium.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the current thinking and newest FDA guidances for coordinated approvals of drugs/therapeutic agents and the *in-vitro* diagnostic devices that are intended to enhance the safe and effective use of the drug or therapeutic agent; and 2) explain the challenges faced by industry for product co-development when both the drug and device are expected to be offered by the same company as well as the additional challenges encountered when drug and device are developed by independent manufacturers.

SPEAKERS

The Regulatory View for Devices
Steven Gutman, MD, MBA, Food & Drug Administration-CDRH, Rockville, MD

The Regulatory View for Drugs
Lawrence Lesko, PhD, Food And Drug Administration, Rockville, MD

The Manufacturer's View for Development and Availability of Devices & Drugs
M.J. Finley Austin, PhD, Roche, Washington, DC

Recent Advances in Clinical Proteomics 32208
Moderator: Daniel Chan, PhD, DABCC, FACB, Johns Hopkins Medical Institutions, Baltimore, MD
Level: Intermediate
CE Credit: 2.5
Developed in cooperation with Proteomics Division

Session Overview: The growth of clinical proteomics has created new opportunities for clinical laboratory scientists to transform health care delivery through the use of personalized diagnostics and therapeutics. This symposium will provide an understanding of clinical proteomics, the application of proteomic technologies in biomarker discovery, validation strategies for these technologies, and the potential for their use in targeted diagnostics and therapeutics.

Expected Outcomes: After attending this session, participants will be able to: 1) explain the concepts of clinical proteomics; 2) evaluate the latest proteomic technologies; and 3) describe clinical applications for proteomics.

SPEAKERS

Clinical Proteomics: Opportunities for Diagnostics
Daniel Chan, PhD, DABCC, FACB, Johns Hopkins Medical Institutions, Baltimore, MD

Cancer Proteomics: Biomarker Identification and Signal Pathway Profiling.
Lance Liotta, MD, PhD, George Mason Univ., Manassas, VA

The Importance of Proteomic Biomarkers for the Pharmaceutical Industry
Scott Patterson, PhD, Amgen, Thousand Oaks, CA

HOT TOPIC – POCT

SUNDAY AFTERNOON INTERACTIVE WORKSHOP 191005
Hot Topics in Point-of-Care Testing

SUNDAY FULL DAY SHORT COURSE 191011
Blood Gas, Calcium, Magnesium, and Lactate Testing: Interpretation, Sample Handling, and Point-of-Care Applications

MONDAY AFTERNOON SYMPOSIUM 32209
Risk Management - A Practical Approach to a Quality POCT Program

TUESDAY BROWN BAG SESSION 43115/53215
POCT: The Right Test...Right Now!

TUESDAY AFTERNOON SYMPOSIUM 33206
Best Practices for the Operation and Management of Point-of-Care Testing

TUESDAY BROWN BAG SESSION 43119/53219
Using Point-of-Care Testing to Guide Transfusion Therapy

WEDNESDAY BROWN BAG SESSION 44116/54216
Effective Implementation of POCT in the Healthcare Setting

WEDNESDAY AFTERNOON SHORT COURSE 74207
Clinical Utilization of Laboratory Data: Using POC Glucose Data to Support Tight Glycemic Control

THURSDAY SPECIAL EVENT
Point-of-Care Coagulation Testing Annual POC Coordinator's Forum

Risk Management — A Practical Approach to a Quality POCT Program 32209
Moderator: Frank LaDuca, PhD, Bayer Healthcare, Tarrytown, NY
Level: Intermediate
CE Credit: 2.5
Developed in cooperation with Critical and Point-of-Care Testing Division

Session Overview: This symposium is designed to offer practical tools that can be used to develop an effective Quality Policy for POCT using a risk management based approach. Risk management theory and concepts, practical tools for implementation and the application of these to ensuring quality in POCT will be addressed.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the concept of applying Risk Management criteria for use in the development of a quality POCT program; 2) develop an awareness of the tools available for application of Risk Management to POCT; and 3) explain how to implement a risk management-based Quality System for POCT in a clinical institution.

SPEAKERS

What is Risk Management?
David Gronostajski, ITC, Edison, NJ

Clinical Application of Risk Management — Laboratory and End User Perspective
Valerie Ng, Alameda County Medical Center, Oakland, CA

Practical Application of Risk Management - Manufacturer and Laboratory Roles
Marcia Zucker, PhD, ITC, Edison, NJ

AFTERNOON INTERACTIVE WORKSHOP
2:30pm - 5:00pm

Having Problems Communicating With Your Staff? Find Out Why And How To Fix It! 22203
Moderator/Speaker: Cherie Petersen, ARUP Laboratories, Salt Lake City, UT
Level: Basic
CE Credit: 2.5

Session Overview: Effective communication skills are key to positive working relationships. This interactive session will provide participants with an easy method for determining preferred behavioral and interaction styles. Participants will assess their own behavioral style, practice assessing others' styles, and learn how to adapt to the individual communication needs of others.

Expected Outcomes: After attending this session, participants will be able to: 1) more comfortably enter into critical conversations by using the preferred behavioral style of those with whom they are communicating; 2) assess their own preferences for communication and learn how to identify and adapt to the communication styles and preferences of others; and 3) deliver verbal information to their employees in a more satisfying, effective and productive manner.

AFTERNOON SHORT COURSES
2:30pm - 5:00pm

Clinical Laboratory Informatics and the Electronic Health Record 72209
Moderator: William Coughlin, BS, MBA, Data Innovations North America, South Burlington, VT
Level: Intermediate
CE Credit: 2.5
Developed in cooperation with Laboratory Information Systems & Medical Informatics and TDM & Toxicology Divisions

Session Overview: This session will explore the process of integrating the laboratory information system with the Electronic Healthcare Record (EHR). It will describe the EHR, system architecture, standardized nomenclature, and use pharmacotherapy and laboratory data to demonstrate how the EHR is utilized. It will offer a framework to assist the laboratory in developing a strategic vision of its function within the healthcare enterprise and address how to participate in strategic planning.

Expected Outcomes: After attending this session, participants will be able to: 1) contribute to the development of an informatics strategic plan for their healthcare enterprise; 2) apply informatics solutions for the clinical laboratory; 3) guide multidisciplinary care teams providing patient-centered care using the EHR; 4) optimize the enterprise information architectures to integrate clinical laboratory components with Electronic Health Record components; and 5) utilize informatics solutions to improve management of the health care enterprise.

SPEAKERS

The National Health Information Infrastructure
David Bates, MD, Partners Healthcare, Boston, MA

Using Standards to Develop the Electronic Health Record
Peter Elkin, MD, Mayo Clinic, Rochester, MN

Application of the Health Information Architecture in Clinical Laboratories
Mark Diehl, DDS, MA, MPH, Computer Sciences Corporation, Frederick, MD

How to Eliminate False Positive and False Negative Results in Clinical Chemistry Laboratories 72210
Moderator: Amitava Dasgupta, PhD, DABCC, NRCC, Univ. of Texas at Houston Medical School
Level: Basic
CE Credit: 2.5
Developed in cooperation with TDM & Toxicology Division

Session Overview: This session will explore various causes of false positive and negative results ("assay discordance") and how to detect such results and resolve them ("find the truth"). Discussions will also include how assays may be designed to minimize such occurrences. During the first part of the session, the effects of preanalytical variables, interference, analyte heterogeneity, heterophilic antibodies, hook effect, and related factors will be presented. The second part of the session will focus on therapeutic drug monitoring and clinical toxicology. This course will be interactive and utilize case studies. Participants are strongly encouraged to bring related cases and problems from their own laboratory; these will be discussed during the course.

Expected Outcomes: After attending this session, participants will be able to: 1) detect false positive and negative ("discordant") results; 2) identify sources of discordant results in clinical laboratory results: preanalytic variables, interferences, analyte heterogeneity, matrix effect, heterophilic antibodies, and hook effect; 3) define the impact of serum collection tubes in TDM; 4) identify cross-reactivity to drug metabolites, endogenous factors, and herbal medicines and supplements as source of discordant results; and 5) identify the effects of urine adulterants on drugs-of-abuse results (includes demonstration).

SPEAKERS

How to Eliminate False Positive and False Negative Results in the Toxicology Laboratory
Amitava Dasgupta, PhD, DABCC, NRCC, Univ. of Texas at Houston Medical School

How to Eliminate False Positive and False Negative Results in General and Special Chemistry
Pradip Datta, PhD, DABCC, Bayer Healthcare LLC-Diagnostics, Tarrytown, NY

Successful Community Laboratory Outreach 72211
Moderator/Speaker: Rodney Forsman, Mayo Clinic, Rochester, MN
Level: Intermediate
CE Credit: 2.5

Session Overview: Community laboratory outreach contributes to enhanced patient care, physician satisfaction and cost effectiveness. In this program the benefits of laboratory outreach together with specific recommendations for developing various areas of service delivery will be explored through case studies and interactive discussion.

Expected Outcomes: After attending this session, participants will be able to: 1) articulate the benefits of a community laboratory outreach program; 2) identify opportunities to successfully compete in the marketplace; and 3) address barriers to service delivery issues that typically arise.

SPEAKER

Successful Community Laboratory Outreach
Linda Spiten, Mayo Clinic, Rochester, MN

ILLUM-0101

Coronary Heart Artery Risk Factors: What and How to Measure 72212

Moderator: Gary Myers, PhD, FACB, Centers for Disease Control & Prevention, Atlanta, GA

Level: Intermediate

CE Credit: 2.5

Developed in cooperation with Centers for Disease Control and Prevention, Lipoproteins and Vascular Diseases Division

Session Overview: This session will present an evaluation of new tests for HDL and LDL — the traditional risk markers of CAD — and will also provide an overview of emerging risk markers including inflammation markers, LDL subclasses, Lp(a), and apolipoproteins. Attendees will be provided with information on clinical utility, how to measure these markers, what factors affect measurement, and recommendations for minimizing their impact.

Expected Outcomes: After this session, participants will be able to: 1) list the various parameters considered as risk factors for coronary disease; 2) describe the advantages and disadvantages of the various analytical methods for testing; 3) list influences that may affect test results; and 4) implement recommended techniques and procedures for assuring quality measurements.

SPEAKERS

New Tests for Traditional Markers of Coronary Heart Disease
Greg Miller, PhD, Virginia Commonwealth Univ., Richmond, VA

Lipoprotein Subclasses and Apolipoproteins — How Important Are They?
Judith McNamara, MT, Jean Mayer USDA Human Nutrition Research on Aging of Tufts Univ., Milton, MA

C-Reactive Protein and Other Markers of Inflammation
Gary Myers, PhD, FACB, Centers for Disease Control & Prevention, Atlanta, GA

Nephrotoxicity: Evaluation of Renal Effects in Multiple Species 72213

Moderator: Kay Criswell, Pfizer Global Research & Development, Ann Arbor, MI

Level: Intermediate

CE Credit: 2.5

Developed in cooperation with Animal Clinical Chemistry Division

Session Overview: This session will discuss anatomy and physiology of the kidney and highlight multispecies differences in such areas as urine formation, electrolyte and water homeostasis, and renal diseases. Participants will also learn about the pitfalls of using routine clinical pathology biomarkers in the diagnosis of nephrotoxicity in animals, as well as advances in gene- and protein-based biomarkers as early predictors of nephrotoxicity.

Expected Outcomes: After attending this session, participants will be able to: 1) describe key components of renal anatomy and physiology; 2) explain key differences in the physiology and anatomy in domestic and laboratory animals; 3) summarize major renal disease processes; 4) define advantages and limitations of using routine clinical pathology parameters to assess nephrotoxicity in animals; and 5) describe alternative renal markers that may play a role in the early detection of subtle nephrotoxicity in animal models.

SPEAKERS

Nephrotoxicity in Multispecies: Anatomic and Physiologic Features of Mechanistic Relevance
Susan Emeigh-Hart, VMD, PhD, DACVP, DABT, Genaera Corporation, Plymouth Meeting, PA

Assessment of Routine and Esoteric Clinical Pathology Biomarkers to Evaluate Nephrotoxicity in Animals
Denise Bounous, DVM, PhD, Bristol-Myers Squibb Co., Princeton, NJ

Biomarkers of Nephrotoxicity: From Gene Expression to Traceable Proteins to Application
Rabih Slim, PhD, Pfizer Global Research & Development, Ann Arbor, MI

ILLUM-0102

HOT TOPIC – REGULATION/QA/QC/STANDARDS

SATURDAY SPECIAL EVENT
MSD Leadership Seminar: The Truth About Quality Today

SUNDAY FULL DAY SHORT COURSE 191012
Concepts and Practices in the Evaluation of Laboratory Methods

MONDAY BROWN BAG SESSION 42119/52219
Alternative Medicinals: Impact on Clinical Laboratory Medicine

MONDAY MORNING SHORT COURSE 72108
An Integrated Incident Reporting System to Reduce Medical Errors and Improve Patient Safety

MONDAY BROWN BAG SESSION 42116/52216
Assuring the Reliability of Manufacturer's QC Recommendations

MONDAY BROWN BAG SESSION 42107/52207
ROC Curves: How, Why and Always - 2006

MONDAY AFTERNOON SYMPOSIUM 32209
Risk Management - A Practical Approach to a Quality POCT Program

MONDAY AFTERNOON SHORT COURSE 72210
How to Eliminate False Positive and False Negative Results in Clinical Chemistry Laboratory

TUESDAY FULL DAY SYMPOSIUM 33302
Improving the Total Testing Cycle Through Partnerships - The New IQLM

TUESDAY MORNING SHORT COURSE 73106
Clinical Laboratory Method Evaluation: How Do CLSI Guidelines Compare With Contemporary Practice?

TUESDAY BROWN BAG SESSION 43109/53209
The Impact of the NGSP on Glycated Hemoglobin (HbA1c) Measurement

TUESDAY BROWN BAG SESSION 43108/53208
Homebrews and Alphabet Soup: An Introduction to Molecular Diagnostics Regulatory Issues

TUESDAY BROWN BAG SESSION 43104/53204
Assay Standardization, From Science, Manufacturing and Regulatory Viewpoints

WEDNESDAY MORNING SHORT COURSE 74104
College of American Pathologists' Laboratory Accreditation Program in 2006

WEDNESDAY FULL DAY SYMPOSIUM 34303
Best Practices in Molecular Pathology

WEDNESDAY MORNING SHORT COURSE 74105
Statistical and Graphical Tools for the Laboratory

WEDNESDAY MORNING SYMPOSIUM 34106
Extending Traceability to the Laboratory, EQAS and Proficiency Systems - Advantages, Obstacles and Issues

WEDNESDAY AFTERNOON SYMPOSIUM 34207
Healthcare Forum: Legislative, Regulatory and Workforce Issues

WEDNESDAY BROWN BAG SESSION 44113/54213
Autoverification of Clinical Chemistry Results

WEDNESDAY AFTERNOON INTERACTIVE WORKSHOP 24201
Training and Competency Testing of Clinical Laboratory Personnel

WEDNESDAY BROWN BAG SESSION 44117/54217
ISO 15189, ISO 9001 and ISO 14001 Standards and Their Applicability in Accreditation and Certification Programs for Clinical Laboratories

WEDNESDAY BROWN BAG SESSION 44104/54204
Opening Pandora's Box: Assessing Linearity

WEDNESDAY BROWN BAG SESSION 44102/54202
Resources for Standardization and Quality in Molecular Diagnostics

WEDNESDAY MORNING SYMPOSIUM 34104
Clinician's Perceptions of Waived Testing: Is There an Impact on Patient Safety?

THURSDAY SYMPOSIUM 35104
A New Level of Quality Management in Clinical Laboratories Through ISO Standards, Lean Principles and Design for Six Sigma.

THURSDAY SYMPOSIUM 35103
Making Sense of the Alphabet Soup of Laboratory Regulations

TUESDAY'S SCHEDULE

7:00am – 9:00am
Local Section Chairs and Chairs Elect Breakfast
Hyatt Regency Chicago

7:30am – 8:30am
Brown Bag Sessions

7:30am – 9:30am
AICCNA Breakfast Meeting
Hyatt Regency Chicago

8:45am – 10:15am
Plenary Session

8:00am – 12noon
OEM Lecture Series
McCormick Place Convention Center

9:30am – 5:00pm
Expo Open

10:00am – 11:30am
DACC Executive Meeting
Hyatt Regency Chicago

10:30am – 11:30am
Meet the Experts

10:30am – 12noon
Symposia

10:30am – 12noon
Short Courses

10:30am – 12noon
Interactive Workshops

11:30am – 2:30pm
CLSI Area Committte on Clinincal Chemistry and Toxicology
Hyatt Regency McCormick

12:00noon – 2:00pm
DACC General Meeting
Hyatt Regency Chicago

12:00noon – 3:00pm
IFCC Corporate Members Meeting
Hyatt Regency Chicago

12:00noon – 4:30pm
History Division Executive Committee Meeting
Hyatt Regency Chicago

12:30pm – 1:30pm
Brown Bag Sessions

12:30pm – 2:00pm
Proteomics Division Luncheon
Hyatt Regency Chicago

12:30pm – 2:00pm
Midwest Section Business Meeting and Luncheon
Hyatt Regency Chicago

1:00pm – 2:00pm
Pediatric and Maternal-Fetal Division Reference Range Initiative Meeting
Hyatt Regency Chicago

2:30pm – 5:00pm
Symposia

2:30pm – 5:00pm
Short Courses

2:30pm – 5:00pm
Interactive Workshops

5:00pm – 6:00pm
CPOCT Annual General Meeting
Hyatt Regency Chicago

5:00pm – 6:00pm
Molecular Pathology Division General Membership Meeting
Hyatt Regency Chicago

5:00pm – 7:00pm
Washington University Clinical Chemistry Alumni Reception
Hyatt Regency Chicago

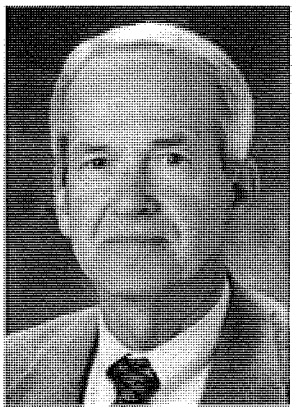
6:00pm – 8:00pm
CPOCT Division Mixer
Hyatt Regency Chicago

ILLUM-0104

PLENARY SESSION
8:45am - 10:15am

Employer Managed Healthcare: Corporations Get Back into the Healthcare Business 13001

Leonard Quadracci, MD, Quad/Graphics, Inc, West Allis, WI



Level: Basic

CE Credit: 1

Session Overview: "Employer Managed Healthcare" used to mean a company clinic with the presence of a nurse and, sometimes, a physician. But the prevailing form of healthcare delivery can change almost as quickly as its mechanisms for reimbursement. This session will spotlight a new model for employer managed healthcare that is fully self-insured, consists of self-delivered primary and specialty care, and achieves desirable health outcomes for one corporation's employees. Two key outcomes to be discussed are those of increased wellness and reduced morbidity in employees. Of particular interest to the AACC audience is the incorporation of onsite laboratory services into the payor/provider's delivery of care.

Expected Outcomes: After attending this session, participants will be able to: 1) Discuss the emerging role of Employer Managed Healthcare; 2) identify the role that laboratory medicine plays in this form of managed healthcare delivery; 3) compare and contrast the key aspects in use of selected models of care delivery in the U.S.; 4) describe the relationship between health, productivity and employer/employee satisfaction; and 5) explain the significance that focusing on quality measures plays in effectively directing the provision of optimal healthcare.

2006 NACB Awards to be presented during this Plenary Session

Y. M. Dennis Lo, MD
Distinguished Scientist Award
Outstanding Research Advances in Clinical Biochemistry
Sponsored by Dade Behring Inc.

John E. Sherwin, PhD, DABCC, FACB
Professor Alvin Dubin Award
Distinguished Contributions to the Profession and the Academy
Sponsored by Abbott Diagnostics

Linnea M. Baudhuin, PhD
George Grannis Award
Excellence in Research and Scientific Publication
Sponsored by NACB and the Ohio Valley Local Section

BROWN BAG SESSIONS

7:30am - 8:30am and 12:30pm - 1:30pm

Brown Bag Sessions are repeated twice daily. Attendance is limited to 10 participants per session. AACC does not provide meals for these sessions. You will be able to purchase your own food in the Convention Center prior to the session.

Session numbers beginning with a "4" are morning sessions. Those beginning with a "5" are noon-time sessions.

CE Credit: Each Brown Bag session is eligible for one hour

Vitamin B12 Deficiency and Its Laboratory Investigation 43101 or 53201
Majid Moridani, PharmD, PhD, DClinChem, Texas Tech School of Pharmacy & School of Medicine, Amarillo
Level: Intermediate
Developed in cooperation with Nutrition Division

Drug Interferences — The Unsolved Problem 43102 or 53202
Oswald Sonntag, Ortho-Clinical Diagnostics Gmbh, Eichenau, Germany
Level: Basic

Evaluation of High Sensitivity C-Reactive Protein Methods 43103 or 53203
William Roberts, MD, PhD, Univ. of Utah, Salt Lake City
Level: Intermediate

Assay Standardization from Scientific, Manufacturing and Regulatory Viewpoints 43104 or 53204
Pradip Datta, PhD, DABCC, Bayer Healthcare LLC-Diagnostics, Tarrytown, NY
Level: Basic
Developed in cooperation with TDM & Toxicology Division

Hepatitis C Virus: Epidemiology, Diagnosis and Patient Management 43105 or 53205
Peter Chou, PhD, DABCC, Quest Diagnostics Nichols Institute, Chantilly, VA
Level: Intermediate

Coagulation Proteins as Biomarkers in Cardiovascular Diseases 43106 or 53206
Shu-Ling Liang, Johns Hopkins Univ. School of Medicine, Baltimore, MD
Level: Basic
Developed in cooperation with Lipoproteins and Vascular Diseases Division

D-dimer Assays and Rapid Emergency Department Triage of Patients Suspected of Thrombotic Disease 43107 or 53207
David Plaut, Plano, TX
Level: Intermediate
Developed in cooperation with Lipoproteins and Vascular Diseases Division

Homebrews and Alphabet Soup: An Introduction to Molecular Diagnostics Regulatory Issues 43108 or 53208
Theresa Ambrose, PhD, DABCC, FACB, RAC, Roche Diagnostics Corporation, Indianapolis, IN
Level: Basic

The Impact of the NGSP on Glycated Hemoglobin (HbA1c) Measurement 43109 or 53209
Randie Little, PhD, Univ. of Missouri at Columbia
Level: Intermediate

New Pharmacogenomic Tests: Coming to a Lab Near You 43111 or 53211
Michael Murphy, Gentris Corporation, Morrisville, NC
Level: Intermediate
Developed in cooperation with Molecular Pathology Division

Antioxidant Supplementation and Its Effect on Clinical Outcomes in Critical Illness 43112 or 53212
Vinita Mishra, Liverpool, United Kingdom
Level: Intermediate
Developed in cooperation with Nutrition Division

ILLUM-0106

Lipemia and Laboratory Interference Issues
43113 or 53213
Patrick Twomey, BSc, MB, BAO, BCh, MRCPath, Ipswich Hospital, United Kingdom
Level: Basic

Risk Assessment For Healthy Persons — A New Concept In Laboratory Medicine 43114 or 53214
Rolf Hinzmann, MD, PhD, SYSMEX GmbH, Norderstedt, Germany
Level: Basic

POCT: The Right Test...Right Now! 43115 or 53215
Charles Weinzierl, BS, ASCP, Beckman Coulter, Inc., Chaska, MN
Level: Intermediate
Developed in cooperation with Critical and Point-of-Care Testing Division

Lipoprotein Subfractions and Their Significance in Healthcare 43116 or 53216
Nehemias Muniz, Quantimetrix Corp., Redondo Beach, CA
Level: Basic

Laboratory Diagnosis of Alcohol Poisoning
43117 or 53217
Kenneth Ihenetu, Univ. of Louisville, KY
Level: Intermediate

Role of the Clinical Laboratory in Clinical Trials for the Development of Drugs by the Pharmaceutical Industry 43118 or 53218
Thomas Cole, PhD, DABCC, FACB, Linco Diagnostic Services, Inc., St. Charles, MO
Level: Basic

Using Point-of-Care Testing to Guide Transfusion Therapy 43119 or 53219
Paula Santrach, MD, Mayo Clinic, Rochester, MN
Level: Intermediate
Developed in cooperation with Critical and Point-of-Care Testing Division

Testing for Alpha 1-antitrypsin Deficiency
43120 or 53220
Joshua Bornhorst, Univ. of Utah/ARUP Labs, Salt Lake City
Level: Intermediate

Prenatal Screening for Fetal Down Syndrome
43121 or 53221
Andrew MacRae, PhD, FCACB, Univ. of Toronto, Canada
Level: Intermediate

Looking Back: Evaluating the Impact of Health and Disease on Famous Artists and Politicians
43122 or 53222
Paul Wolf, MD, ABP, Univ. of California, San Diego
Level: Basic
Developed in cooperation with History of Clinical Chemistry Division

Driving Exponential Results with Value Stream Mapping: A Visual Link between Lean and Six Sigma 43125 or 53225
Michele Long, Ortho-Clinical Diagnostics, Raritan, NJ
Level: Basic
Developed in cooperation with Management Sciences Division

Protocols for Use of Thyroid Function Tests
43126 or 53226
Vidya Bhogadi, MBBS, MD, S.F.G.H, San Fernando, Trinidad & Tobago
Level: Intermediate

Emerging Biochemical Markers for the Evaluation of Anemia 43127 or 53227
Susan Retka, Beckman Coulter, Inc., Chaska, MN
Level: Intermediate

MEET THE EXPERTS

10:30am - 11:30am

Attendance in these sessions is strictly limited. Advance registration is highly encouraged.

One Corporation's Entry Back into the Healthcare Business 63001

Leonard Quadracci, MD, Quad/Graphics, Inc, West Allis, WI

Level: Intermediate

CE Credit: 1

Session Overview: Healthcare delivery is dynamic. In something of a return to more innocent times, Dr. Quadracci's corporation has created a model of care that is fully self-insured and includes self-delivered primary and specialty care for its employees. Significant inroads into increasing wellness and reducing morbidity have been made. The incorporation of laboratory services has been an important element of this onsite care delivery model. This session will provide a more in-depth and more intimate discussion of the topics raised in the accompanying Plenary session.

Expected Outcomes: After attending this session, participants will be able to: 1) list the reasons for the re-emergence of employer-provided healthcare; 2) evaluate the role that laboratory medicine plays in this model of healthcare delivery; 3) describe the models of care delivery in the United States and their track record; 4) explain the relationship between health, productivity and employer/employee satisfaction; and 5) understand the role that quality measurements play in directing the provision of optimal care.

The Role of the Clinical Laboratory during an Influenza Outbreak 63002

Angela Caliendo, MD, PhD, Emory Univ. Hospital, Atlanta, GA

Level: Intermediate

CE Credit: 1

Session Overview: This session will cover current issues that the clinical laboratory may face if challenged with an influenza outbreak. Dr. Caliendo will offer a short overview of the diagnostic options, describe which tests fit which clinical situations, and suggest what to think about in a pandemic when drug and diagnostic reagents may be in short supply. The session will be devoted to participant-led discussions of topics such as what is going on in the field, experiences, application of new tests and technologies and various institutional programs to address an influenza outbreak.

Expected Outcomes: After attending this session, participants will be able to: 1) better address questions that may arise from clinicians and patients; 2) participate more effectively in institutional preparedness for an influenza outbreak; and 3) decide which technologies and tests can be applied in their own laboratories.

FULL DAY SYMPOSIA

10:30am - 12noon and 2:30pm - 5:00pm

Pharmacogenetics Practice Guidelines I: Establishing Clinical Applications 33301

Moderator: Roland Valdes, Jr., PhD, DABCC, FACB, Univ. of Louisville School of Medicine, KY

Level: Intermediate

CE Credit: 1.5 & 2.5

Developed in cooperation with NACB, and the Molecular Pathology and TDM & Toxicology Divisions

Session Overview: The National Academy of Clinical Biochemistry (NACB; The Academy of the AACC) is in the process of establishing laboratory management practice guidelines (LMPGs) for the clinical application of pharmacogenetics (PGx) testing in healthcare. This new dynamic discipline of clinical pharmacogenetics is recognized to have significant potential for reducing serious adverse drug reactions, including consequences to healthcare that surround use of multiple medications, etc. In this two-day symposium we will review the NACB practice guidelines as developed by experts in this discipline who have contributed to this important topic through committees and extensive review activities. Evidence-based applications of pharmacogenetics will be presented to support the recommended guidelines and will include a grading of the evidence available. Importantly, these guidelines will also point to and suggest areas where evidence still needs to be strengthened and recommend criteria for providing that evidence. The symposia will provide the audience insight into this growing clinical laboratory service, as well as an open forum for discussing these guidelines before they are finalized and published. Input from clinical laboratory personnel, the *in-vitro* diagnostic industry, pharmacists, clinical practitioners and regulatory agencies will be very important in finalizing these practice guidelines in pharmacogenetics.

Expected Outcomes: After attending this session, participants will be able to: 1) cite the parameters that are necessary to provide optimum pharmacogenetics testing in specific clinical settings; 2) explain the potential links in the roles of pharmacogenetics and therapeutic drug monitoring in clinical settings; 3) describe and formulate recommended guidelines for clinical laboratories introducing pharmacogenetics testing services; 4) list the necessary parameters for optimizing clinical assays needed in pharmacogenetics testing; and 5) describe recommended parameters for optimizing their reimbursement and regulatory functions.

MORNING SPEAKERS

General Introduction (Scope and Approach-Objectives of LMPG, Definitions in PGx, Grading Evidence)
Roland Valdes, Jr., PhD, DABCC, FACB, Univ. of Louisville School of Medicine, KY

Fundamentals of Population Genetics Applied to Pharmacogenomics
Gualberto Ruano, MD, PhD, Genomas, Inc., Hartford, CT

AFTERNOON SPEAKERS

Methodology and Quality Assurance in PGx Testing
Deborah Payne, PhD, Univ. of Texas Medical Branch, Galveston

Providing Clinical Laboratory Services in PGx
Mark Linder, PhD, DABCC, Univ. of Louisville, Louisville, KY

Reporting and Interpretation of PGx Test Results
Jean-Pierre Morello, Seryx-Signature Genetics, Montreal, Canada

HOT TOPIC – GENOMICS/PROTEOMICS

SATURDAY SPECIAL EVENT
Metabolomic Markers in Diet and Health

SUNDAY FULL DAY SHORT COURSE 191010
LC/MS/MS Instrumentation and Its Applications in Clinical Laboratory

MONDAY PLENARY 12001
Computing in the Age of the Genome

MONDAY SYMPOSIUM 32301
Novel Applications of Genomic Profiling

MONDAY AFTERNOON SYMPOSIUM 32208
Recent Advances in Clinical Proteomics

TUESDAY MORNING SYMPOSIUM 33104
Urinary Proteomics: A Golden Opportunity for Improved Diagnosis of Renal and Systemic Disorders

TUESDAY AFTERNOON SHORT COURSE 73210
Proteomics: Introduction to Mass Spectrometric Analysis of Proteins

WEDNESDAY AFTERNOON SHORT COURSE 74206
The New Tools of Proteomics: Mass Spectrometry and Protein Microarrays

THURSDAY SYMPOSIUM 35102
Nutrigenomics: The Connection Between Nutrition and Genes

Improving the Total Testing Cycle Through Partnerships — The New IQLM 33302

Moderator: D. Robert Dufour, MD, VA Medical Center, Washington, DC
Level: Intermediate
CE Credit: 1.5 & 2.5
Developed in cooperation with Institute for Quality in Laboratory Medicine

Session Overview: The Institute of Quality of Laboratory Medicine (IQLM) is a partnership of laboratorian and clinician organizations, diagnostics manufacturers, government agencies, patient groups and payers that has been developed to focus on improvements in laboratory testing. This symposium will give an overview of IQLM, summarize its activities in developing quality indicators and laboratory networks, and review significant laboratory quality and patient safety data compiled, in part, through IQLM activities.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the structure and function of the IQLM and the role it will play in improving laboratory quality; 2) identify key indicators of laboratory quality for consideration in their own laboratories; and 3) identify sources of laboratory quality information to be used to compare their own performance.

MORNING SPEAKERS

The Institute for Quality in Laboratory Medicine — A New Entity in the Quality Field
D. Joe Boone, PhD, Centers For Disease Control and Prevention, Atlanta, GA

The Physician's Perspective on Laboratory Errors in the Ambulatory Setting
Nancy Elder, MD, Univ. of Cincinnati, OH

AFTERNOON SPEAKERS

Quality Practices Used by Laboratories — Report of the IQLM Laboratory Network
Barbara Goldsmith, PhD, St. Elizabeth's Medical Center, Boston, MA

Laboratory Quality Indicators — How Do We Know How We're Doing?
Lee Hilborne, MD, MPH, DLM, Univ. of California Los Angeles, CA

The National Laboratory Quality Report — Where Are We Now?
D. Robert Dufour, MD, VA Medical Center, Washington, DC

Nanotechnology: Clinical Applications, Diagnostics and Therapeutics 33303
Moderator: Paul Jannetto, PhD, Medical College of Wisconsin, Milwaukee
Level: Intermediate
CE Credit: 1.5 & 2.5
Developed in cooperation with Molecular Pathology Division

Session Overview: This symposium will introduce attendees to nanotechnology and the regulatory issues raised in implementing its use. In this session, several clinical applications of nanotechnology in diagnostics and therapeutics will be presented.

Expected Outcomes: After attending this session, participants will be able to: 1) explain the basic concepts of nanotechnology and identify its role in medicine; and 2) list specific clinical and medical applications of nanotechnology.

MORNING SPEAKERS

Nanotechnological Tools that will Impact Molecular Diagnostics
Chad Mirkin, Ph.D., Northwestern Univ., Evanston, IL

Microminiaturization: Current Status and Link to Nanoscale Diagnostics
Larry Kricka, DPhil, FACB, Univ. of Pennsylvania Medical Center, Philadelphia

AFTERNOON SPEAKERS

Nano-Technology: Bringing the Big Picture to Clinical Applications
Kaiser Aziz, PhD, Medical Quality International, Silver Spring, MD

Nanotechnology for SNP Detection
Paolo Fortina, MD, PhD, Thomas Jefferson Univ., Philadelphia, PA

Molecular Diagnostic Applications of Nanotechnology-Coagulation, CYP450
Paul Jannetto, Ph.D., Medical College of Wisconsin, Milwaukee

FULL DAY SHORT COURSE
10:30am - 12noon and 2:30pm - 5:00pm

Business Opportunities for Clinical Labs in Pharmaceutical Discovery and Development 73303
Moderator: Michael Stocum, MS, Tricon Pharmaceuticals, Research Triangle Park, NC
Level: Intermediate
CE Credit: 1.5 & 2.5
Developed in cooperation with the Industry and Molecular Pathology Divisions

Session Overview: This session will explore clinical laboratory testing and assay development support needed by pharmaceutical companies, such as developing genomics and proteomics biomarkers (needed for clinical validation during clinical trials) or developing new TDM tests. Business aspects will also be discussed, including generation of revenue from testing and transitioning validated biomarkers into novel products for IVD companies.

Expected Outcomes: After attending this session, participants will be able to: 1) identify testing and product opportunities for their own laboratories; 2) describe how business revenues may be extracted from clinical service testing, biomarker validation and partnering for diagnostic product development; and 3) translate the needs of pharmaceutical companies seeking to integrate genomic, proteomic and other biomarker discovery initiatives into clinical trials and ultimately clinical practice.

MORNING SPEAKERS

Biomarker Driven Pharmaceutical Trials: Business Opportunities for Clinical Laboratories and Diagnostic Companies
Michael Stocum, MS, Tricon Pharmaceuticals, Research Triangle Park, NC

Clinical Laboratory Testing Needs of Biotechnology Companies
Scott Patterson, PhD, Amgen, Thousand Oaks, CA

AFTERNOON SPEAKERS

Genetics in Clinical Medicine
Raju Kucherlapati, PhD, Harvard Partners Center for Genetics and Genomics, Boston, MA

Building A Biomarker Business: Clinical Validation Testing and Biomarker Licensing
Meeta Patnaik, MD, Pathway Diagnostics, Malibu, CA

Pharmaceutical Testing: Transitioning From Service Laboratory to IVD Products
Walter Carney, PhD, Oncogene Science/Bayer HealthCare LLC, Cambridge, MA

ILLUM-0110

MORNING SYMPOSIA
10:30am - 12noon

Urinary Proteomics: A Golden Opportunity for Improved Diagnosis of Renal and Systemic Disorders 33104
Moderator: Glen Hortin, MD, PhD, NIH Department of Laboratory Medicine, Bethesda, MD
Level: Basic
CE Credit: 1.5
Developed in cooperation with Proteomics Division

Session Overview: This symposium will provide an overview of the current test methods and applications for analysis of urinary proteins. This session will also focus on the prospects for new markers and tests based on analysis of proteins by mass spectrometry and other new technologies.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the physiology of protein, urinary protein and peptide excretion; 2) cite current methods and diagnostic applications for urinary protein analysis; and 3) identify potential new methods and applications for urinary protein analysis.

SPEAKERS

From Current Laboratory Practice to Future Proteomic Analysis of Urine Specimens
Glen Hortin, MD, PhD, NIH Department of Laboratory Medicine, Bethesda, MD

Urine Proteomics in Renal Dysfunction: Transplant Rejection and Renal Ischemia
William Clarke, PhD, Johns Hopkins Medical Institutions, Baltimore, MD

Menopause: Diagnosis, Symptoms and Clinical Management 33105
Moderator: Laurence Demers, PhD, DABCC, FACB, MS Hershey Medical Center/Penn State Univ., Hershey
Level: Basic
CE Credit: 1.5

Session Overview: This symposium will focus on the key issues associated with the diagnosis, symptoms and clinical management of menopause. Menopause is a natural process associated with a decline in reproductive potential of the middle-age woman. During menopause, many women experience moderate to severe clinical problems and symptoms such as hot flashes and osteoporosis that are due to decreased production of estrogen, a problem that can be effectively treated if properly diagnosed. In fact, a wide variety of treatment strategies are used to minimize or eliminate the symptoms of menopause. Hormonal testing is frequently used to both confirm the presence of menopause and to gauge efficacy of the various treatments used to moderate this condition in post-menopausal women.

Expected Outcomes: After attending this session, participants will be able to: 1) explain the key physiologic and clinical features of menopause, its prevalence and the severity of selected symptoms; 2) describe the appropriate use of laboratory tests to establish the diagnosis of menopause; and 3) monitor the response to different therapies used to treat the menopausal symptoms.

SPEAKERS

Prevalence, Severity and Treatment of Menopausal Symptoms
Rhoda Cobin, MD, Mt. Sinai School of Medicine, Midland Park, NJ

Clinical Management of Menopause: Laboratory Perspective
Laurence Demers, PhD, DABCC, FACB, MS Hershey Medical Center/Penn State Univ., Hershey

MORNING INTERACTIVE WORKSHOP
10:30am - 12noon

Adventures in the Gamma Zone 23101
Moderator/Speaker: James Faix, MD, Stanford Univ. Medical Center, CA
Level: Advanced
CE Credit: 1.5
Developed in cooperation with Clinical & Diagnostic Immunology Division

Session Overview: This session deals with the identification of monoclonal immunoglobulin in patients suspected of having multiple myeloma, lymphoma, amyloidosis or other lymphoproliferative disorders. After a brief introduction detailing traditional approaches (protein electrophoresis, immunoelectrophoresis and immunofixation) and recent alternatives (capillary electrophoresis and serum free light chain), the moderator will present cases submitted by the participants. Participants should contact the moderator in advance and submit a puzzling pattern or perfect example of a classic finding. These may be the actual stained gels or (preferably) digitized images. The participant may, if she or he chooses, introduce the submitted case to the group. The moderator will organize the submitted cases into several themes and, after discussion of the cases in each theme, present a brief summary of the teaching points. Probable themes will include: sensitivity during screening and follow-up; criteria for "monoclonal gammopathy of undetermined significance" (MGUS); "pseudo"-bands; quantifying Bence-Jones protein; analysis of cerebrospinal fluid; unusual clinical syndromes associated with monoclonal immunoglobulin; and interferences by monoclonal immunoglobulin with other laboratory assays.

Expected Outcomes: After attending this session, participants will be able to: 1) improve interpretation of non-specific findings when reviewing protein and immunofixation electrophoresis of serum and urine; 2) utilize alternative markers for monitoring of myeloma and monoclonal gammopathy of undetermined significance; and 3) recognize unusual clinical syndromes and assay interferences associated with monoclonal immunoglobulin.

MORNING SHORT COURSES
10:30am - 12noon

Fetal and Perinatal Nutrition: Impact on Future Health 73104
Moderator: Vijay Laxmi Grey, PhD, FCACB, McMaster Univ. Medical Centre, Hamilton, Canada
Level: Intermediate
CE Credit: 1.5
Developed in cooperation with Pediatric and Maternal-Fetal Division

Session Overview: This session is intended to review the current information on the fetal and neonatal origins of chronic diseases of adulthood such as cardiovascular disease, type 2 diabetes and osteoporosis. It will include a discussion of pre- and perinatal nutrition, the physiological responses and possible effects on long-term health.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the impact of maternal health and fetal nutrition on future health; 2) describe how perinatal nutrition (breast milk, formula and parental nutrition) impacts body mass and future health; 3) list adult diseases that have been linked epidemiologically with poor nutrition; and 4) discuss the effect of nutrition on endocrine responses.

SPEAKERS

Fetal and Early Childhood Origins of Adult Disease
Katherine Morrison, MD, FRCP(C), McMaster Univ., Hamilton, Canada

Early Life Programming of Bone Mass
Hope Weiler, RD, PhD, McGill Univ., Ste-Anne-de-Bellevue, Canada

Increasing Productivity Through Effective Time Management 73105
Moderator/Speaker: Christopher Frings, PhD, CSP, Chris Frings & Associates, Birmingham, AL
Level: Intermediate
CE Credit: 1.5
Developed in cooperation with Management Sciences Division

Session Overview: This is a practical program for those who wish to better manage their time, accomplish their top priorities and increase productivity. Topics to be addressed include: ten ways to better use your time, setting and achieving goals, electronic organizers, managing interruptions, meetings, delegation, priorities and controlling procrastination.

Expected Outcomes: After attending this session, participants will be able to: 1) identify specific ways they can work smarter; 2) apply practical ways to manage time and multiple priorities that result in increased productivity; and 3) develop a 30 day written plan to free up approximately two hours each day.

Clinical Laboratory Method Evaluation: How Do CLSI Guidelines Compare With Contemporary Practice? 73106
Moderator: William Clarke, PhD, Johns Hopkins Medical Institutions, Baltimore, MD
Level: Intermediate
CE Credit: 1.5

Session Overview: This short course is designed to provide the audience with a fresh look at method evaluation, specifically with regard to precision, as recommended in the latest CLSI guidelines. This course is designed to discuss potential shortfalls in current protocols and how CLSI guidelines for method evaluation address them.

Expected Outcomes: After attending this session, participants will be able to: 1) delineate differences between current practice for evaluation of imprecision and the protocol outlined in CLSI EP5-A2; 2) characterize and determine components of variance and assess their impact on precision and test method comparisons; 3) apply CLSI guidelines for method evaluation to future assessments of assays or instruments; and 4) compare CLSI guidelines with FDA and ICH guidelines for Method Validation Studies, e.g. repeatability, intermediate precision and reproducibility studies.

SPEAKERS

Traditional Practice for Method Evaluation
William Clarke, PhD, Johns Hopkins Medical Institutions, Baltimore, MD

Application of NCCLS Guidelines for Method Evaluation
Kimberlee Borden, Research Oriented Biostatistics Inc (ROB Inc.), Mundelein, IL

AFTERNOON SYMPOSIA
2:30pm - 5:00pm

Best Practices for the Operation and Management of Point-of-Care Testing 33206
Moderator: James Nichols, PhD, FACB, Baystate Health System, Springfield, MA
Level: Basic
CE Credit: 2.5
Developed in cooperation with Critical and Point-of-Care Testing Division

Session Overview: This symposium will highlight the best practices for operation, management and implementation of point-of-care-testing (POCT) by using practical examples and case studies from several different laboratories. The application of quality systems, the role of evidence based medicine and the value of methods used to enhance physician communication will also be addressed in this best practices session on POCT.

Expected Outcomes: After attending this session, participants will be able to: 1) improve interdisciplinary communication regarding POCT with clinical staff; 2) identify common issues of concern with POCT and describe potential, as well as optimal, solutions to these issues; 3) utilize a quality systems approach for development of a POCT program; 4) explain how to implement an effective POCT program based on published and generally accepted standards of practice; and 5) describe how POCT is best used and managed in order to minimize medical errors.

SPEAKERS

Evidence Based POCT: Translating Research into Clinical Practice
James Nichols, PhD, FACB, Baystate Health System, Springfield, MA

Quality Systems as Best Practice
Paula Santrach, MD, Mayo Clinic, Rochester, MN

Building a POCT Program to Prevent Error
Lou Ann Wyer, MT (ASCP), Sentara Healthcare, Norfolk, VA

ILLUM-0113

New Developments in Diabetes Testing and Management 33207

Moderator: Mitchell Scott, PhD, Washington Univ. School of Medicine, Saint Louis, MO
Level: Intermediate
CE Credit: 2.5
Developed in cooperation with American Diabetes Association

Session Overview: This symposium will focus on the key issues related to changing standardization of selected HbA1c methods to be traceable to the IFCC calibrated HbA1c material. Preliminary results from an ADA-sponsored study examining the relationship of HbA1c to mean blood glucose will be presented as well as results from the EPIC study demonstrating decreased macrovascular complications in DCCT subjects eight years after intensive insulin therapy.

Expected Outcomes: After attending this session, participants will be able to: 1) quantify differences in IFCC and NGSP standardized HbA1c methods and list the educational challenges encountered by a laboratory changing to a method standardized with the IFCC standard material; 2) describe the relationship of HbA1c levels to mean blood glucose over a 3-month period; and 3) cite the decreased incidence of micro- and macrovascular complications with intensive insulin therapy as data from the EPIC studies suggest.

SPEAKERS

Glycated Hemoglobin Standardization (The NGSP/IFCC Dilemma!)
David Sacks, MB, ChB, FRCPath, Brigham and Woman's Hospital, Boston, MA

The Relationship of Mean Blood Glucose Concentration to HbA1c Values
David Nathan, MD, Mass General Hospital, Boston

New Developments Impacting Diabetes Management
Mayer Davidson, MD, UCLA School of Medicine, Los Angeles, CA

AFTERNOON INTERACTIVE WORKSHOP
2:30pm - 5:00pm

High-Resolution DNA Melting Analysis: Simpler and More Efficient Next-generation Molecular Diagnostics. 23202

Moderator: Carl Wittwer, MD, PhD, Univ. of Utah, Salt Lake City
Level: Intermediate
CE Credit: 2.5

Session Overview: High-resolution DNA melting analysis is a simple solution for mutation scanning and genotyping in modern molecular diagnostics. Neither probes nor physical processing is required. This highly interactive session will provide direct experience in DNA melting and computer analysis of melting data. Use of personal laptops will be required for full interactivity.

Expected Outcomes: After attending this session, participants will be able to: 1) use high-resolution DNA melting equipment; 2) analyze DNA melting data on a computer for mutation scanning, genotyping, and HLA matching; 3) interpret results of DNA melting analysis for mutation scanning and HLA matching; and 4) design melting experiments for genotyping, including Tm estimation and primer design.

SPEAKERS

Introduction to DNA Melting Analysis for Diagnostics
Carl Wittwer, MD, PhD, Univ. of Utah, Salt Lake City

Software Analysis of DNA Melting Data
Bob Palais, Univ. of Utah, Salt Lake City

HOT TOPIC – MASS SPEC

SUNDAY FULL DAY SHORT COURSE 191010
LC/MS/MS Instrumentation and Its Applications in Clinical Laboratory

MONDAY BROWN BAG SESSION 42114/52214
Tandem Mass Spectrometry Assay Development: What it Takes to Bring and Keep an Assay Successfully On-Line

TUESDAY AFTERNOON SHORT COURSE 73210
Proteomics: Introduction to Mass Spectrometric Analysis of Proteins

WEDNESDAY AFTERNOON SHORT COURSE 74206
The New Tools of Proteomics: Mass Spectrometry and Protein Microarrays

ILLUM-0114

AFTERNOON SHORT COURSES
2:30pm - 5:00pm

Laboratory Investigation of Neurological Disease 73207
Moderator: Ian Watson, PhD, FRCPath, Univ. Hospital Aintree, Liverpool, United Kingdom
Level: Intermediate
CE Credit: 2.5
Developed in cooperation with United Kingdom National External Quality Assurance Immunochemistry Group

Session Overview: Cerebrospinal fluid (CSF) analysis is clinically helpful in a number of neurological situations such as demyelinating disease, intra-cranial hemorrhage and rupture of the dura. In this session, the faculty — who have extensive experience in providing laboratory services for neurological patients — will discuss the appropriate laboratory investigations in defined neurological problems.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the sample requirements for investigating CSF for neurological disease; 2) describe the methodologies used in CSF analysis when investigating neurological disease; 3) list and explain the causes of abnormal findings in CSF analysis; and 4) develop appropriate investigation protocols.

SPEAKERS

Laboratory Confirmation of an Intra-Cranial Bleed
Robert Beetham, PhD, FRCPath, Frenchay Hospital, Bristol, United Kingdom

Laboratory Investigation of Demyelinating and Neuroinflammatory Disease
Geoffrey Keir, PhD, National Hospital for Neurology and Neurosurgery, London, United Kingdom

Investigation of Rhinnorhea
Ian Watson, PhD, FRCPath, Univ. Hospital Aintree, Liverpool, United Kingdom

Therapeutic Drug Management of the Newer Antiepileptic Drugs 73208
Moderator: David Berry, PhD, Medical Toxicology Unit, London,
United Kingdom
Level: Intermediate
CE Credit: 2.5
Developed in cooperation with TDM & Toxicology Division

Session Overview: This session will complement presentations at the TDM Renaissance 2003 and AACC 2005 Annual Meetings, giving a comprehensive and balanced update on the current issues and practice of TDM of the newer antiepileptic drugs. The speakers will address the rationale and clinical issues related to monitoring the newer AEDs and also discuss method options for their analyses.

Expected Outcomes: After attending this session, participants will be able to: 1) explain the rationale for monitoring the newer AEDs; 2) describe the analytical methods currently available for the newer AEDs; 3) provide guidance to clinicians on appropriate sampling and interpretation of analytical data for the newer AEDs; and 4) list the issues relating to special patient populations.

SPEAKERS

Rationale for Monitoring the Newer Antiepileptic Drugs
David Berry, PhD, Medical Toxicology Unit, London, United Kingdom

Monitoring the Newer Antiepileptic Drugs — Clinical Perspectives
Frank Besag, FRCPsych, FRCP, FRCPCH, MB, ChB, PhD, Bedfordshire and Luton NHS Trust, Bedford, United Kingdom

Analytical Methodology and Practical Consideration
John Wilson, PhD, William Beaumont Hospital, Royal Oak, MI

Laboratory Ambassadors: Agents of Change for Improved Service, Patient Safety and Morale 73209
Moderator: David Grenache, PhD, MT(ASCP), DABCC, FACB, Univ. of North Carolina School of Medicine, Chapel Hill
Level: Basic
CE Credit: 2.5

Session Overview: Laboratory ambassadors are appropriately trained technologists that visit clinical service areas to monitor, identify and respond to laboratory-related patient care needs. This session will focus on one medical center's experience with implementing a laboratory ambassador program to increase the visibility of the clinical laboratory among other healthcare professionals, improve the level of service provided by the laboratory, involve technologists in patient care issues to increase morale, improve career satisfaction and enhance patient safety.

Expected Outcomes: After attending this session, participants will be able to: 1) describe how joint problem-solving can improve patient care and safety; 2) discuss the benefits of improved communication at the clinical level; 3) explain key factors for evaluating the program; 4) identify challenges to implementing this service; 5) list benchmarks to monitor results; and 6) explore ways to work with the clinical staff to make this service successful.

SPEAKERS

Laboratory Ambassadors as Agents of Change
Connie Bishop, MT(ASCP-SH), Univ. of North Carolina Hospitals, Chapel Hill

Laboratory Ambassadors: A Training Program
Christopher Parker, MT(ASCP), Univ. of North Carolina Hospitals, Chapel Hill

Laboratory Ambassadors: Outcomes, Benefits, and Challenges
David Grenache, PhD, MT(ASCP), DABCC, FACB, Univ. of North Carolina School of Medicine, Chapel Hill

Proteomics: Introduction to Mass Spectrometric Analysis of Proteins 73210
Moderator: Glen Hortin, MD, PhD, NIH Department of Laboratory Medicine, Bethesda, MD
Level: Basic
CE Credit: 2.5
Developed in cooperation with Proteomics Division

Session Overview: This session will address how mass spectrometry offers new approaches for qualitative and quantitative analysis of proteins. These tools are being applied for clinical laboratory analyses as well as for discovery of new markers for disease.

Expected Outcomes: After attending this session, participants will be able to: 1) list current clinical applications of mass spectrometric analysis of proteins; 2) explain basic principles of analysis of different mass spectrometric methods; 3) discuss how mass spectrometric methods can be applied for analysis of structural variants of proteins and for quantitation of proteins and peptides; and 4) describe how these methods can be used for discovery of new markers for disease.

SPEAKERS

Introduction to Electrospray and MALDI TOF Techniques
Steven Drake, PhD, NIH, Bethesda, MD

SELDI TOF Mass Spectrometry and Biomarker Discovery
Gerard Hoehn, PhD, NIH, Bethesda, MD

Mass Spectrometric Analysis of Proteins: Current and Potential Clinical Applications
Glen Hortin, MD, PhD, NIH Department of Laboratory Medicine, Bethesda, MD

How Any Lab Can Be Better — For Everyone 73211
Moderator: Pennell Painter, PhD, Univ. of Tennessee Medical Center, Knoxville
Level: Intermediate
CE Credit: 2.5

Session Overview: Very significant gains in productivity and clinician satisfaction can be attained while making the lab "the place in town where everyone wants to work," when laboratory decisions, like new equipment selection, are made an integral part of improved laboratory processes. This session will show participants, through case examples, how process improvement teams operate best. Participants will learn how to select automated laboratory equipment that will yield the best benefits for everyone.

Expected Outcomes: After attending this session, participants will be able to: 1) describe how process improvement (PI) can be used to create significantly better and more productive labs where people want to be employed; 2) organize and participate in Process Improvement teams; 3) select laboratory equipment and instrumental systems based on PI team output; and 4) determine and evaluate the outcomes of PI initiatives to formulate additional improvement plans.

SPEAKERS

Using Instrumental Systems and Other Lab Solutions to Make a Better Lab for All
Pennell Painter, PhD, Univ. of Tennessee Medical Center, Knoxville

Using Process Improvement Initiatives to Make Better Decisions for All
Norman Crowe, MPH, Dynacare Tennessee Laboratory, Knoxville

The Clinical Chemistry Professional Transitioning to the Core Laboratory: A Primer on Coagulation Testing and Disorders 73212
Moderator: William Winter, MD, FCAP, FACB, Univ. of Florida, Gainesville
Level: Basic
CE Credit: 2.5

Session Overview: This introductory course is designed for the clinical chemistry professional that is transitioning to the core laboratory and must understand the coagulation testing. Normal coagulation pathways, coagulation disorders and laboratory studies needed for correct clinical diagnosis and management will be covered.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the normal coagulation pathways and their regulation involving the endothelium, platelets and plasma protein clotting; 2) explain the basic and advanced laboratory tests used to assess plasma clotting factors and platelets as applicable to the understanding of bleeding and thrombotic disorders; and 3) enumerate clotting factor and platelet disorders that cause bleeding or thrombosis while explaining the pathophysiology of these disorders.

SPEAKERS

The Clinical Chemistry Professional Transitioning to the Core Laboratory: A Primer on Coagulation Testing and Disorders
William Winter, MD, FCAP, FACB, Univ. of Florida, Gainesville

The Clinical Chemistry Professional Transitioning to the Core Laboratory: A Primer on Coagulation Testing and Disorders
Neil Harris, MD, Univ. of Florida College of Medicine, Gainesville

HOT TOPIC – TDM/TOX

SATURDAY SPECIAL EVENT
Issues in Immunodiagnostics Symposium: Organ Transplantation and the Clinical Laboratory - What's on the Horizon

MONDAY BROWN BAG SESSION 42113/52213
An Introduction to Crystal "Meth" - The Lab's Perspective

MONDAY AFTERNOON SHORT COURSE 72210
How to Eliminate False Positive and False Negative Results in Clinical Chemistry Laboratory

MONDAY BROWN BAG SESSION 42118/52218
Therapeutic Drug Management in the Pain Clinic Setting

MONDAY MORNING INTERACTIVE WORKSHOP 22102
Clinical Toxicology Cases

MONDAY BROWN BAG SESSION 42119/52219
Alternative Medicinals: Impact on Clinical Laboratory Medicine

TUESDAY AFTERNOON SHORT COURSE 73208
Therapeutic Drug Management of the Newer Antiepileptic Drugs

TUESDAY BROWN BAG SESSION 43102/53202
Drug Interference - The Unsolved Problem

TUESDAY BROWN BAG SESSION 43117/53217
Laboratory Diagnosis of Alcohol Poisoning

WEDNESDAY BROWN BAG SESSION 44109/54209
How People Try to Beat Drug Tests and Defend Positive Results

WEDNESDAY MORNING SHORT COURSE 74103
Beyond Herbals: The Toxicology of Plants

THURSDAY SYMPOSIUM 35101
Clinical Applications of Liquid Chromatography/Mass Spectrometry

THURSDAY SYMPOSIUM 35105
Contemporary Therapeutic Drug Management: Merging Pharmacogenomics, Biomarkers, Drug Concentrations, and Informatics to Improve Patient Care.

WEDNESDAY'S SCHEDULE

7:30am – 8:30am
Brown Bag Sessions

8:00am – 12noon
OEM Lecture Series
McCormick Place Convention Center

8:45am – 10:15am
Plenary Session

9:30am – 5:00pm
Expo Open

10:30am – 11:30am
Meet the Experts

10:30am – 12noon
Chair's Invited Session

10:30am – 12noon
Symposia

10:30am – 12noon
Short Courses

12:30pm – 1:30pm
Brown Bag Sessions

12:30pm – 2:15pm
NACB Awards Luncheon and Membership Meeting
Hyatt Regency Chicago

2:30pm – 4:00pm
Chair's Invited Session

2:30pm – 5:00pm
Symposia

2:30pm – 5:00pm
Short Courses

2:30pm – 5:00pm
Interactive Workshops

3:00pm – 5:00pm
BMA Seminar
Hyatt Regency Chicago

4:30pm – 5:30pm
Van Slyke Foundation Reception
Hyatt Regency Chicago

6:00pm – 7:00pm
Industry Division Membership Meeting
Hyatt Regency Chicago

PLENARY SESSION
8:45am - 10:15am

The Convergence of Diagnostics and the Transformation of Medicine 14001

William Clarke, MD, MSc, GE Healthcare, Waukesha, WI

Level: Intermediate

CE Credit: 1

Session Overview: This plenary session will elucidate the role that molecular *in-vitro* diagnostics play in directing clinicians towards effective use of highly specific *in-vivo* molecular imaging diagnostics. This session will also highlight the convergence of *in-vivo* and *in-vitro* diagnostics with new targeted therapies in relevant clinical disciplines such as oncology.

Expected Outcomes: After attending this session, participants will be able to: 1) describe key features of the emerging field of molecular *in-vivo* imaging; 2) explain the synergy between *in-vitro* molecular diagnostics tests and molecular *in-vivo* imaging in selected disease states; and 3) identify the utility of, and interplay between, *in-vitro* diagnostics testing and *in-vivo* imaging in selected clinical scenarios of predisposition testing for populations at-risk, residual tumor burden and recurrence of disease.

BROWN BAG SESSIONS

7:30am - 8:30am and 12:30pm - 1:30pm

Brown Bag Sessions are repeated twice daily. Attendance is limited to 10 participants per session. AACC does not provide meals for these sessions. You will be able to purchase your own food in the Convention Center prior to the session.

Session numbers beginning with a "4" are morning sessions. Those beginning with a "5" are noon-time sessions.

CE Credit: Each Brown Bag session is eligible for one hour

The Application of Pharmacogenetics in Personalized Treatment: New Roles for Laboratory Medicine and Clinicians 44101 or 54201
Majid Moridani, PharmD, PhD, DClinChem, Texas Tech School of Pharmacy & School of Medicine, Amarillo
Level: Intermediate
Developed in cooperation with Molecular Pathology Division

Resources for Standardization and Quality in Molecular Diagnostics 44102 or 54202
Roberta Madej, Roche Molecular Systems, Pleasanton, CA
Level: Basic

Opening Pandora's Box: Assessing Linearity 44104 or 54204
David Plaut, Plano, TX
Level: Intermediate

Standardization of High-Sensitivity C-Reactive Protein Assays 44105 or 54205
Mary Kimberly, PhD, Centers for Disease Control & Prevention, Atlanta, GA
Level: Intermediate
Developed in cooperation with Lipoproteins and Vascular Diseases Division

Core Profile Testing During Cardiac Crises 44106 or 54206
Terry Shirey, PhD, DABCC, Nova Biomedical Corporation, Waltham, MA
Level: Intermediate

Personalized Medicine: What Does it Mean for the Laboratory? 44107 or 54207
Deborah Payne, PhD, Univ. of Texas Southwestern Medical Center, Dallas
Level: Basic
Developed in cooperation with AACC's Pharmacogenomics Committee and Molecular Pathology Division

Laboratory Automation, If I Knew Then What I Know Now 44108 or 54208
Carmen Wiley, PhD, Marshfield Clinic/St Joseph's Hospital, Marshfield, WI
Level: Basic

How People Try to Beat Drug Tests and Defend Positive Results 44109 or 54209
Amitava Dasgupta, PhD, DABCC, NRCC, Univ. of Texas at Houston Medical School
Level: Basic
Developed in cooperation with TDM & Toxicology Division

Clinical Value of Very Sensitive PSA Measurements Following Prostatectomy 44110 or 54210
Lynn Witherspoon, MD, ABIM, ABNM, Ochsner Clinic Foundation, New Orleans, LA
Level: Intermediate

Lipid and Cardiac Profiling In Laboratory Animals 44111 or 54211
Joseph Sansone, BA, MT, Johnson & Johnson Pharmaceutical R & D., LLC, Raritan, NJ
Level: Intermediate
Developed in cooperation with the Animal Clinical Chemistry and Lipoproteins & Vascular Diseases Divisions

Strategies to Reduce Medical Error: A Clinical Laboratory Model 44112 or 54212
Jawahar (Jay) Kalra, MD, PhD, FRCPC, FCACB, Royal Univ. Hospital, Saskatoon, Canada
Level: Basic

Autoverification of Clinical Chemistry Results 44113 or 54213
Sihe Wang, Children's Memorial Hospital, Chicago, IL
Level: Basic

Challenges in Drug Development — Assessment of *In-vitro* Hemolysis: Study Design and Interpretation 44114 or 54214
Dirk Sprenger, MS, MT(ASCP), GlaxoSmithKline, Research Triangle Park, NC
Level: Basic
Developed in cooperation with Animal Clinical Chemistry Division

C-Reactive Protein: A New Inflammatory Risk Factor for Cardiovascular Disease and Diabetes. 44115 or 54215
Gerald Cooper, MD, PhD, Centers for Disease Control and Prevention, Atlanta, GA
Level: Intermediate
Developed in cooperation with Lipoproteins and Vascular Diseases Division

Effective Implementation of POCT in the Healthcare Setting 44116 or 54216
Diana DeHoyos, Univ. of Texas Medical Branch, Galveston
Level: Basic
Developed in cooperation with Critical and Point-of-Care Testing Division

ISO 15189, ISO 9001 and ISO 14001 Standards and Their Applicability in Accreditation and Certification Programs for Clinical Laboratories 44117 or 54217
Daniel Perigo, RPh, Fleury Diagnostics, São Paulo, Brazil
Level: Basic

Error Proofing and Process Improvement Techniques for Laboratory and IVD Industry Scientists 44118 or 54218
Richard Miller, BS, Dade Behring, Inc., Newark, DE
Level: Basic
Developed in cooperation with Industry Division

Circulating Molecular Variants of Prolactin: How to Investigate Their Presence and Limit their Interference in Immunoassays. 44119 or 54219
Ibrahim Hashim, PhD, DABCC, FACB, Univ. of Texas Southwestern Medical Center, Dallas
Level: Basic

Laboratory Support of Assisted Reproduction 44120 or 54220
Linda Rogers, PhD, DABCC, FACB, Laguna Hills, CA
Level: Intermediate

Prealbumin as a Nutritional Marker: Its Financial Impact and Positive Patient Outcome 44121 or 54221
Elia Mears, MS, MT(ASCP)SM, Chabert Medical Center-LSUHSC, Houma, LA
Level: Basic
Developed in cooperation with Nutrition Division

Installing an Interface for Point-of-Care Testing 44122 or 54222
Deanna Bogner, MS, MT(ASCP), Christus Santa Rosa Health Care, San Antonio, TX
Level: Basic

Tests for Evaluating Fetal Lung Maturity 44124 or 54224
Edward Ashwood, MD, ARUP/Univ. of Utah, Salt Lake City
Level: Basic
Developed in cooperation with Pediatric and Maternal-Fetal Division

Successful Clinical Trials Management: Practical Techniques, Regulations, Roles and Responsibilities 44125 or 54225
Robert Dworschack, PhD, Roche Diagnostics Corp., Indianapolis, IN
Level: Intermediate

MEET THE EXPERTS

10:30am - 11:30am

Attendance in these sessions is strictly limited. Advance registration is highly encouraged.

***In-vivo* Molecular Imaging Diagnostics** 64001
William Clarke, MD, MSc, GE Healthcare, Waukesha, WI
Level: Intermediate
CE Credit: 1

Session Overview: Molecular in-vivo diagnostics is an up-and-coming specialty, an outgrowth of molecular diagnostics and enhanced 21st century imaging technologies. Dr. Clarke will describe this new tool and how it plays a role in directing clinicians towards highly specific in-vivo molecular imaging diagnostics. This session will touch on the convergence of in-vivo and in-vitro diagnostics with new targeted therapies in oncology, for example. This session will provide the opportunity for a more in-depth discussion of the topics raised in the accompanying Plenary session.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the emerging field of molecular in-vivo imaging; 2) Explain the synergy between in-vitro molecular diagnostics tests and molecular in-vivo imaging in different disease states; and 3) understand the utility of and interplay between in-vitro testing and in-vivo imaging in a variety of clinical scenarios including predisposition testing for populations at-risk, residual tumor burden and disease recurrence.

Molecular Pathology Laboratory Testing for Breast Cancer: State of the Art 64002
Matthew Ellis, MD, PhD, Washington Univ. School of Medicine, St. Louis, MO
Level: Intermediate
CE Credit: 1

Session Overview: This interactive session will discuss advances in molecular diagnostics for breast cancer. Dr. Ellis will begin with a short overview of the strengths and weaknesses of the multigene prognostic and predictive tests currently in development. The remainder of the session will be devoted to a participant-led discussion of topics such as the barriers to the application of new tests and technologies and what criteria should be used to implement these approaches into routine clinical.

Expected Outcomes: After attending this session, participants will be able to: 1) better address questions that may arise from clinicians and patients; 2) participate more effectively in institutional discussion regarding the implementation of new breast cancer diagnostics; and 3) decide which technologists and tests can be applied in their own laboratories.

CHAIR'S INVITED SESSION

10:30am - 12noon

Open to all conference participants.

Strategies for Dealing with the Workforce Shortage: A Town Hall Meeting 94101

Moderator: Stephen E. Kahn, PhD, DABCC, FACB, Loyola University Medical Center, Maywood, IL

Level: Intermediate

CE Credit: None

Session Overview: This town hall meeting will explore key strategies for dealing with the growing shortage in the technical workforce — a critical issue in pathology and laboratory medicine. A panel of experts will present unique perspectives on the benefits of automation in improving staff utilization, novel staff recruitment and retention strategies, industry's involvement in addressing this shortage as well as providing new job opportunities, and the role of professional laboratory associations in exercising leadership on these issues through the Coordinating Council for the Clinical Laboratory Workforce. The session also includes an extended question and answer period where participants and panel members can explore constructive solutions for this growing workforce challenge.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the current status of workforce shortage issues in laboratories in the U.S. and the role that professional laboratory associations can play; 2) explain the roles that automation, novel recruitment and retention strategies, and increased educational funding play in providing solutions to address the workforce shortage; and 3) list three new strategies learned that can be taken back to their work setting to address staff shortage challenges.

SPEAKERS

The Role of the Coordinating Council for the Clinical Laboratory Workforce (CCCLW)
Paula Garrott, EdM, CLS(NCA), Univ. of Illinois at Springfield

The Role of Industry in Addressing the Workforce Shortage
Mary Lou Gantzer, PhD, Dade Behring, Newark, DE

The Role of Automation in Making the Best Use of Your Staff
Denise Uettwiller-Geiger, PhD, DLM(ASCP), John T. Maher Memorial Hospital, Port Jefferson, NY

The Role of Novel Staff Recruitment and Retention Strategies
Connie Bishop, MT(ASCP)SH, Core Laboratory, Chapel Hill, NC

FULL DAY SYMPOSIA

10:30am - 12noon and 2:30pm - 5:00pm

Pharmacogenetics Practice Guidelines II: Clinical Utilization of Pharmacogenetics 34301

Moderator: Roland Valdes, Jr., PhD, DABCC, FACB, Univ. of Louisville School of Medicine, KY

Level: Intermediate

CE Credit: 1.5 & 2.5

Developed in cooperation with NACB and AACC's Molecular Pathology and TDM & Toxicology Divisions

Session Overview: The National Academy of Clinical Biochemistry (NACB; The Academy of the AACC) is establishing laboratory management practice guidelines (LMPGs) for the clinical application of pharmacogenetics (PGx) testing in healthcare. This new dynamic discipline of clinical pharmacogenetics has significant potential for reducing serious adverse drug reactions. In this two-day symposia we will review the NACB practice guidelines as developed by experts in this discipline. Evidence-based applications of pharmacogenetics will be presented to support the recommended guidelines and will include a grading of the evidence available. Importantly, these guidelines will also clarify areas where evidence still needs to be strengthened and recommend criteria for providing that evidence. The symposia will provide the audience both insight into this growing clinical laboratory service and an open forum for discussing these guidelines before they are finalized and published. Input from clinical laboratory personnel, the in-vitro diagnostic industry, pharmacists, clinical practitioners and regulatory agencies will be very important in finalizing these practice guidelines in pharmacogenetics.

Expected Outcomes: After attending this session, participants will be able to: 1) cite parameters that are necessary to provide optimum pharmacogenetics testing in specific clinical settings; 2) explain the potential links in the roles of pharmacogenetics and therapeutic drug monitoring in clinical settings; 3) describe and formulate recommended guidelines for clinical laboratories introducing pharmacogenetics testing services; 4) list the necessary parameters for optimizing clinical assays needed in pharmacogenetics testing; and 5) describe recommended parameters for optimizing reimbursement and regulatory functions.

EXHIBIT 5

(Part III of VII)

OF

DECLARATION OF GREGORY F. HEATH

MORNING SPEAKERS

Clinical Practice and Utilization of PGx Information (Part I)
Gualberto Ruano, MD, PhD, Genomas, Inc., Hartford, CT

Clinical Practice and Utilization of PGx Information (Part II)
David Flockhart, MD, PhD, Indiana School of Medicine, Indianapolis

AFTERNOON SPEAKERS

TDM and PGx Interface Considerations
Leslie Shaw, PhD, Hospital of Univ. of Pennsylvania, Philadelphia

Ancillary Considerations for PGx Testing: Forensics, Pharmaceutical Dispensing et al.
Saeed Jortani, PhD, Univ. of Louisville, KY

Regulatory and Reimbursement Considerations
Nam Rahman, Food & Drug Administration, Rockville, MD

HOT TOPIC – CANCER/TUMOR MARKERS

SUNDAY FULL DAY SHORT COURSE 191008
Tumor Markers: How We Use Them in the Clinic and New Developments

MONDAY AFTERNOON SYMPOSIUM 32208
Recent Advances in Clinical Proteomics

MONDAY BROWN BAG SESSION 42110/52210
The "Value Added" Surgical Pathology Report: Integrating Serum Tumor Markers with Histopathology

MONDAY FULL DAY SYMPOSIUM 32303
Health Issues After 40: Preparing the Laboratory to Meet the Demand

TUESDAY MORNING INTERACTIVE WORKSHOP 23101
Adventures in the Gamma Zone

WEDNESDAY AFTERNOON SHORT COURSE 74209
Pharmacogenetics and Cancer Treatment Efficacy

WEDNESDAY BROWN BAG SESSION 44110/54210
Clinical Value of Very Sensitive PSA Measurements Following Prostatectomy

Time and Tide: Technologies That Change Laboratory Medicine 34302

Moderator: Donald Young, MD, PhD, Univ. of Pennsylvania, Philadelphia
Level: Intermediate
CE Credit: 1.5 & 2.5
Developed in cooperation with History of Clinical Chemistry Division

Session Overview: The symposium will highlight notable technologies and events that markedly affected the practice of laboratory medicine. Participants will also gain insight into future trends in the evolution of these technologies and what their impact will be in shaping the future practice of laboratory medicine.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the impact of the AutoAnalyzer in the revolution of diagnostic testing; 2) discuss the evolution of laboratory testing for the diagnosis of myocardial infarction; 3) describe the problems created by AIDS and the impact of molecular diagnostics testing in the management of HIV-infected patients; 4) explain the impact of PCR and Real Time PCR technology in the clinical laboratory; and 5) predict the impact of future developments with each of these technologies.

MORNING SPEAKERS

The AutoAnalyzer and The Revolution of Diagnostic Testing
Jacob Levine, Bayer Healthcare LLC-Diagnostics, Tarrytown, NY

From Early Markers of Cardiac Disease to Troponin and Beyond
Robert Christenson, PhD, DABCC, FACB, Univ. of Maryland Medical Center, Baltimore

AFTERNOON SPEAKERS

The HIV Story From 1982 to 2006
Angie Caliendo, MD, PhD, Emory Univ. Hospital, Atlanta, GA

The Evolution of Chips, Arrays and Their Applications
Larry Kricka, DPhil, FACB, Univ. of Pennsylvania Medical Center, Philadelphia

From PCR to Real-Time PCR and Beyond
Carl Wittwer, MD, PhD, Univ. of Utah, Salt Lake City

Best Practices in Molecular Pathology 34303
Moderator: Vivianna Van Deerlin, MD, PhD, Hospital of the Univ. of Pennsylvania, Philadelphia
Level: Intermediate
CE Credit: 1.5 & 2.5
Developed in cooperation with Molecular Pathology Division

Session Overview: This symposium will focus on best practices in molecular pathology, particularly highlighting the areas of new assay development and implementation, quality control and regulatory issues. Required elements of test reports, standard nomenclature in molecular pathology and issues unique to testing for heritable disorders will also be presented, in part, through use of examples for the development of specific assays.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the different steps of test validation and implementation processes for molecular assays; 2) describe issues related to CPT coding, billing and reimbursement for molecular assays; 3) list the necessary elements of a molecular pathology report and explain the use of standard nomenclature; and 4) identify special issues associated with testing for heritable disorders including proper attention to informed consent requirements.

MORNING SPEAKERS

Bringing New Tests Online: Assay Validation and Implementation
Vivianna Van Deerlin, MD, PhD, Hospital of the Univ. of Pennsylvania, Philadelphia

Assay Validation Success Stories: Issues and Resolutions
Karen Kaul, MD, Evanston Hospital, IL

AFTERNOON SPEAKERS

Regulatory Issues: Coding and Billing for Molecular Pathology
Jeffrey Kant, UPMC Presbyterian, Pittsburgh, PA

Clinical Laboratory Reports in Molecular Pathology
Margaret Gulley, MD, Univ. of North Carolina, Chapel Hill

Unique Issues in the Testing for Heritable Disorders
Wayne Grody, MD, UCLA Medical Center

MORNING SYMPOSIA
10:30am - 12noon

Clinician's Perceptions of Waived Testing: Is There an Impact on Patient Safety? 34104
Moderator: Melissa Pessin-Minsley, MD, PhD, FABP, FCAP, FASCP, Weill Medical College of Cornell Univ., New York, NY
Level: Intermediate
CE Credit: 1.5
Developed in cooperation with AACC Patient Safety Task Force

Session Overview: This symposium will focus on patient safety issues relating to point-of-care testing and, specifically, ensuring the accuracy of results for waived tests. This session will explore the clinician's view of waived testing and focus on possible conceptual/performance errors that users can make. Other issues to be discussed include how industry has addressed the potential pitfalls in waived testing to minimize the occurrence of errors and/or alert the operator (and/or physician) that the given result may be in question.

Expected Outcomes: After attending this session, participants will be able to: 1) explain why the current definition of waived testing leads to misunderstandings by practicing clinicians; 2) identify two critical steps particularly prone to misperformance by clinicians; 3) describe two industry interventions made to minimize clinician error in test performance; and 4) name two actions that POCT laboratorians can take to improve clinician waived-test performance.

SPEAKERS

The Clinician's View of Waived Testing
Melissa Pessin-Minsley, MD, PhD, FABP, FCAP, FASCP, Weill Medical College of Cornell Univ., New York, NY

An Industry Response to Assuring Accuracy in Waived Testing
Speaker to be determined.

ILLUM-0124

Coagulation Testing: The Role of the Laboratory Director in Optimizing Patient Outcome 34105
Moderator: Michael Laposata, MD, PhD, Massachusetts General Hospital, Boston
Level: Intermediate
CE Credit: 1.5

Session Overview: This symposium will present successful strategies to assist ordering physicians in the selection of proper coagulation tests for specific clinical conditions. In this session, information will also be provided on the role of the laboratory director in assisting physicians — who may be unfamiliar with this field and may require assistance in interpreting coagulation test results — so that the correct clinical actions are taken. Software that enables these important practices and strategies will also be described.

Expected Outcomes: After attending this session, participants will be able to: 1) describe how to construct a clinically useful diagnostic algorithm to promote correct test selection; 2) explain how a laboratory director interfaces with clinicians to provide clinically relevant information in the area of coagulation testing; and 3) cite technology solutions that promote interaction between clinicians and the laboratory director in the coagulation area.

SPEAKERS

Enabling Physicians to Order the Right Tests and Correctly Interpret Test results in Coagulation
Michael Laposata, MD, PhD, Massachusetts General Hospital, Boston

Technology Solutions that Promote Correct Test Selection and Enhance Communication with the Clinical Laboratory
Anand Dighe, Massachusetts General Hospital, Boston

Extending Traceability to the Laboratory, EQAS and Proficiency Systems - Advantages, Obstacles and Issues 34106
Moderator: William Koch, PhD, NIST, Gaithersburg, MD
Level: Intermediate
CE Credit: 1.5
Developed in cooperation with Industry Division

Session Overview: Traceability is a continuing hot topic that is currently a top priority in the laboratory setting, due in part, to several parallel and joint efforts in the area of standardization by CLSI, IFCC and ISO. This symposium will highlight the impact of these efforts on quality and patient safety. Particular topics to be explored include "value-added" considerations for establishing traceability as well as reviewing the implications of extending traceability for instrument development, regulations, and accreditation.

Expected Outcomes: After attending this session, participants will be able to: 1) explain the relationship of traceability and quality, and the potential for added value; 2) list the different regulatory and accreditation procedures envisioned for implementing traceability requirements; and 3) describe the resources available to assist laboratories in implementing materials with traceable target values.

SPEAKERS

What Regulatory Obstacles Must be Overcome to Move from Peer-Assigned to Traceable Targets
Steven Gutman, MD, MBA, Food & Drug Administration-CDRH, Rockville, MD

What Changes will Laboratories Have to Make
David Bullock, PhD, FACB, Wolfson EQA Laboratory, Birmingham, United Kingdom

HOT TOPIC – MOLECULAR DIAGNOSTICS/GENOMICS

SATURDAY SPECIAL EVENT
Metabolomic Markers in Diet and Health

SUNDAY FULL DAY INTERACTIVE WORKSHOP 191001
Alphabet Soup - The Hepatitis Viruses

SUNDAY FULL DAY SHORT COURSE 191014
Principles of Molecular Diagnostics

MONDAY BROWN BAG SESSION 42106/52206
An Introductory Overview of Technologies in Molecular Diagnostics

MONDAY BROWN BAG SESSION 42103/52203
Testing for Hepatitis C Virus Infection

MONDAY FULL DAY SYMPOSIUM 32301
Novel Applications of Genomic Profiling

TUESDAY AFTERNOON INTERACTIVE WORKSHOP 23202
High-Resolution DNA Melting Analysis

TUESDAY BROWN BAG SESSION 43108/53208
Homebrews and Alphabet Soup: An Introduction to Molecular Diagnostics Regulatory Issues

WEDNESDAY AFTERNOON SHORT COURSE 74206
The New Tools of Proteomics: Mass Spectrometry and Protein Microarrays

WEDNESDAY BROWN BAG SESSION 44102/54202
Resources for Standardization and Quality in Molecular Diagnostics

WEDNESDAY FULL DAY SYMPOSIUM 34303
Best Practices in Molecular Pathology

WEDNESDAY AFTERNOON SHORT COURSE 74209
Pharmacogenetics and Cancer Treatment Efficacy

WEDNESDAY PLENARY 14001
The Convergence of Diagnostics and the Transformation of Medicine

THURSDAY SYMPOSIUM 35101
Clinical Applications of Liquid Chromatography/Mass Spectrometry

THURSDAY SYMPOSIUM 35102
Nutrigenomics: The Connection Between Nutrition and Genes

MORNING SHORT COURSES
10:30am - 12noon

Glycated Hemoglobin (HbA1c) Measurement and Standardization - A Review 74102

Moderator: Randie Little, PhD, Univ. of Missouri at Columbia
Level: Intermediate
CE Credit: 1.5

Session Overview: This session will give an overview of glycated hemoglobin (HbA1c) measurement — available methods, quality of results, ways to evaluate field precision and accuracy, assay interferences and factors to consider when choosing a method. Different approaches to standardization of HbA1c, including the NGSP and IFCC approaches, will also be discussed.

Expected Outcomes: After attending this session, participants will be able to: 1) identify the major methods for HbA1c analysis and list the weaknesses and strengths of the methods; 2) state the recommendations of the 2002 NACB guidelines for the measurement of HbA1c as well as strategies to meet these recommendations; 3) evaluate data to determine if a method's imprecision is clinically acceptable; and 4) summarize the challenges involved in the standardization of HbA1c as well as the proposed systems for reporting HbA1c.

SPEAKERS

The Current State of HbA1c Testing: Standardization, Assay Methods and Potential Interferences
Randie Little, PhD, Univ. of Missouri at Columbia

QC and QA Aspects of HbA1c Measurements
Trefor Higgins, Dynacare Kasper Medical Laboratory, Edmonton, Canada

Beyond Herbals: The Toxicology of Plants 74103

Moderator: Catherine Hammett-Stabler, PhD, DABCC, FACB, Univ. of North Carolina, Chapel Hill
Level: Intermediate
CE Credit: 1.5
Developed in cooperation with TDM & Toxicology Division

Session Overview: Plant ingestion accounts for 5% of US pediatric poisonings. In many developing countries, poisonous plants are commonly used to commit suicide or homicide. In addition, many of the adverse reactions and events reported following the use of herbal remedies are related to the unintentional substitution of poisonous plants. This session, using case studies and describing antidotes, will address common poisonous plants, clinical manifestations following ingestion, and the role of the laboratory in the treatment of these patients.

Expected Outcomes: After attending this session, participants will be able to: 1) list commonly encountered poisonous plants; 2) list plants commonly misidentified as herbals and substituted inappropriately; 3) discuss the use of the laboratory in patient management; and 4) use Internet and text resources to identify poisonous plants as well as methods of analysis of the inherent toxic compounds.

SPEAKERS

General Overview of Plant Poisonings: Epidemology and Case Presentations
Catherine Hammett-Stabler, PhD, DABCC, FACB, Univ. of North Carolina, Chapel Hill

Role of Clinical Laboratory in Diagnosis of Specific Plant Poisonings and Antidotes
Amitava Dasgupta, PhD, DABCC, NRCC, Univ. of Texas at Houston Medical School

College of American Pathologists' Laboratory Accreditation Program in 2006 74104

Moderator: Nancy Yeransian, MT, (ASCP)SC, College of American Pathologists, Northfield, IL
Level: Intermediate
CE Credit: 1.5

Session Overview: Learn important information regarding changes to the CAP's Laboratory Accreditation Program Chemistry and Point-of-Care Testing Checklists. Participants will be able to take home practical examples and recommendations for complying with the recent changes to the checklists.

Expected Outcomes: After attending this session, participants will be able to: 1) recognize recent changes to the LAP Chemistry and Point-of Care Testing Checklists; and 2) explain the rationale behind the changes and what constitutes compliance.

SPEAKERS

New Directions
Nancy Yeransian, MT, (ASCP)SC, College of American Pathologists, Northfield, IL

Checklist Update
William Castellani, BS, MD, Penn State Hershey Medical Center, Hershey

Statistical and Graphical Tools for the Laboratory 74105

Moderator: Kristian Linnet, MD, PhD, Univ. of Copenhagen, Denmark
Level: Intermediate
CE Credit: 1.5

Session Overview: The session is intended to inspire and motivate the participants in statistics-based understanding of test performance. From graphical analysis to method evaluation, the audience will travel through the respective statistics and graphics, learning them "enpassant."

Expected Outcomes: After attending this session, participants will be able to: 1) understand the statistical concepts underlying laboratory testing and method evaluation (Bland-Altman, Deming regression); and 2) use graphical analysis to evaluate laboratory data.

SPEAKERS

Graphical Analysis of Data
Dietmar Stockl, PhD, STT Consulting, Horebeke, Belgium

Method Evaluation by Bland-Altman Procedure and Deming Regression
Kristian Linnet, MD, PhD, Univ. of Copenhagen, Denmark

CHAIR'S INVITED SESSION

2:30pm - 4:00pm
Open to all conference participants

Patient Education in the 21st Century: An Open Forum 94201

Moderator: George Linzer, AACC, Washington, DC
Level: Basic
CE Credit: None

Session Overview: Personalized and preventive medicine, the aging Baby Boomer generation, and increased fears of a pending public health crisis are all contributing to a greater need for reliable patient education. The exponential growth of healthcare information published on the Internet, however, is making it difficult for patients to find trusted sources. In this context, Lab Tests Online and other credible medical resources attempt to inform, educate, and reassure patients and their families with clearly written, science-based information. Join us as a panel of thought leaders discuss the benefits and challenges of educating patients in the 21st century, with a particular focus on helping patients understand the role laboratory medicine plays in healthcare.

Expected Outcomes: After the session, attendees will be able to: 1) describe the landscape in which the patient is attempting to assimilate health information; 2) characterize the value of promoting a clear health objective in patient communications; and 3) describe the best practices for communicating health information online.

SPEAKERS

Patient Education as a Public Health Mission
David Sundwall, MD, Utah State Department of Health, Salt Lake City

A Watchdog's Perspective: Helping the Patient Find Quality Information
Beau Brendler, Consumer Reports WebWatch, Yonkers, NY

New Models for Patient Education in a Personalized Medicine World
Patrick F. Terry, Personalized Medicine Coalition, Washington, DC

Patient's Viewpoint: Finding Quality Information
Karyn Williams, RN, Pancreatitis Association International, Indianapolis, IN

A Physician's Perspective on Patient Education
Kenneth Goodman, MD, Cleveland Clinic, Beachwood, OH

AFTERNOON SYMPOSIA
2:30pm - 5:00pm

Healthcare Forum: Legislative, Regulatory and Workforce Issues 34207

Moderator: Don Lavanty, JD, J.T. Rutherford and Associates, Arlington, VA
Level: Intermediate
CE Credit: 2.5
Developed in cooperation with Government Relations Committee and American Society for Clinical Laboratory Science

Session Overview: The Healthcare Forum provides laboratorians with up-to-date information on key issues affecting the clinical laboratory. This year, this symposium will focus on the Federal government's ongoing efforts to eliminate medical errors, as well as its plan to create a technology-based network for sharing health information, and such a network's potential impact on laboratory operations. This session will also review proposals to modernize the Medicare program through competitive bidding and the adoption of pay for performance measures. Finally, the Forum will describe efforts of the laboratory community to address its ongoing staffing shortage.

Expected Outcomes: After attending this session, participants will be able to: 1) outline new government efforts to reduce medical errors and develop a plan for their participation in these endeavors; 2) describe health information technology changes that are on the horizon and how they will affect clinical laboratories; 3) list new payment initiatives under consideration by Medicare; and 4) describe private and public sector initiatives that are being advanced to address the laboratory staffing shortage.

SPEAKERS

Medical Errors — Seven Years Later
Marge Keyes, MA, Agency for Healthcare Research and Quality, Rockville, MD

Health IT and the Clinical Lab
Jay Jones, PhD, DABCC, FACB, Geisinger Health System, Danville, PA

What's on the Horizon with Medicare Modernization
Peter Kazon, Esq, Alston & Bird, Washington, DC

Ongoing Efforts to Alleviate the Staffing Shortage
Elissa Passiment, EdM, CLS (NCA), ASCLS, Bethesda, MD

Acute Coronary Syndromes: The Complete Story 34208

Moderator: David Morrow, MD, MPH, Brigham & Women's Hospital, Boston, MA
Level: Intermediate
CE Credit: 2.5

Session Overview: This symposium will focus on the acute coronary syndromes (ACS) and the use of cardiac biomarkers to guide clinical management of ACS patients. This session has been developed to create an innovative educational program that will bring together the perspectives of an emergency medicine physician, a clinical cardiologist, an interventional cardiologist and a biochemist to consider the appropriate management of the ACS patient.

Expected Outcomes: After attending this session, participants will be able to: 1) identify the key aspects of clinical management — in the emergency department and cardiology wards — of patients with suspected ACS; 2) discern, with enhanced insight, the role of laboratory services in the optimal care of patients with suspected ACS; and 3) list unmet clinical needs that could be more effectively addressed with enhancements to testing capabilities for cardiac biomarkers.

SPEAKERS

ACS — The Emergency Physician's View
W. Frank Peacock, MD, Cleveland Clinic, OH

ACS — The General Cardiologist's View
David Morrow, MD, MPH, Brigham & Women's Hospital, Boston, MA

ACS — The Interventional Cardiologist's View
Warren Cantor, MD, St. Michael's Hospital, Univ. of Toronto, Canada

ACS — The Biochemist's View
Robert Christenson, PhD, DABCC, FACB, Univ. of Maryland Medical Center, Baltimore

ILLUM-0128

AFTERNOON INTERACTIVE WORKSHOP
2:30pm - 5:00pm

Training and Competency Testing of Clinical Laboratory Personnel 24201
Moderator: Jeanne Carr, PhD, MT(ASCP), BCLD, St. Jude Children's Research Hospital, Memphis, TN
Level: Basic
CE Credit: 2.5
Developed in cooperation with the Management Sciences and Molecular Pathology Divisions

Session Overview: This interactive workshop will introduce practical topics and items for discussion: developing training checklists; setting guidelines for training new techs (techs transferring from other disciplines, current staff on new procedures, instrument training, and routine competency); setting guidelines for acceptable performance; and action for unacceptable performance. The emphasis areas will be Molecular Pathology, Virology and Hematology; however, the concepts and forms are adaptable for other laboratory disciplines. Attendees will be asked to participate in an open exchange of their experiences and ideas on this topic.

Expected Outcomes: After attending this session, participants will be able to: 1) recognize the difference between training and competency; 2) design a program for initial training of laboratory personnel; 3) design a program for competency assessment; and 4) modify the session's example forms for use in their own institutions.

SPEAKERS

Designing a Program for Training and Competency Testing of Medical Laboratory Personnel
Jeanne Carr, PhD, MT(ASCP), BCLD, St. Jude Children's Research Hospital, Memphis, TN

A Review of Regulatory Agencies' Requirements for Training and Competency Testing of Medical Laboratory Personnel
Richard Warren, BS, MHA, MT(ASCP)SH, DLM, Memphis, TN

AFTERNOON SHORT COURSES
2:30pm - 5:00pm

The New Tools of Proteomics: Mass Spectrometry and Protein Microarrays 74206
Moderator: Eleftherios Diamandis, MD, PhD, FRCPC, Mount Sinai Hospital, Toronto, Canada
Level: Intermediate
CE Credit: 2.5

Session Overview: This session will describe the various types of mass spectrometry instrumentation used in proteomics as well as the principles and application of protein microarrays.

Expected Outcomes: After attending this session, participants will be able to: 1) describe how mass spectrometry works, especially as it applies to protein analysis; 2) explain the principles behind the various types of instrumentation available and their advantages and disadvantages; 3) select which types of devices are more appropriate to solve specific proteomic questions; and 4) determine how protein microarrays can aid in the development of novel diagnostic technologies.

SPEAKERS

Mass Spectrometry: Past, Present and Future
Eleftherios Diamandis, MD, PhD, FRCPC, Mount Sinai Hospital, Toronto, Canada

Protein Microarrays: Their Application in Clinical Diagnostics
Vathany Kulasingam, Mount Sinai Hospital, Toronto, Canada

Clinical Utilization of Laboratory Data: Using POC Glucose Data to Support Tight Glycemic Control 74207
Moderator: Gail Kongable, MSN, FNP, The Epsilon Group, Charlottesville, VA
Level: Basic
CE Credit: 2.5
Developed in cooperation with Critical and Point-of-Care Testing Division

Session Overview: This session will review diabetes disease management through hospital implementation of tight glycemic control programs in hospitals. The laboratorian is often not included in the initial discussions and may be brought in late in the planning stage. Requests for data to support patient and disease management place increasing demands on laboratory personnel. This session will address the laboratory's role and the appropriate use of tight glycemic control protocols for various areas within a healthcare setting.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the pathophysiology of hyperglycemia and its impact on hospitalized patients; 2) explain the basic components and pitfalls of a tight glycemic control program; 3) discuss how laboratory data can be used for discovery of new evidence in Diabetes Care Management; 4) evaluate the appropriate use of tight glycemic control initiatives within various areas of the healthcare setting; and 5) understand the evidence in the medical literature supporting the adoption of tight glycemic control protocols in critically ill patients.

SPEAKERS

The Pathophysiology of Hyperglycemia and its Affect on Hospitalized Patients
Gail Kongable, MSN, FNP, The Epsilon Group, Charlottesville, VA

Understand the Evidence in The Medical Literature Supporting The Adoption of Tight Glycemic Control Protocols in Critically Ill Patients
James Kringsley, MD, Stamford, CT

Clinical Utilization of Laboratory Data: Using POC Glucose Data to Support Tight Glycemic Control
Denise Zito, Medical Automation Systems, Charlottesville, VA

A cLEAN Bill of Health for Your Lab: Recognizing Waste and Identifying Improvement Opportunities 74208
Moderator: Michele Long, Ortho-Clinical Diagnostics, Raritan, NJ
Level: Intermediate
CE Credit: 2.5

Session Overview: This session utilizes simulation exercises to educate participants in concepts of Process Excellence through Lean and Six Sigma. Registrants will learn of opportunities for improvement in their own facilities as well as how to choose the right metrics to measure and monitor performance.

Expected Outcomes: After attending this session, participants will be able to: 1) define the basic concepts of Process Excellence; 2) select possible metrics to measure and monitor performance; 3) list possible process improvement goals; and 4) effectively utilize best practices and benchmark data.

SPEAKER

A cLEAN Bill of Health for Your Lab
Chetan Shukla, Pembroke Pines, FL

Pharmacogenetics and Cancer Treatment Efficacy 74209
Moderator: Barbara Zehnbauer, PhD, FACMG, Washington Univ. School of Medicine, St. Louis, MO
Level: Intermediate
CE Credit: 2.5
Developed in cooperation with the Molecular Pathology Division

Session Overview: Molecular diagnostic methods have focused upon detection of tumor-specific genetic signatures for diagnosis, prognosis, and minimal residual disease detection. This session will help participants understand how the pharmacogenetic variations in the genome of the cancer patient can be used to select treatment, predict response to anti-cancer drugs, and maximize overall therapeutic outcome.

Expected Outcomes: After attending this session, participants will be able to: 1) recognize the difference between tumor-specific and patient-specific genetic changes; 2) describe the relationship between the anti-cancer drug on the tumor cells and the genes that regulate metabolism of the anti-cancer drug; and 3) explain how the genome of the patient can influence the response to an anti-cancer treatment.

SPEAKERS

Colorectal Cancer Pharmacogenetics
Howard McLeod, PharmD, Washington Univ. School of Medicine, St. Louis, MO

Breast Cancer Pharmacogenetics
Matthew Ellis, MD, PhD, Washington Univ. School of Medicine, St. Louis, MO

Pharmacogenomics of Cancer Chemotherapy
Barbara Zehnbauer, PhD, FACMG, Washington Univ. School of Medicine, St. Louis, MO

ILLUM-0130

How to Minimize Personal and Laboratory Litigation Risk 74210
Moderator/Speaker: Pennell Painter, PhD, Univ. of Tennessee Medical Center, Knoxville
Level: Intermediate
CE Credit: 2.5

Session Overview: In the current climate where lawsuits can be easily filed, many laboratories, laboratory personnel and diagnostic companies are finding that adverse patient experiences increasingly lead to litigation. This session will provide participants with an understanding of how principles of risk management can be applied to their laboratory and to their job. Examples of lawsuits against laboratories, lab personnel and IVD companies will be presented. These examples serve to illustrate activities that increase exposure. Ideas to decrease litigation exposure and minimize the likelihood of adverse patient experiences will be presented.

Expected Outcomes: After attending this session, participants will be able to: 1) perform risk assessments on activities they and their laboratory are doing with the goal of reducing adverse patient experiences and risk of litigation; and 2) recognize opportunities for adverse patient experience and other litigation risks and understand how those risks can be mitigated.

HOT TOPIC – MANAGEMENT/FINANCIAL/OUTREACH

SUNDAY AFTERNOON SHORT COURSE 191015
How Laboratorians Can Gain Hospital Executives' Support for Implementing Laboratory Automation Technology

SUNDAY AFTERNOON SHORT COURSE 191013
Service Excellence Is Sweeping Through Healthcare: Applying These Principles In Laboratory Management

SUNDAY AFTERNOON INTERACTIVE WORKSHOP 191007
Solving Day-To-Day Management Challenges: Case Histories & Applications

SUNDAY FULL DAY SHORT COURSE 191012
Concepts and Practices in the Evaluation of Laboratory Methods

MONDAY AFTERNOON INTERACTIVE WORKSHOP 22203
Having Problems Communicating With Your Staff? Find Out Why And How To Fix It!

MONDAY AFTERNOON SYMPOSIUM 32209
Risk Management - A Practical Approach to a Quality POCT Program

MONDAY BROWN BAG SESSION 42111/52211
Communicating for Success

MONDAY BROWN BAG SESSION 42117/52217
Laboratory Outreach Programs: Competing on Service

MONDAY AFTERNOON SHORT COURSE 72211
Successful Community Laboratory Outreach

MONDAY AFTERNOON SHORT COURSE 72209
Clinical Laboratory Informatics and the Electronic Health Record

TUESDAY BROWN BAG SESSION 43118/53218
Role of the Clinical Laboratory in Clinical Trials for the Development of Drugs by the Pharmaceutical Industry

TUESDAY MORNING SHORT COURSE 73105
Increasing Productivity Through Effective Time Management

TUESDAY AFTERNOON SHORT COURSE 73211
How Any Lab Can Be Better - For Everyone

TUESDAY AFTERNOON SHORT COURSE 73213
How to Minimize Personal and Laboratory Litigation Risk

TUESDAY MORNING SHORT COURSE 73106
Clinical Laboratory Method Evaluation: How Do CLSI Guidelines Compare With Contemporary Practice?

TUESDAY FULL DAY SHORT COURSE 73303
Business Opportunities for Clinical Labs in Pharmaceutical Discovery and Development

TUESDAY AFTERNOON SYMPOSIUM 33206
Best Practices for the Operation and Management of Point of Care Testing

TUESDAY AFTERNOON SHORT COURSE 73209
Laboratory Ambassadors: Agents of Change for Improved Service, Patient Safety, and Morale

WEDNESDAY AFTERNOON SHORT COURSE 74208
A "Clean" Bill of Health for Your Lab: Recognizing Waste and Identifying Improvement Opportunities

WEDNESDAY BROWN BAG SESSION 44108/54208
Laboratory Automation, If I Knew Then What I Know Now

WEDNESDAY MORNING SHORT COURSE 74104
College of American Pathologists' Laboratory Accreditation Program in 2006

WEDNESDAY AFTERNOON INTERACTIVE WORKSHOP 24201
Training and Competency Testing of Clinical Laboratory Personnel

WEDNESDAY BROWN BAG SESSION 44116/54216
Effective Implementation of POCT in the Healthcare Setting

WEDNESDAY AFTERNOON SYMPOSIUM 34207
Healthcare Forum: Legislative, Regulatory and Workforce Issues

THURSDAY SYMPOSIUM 35103
Making Sense of the Alphabet Soup of Laboratory Regulations

THURSDAY SYMPOSIUM 35104
A New Level of Quality Management in Clinical Laboratories Through ISO Standards, Lean Principles and Design For Six Sigma

ILLUM-0131

THURSDAY'S SCHEDULE

8:00am – 10:00am
Point-of-Care Coagulation Testing
Annual POC Coordinator's Forum
McCormick Place Convention Center

8:30am – 2:00pm
Expo Open

9:30am – 12noon
Symposia

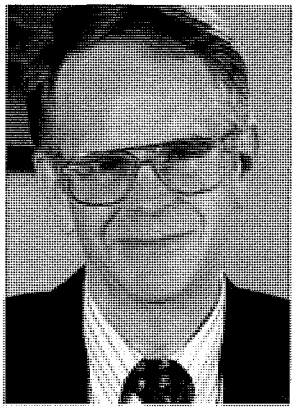
12:30pm – 2:00pm
Plenary Session

ILLUM-0132

PLENARY SESSION
12:30pm - 2:00pm

Mitochondria: The Missing Link Among Degenerative Diseases, Cancer and Aging, and the Next Molecular Diagnostics Frontier 15001

Douglas Wallace, PhD, MAMMAG, Irvine, CA



Level: Basic

CE Credit: 1

Session Overview: Mitochondrial analysis has allowed the exploration of the relationship between human evolution and some of the most common and disabling diseases, including diabetes, Alzheimer's disease, seizure disorders and Parkinson's disease. The degenerative effects of aging itself may largely be fueled by accumulated mitochondrial mutations and the resulting malfunction of organs and systems throughout the body. Many mtDNA malfunctions have their roots in evolutionary adaptations hidden in the history of the human species. This Plenary session will allow attendees to better understand the relationship between mitochondrial function, mitochondrial mutations, and the likelihood of specific disorders.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the role of mitochondria in normally functioning cells; 2) explain how mutations in mitochondrial DNA can lead to disease; and 3) list the ways in which mitochondrial research can lead to further understanding of major diseases as well as the aging process.

MORNING SYMPOSIA
9:30am - 12noon

Nutrigenomics: The Connection Between Nutrition and Genes 35102

Moderator: Elia Mears, MS, MT(ASCP)SM, Chabert Medical Center-LSUHSC, Houma
Level: Basic
CE Credit: 2.5
Developed in cooperation with the Lipoproteins & Vascular Diseases, Molecular Pathology, TDM & Toxicology, and Nutrition Divisions

Session Overview: The strong relationship among nutrition, health and disease is well known. This symposium will focus on nutritional genomics, or nutrigenomics, an emerging field for studying the interaction between genomics and nutrient metabolism. A key aspect that will be discussed is the analysis of intricate relations among diet, genetics and metabolism. Rationale for the use of individual genomic information — as it relates to demographic, physiological and environmental measures in response to controlled dietary interventions — will be provided as it is necessary to guide personalized diet prescriptions and maximize clinical outcomes.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the developments in human genetics that apply to complex chronic disorders; 2) describe the interplay between nutrition and genetics; 3) explain the interaction between genetic and environmental factors that determine the expression of risk factors and disease; and 4) describe how nutritional systems biology utilizing knowledge of the genome and new technologies can provide new opportunities for disease prevention.

SPEAKERS

Nutrigenetics, Lipid Metabolism and Cardiovascular Disease
Jose Ordovas, PhD, USDA Human Nutrition Research Center on Aging, Boston, MA

Nutritional Systems Biology
Ben van Ommen, TNO Quality of Life, Zeist, the Netherlands

Nutrigenomics: Opportunities and Challenges in Cancer Prevention
John Miler, PhD, Chief, Nutritional Science Research Group, National Institutes of Health, Rockville, MD

Clinical Applications of Liquid Chromatography/Mass Spectrometry 35101

Moderator: Alan Wu, PhD, DABCC, San Francisco General Hospital, CA
Level: Intermediate
CE Credit: 2.5

Session Overview: This symposium will focus on the latest applications of liquid chromatography/mass spectrometry (LC/MS) in the areas of clinical chemistry, toxicology and endocrinology.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the role of LC/MS for an expanded urine drug testing panel; 2) list the limitations of immunoassays for steroid assays and how LC/MS offers a more accurate alternative for their measurement; 3) explain the role of LC/MS for testing novel immunosuppressant drugs; and 4) describe how LC/MS can be effectively used in newborn screening programs.

SPEAKERS

LC/MS for Steroid Analysis
Steven Soldin, PhD, Georgetown Clinical Research Center, Washington, DC

LC/MS for Genetic Disease Detection
Kenneth Pass, PhD, Wadsworth Center, NYS DOH, Albany, NY

LC/MS for Drugs of Abuse Testing
Judith Stone, PhD, ABCC, San Francisco General Hospital, CA

ILLUM-0134

Making Sense of the Alphabet Soup of Laboratory Regulations 35103

Moderator: Linnea Baudhuin, PhD, Mayo Clinic, Rochester, MN
Level: Basic
CE Credit: 2.5
Developed in cooperation with Society for Young Clinical Laboratorians

Session Overview: This symposium will focus on the federal regulation of laboratory testing principally through the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) regulations. Additional topics to be discussed include how the Joint Commission on the Accreditation of Health Organizations (JCAHO) standards impact the clinical laboratory as well as how the laboratory accreditation program of the College of American Pathologists (CAP) contributes to ensuring the quality of laboratory services.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the regulatory steps involved in establishing a new testing site; 2) describe the latest requirements for CLIA '88 compliance; 3) describe the evolution and relationship of the significant regulatory and accreditation agencies; and 4) explain the mission and purpose of the CAP Laboratory Accreditation Program.

SPEAKERS

JCAHO — Explained and Understood
Megan Sawchuk, Joint Commission on Accreditation, Oakbrook Terrace, IL

CAP Laboratory Accreditation Program
Nancy Yeransian, MT, (ASCP)SC, College of American Pathologists, Northfield, IL

CLIA 2006 Update: The Latest!
Sharon Ehrmeyer, PhD, Univ. of Wisconsin, Madison

A New Level of Quality Management in Clinical Laboratories Through ISO Standards, LEAN Principles and Design for Six Sigma 35104

Moderator: James Love, Jr., PhD, DABCC, JL Consulting Services, Penfield, NY
Level: Basic
CE Credit: 2.5
Developed in cooperation with the Industry and Management Sciences Divisions

Session Overview: This symposium will explore the value in integrating ISO 15189-based accreditation and ISO 9001:2000 certification to assure optimal effectiveness of a laboratory's quality management system. This session will also focus on the use of these ISO standards in conjunction with that of LEAN and Design for Six Sigma techniques for development of new processes and systems which can help laboratorians further enhance the quality and effectiveness of test results.

Expected Outcomes: After attending this session, participants will be able to: 1) describe how to use a step-by-step approach to implement ISO Standards; 2) identify the gains of successfully implementing an ISO-based quality management system; 3) list the 7 categories of waste according to LEAN theory; 4) cite 3 key non-negotiable principles of LEAN that should be utilized when building criteria for making new process and equipment decisions; 5) describe how to apply the 4-step Design for Six Sigma (DFSS) process; and 6) determine whether DMAIIC or DFSS will be the more appropriate process improvement technique to use in their laboratory setting.

SPEAKERS

ISO 15189 and ISO 9001 in the Clinical Laboratory: A New Quality Management System Approach.
Rogerio Rabelo, MD, PhD, MBA, Fleury Diagnostics, São Paulo, Brazil

Where Do We Go From LEAN?
Maureen Harte, MT (ASCP), Six Sigma Master Black Belt, Ortho-Clinical Diagnostics, Salt Lake City, UT

New Approaches in Six Sigma for the Clinical Laboratory.
Carl Garber, PhD, Quest Diagnostics, Incorporated, Lyndhurst, NJ

Contemporary Therapeutic Drug Management: Merging Pharmacogenomics, Biomarkers, Drug Concentrations, and Informatics to Improve Patient Care. 35105
Moderator: William Clarke, PhD, Johns Hopkins Medical Institutions, Baltimore, MD
Level: Intermediate
CE Credit: 2.5
Developed in cooperation with TDM & Toxicology Division

Session Overview: This session will provide attendees with a contemporary view of the key aspects in therapeutic drug management. Participants will learn how individualization and optimization of drug therapy for patients can lead to an improved understanding of new tools from key disciplines including pharmacogenomics, biomarkers, informatics, pharmacokinetic modeling, and the traditional determinations of serum drug concentrations.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the processes and variables that contribute to inter- and intra-patient differences in serum drug concentrations at the same dosages; 2) list the most appropriate specimens for therapeutic drug management; 3) describe the use of emerging therapeutic drug management tools including pharmacogenomics, biomarkers, and informatics, as well as traditional drug concentration determination; and 4) describe how application of contemporary tools can improve individualization of pharmacotherapy.

SPEAKERS

Review of Pharmacogenetic Testing for TDM Today
Gwen McMillin, ARUP Laboratories and Univ. of Utah, Salt Lake City

Biomarker Discovery and Testing for TDM Today
William Clarke, PhD, Johns Hopkins Medical Institutions, Baltimore, MD

Interpretation of TDM Results: Assistance from Informatics, PK Software, and More
Sander Vinks, PharmD, PhD, FCP, Cincinnati, OH

Laboratory Evaluation of Endocrine Function 35106
Moderator: Anthony Butch, PhD, DABCC, Geffen School of Medicine at UCLA, Los Angeles, CA
Level: Intermediate
CE Credit: 2.5

Session Overview: This symposium will provide an overview of thyroid, adrenal and pituitary gland physiology as well as the key clinical manifestations during endocrine dysfunction. Application of currently available tests for diagnosing dysfunction and disease will be discussed, with an emphasis on appropriate test selection, interpretation of test results, and potential analytical issues that must be considered.

Expected Outcomes: After attending this session, participants will be able to: 1) describe the anatomy and physiology of the thyroid, adrenal and pituitary glands; 2) identify clinical manifestations associated with altered endocrine function; 3) select the appropriate test and understand the principles behind tests that are currently used in endocrinology laboratories; and 4) interpret and explain the limitations of each test described.

SPEAKERS

A Look Inside the Adenohypophysis: Laboratory Assessment of Anterior Pituitary Function
Dennis Dietzen, PhD, DABCC, St. Louis Children's Hospital, St. Louis, MO

Frontiers in Thyroid Function Testing
Anthony Butch, PhD, DABCC, Geffen School of Medicine at UCLA, Los Angeles, CA

The Intermediate and Posterior Pituitary Lobe: Neuroendocrine, Clinical and Diagnostic Implications
Geza Bodor, MD, DABCC, Denver Health Medical Center & Univ. of Colorado Health Sciences Center, Denver

At this year's Annual Meeting, you can take advantage of others' experiences via Case Study sessions.

Education experts tell us that "learning by doing" is one of the most effective ways to retain information. The presenters of the following sessions have indicated they will include case study presentations. Some invite participants to bring their own cases for group discussion.

Alphabet Soup - The Hepatitis Viruses 191001
Sunday Full Day Interactive Workshop: AACC University *(page 14)*

Perspective and Tools: How to Interpret PGx Testing 191003
Sunday Full-Day Interactive Workshop: AACC University *(page 14)*

Tumor Markers: How We Use Them in the Clinic and New Developments 191008
Sunday Full Day Short Course: AACC University *(page 15)*

Biomarkers for Detection of Myocardial Injury, Risk Stratification and Heart Failure 191016
Sunday Full Day Short Course: AACC University *(page 18)*

Hemoglobinopathies and Thalassemias: A Case Study Approach 191002
Sunday Afternoon Interactive Workshop: AACC University *(page 19)*

Hot Topics in Point-of-Care Testing 191005
Sunday Afternoon Interactive Workshop: AACC University *(page 19)*

Solving Day-To-Day Management Challenges: Case Histories & Applications 191007
Sunday Afternoon Interactive Workshop: AACC University *(page 20)*

The Opportunities and Pitfalls of Using Information Technology to Decrease Postanalytic Errors 32105
Monday Morning Symposium *(page 29)*

Veterinary Hematology: The Diagnostic Power of Peripheral Blood and Bone Marrow Evaluation 22101
Monday Morning Interactive Workshop *(page 30)*

Clinical Toxicology Cases 22102
Monday Morning Interactive Workshop *(page 30)*

How to Eliminate False Positive and False Negative Results in Clinical Chemistry Laboratories 72210
Monday Afternoon Short Course *(page 35)*

Successful Community Laboratory Outreach 72211
Monday Afternoon Short Course *(page 35)*

Adventures in the Gamma Zone 23101
Tuesday Morning Interactive Workshop *(page 46)*

Best Practices for the Operation and Management of Point-of-Care Testing 33206
Tuesday Afternoon Symposium *(page 47)*

How Any Lab Can Be Better — For Everyone 73211
Tuesday Afternoon Short Course *(page 51)*

Beyond Herbals: The Toxicology of Plants 74103
Wednesday Morning Short Course *(page 60)*

ILLUM-0137

Saturday, July 22, 2006

8:00am – 5:00pm
ABCC Exams
Hyatt Regency Chicago

1:00pm – 4:00pm
CPOCT Certificate Program Committee Task Force Meeting
Hyatt Regency Chicago

1:00pm – 5:00pm
AACC House of Delegates Meeting
Hyatt Regency Chicago

5:00pm – 9:00pm
Issues in Immunodiagnostics Symposium
Hyatt Regency Chicago

5:30pm – 8:30pm
Management Sciences Division Reception and Leadership Seminar
Hyatt Regency Chicago

5:30pm – 9:00pm
Metabolomic Markers in Diet and Health Joint Division Symposium
Hyatt Regency Chicago

6:00pm – 10:00pm
CPOCT Executive Committee Meeting
Hyatt Regency Chicago

Sunday, July 23, 2006

9:00am – 10:30am
Clinical Chemistry Journal Board of Editors Meeting
Hyatt Regency Chicago

1:30pm – 3:00pm
Division Awards and Networking Session
Hyatt Regency Chicago

2:00pm – 4:00pm
NGSP Steering Committee Meeting
Hyatt Regency Chicago

6:30pm – 7:30pm
AACC Annual Meeting Opening Mixer
Hyatt Regency McCormick Place

7:30pm – 8:30pm
Joint Reception of the TDM/Tox and the Molecular Pathology Divisions
Hyatt Regency Chicago

Monday, July 24, 2006

7:00am – 9:00am
University HealthSystem Consortium Lab Council Steering Committee Meeting
Hyatt Regency Chicago

8:00am – 12noon
NRCC Certification Exams
Hyatt Regency Chicago

8:00am – 12noon
ABCC Board of Directors Meeting
Hyatt Regency Chicago

8:00am – 5:00pm
University HealthSystem Consortium Lab Council Meeting
Hyatt Regency Chicago

8:30am – 10:00am
International Advisory Group
Hyatt Regency Chicago

10:30am – 12noon
CLSI's Commitment to Quality: Progress on Alternative Quality Control
Hyatt Regency McCormick

12noon – 1:00pm
CPOCT Industry Liaison Committee Meeting
Hyatt Regency Chicago

12noon – 1:30pm
AACC Annual Meeting of the Membership
McCormick Place Convention Center

12noon – 4:00pm
LISMI Membership Meeting
Hyatt Regency Chicago

1:30pm – 3:00pm
NACB Board Meeting
Hyatt Regency Chicago

Monday, July 24, 2006 *(continued)*

2:00pm – 4:30pm
Student Oral Presentations and Poster Contest
McCormick Place Convention Center

2:30pm – 4:30pm
NGSP Manufacturer Forum
Hyatt Regency Chicago

3:00pm – 5:30pm
NRCC Board of Directors Meeting
Hyatt Regency Chicago

3:00pm – 6:00pm
IFCC Working Group on Standardization of Thyroid Function Tests
Hyatt Regency Chicago

4:30pm – 6:30pm
California Local Sections Mixer
Networks Bar & Lounge, Hyatt Regency McCormick Place

5:00pm – 5:30pm
ABCC Forum: What Are the Benefits of ABCC Certification?
Hyatt Regency Chicago

5:30pm – 6:30pm
SYCL Networking Reception
Hyatt Regency Chicago

5:30pm – 9:30pm
Annual LVD Annual Dinner Meeting and Mixer: Current Topics in Cardiovascular Disease and Stroke
Hyatt Regency Chicago

6:00pm – 7:00pm
International Reception
Hyatt Regency Chicago

6:00pm – 7:30pm
ABCC Reception
Hyatt Regency Chicago

ILLUM-0138

Tuesday, July 25, 2006

7:00am – 9:00am
Local Section Chairs and Chairs Elect Breakfast
Hyatt Regency Chicago

7:30am – 9:30am
AICCNA Breakfast Meeting
Hyatt Regency Chicago

8:00am – 12noon
OEM Lecture Series
McCormick Place Convention Center

10:00am – 11:30am
DACC Executive Meeting
Hyatt Regency Chicago

11:30am – 2:30pm
CLSI Area Committee on Clinical Chemistry and Toxicology
Hyatt Regency McCormick

12noon – 2:00pm
DACC General Meeting
Hyatt Regency Chicago
Congratulations to the AACC Division of Animal Clinical Chemistry Celebrating 30 Years, 1976 - 2006

12noon – 3:00pm
IFCC Corporate Members Meeting
Hyatt Regency Chicago

12noon – 4:30pm
History Division Executive Committee Meeting
Hyatt Regency Chicago

Tuesday, July 25, 2006 *(continued)*

12:30pm – 2:00pm
Midwest Section Business Meeting and Luncheon
Hyatt Regency Chicago

12:30pm – 2:00pm
Proteomics Division Luncheon
Hyatt Regency Chicago

1:00pm – 2:00pm
Pediatric and Maternal-Fetal Division Reference Range Initiative Meeting
Hyatt Regency Chicago

5:00pm – 6:00pm
CPOCT Annual General Meeting
Hyatt Regency Chicago

5:00pm – 6:00pm
Molecular Pathology Division General Membership Meeting
Hyatt Regency Chicago

5:00pm – 7:00pm
Washington University Clinical Chemistry Alumni Reception
Hyatt Regency Chicago

6:00pm – 8:00pm
CPOCT Division Mixer
Hyatt Regency Chicago

Wednesday, July 26, 2006

8:00am – 12noon
OEM Lecture Series
McCormick Place Convention Center

12:30pm – 2:15pm
NACB Awards Luncheon and Membership Meeting
Hyatt Regency Chicago

3:00pm – 5:00pm
BMA Seminar
Hyatt Regency Chicago

4:30pm – 5:30pm
Van Slyke Foundation Reception
Hyatt Regency Chicago

6:00pm – 7:00pm
Industry Division Membership Meeting
Hyatt Regency Chicago

Thursday, July 27, 2006

8:00am – 10:00am
Point-of-Care Coagulation Testing Annual POC Coordinator's Forum
McCormick Place Convention Center

Please check the AACC Annual Meeting website at www.aacc.org/2006am for the most up-to-date schedule.

Issues in Immunodiagnostics Symposium: Organ Transplantation and the Clinical Laboratory – What's on the Horizon

Saturday, July 22
5:00pm – 9:00pm
Hyatt Regency Chicago Hotel

Sponsored by the AACC Clinical & Diagnostic Immunology Division

Supported by an educational grant from Bayer HealthCare LLC, Diagnostics Division

Overview: This year's Issues in Immunodiagnostics Symposium will examine new technologies and strategies for managing the immune system of organ transplant recipients to optimize allograft survival and recipient outcomes.

- Immunosuppression or Allograft Tolerance—Which Way to Go?
  Edward K. Geissler, PhD, University of Regensburg, Department of Surgery
- Applications of Pharmacogenomics in the Transplant Recipient
  Gilbert Burckart, Pharm.D, University of Southern California, School of Pharmacy

Registration: $15 CDI Division Members; $35 AACC Members; $50 AACC non-Member. Your registration includes a light dinner at 5:00, scientific sessions at 6:15, and dessert with coffee/tea following the presentation.

Register online at www.aacc.org/2006AM . Please note: A Full conference registration will be required when registering online. Register by fax, mail or onsite using the Annual Meeting Registration Form on page 81. Full conference registration is not required when registering via these methods. CDID members must register by fax, mail or onsite to get the discounted Division member fee.

11th Annual Management Sciences Division Leadership Seminar: The Truth about Quality Today

Saturday, July 22
5:30pm – 8:30pm
Hyatt Regency Chicago Hotel

Sponsored by the AACC Management Sciences Division

Overview: The 11th annual leadership seminar will feature a presentation by Dr. James Westgard of the University of Wisconsin Medical School, Madison, WI.

Registration: $15 AACC Member/Non-member. Your registration includes a reception at 5:30 and scientific session at 6:30.

Register online at www.aacc.org/2006AM. Please note: A Full conference registration will be required when registering online. Register by fax, mail or onsite using the Annual Meeting Registration Form on page 81. Full conference registration is not required when registering via these methods.

Metabolomic Markers in Diet and Health

Saturday, July 22
5:30pm – 9:00 pm
Hyatt Regency Chicago Hotel

Sponsored by the AACC Nutrition, Lipoproteins and Vascular Diseases, Molecular Pathology and TDM/Toxicology Divisions

Overview: New research shows that setting dietary recommendations for an entire population may be coming to an end. Instead, individual genetic variations may affect the response to dietary intake and our nutritional status.

- The Emerging Science of Nutrigenetics
  Martin Kohlmeier, MD, University of North Carolina, Chapel Hill
- Metabolomics: Enabling Nutrition by Quantitative Health Assessment
  Bruce German, University of California, Davis

Registration: $15 AACC Members; $50 Non-AACC Members. Your registration includes scientific sessions at 5:30 followed by a reception.

Register online at www.aacc.org/2006AM. Please note: A Full conference registration will be required when registering online. Register by fax, mail or onsite using the Annual Meeting Registration Form on page 81. Full conference registration is not required when registering via these methods.

Opening Mixer

Sunday, July 23, 2006
6:30pm – 7:30pm
Hyatt Regency McCormick Place Hotel

Immediately following the Opening Plenary Session, join us for a beer/wine reception in the Hyatt Regency McCormick Place Hotel, adjacent to the McCormick Place Convention Center. Transportation will be available, from the Convention Center, at the end of the Opening Mixer to official AACC hotels. No additional ticket is required; just wear your badge as a registered attendee or guest of the meeting. The Opening Mixer is included in this year's registration fees.

AACC Annual Meeting of the Membership

Monday, July 24, 2006
12noon – 1:30pm
McCormick Place Convention Center

Student Oral Presentations and Poster Contest

Monday, July 24, 2006
2:00pm – 4:30pm
McCormick Place Convention Center

This symposium, intended to highlight student-generated research, presents student abstracts in both oral and poster format. The first hour consists of four selected oral presentations, and the second hour and a half consists of the student poster contest. Students compete for cash awards as they are judged on scientific content, originality, and presentation style. The winners of the student awards will be announced at the SYCL Networking Reception to be held from 5:30pm to 6:30pm.

The Benefits of ABCC Certification

Monday, July 24, 2006
5:00pm – 5:30pm
Hyatt Regency Chicago Hotel
Sponsored by ABCC and NACB.

Professional certification represents a commitment to quality, competence, and upholding the highest standards of care. Learn how to advance your career as a Diplomate of the ABCC. Free forum.

The Society for Young Clinical Laboratorians (SYCL) Networking Reception

Monday, July 24, 2006
5:30pm – 6:30pm
Hyatt Regency Chicago Hotel

SYCL is now 2 years old! Join us for an opportunity to learn more about SYCL, meet other SYCL members and network with colleagues. In addition, the winners from the Student Awards will be announced and presented. Come and join the celebration!

Current Topics in Cardiovascular Disease and Stroke AACC LVD Annual Dinner Meeting and Mixer

Monday, July 24
5:30pm – 9:30pm
Hyatt Regency Chicago Hotel
Sponsored by the AACC Lipoproteins and Vascular Diseases Division

Overview: Scientific presentations at this year's LVD dinner meeting will address genetic predisposition to CVD and look at recent efforts to identify markers for stroke.

- Genetic Predisposition to Cardiovascular Disease—An Update
  Michael Y. Tsai, PhD, University of Minnesota, Minneapolis
- Serum Biomarkers for Diagnosis and Management of Stroke
  Alan H. Wu, PhD, University of California, San Francisco

Registration: $20 LVD Division Members; $35 AACC Members; $60 Non-AACC Members. Your registration includes a reception at 5:30; awards at 6:40, dinner at 7:00 and scientific sessions at 7:50.

Register online at www.aacc.org/2006AM. Please note: A Full conference registration will be required when registering online. Register by fax, mail or onsite using the Annual Meeting Registration Form on page 81. Full conference registration is not required when registering via these methods. LVD Division members must register by fax, mail, or onsite to get the discounted Division member fee.

The OEM Lecture Series

Tuesday, July 25 and Wednesday, July 26, 2006
8:00am – 12noon
McCormick Place Convention Center
Developed in cooperation with the Industry Division

The OEM Lecture Series offers the opportunity for OEM vendors (those organizations that supply components, subsystems and contract services to IVD manufacturers) to present their latest advances to meeting participants. These sessions are intended for those involved in product research and development.

NACB Awards Luncheon

Wednesday, July 26
12:30pm – 2:15 pm
Hyatt Regency Chicago Hotel

Registration: $25 NACB Fellows. Academy Fellows are invited to attend this luncheon in honor of NACB award winners.

Register online at www.aacc.org/2006AM. Please note: A Full conference registration will be required when registering online. Register by fax, mail or onsite using the Annual Meeting Registration Form on page 81. Full conference registration is not required when registering via these methods.

Point-of-Care Coagulation Testing Annual POC Coordinator's Forum

Thursday, July 27
8:00am – 10:00 am
McCormick Place Convention Center
Sponsored by the AACC Critical and Point-of-Care Testing Division

Overview: This year's POCC Forum will review clinical guidelines for managing patients on warfarin and heparin and review compliance and regulatory needs for implementing POC devices in an anticoagulation clinic.

- Anticoagulation with Warfarin and Heparin: How the Drugs Work, How They are Monitored and What the Results Mean.
  Michael Laposata, MD, PhD, Harvard Medical School, Boston, MA
- Point-of-Care Testing in Coagulation: Barriers to Effective Implementation.
  Michael Laposata, MD, PhD, Harvard Medical School, Boston, MA
- Laboratory Issues in the Management of Anticoagulation Clinics Using POC Instruments and Patient Self Testing.
  Sheila Coffman, MT(ASCP), University Hospital, San Antonio, TX

Registration: $15 AACC member/non-member

Register online at www.aacc.org/2006AM. Please note: A Full conference registration will be required when registering online. Register by fax, mail or onsite using the Annual Meeting Registration Form on page 81. Full conference registration is not required when registering via these methods.

Van Slyke Foundation

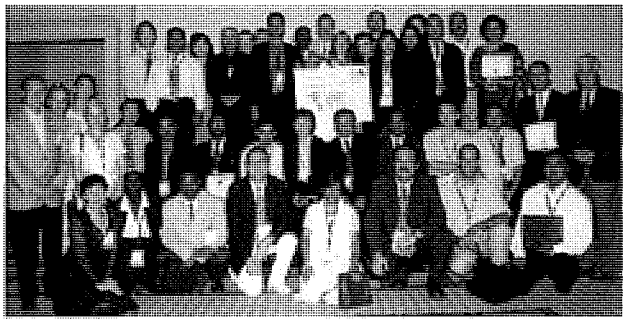
AACC's Van Slyke Foundation (VSF) works with the laboratory community to improve healthcare worldwide by encouraging and funding deserving clinical laboratory scientists and students across the globe. Foundation donors and volunteers give back to the clinical laboratory science field by supporting clinical laboratory scientists everywhere.

AT THE 2006 ANNUAL MEETING THE FOUNDATION WILL SUPPORT:

> **International scientists from emerging areas** through travel grants. Grant winners will be able to attend the scientific meeting and visit the Clinical Lab Expo, where they'll meet new colleagues and learn about the latest developments in laboratory medicine and technology.

> **Promising young clinical laboratorians in the US** through domestic travel grants. Grant winners attend the AACC Annual Meeting to experience the latest in laboratory science and technology and network with the best clinical scientists in the world.

> **Deserving science students** with recognition at the Annual Meeting through poster contest awards and poster presentation awards. VSF travel grants enable young investigators to attend the Annual Meeting, rewarding outstanding scientific achievement by the laboratory leaders of tomorrow.



2005 International Travel Grant Attendees

Throughout the year, the Foundation also advances scientific knowledge and discovery by: providing AACC memberships for laboratory directors in emerging areas; supplying laboratorians in underserved areas with scientific publications, educational programs and other materials, to bring the latest in diagnostics science and technology to labs and patients in all parts of the world; and funding science fair awards for our best and youngest science students.

JOIN THE VAN SLYKE FOUNDATION'S EFFORTS NOW...

...contribute via the Annual Meeting Registration Form *(see page 81)*, You can also donate online at: www.aacc.org/vsf/contribution_form.htm or contact Kia Reid, the Foundation's Coordinator, at 1-800-892-1400 ext. 712 (email her at kreid@aacc.org).

... volunteer your time. Just check the "I want to volunteer" box on the internet VSF contribution form (www.aacc.org/vsf/contribution_form.htm). As a VSF volunteer, you could mentor a science student, host a travel grantee, arrange a lab tour at your facility or help in many other ways.

Special thanks to major donors to VSF programs at the 2006 AACC Annual Meeting

(donations and pledges as of January 2006)

Jerry and Sandy Gallwas
Abbott Fund
Beckman Coulter
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THE FOUNDATION'S 2005/2006 MAJOR DONORS

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Gopal Savjani, Jerry & Sandy Gallwas, Richard Flaherty, Jocelyn Hicks, Richard Nadeau, Bernard Brody, Mary Lou Gantzer and Laurence Demers

AACC Local Sections and Divisions

TDM and Toxicology Division
Management Sciences Division
Clinical and Diagnostic Immunology Division
Lipoproteins and Vascular Diseases Division
Northeast Local Section
Southern California Local Section
New York Upstate Local Section
Capital Local Section
Ohio Valley Local Section
Pacific Northwest Local Section

Recent VSF contributors are invited to attend the VSF reception on Wednesday, July 26th (By invitation only, please).

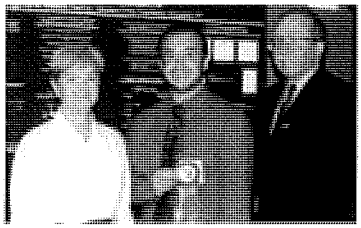
A complete list of all Van Slyke Foundation donors may be found in each issue of the *Clinical Laboratory News* Dailies at the Annual Meeting, or on the AACC Web site at www.aacc.org/vsf.

Add your name to the list of those who've invested in the future of clinical laboratory medicine — give to the Van Slyke Foundation today!

THE NATIONAL ACADEMY OF CLINICAL BIOCHEMISTRY

The Academy of AACC

The National Academy of Clinical Biochemistry, the Academy of AACC, is dedicated to advancing the science and practice of clinical laboratory medicine through research, education, and professional development. NACB will conduct the following activities at the AACC Annual Meeting:



NACB officers Mary Burritt and Bob Dufour honor 2005 Distinguished Abstract Award recipient Ross Molinaro.

Monday, July 24
1:30pm – 3:00pm
NACB Board of Directors Meeting

Tuesday, July 25
10:30am – 12noon and 2:30pm – 5:00pm
Pharmacogenetics Practice Guidelines I: Establishing Clinical Applications
McCormick Place Convention Center

Wednesday, July 26
10:30am – 12noon and 2:30pm – 5:00pm
Pharmacogenetics Practice Guidelines II: Clinical Utilization of Pharmacogenetics
McCormick Place Convention Center

Wednesday, July 26
12:30pm – 2:15pm
NACB Awards Luncheon and Membership Meeting
Luncheon cost: $25.00
Make reservations in advance using the AACC Annual Meeting registration form.

NACB members are invited to attend this luncheon in honor of new Academy Fellows and recipients of the following awards:

Y.M. Dennis Lo, MD
DISTINGUISHED SCIENTIST AWARD
Outstanding Research Advances in Clinical Biochemistry
Supported by Dade Behring Inc.

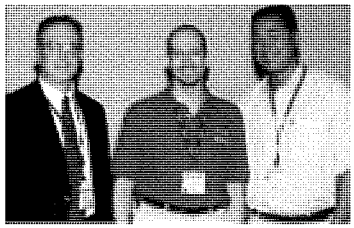
John E. Sherwin, PhD, DABCC, FACB
PROFESSOR ALVIN DUBIN AWARD
Distinguished Contributions to the Profession and the Academy
Supported by Abbott Diagnostics

Linnea M. Baudhuin, PhD
GEORGE GRANNIS AWARD
Excellence in Research and Scientific Publication
Supported by NACB and the Ohio Valley Local Section

For information about the Academy, go to the NACB web site at www.nacb.org or stop by the NACB booth at the AACC Clinical Lab Exposition.

THE AMERICAN BOARD OF CLINICAL BIOCHEMISTRY, INC.

The ABCC certifies doctoral level scientists in the practice of clinical chemistry, toxicological chemistry, and molecular diagnostics. ABCC will offer the following activities during the AACC Annual Meeting:



ABCC officers Doug Stickle and Stanley Lo honor Diplomate David Grenache during 2005 reception.

Saturday, July 22
8:30am – 5:00pm
ABCC Certification Exams

Monday, July 24
8:00am – 12noon
ABCC Board of Directors Meeting

Monday, July 24
5:00pm – 5:30pm
ABCC Forum:
What are the Benefits of ABCC Certification?
Open to lab professionals interested in doctoral level certification in clinical chemistry, toxicological chemistry, or molecular diagnostics.

Monday, July 24
6:00pm – 7:30pm
ABCC Reception in Honor of New Diplomates
Open to all Diplomates

For information about certification, go to the ABCC web site at www.aacc.org/abcc or stop by the ABCC booth at the AACC Clinical Lab Exposition.

CONFERENCE REGISTRATION – WHAT'S INCLUDED

Full Conference Registration for AACC Members, Non-Members, Students and Emeritus Members includes:

- Plenary Sessions
- Symposia
- Poster Sessions
- Oral Abstract Presentations
- Chair's Invited Sessions
- Exhibits
- Opening Mixer

Daily Registration/One Day Registration only includes:

- Plenary Session for that Day
- Symposia for that Day
- Poster Sessions for that Day
- Oral Abstract Presentations for that Day
- Chair's Invited Sessions for that Day
- Exhibit Hall Entry for that Day (Tues – Thurs)

Guest Registration includes:

- Plenary Sessions
- Symposia
- Poster Sessions
- Chair's Invited Sessions
- Oral Abstract Presentations
- Exhibits
- Opening Mixer

Expo-Only Registration (includes admission to Expo and Posters only. Note – Poster Presenters must register for the conference.):

Exhibits (Tuesday - Thursday)

If you pay a Conference Registration fee, do not register separately for the Exhibits. To register for the Expo-Only, complete the form at www.aacc.org/2006AM. If you do not have web access, contact Customer Service at 1-800-892-1400 or 202-857-8717 to obtain a form.

Only individuals registered for the 2006 AACC Annual Meeting and wearing an appropriate badge may attend Annual Meeting events. Tickets are required for all Brown Bags, Short Courses, Meet the Expert Sessions, and Interactive Workshops.

If you are purchasing tickets to either Short Courses, Interactive Workshops, Meet the Expert Sessions or Brown Bag Sessions, you must pay the Full or Daily Conference Registration Fee and complete a separate registration form. If you are presenting a poster, you must also pay the appropriate Conference Registration Fee (either a full conference registration or a daily registration fee for the day on which you are presenting).

Seats are limited and are assigned on a first-come, first served basis. Register early!

REGISTRATION FEES

***Save $220 on your registration, join AACC today!** See pages 85–86 for details. You may join at the same time as you register.

	EARLY BIRD RECEIVED BY 6/8/06	ON-SITE RECEIVED AFTER 6/8/06*
Conference Registration		
AACC Member	$435	$560
Non-Member*	$655	$780
Student	$145	$160
Emeritus Member	$145	$160
Daily Registration	$260	$260
Guest/Spouse	$115	$145
AACC University, Short Courses and Interactive Workshops		
Morning:		
Member	$150	$150
Non-Member	$200	$200
Afternoon:		
Member	$200	$200
Non-Member	$250	$250
Full Day:		
Member	$250	$250
Non-Member	$300	$300
Brown Bag Sessions:		
Member/Non-Member *(meal is not included)*	$25	$25
Meet the Experts:	$10	$10

Opening Mixer: (included with Registration – may not attend if not registered)

***Any forms received after July 6 will be processed at the meeting.**

ILLUM-0144

REGISTERING FOR INDIVIDUAL SESSIONS

Short Courses, Interactive Workshops, and Meet the Experts Sessions Registration:

- All fees must accompany the registration form.
- Indicate choice for each day on form, using the five or six-digit code number.
- Tickets may not be purchased for individuals other than those who have paid the full or daily conference basic registration fees.
- Due to limited seating, guests of speakers and registrants cannot be seated.
- On-site registration will be available only for those sessions that have space.

There will be no wait list maintained for sold-out sessions. Any space available will be sold on-site. Your credit card will not be charged for sold-out sessions. Refunds will be processed for sold-out sessions paid by check or wire transfer.

Brown Bag Sessions Registration

- Limit 10 people per session. There can be no exceptions. Register Early!
- Morning Brown Bag Sessions (40000 series five-digit code numbers) may be repeated in the afternoon (50000 series five-digit code number) on the same day. Some Brown Bag Sessions may not be presented twice.
- Brown Bag Session tickets may only be purchased for those who have paid the full or daily conference registration fees.
- Due to limited seating, guests of registrants cannot be seated.
- On-site registration will only be available for Brown Bag Sessions with space.

There will be no wait list maintained for sold-out sessions. Any space available will be sold on-site. Your credit card will not be charged for sold-out sessions. Refunds will be processed for sold-out sessions paid by check or wire transfer.

Symposia, Plenary Sessions, Chair's Invited Sessions and Oral Abstract Presentations

- Symposia, Plenary Sessions, Chairs Invited Sessions and Oral Abstract Presentations are available at no charge to conference registrants who have paid the full conference registration fee or daily registration fee (for that day), paid registered guests, and exhibit staff.
- Please indicate on your registration form (using the five-digit code number) which symposia session you plan to attend. This will help us match meeting room sizes to demand. Tickets will not be issued for these sessions.

AACC University

- No Conference or Daily Registration Fee required. Requires payment only for courses offered on Sunday, July 23, 2006.
- All fees must accompany the registration form.
- Using the six-digit code, indicate your session choices for this day.
- Due to limited seating, guests of speakers and registrants cannot be seated.
- On-site registration will only be available only for sessions with space.

There will be no wait list maintained for sold-out sessions. Any space available will be sold on-site. Your credit card will not be charged for sold-out sessions. Refunds will be processed for sold-out sessions paid by check or wire transfer.

HOW TO REGISTER

- AACC must receive payment for ALL fees along with your registration form, or your request will not be processed.
- Payment may be made by: Check (payable to AACC in US dollars drawn on a US bank); VISA; MasterCard; American Express; or wire transfer.
- You can register three ways:

Online at www.aacc.org/2006AM

Mail registration form (pages 81–84) and payment to: 2006 Annual Meeting Registration, P.O. Box 630623, Baltimore, MD 21263-0623

Fax registration form (pages 81–84) to: 202-887-5093 *(credit card registrations only)*. Your fax copy will be treated as an original. To avoid duplicate charges, do not mail your original.

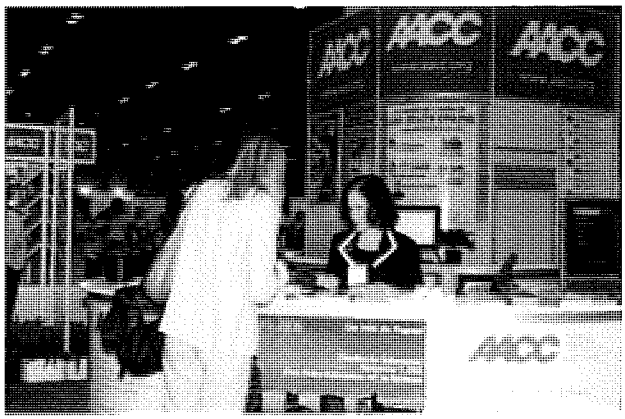
Confirmation of your registration will be mailed within two weeks of receipt of the registration form with complete payment. Conference attendee badges and tickets will NOT be mailed prior to the meeting. You will be able to pick up your credentials on-site. **All individuals must show a government-issued photo ID when they pick up their badges and tickets.**

CANCELLATION POLICY

All Annual Meeting cancellations must be received in writing. Written cancellations received by Thursday, June 8, 2006 will be assessed a $50 processing fee. Written cancellation received between Friday, June 9 and Thursday, July 6, 2006 will be assessed a cancellation fee equal to 35% of the total registration fees. No refunds will be granted after Thursday, July 6, 2006. Refunds will be processed three to four weeks after the conclusion of the meeting. Fees paid for sold-out sessions may be returned sooner.

STOP BY BOOTH #2051 TO SEE WHAT'S NEW AT AACC!

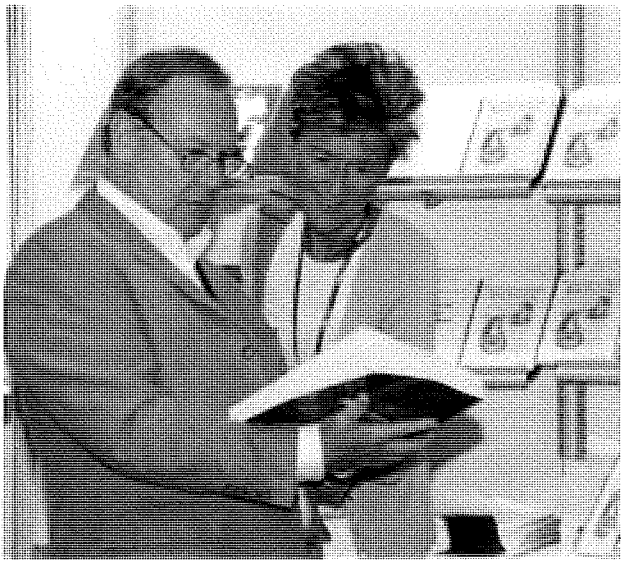
Here you will find information on publications, membership, continuing education, upcoming meetings, AACC online, Lab Tests Online and much more. Representatives from AACC will be in the booth to answer any questions you may have.



The AACC Booth (located on the exhibit hall floor) will be open during regular expo hours:

Tuesday, July 25	**9:30am – 5:00pm**
Wednesday, July 26	**9:30am – 5:00pm**
Thursday, July 27	**8:30am – 2:00pm** (New hours!)

VISIT THE AACC BOOKSTORE TO BROWSE AND PURCHASE THE LATEST PUBLICATIONS IN YOUR FIELD.



The bookstore (located in the registration area) will be open during the following hours:

Sunday, July 23	**9:00am – 5:00pm**
Monday, July 24	**9:00am – 5:00pm**
Tuesday, July 25	**9:00am – 5:30pm**
Wednesday, July 26	**9:00am – 5:30pm**
Thursday, July 27	**8:30am – 2:00pm**

Pick up the latest 2006 Publications Catalog!

Eight new releases from AACC Press are expected to be available at the meeting:

- Clinical Diagnostic Technology, Volume 3: The Postanalytical Phase
- A to Z Guide to Pharmacogenomics
- Pharmacogenomics and Proteomics: Enabling the Practice of Personalized Medicine
- Effects of Preanalytical Variables on Clinical Laboratory Tests
- A Quick Guide to Coagulation Testing
- Point-of-Care Testing for Managers and Policymakers—From Rapid Testing to Better Outcomes
- Principles of Forensic Toxicology, Revised and Updated 2nd Ed.
- Contemporary Practice in Clinical Chemistry

AACC ANNUAL MEETING
July 23-27, 2006 • Chicago, IL

HOW TO REGISTER

>PRINT OR TYPE INFORMATION ON ALL PAGES
>Make a copy of all pages for your files
>Please submit all 4 pages of this form to AACC.
Please include registrant name on all pages of the form.
>Full payment of all fees (in US Dollars payable through a US Bank) must accompany this form for registration to be processed.

Internet: www.aacc.org/2006AM *(Credit card payments only).*

Mail: 2006 Annual Meeting, P.O. Box 630623, Baltimore, MD 21263-0623

Fax: 202-887-5093 *(Credit card payments only). Fax copy will be considered original. To avoid duplication, do not mail original.*

Deadlines: **Early Bird registration ends June 8, 2006.**
Advance registration ends July 6, 2006.
All forms received after July 6 will be processed at the meeting.

I. Personal Information

Please verify your personal information from the mailing label above. Complete the information below if changes are necessary. This information will appear on your badge and Expo Card. This is also where we will send your confirmation letter.

Member ID # ___|___|___|___|___|___| Degree |___|___|___|

First/Given Name ___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

Middle Name ___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

Last/FamilyName___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

Mailing Address ☐ Business ☐ Home ☐ *This is a change of address. Please update my record.*

Institution___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

Department ___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

Street Address ___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

Street Address ___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

City/Province |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___| State |___|___|

Postal Code___|___|___|___|___|___|___|___|___|___|___| Country |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

Be sure to complete this information:

E-mail Address ___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

Business Phone ___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

Fax # |___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|___|

Please do not include my ☐ email address and ☐ fax number on my Expo Card. If you check either box exhibitors may not be able to contact you after the meeting.

☐ Please do not share my information with other organizations.

ILLUM-0147

Registrant's Name: _____

II. Your Information

The following information MUST BE completed to process your application.

A. What is your Title/Position? (select one)

01 ☐ President, VP, Other Executive
02 ☐ Pathologist, other MD
03 ☐ Director, Asst Director
04 ☐ Lab Manager, Lab Administrator
05 ☐ Chief Med Tech
06 ☐ Lab Supervisor
07 ☐ POCT, QA Coordinator
08 ☐ Lab Technologist
09 ☐ Buyer, Purchasing Agent
10 ☐ Research or Development Scientist, Engineer
11 ☐ Manufacturing/Operations
12 ☐ Marketing, Sales, Analysis
13 ☐ Clinical, Regulatory Affairs
14 ☐ Educator, Student
15 ☐ Other (please specify)

_____

B. Which best describes your organization's primary function? (select one)

01 ☐ Hospital/Laboratory
02 ☐ Group Purchase Org
03 ☐ Government Agency
04 ☐ Educational Institution
05 ☐ IVD, Pharma, LIS Company
06 ☐ OEM Company
07 ☐ Distributor, Lab Supplier
08 ☐ Lab Consultant
09 ☐ Industry Consultant
10 ☐ Investment
11 ☐ Other (please specify)

_____

C. Which of the following best describes your business interests at this exposition? (select one)

01 ☐ Evaluate/acquire lab products or services for the lab or practice
02 ☐ Market lab products or services
03 ☐ Evaluate OEM suppliers, distribution opportunities, or technology licensing.
04 ☐ Solicit OEM, distribution, or other B2B collaborations
05 ☐ No product or business interest
06 ☐ Other (please specify)

_____

D. If your organization is a laboratory, which best describes it? (select one)

01 ☐ University
02 ☐ State, County, Local Hospital
03 ☐ Private Hospital
04 ☐ Veterans, Military Hospital
05 ☐ Gov't/Public Health Lab
06 ☐ Commercial Lab
07 ☐ Group Practice, POL
08 ☐ Blood Center, Blood Bank
09 ☐ Basic Research Lab
10 ☐ Pharma, IVD Manufacturer Lab
11 ☐ Forensic Lab
12 ☐ Veterinary Lab
13 ☐ Other (please specify)

_____

E. If your organization is a laboratory, what was the most important role you played in the acquisition of Clinical Laboratory, Point-of-Care, or POL Systems in the last 2 years?

01 ☐ Final Decision Maker in the Laboratory or Practice
02 ☐ Recommended products
03 ☐ Evaluated product options for purchase
04 ☐ No Role

F. In which Country/Region do you work?

01 ☐ United States
02 ☐ Canada
03 ☐ Mexico
04 ☐ C. America/ Caribbean
05 ☐ South America
06 ☐ Central/Eastern Europe
07 ☐ Western Europe
08 ☐ Middle East/North Africa
09 ☐ Sub-Saharan Africa
10 ☐ S. Pacific/Australia/New Zealand
11 ☐ East Asia
12 ☐ Southeast Asia
13 ☐ Central/South Asia

G. What Products/Services are of interest to you? (check as many as apply)

01 ☐ Automation/Robotics
02 ☐ Cancer Diagnostic/Markers
03 ☐ Cardiac Diagnostics/Markers
04 ☐ Chemistry
05 ☐ Cholesterol/Lipids Testing
06 ☐ Cytology/Histology
07 ☐ Endocrine/Diabetes Testing
08 ☐ Genomics/Proteomics
09 ☐ Hematology/Hemostasis/ Coagulation
10 ☐ Immunology/Autoimmune Testing
11 ☐ Microbiology/Infectious Diseases
12 ☐ Molecular Diagnostics/Genetics
13 ☐ OEM/R&D/B2B
14 ☐ Pathology
15 ☐ Reference Lab Services
16 ☐ POCT/Patient Self-Testing
17 ☐ Serology
18 ☐ TDM/Toxicology
19 ☐ Urinalysis
20 ☐ Veterinary Testing Products

III. Conference Registration Fees

Please check choice(s)	Early Bird *(received by 6/8/06)*	Regular *(received after 6/8/06)*
☐ 01 AACC Member	$435	$560
☐ 02 Non-Member	$655	$780
☐ 03 Student	$145	$160
☐ 04 AACC Emeritus Member	$145	$160
Daily Registration	$260	$260
Check days that apply:		
☐ 05 Sun ☐ 06 Mon ☐ 07 Tues ☐ 08 Wed ☐ 09 Thu		
☐ 10 Guest/Spouse	$115	$145

Spouse/Guest First/Given Name

|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|

Last/Family Name

|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|

☐ Check here if you have a disability and/or require special assistance. You will be contacted by the AACC Meetings Department

IV. Sessions

Indicate your preference by session number. Individuals registered as guests/spouse may not register for sessions or receive continuing education credits.

A. AACC University (190000 series)

All courses held on Sunday, July 23. Conference registration is not required; only fees for individual courses.

Full Day: $250 AACC Member/$300 Nonmember

Morning Only: $150 AACC Member/$200 Nonmember

Afternoon Only: $200 AACC Member/$250 Nonmember

Sunday:

Full Day	☐ 191001	☐ 191003	☐ 191004
	☐ 191008	☐ 191010	☐ 191011
	☐ 191012	☐ 191014	☐ 191016
Morning	☐ 191009		
Afternoon	☐ 191002	☐ 191005	☐ 191007
	☐ 191013	☐ 191015	

Total # of Sessions_____Total $ _____

Registrant's Name: _____

B. Symposia (30000 series)

No Charge; Please Check Choices.

Monday	Full Day:	☐ 32301	☐ 32302	☐ 32303
	Morning:	☐ 32104	☐ 32105	☐ 32106
	Afternoon:	☐ 32207	☐ 32208	☐ 32209
Tuesday	Full Day:	☐ 33301	☐ 33302	☐ 33303
	Morning:	☐ 33104	☐ 33105	
	Afternoon:	☐ 33206	☐ 33207	
Wednesday	Full Day:	☐ 34301	☐ 34302	☐ 34303
	Morning:	☐ 34104	☐ 34105	☐ 34106
	Afternoon:	☐ 34207	☐ 34208	
Thursday	Morning:	☐ 35101	☐ 35102	☐ 35103
		☐ 35104	☐ 35105	☐ 35106

C. Interactive Workshops (20000 series)

Morning Interactive Workshops: $150 AACC Member/$200 Nonmember

Afternoon Interactive Workshops: $200 AACC Member/$250 Nonmember

Monday	Morning:	☐ 22101	☐ 22102
	Afternoon:	☐ 22203	
Tuesday	Morning:	☐ 23101	
	Afternoon:	☐ 23202	
Wednesday	Afternoon:	☐ 24201	

Total # of Sessions _____ Total $ _____

D. Short Courses (70000 series)

Full Day Short Courses: $250 AACC Member/ $300 Nonmember

Morning Short Courses: $150 AACC Member/$200 Nonmember

Afternoon Short Courses: $200 AACC Member/$250 Nonmember

Monday	Full Day:	☐ 72304			
	Morning:	☐ 72105	☐ 72106	☐ 72107	☐ 72108
	Afternoon:	☐ 72209	☐ 72210	☐ 72211	☐ 72212
		☐ 72213			
Tuesday	Full Day:	☐ 73303			
	Morning:	☐ 73104	☐ 73105	☐ 73106	
	Afternoon:	☐ 73207	☐ 73208	☐ 73209	☐ 73210
		☐ 73211	☐ 73212		
Wednesday	Morning:	☐ 74102	☐74103	☐ 74104	☐ 74105
	Afternoon:	☐ 74206	☐74207	☐ 74208	☐ 74209
		☐ 74210			

Total # of Sessions _____ Total $ _____

E. Meet the Experts (60000 series)

$10 each AACC Member/Nonmember

Monday	Morning:	☐ 62001	☐ 62002
	Afternoon:	☐ 62003	
Tuesday	Morning:	☐ 63001	
	Afternoon:	☐ 63002	
Wednesday	Morning:	☐ 64001	☐ 64002

Total # of Sessions _____ Total $ _____

F. Brown Bag Sessions

$25 each AACC Member/Nonmember. No meal is included

Morning Sessions (40000 Series) Afternoon Sessions (50000 Series)

		1st Choice	2nd Choice	3rd Choice
Monday	Morning	_____	_____	_____
	Afternoon	_____	_____	_____
Tuesday	Morning	_____	_____	_____
	Afternoon	_____	_____	_____
Wednesday	Morning	_____	_____	_____
	Afternoon	_____	_____	_____

Total # of Sessions _____ Total $ _____

V. Special Events

(see page 74 for descriptions)

91. Opening Mixer – Sunday, July 23
(included with conference and guest registrations) ☐ Yes, I will attend.

92. Issues in Immunodiagnostics Symposium: Organ Transplantation and the Clinical Laboratory - Saturday, July 22
CDI Division Members: $15; AACC Members: $35;
Non-AACC Members: $50
# of Tickets _____ $ _____

93. Management Sciences Division Leadership Seminar: The Truth About Quality Today - Saturday, July 22
AACC Member/Non-Member: $15
# of Tickets _____ $ _____

94. Metabolomic Markers in Diet and Health - Saturday, July 22
AACC Members: $15; Non-AACC Members: $50
# of Tickets _____ $ _____

95. Current Topics in Cardiovascular Disease and Stroke: LVD Dinner Meeting - Monday, July 24
LVD Division Members: $20; AACC Members: $35;
Non-AACC Members: $60
# of Tickets _____ $ _____

96. NACB Awards Luncheon: Wednesday, July 26
NACB Fellows: $25
# of Tickets _____ $ _____

97. POC Coordinators Forum: POC Coagulation Testing - Thursday, July 27
AACC Member/Non-Member: $15
# of Tickets _____ $ _____

Special Events_____ Total $_____

Registrant's Name: _____

VI. Payment Information

Conference Fees	Section III	$_____
Guest/Spouse Fees	Section III	$_____
AACC 2006 Membership Dues *(Attach application see page 86)*		$_____
AACC University	Section IV A	$_____
Interactive Workshops	Section IV C	$_____
Short Courses	Section IV D	$_____
Meet the Experts	Section IV E	$_____
Brown Bags	Section IV F	$_____
Special Events	Section V	$_____
Van Slyke Foundation Contribution *(See page 76)*		$_____
Total Payment Enclosed:		$_____

Full payment must accompany all orders. Purchase orders are not accepted.

☐ Check Enclosed *(Payable to AACC, in US Dollars, through a US Bank Only)*

☐ Company Check ☐ Personal Check

☐ Wire Transfer Date Sent_____ Sending Bank _____

Routing Information: Bank of America, Account # 001924126881 Routing # 026009593, Swift Code BOFAUS3N (Mail or Fax registration form)

Credit Card ☐ VISA ☐ MasterCard ☐ American Express

Card Number

|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

Expiration Date ___/___ - ___/___

Credit Card Code *|_|_|_|_|

*Visa/MasterCard code is last 3 digits in signature box on back of card. American Express code is 4 small digits above credit card number on front of card.

Signature _____ Date _____

Card Holder's Name

|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

Billing Address EXACTLY as it appears on your credit card statement

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Mail all 4 pages to: 2006 Annual Meeting, P.O. Box 630623, Baltimore, MD 21263-0623, or fax all 4 pages to: 202-887-5093 (credit card payments only)

Cancellation Policy

All Annual Meeting cancellations must be received in writing. Written cancellations received by Thursday, June 8, 2006 will be assessed a $50 processing fee. Written cancellations received between Friday, June 9 and Thursday, July 6, 2006 will be assessed a cancellation fee equal to 35% of the total registration fees. No refunds will be granted after Thursday, July 6, 2006. Refunds will be processed three to four weeks after the conclusion of the meeting. Fees paid for sold-out sessions may be returned sooner.

For AACC USE ONLY: Date Received: _____ Check # _____ Check Amount _____

ILLUM-0150

JOIN AACC TO BENEFIT NOW AND THROUGHOUT THE YEAR.

Now...
Save $220 off the nonmember registration fee by joining AACC today and registering for the Annual Meeting as a member – that's more than the cost of your annual membership.

Throughout the year...
The Annual Meeting registration discount is only the beginning. As an AACC member, you can take advantage of additional savings offers, gain access to invaluable information, and participate in unique networking opportunities.

Attend information-packed meetings and conferences — at discount rates. As a member, you'll be **eligible** to receive discounts on the fees for AACC-sponsored meetings, educational programs and conferences.

Educate yourself — and fulfill accreditation requirements at your own pace with AACC's distance learning programs and online symposia. You can also take part in monthly, live discussions featuring a hot topic in areas of laboratory medicine, technology, management, regulation or science as part of our Experts Live-On-Line program.

Receive top-notch publications — at no charge
Your AACC membership includes subscriptions to these highly regarded periodicals...

... *Clinical Chemistry*, International Journal of Molecular Diagnostics and Laboratory Medicine. The most-cited periodical in the field of clinical chemistry, the journal contains more than 2,000 pages of original, peer-reviewed scientific articles annually. Non-members pay more than $200 for print and online access.

...*Clinical Laboratory News* provides timely analysis of issues and trends affecting clinical laboratories, laboratorians and laboratory science. U.S. members receive the publication free, and international members can access it via the Web at no cost.

...*Strategies* is for clinical laboratory directors who want to stay on top of complex and evolving regulatory, scientific, and clinical issues affecting their lab operations. This online newsletter is published twice monthly.

You can also purchase discounted, expert and timely educational texts through AACC Press, and our online bookstore, www.aaccdirect.org.

Be part of a network of peers — on- and off-line
AACC lets you network with colleagues at conferences or meetings, or connect with fellow professionals via online communities.

Access is easy with our **fully searchable online Membership Directory.** And when it's time to search for or post a position, members can turn to **Clin Lab Job Center,** the only Web-based job center that focuses on the clinical laboratory and IVD industry.

New members from North America can **meet face-to-face at local section meetings.** All AACC members can **affiliate with 13 divisions that provide specialized topical information and services** in particular fields of interest.

AACC offers all these benefits and many, many more. Through government and media relations programs, our members influence legislation and shape how the world views the clinical chemistry field. Our awards programs ensure worthy clinicians and laboratorians get well-deserved recognition.

Complete the Membership Application. Join AACC today.

Full Membership is open to those holding an earned baccalaureate or higher degree in science or medicine or the academic equivalent and who are engaged in professional activities commonly associated with the practice of clinical laboratory science. Membership provides all benefits, voting privileges, and the opportunity to hold Association office ($185/yr.).

Student Associate Membership is open to undergraduate or graduate students engaged in full-time academic studies, and to residents and fellows. Please include proof of your student status (Copy of current student ID or letter from a Professor) with your application. Student members enjoy all benefits except voting privileges and the opportunity to hold Association office ($25/yr.).

3 Easy Ways to Join AACC When You Register:

1. Register for the Annual Meeting online at www.aacc.org/2006am.
   Join as a Full Member when you click the Check Out button and you'll instantly receive the member discount.
2. Submit a completed Membership Application (see next page) and dues payment with your Meeting Registration Form (see page 81) and return it by mail to: AACC, PO Box 630623, Baltimore, MD 21263-0623.
3. Submit a completed Membership Application (see next page) and dues payment with your Meeting Registration Form (see page 81) and return it by fax to 1-202-887-5093.

Please note: When joining via option 2 or 3 above, allow 7-10 business days for member benefits, including discounted registration, to be available online. For assistance call Customer Service, toll-free at 800-892-1400 (North America), or 202-857-0717, then press 2.

2006 Membership Acceptance Form

Simply return this form with your membership dues today to begin receiving full AACC Member benefits, including a FREE subscription to *Clinical Chemistry*, the most cited journal in our profession, and member-only discounts on publications, educational programs and registration to AACC's Annual Meeting! Register online at www.aacc.org/2006AM. Join as a Full Member when you click the Check Out button and you will instantly receive the member discount.

1. Membership Information

NAME

JOB TITLE

COMPANY NAME

DEPARTMENT

COMPANY ADDRESS

COMPANY ADDRESS

CITY STATE/PROVINCE

ZIP/POSTAL CODE COUNTRY

HOME ADDRESS

HOME ADDRESS

CITY STATE/PROVINCE

ZIP/POSTAL CODE COUNTRY

E-MAIL

BUSINESS PHONE

FAX

HOME PHONE YEAR OF BIRTH

DEGREES HELD CERTIFICATION

I prefer to receive AACC mail at (check one) ☐ Home ☐ Business
In the AACC Membership Directory, list this address (check one) ☐ Home ☐ Business
Please do not share my address with other organizations. ☐

2. Select Your Membership Category

☐ Member $185

Open to persons holding an earned baccalaureate or higher degree in science, medicine, or academic equivalent and engaged in professional activities commonly associated with clinical chemistry. Members receive a subscription to *Clinical Chemistry* Journal.

☐ Student Associate $25

Open to all undergraduate and graduate students engaged in full-time academic studies, and to residents and fellows. Student associates are entitled to all member benefits, except voting privileges and the opportunity to hold Association office. Students must send in proof of academic status: i.e., a copy of a current student I.D. card or a letter from a professor.

3. Join AACC Divisions for Specialty Information

Customize your Membership by joining one or more Divisions, which target your specialized area(s) of interest. A newsletter is included with your Division Membership and some Divisions offer listserv discussion groups. For more information, visit www.aacc.org/divisions/divisions.stm.

☐ Animal Clinical Chemistry	$15
☐ Clinical and Diagnostic Immunology	$15
☐ Critical and Point-of-Care Testing	$15
☐ History of Clinical Chemistry	$15
☐ Industry	$15
☐ Laboratory Information Systems and Medical Informatics	$15
☐ Lipoproteins and Vascular Diseases	$15
☐ Management Sciences	$15
☐ Molecular Pathology	$15
☐ Nutrition	$15
☐ Pediatric and Maternal-Fetal	$15
☐ Proteomics	$15
☐ TDM/Toxicology	$15

Total Division Dues: $

4. Choose Your Preferred Payment Method

Total Dues Enclosed: $

Include membership category, division(s) and postage

Members outside North America receive upgraded Air Lift delivery of *Clinical Chemistry* Journal at no extra charge - delivery within approximately 2-4 weeks.

☐ Check here to expedite Journal delivery. Members may pay an optional postal fee of $250 for U.S. Air Mail - delivery within approximately 5-10 days

☐ My check is enclosed, payable in US dollars to AACC.

☐ Please charge my credit card:

☐ American Express ☐ MasterCard ☐ VISA

☐☐☐☐ - ☐☐☐☐ - ☐☐☐☐ - ☐☐☐☐

CREDIT CARD SECURITY CODE ☐☐☐☐
(Visa & MC last 3 digits on back of card.
AmEX 4 small digits on front of card.)

EXPIRATION DATE

AUTHORIZED SIGNATURE

NAME ON CARD

CREDIT CARD BILLING ADDRESS (exactly as it appears on your statement)

Membership year is January 1 - December 31. Applications received before September 1 will be effective for current year.

5. Send Completed Application and Payment To:

AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY
1850 K Street, NW, Suite 625 • Washington, D.C. 20006
Phone 800-892-1400 (press 2) or 202-857-0717 • Fax 202-887-5093
Email custserv@aacc.org.
Join online when you register at www.aacc.org/2006AM.

Source Code 250489

DECIDE WHERE YOU'D LIKE TO STAY.

We've reserved a block of Chicago hotel rooms for AACC Annual Meeting registrants. Please review the hotel descriptions and amenities chart and indicate your top three choices on the Attendee Housing Form on page 91.
Or book online at www.aacc.org/2006am.

WHY SHOULD YOU BOOK THROUGH THE AACC ROOM BLOCK?
You benefit in multiple ways, with great rates, convenience, protection and AACC clout.

The guaranteed best rate During our Annual Meeting, the rates offered for hotels in our block are the lowest available. If you find a lower rate on the Internet, or through individual or group reservations, notify us. We'll make sure that you – and other attendees booked at that hotel through our hotel block – receive a matching low rate.

Direct transportation to AACC events AACC provides shuttle bus service between McCormick Place Convention Center and hotels that are in the official AACC room block. This is particularly important in Chicago because of the distance between hotels and the Convention Center. Stay in a non-AACC block hotel and you're responsible for providing your own transportation.

Protection if your hotel denies you a confirmed room AACC hotel contracts guarantee that confirmed rooms will be preferentially held if you book via our block. If the hotel is oversold and denies you a confirmed room booked through our block, they'll have to find you equivalent or better accommodations. Until they can fulfill their obligation to house you, block hotels must cover the costs of your alternate housing. If you book a room outside the AACC block, and the hotel is oversold, the hotel is only obligated to find you another place to stay.

Top-notch hotels and meeting space for future Annual Meetings Booking through the housing block supports AACC and our ability to negotiate for future Annual Meeting sites keeping AACC's and your costs as low as possible.

Hotel Descriptions

Hotel Allegro
171 W Randolph Street, Chicago, IL
Rates: $142/$142 (single/double)
Located steps from Chicago's bustling business and theatre districts, this stylish hotel attracts guests looking for something a little different. In addition to complimentary cocktail receptions each evening, Hotel Allegro also offers in-room luxuries such as pillow-top mattresses with down pillows and comforters, Sony sound systems and Toshiba flat screen televisions. Hotel Allegro features 24-hour fitness and business centers. The hotel's restaurant, 312 Chicago, serves American cuisine with Italian flair.

Best Western Inn of Chicago
162 East Ohio Street, Chicago, IL
Rates: $124/$124 (single/double)
Just one block east of Chicago's Magnificent Mile, Best Western Inn of Chicago is a timeless classic. Recently renovated, guestrooms are filled with cherry wood furniture and offer captivating views of the city. Hotel amenities include airport transportation, fitness and business centers. Free high speed Internet service is available in the lobby. The All-Stars Lounge features a wide variety of soups, salads and sandwiches at reasonable prices. For spectacular views of the Chicago skyline, guests are encouraged to visit the Rooftop Terrace.

Chicago Marriott Downtown Magnificent Mile
540 N Michigan Avenue, Chicago, IL
Rates: $199/$199 (single/double)
A sparkling jewel on Michigan Avenue, the Marriott has just completed a $15 million renovation. Guestrooms feature triple-sheeted feather beds, down comforters, sleek furnishings and flat screen televisions. The hotel has a 24-hour business center that offers complimentary high-speed Internet access. For $12.95 a day, guests can enjoy high-speed Internet access, unlimited local calls and unlimited domestic long distance calls (US only) from their room. The hotel's modern fitness center offers an array of equipment for guest use and features a lap pool, steam rooms and two basketball courts. The Marriott has two restaurants, a lounge, a bar and a coffee shop in the building. Nearby restaurants include Grand Lux Café (American cuisine), BICE (Italian) and Kamehachi (award winning sushi, sashimi and traditional Japanese).

The Drake Hotel
140 East Walton Place, Chicago, IL
Rates: $195/$215 (single/double)
Listed on the National Register of Historic Places, the Drake hotel is a symbol of refinement and class, regularly hosting celebrities, royalty and heads of state. While some rooms in this hotel tend to be on the small side, the services provided are second to none. (The concierges have been known to perform miracles such as obtaining tickets for shows previously sold out, or gaining reservations at completely booked restaurants.) The classically furnished guestrooms receive nightly turndown service with chocolates and feature twice-daily housekeeping, plush bathrobes and designer toiletries. Hotel facilities include a well-equipped fitness center, a fully staffed business center and a handful of specialty shops. High speed Internet service is available in rooms at a fee of $11.40 per day. Hotel restaurants include: the award-winning Cape Cod Room, considered one of the best seafood restaurants in Chicago; the more casual Oak Terrace; and the hotel bar, Coq d'Or — which was one of the first bars to open following the end of Prohibition — specializing in martinis and live jazz.

The Fairmont Hotel — *Co-Headquarters Hotel*
200 North Columbia Drive, Chicago, IL
Rates: $219/$219 (single/double)
Located across the street from Millennium Park in Chicago's Loop, the Fairmont Chicago seamlessly blends high quality service, deluxe accommodations and reasonable prices. Guestrooms are spacious and offer plush triple-sheeted beds, bathrobes, windows that open to the outside and large bathrooms with oversized tubs. High-speed wireless Internet access is available in the hotel lobby and in the fully staffed business center. High speed Internet access is available in rooms for $14.95 a day. The hotel does not have a fitness center but you may purchase day passes ($20/day) to the exclusive Lakeshore Athletic Club. The hotel's stylish restaurant, Aria, offers a globally influenced menu, and the bar provides more casual American fare.

HOTEL AMENITIES AT-A-GLANCE

HOTEL NAME	RATES	EXERCISE FACILITY/ HEALTH CLUB	ROOM SERVICE	RESTAURANTS, LOUNGES OR FOOD OUTLETS	GUEST ROOM INTERNET AVAILABILITY	PARKING	PROXIMITY TO CONVENTION CENTER	DISTANCE TO O'HARE AIRPORT	CHECK IN/ CHECK OUT	CANCELLATION POLICY
Hotel Allegro	$142/$142	Yes	Yes	2	High Speed Comp	$36	2 Miles	12 Miles	3PM 12NOON	72 Hours Prior to Arrival
Best Western Inn of Chicago	$124/$124	Yes	No	0	In Hotel Lobby	$26	3 Miles	17 Miles	3PM 12NOON	72 Hours Prior to Arrival
Chicago Marriott	$199/$199	Yes	Yes	4	Data Port at $12.95	$35	2.87 miles	19 Miles	4PM 12NOON	72 Hours Prior to Arrival
Drake Hotel	$195/$215	Yes	Yes	3	High Speed at $11.40/24	$33	3.5 Miles	18 Miles	3PM 12NOON	72 Hours Prior to Arrival
Fairmont Hotel	$219/$219	Yes	Yes	4	Wireless $13.88/24	$41	1.5 miles	15 Miles	3PM 1PM	72 Hours Prior to Arrival
Fitzpatrick Hotel	$175/$175	Yes	Yes	1	Data Port at $12.95	$33	6 Miles	17 Miles	3PM 12NOON	72 Hours Prior to Arrival
Hilton Garden Inn	$159/$159	Yes	Yes	1	High Speed at $10.00/24	$35	4 Miles	17 Miles	3PM 12NOON	72 Hours Prior to Arrival
Holiday Inn Chicago City Centre	$159/$159	No	Yes	2	High Speed Comp	$28	2.88 miles	17 Miles	3PM 12NOON	72 Hours Prior to Arrival
Hyatt Regency Chicago	$206/$226	Yes	Yes	4	High Speed at $10.00/24	$24	2.63 miles	23 Miles	3PM 12NOON	72 Hours Prior to Arrival
Hyatt McCormick Place	$219/$244	Yes	Yes	1	High Speed at $9.95/24	$29	Connected	23 Miles	3PM 12NOON	72 Hours Prior to Arrival
James Hotel	$165/$165	Yes	Yes	1	High Speed Comp	$35	2 Miles	18 Miles	3PM 12NOON	72 Hours Prior to Arrival
Raddisson Hotel & Suites	$149/$149	Yes	Yes	1	High Speed at $14.22/24	$37	3 Miles	20 Miles	3PM 12NOON	72 Hours Prior to Arrival
Sheraton Hotel & Towers	$207/$227	Yes	Yes	3	High Speed at $9.95/24	$36	2.67 miles	18 Miles	3PM 12NOON	72 Hours Prior to Arrival
Swissôtel	$165/$185	Yes	Yes	2	High Speed at $9.95/24	$41	2.56 miles	18 Miles	3PM 12NOON	72 Hours Prior to Arrival
Westin Chicago River North Hotel	$207/$227	Yes	Yes	2	High Speed at $9.95/24	$38	2 Miles	19 Miles	3PM 12NOON	72 Hours Prior to Arrival
Westin Michigan Ave	$197/$217	Yes	Yes	1	12.95	$38	3.5 Miles	18 Miles	3PM 12NOON	72 Hours Prior to Arrival

Fitzpatrick Chicago Hotel

166 E Superior Street, Chicago, IL
Rates: $175/$175 (single/double)

Irish-themed and Irish-owned, the Fitzpatrick Hotel is an all-suite boutique property that caters to discriminating travelers. Spacious suites offer king or queen canopy bed lushly outfitted with pillow top mattresses and down comforters. Hotel sitting rooms feature pullout beds, a refrigerator and a trouser press. Internet access is available through data ports at a daily fee of $12.95. Guests can exercise at the hotel's fitness center or be pampered with manicures, facials and massages in the day spa. Guests can also enjoy the rooftop pool and sundeck with 360 degree views of the city and lake. The hotel is home to Chicago's newest Irish pub: Fitzers. All of the décor and furnishings, down to the bar itself were imported from Ireland.

Hilton Garden Inn

10 E Grand Avenue, Chicago, IL
Rates: $159/$159 (single/double)

This art-deco inspired hotel is graced with spectacular views of the city from its stunning lobby windows. Guest rooms are designed for comfort and convenience. Each room features either a king or two double beds, a large work desk coupled with an ergonomic chair, and a refreshment center (including microwave, coffee maker and refrigerator). Neutrogena products are featured in the average-sized bathroom. The 24-hour business center offers high-speed Internet access, fax machines, printing and copy services, and stationery supplies. If you require notary or secretarial services, both are available here. The hotel offers a modern fitness center with cardiovascular and strength training equipment plus an indoor pool and spa tub. You can also ask for a complimentary pass to the nearby fitness club where you can participate in a variety of classes. There are many excellent restaurants within walking distance, including The Weber Grill, Napa Valley Grille, Mother Hubbards, PF Changs, Rock Bottom Brewery and Hard Rock Café.

Holiday Inn Chicago City Centre

300 East Ohio Street, Chicago, IL
Rates: $159/$159 (single/double)

The Holiday Inn Chicago City Centre is just two blocks from Michigan Avenue and Chicago's top tourist destinations. Guest rooms offer king or double beds and incredible views of either the city or the lake. Each room has a "Smart Desk" workstation, with two multi-line speaker phones and data ports. The business center offers traditional services such as copy and fax machines in addition to workstations with Internet access. Complimentary passes to the Lake Shore Athletic Club are available to all hotel guests. The spectacular fitness center was voted by Men's Health magazine as one of the top ten fitness centers in the country. The Holiday Inn has three restaurants: 300 East — An American Café, Corner Copia, and Winners Bar & Grill.

Hyatt Regency Chicago — *Co-Headquarters Hotel*
151 East Wacker Drive, Chicago, IL
Rates: $206/$226 (single/double)
Overlooking the Chicago River, this Hyatt flagship property is a luxurious, full-service hotel located within walking distance of the best that Chicago offers. Guest rooms feature air purifiers and are comfortable and well-appointed with either a king or two double beds. Managed by Pitney Bowes, the business center is lacking nothing and offers one-stop shopping for all business needs. Wired and wireless high speed Internet access is available in guest rooms for $10 per day. Wireless access is also available in the hotel lobby. Hotel guests can exercise in the in-house fitness center that offers Lifecycle stationary bicycles, treadmills and weights. For more services, guests can purchase a day pass to the exclusive Lakeshore Athletic Club for $20 per day. Stetson's Chop House serves a classic menu specializing in steaks and seafood. Networks, in the East Tower atrium — surrounded by a 4,000 square-foot reflecting pond with fountains — features American and Mediterranean cuisine. Connie's Ristorante & Pub offers a casual menu and micro brewed beers.

Hyatt Regency McCormick
2233 S Martin Luther King Drive, Chicago, IL
Rates: $219/$244 (single/double)
The Hyatt Regency McCormick is the closest hotel to McCormick Place. Guest rooms are comfortable and well appointed with either a king or two double beds. Wired and wireless high speed Internet access is available in guest rooms for $10 per day. The business center is well equipped to keep up with the needs of the business traveler. On-site digital printing and binding services are available in addition to traditional copying and faxing services. Computer workstations are available at a nominal cost. The hotel offers a fitness center with an indoor lap pool and sauna in addition to cardiovascular and strength training equipment. There is also complimentary shuttle service to downtown shopping areas and Navy Pier. Dining options in the hotel are limited to NetWorks, with its hometown favorites-filled menu. A cab or shuttle ride is necessary for a better selection.

James Hotel
616 North Rush Street, Chicago, IL
Rates: $165/$165 (single/double)
Great care has been taken in the design and furnishing of the spacious rooms, provoking a sense of calm with a touch of modernity. Luxurious beds have pillow top mattresses and high thread count sheets, while the bathrooms feature plush Turkish cotton towels and the very best in bath products. All suites have WiFi connections and 42" plasma televisions with satellite service. Mini bars are stocked with a mixology kit so that guests can concoct their own signature beverages. The hotel has a 2000+ square foot fitness center with top-of-the-line exercise equipment, innovative classes, a sauna and a full-service day spa.

Radisson Hotel & Suites Chicago
160 E Huron Street, Chicago, IL
Rates: $149/$149 (single/double)
Newly renovated, the Radisson Hotel & Suites Chicago is just a half block from Michigan Avenue. Spacious guest rooms decorated in warm neutral tones feature Serta Elite pillow top mattresses and 27" televisions, executive-sized desks and ergonomic chairs. High-speed Internet access is available in guest rooms for $12.95 per day. The 24-hour business center offers copy and fax machines, digital printing and other traditional services. A state-of-the-art fitness center is located on the 40th floor, providing breathtaking views of the city and Lake Michigan. Elephant and Castle Pub offers a traditional British menu as well as a large collection of single malt scotches, imported beers and ales. There are also numerous restaurants west of Michigan Avenue, to both the north and south.

Sheraton Hotel & Towers
301 East North Water Street, Chicago, IL
Rates: $207/$227 (single/double)
Located near the mouth of the Chicago River and overlooking Lake Michigan, the Sheraton Hotel & Towers is an award-winning luxury hotel. Full of rich inlaid wood and polished marble, the spacious, domed lobby creates an impressive entrance. Newly renovated rooms feature the Sheraton Sweet Sleeper Bed and large bathrooms with massaging showerheads. High-speed Internet access is available for $14 per day. There is a full-service business center on the premises. The Sheraton's exercise facility is a complete health club with an indoor lap pool, state-of-the-art exercise equipment and rejuvenating massage treatments. Dining options include Shula's Steakhouse, Riverside Café (Bistro) and Spectator's Sports Bar.

Swissôtel
323 East Wacker Street, Chicago, IL
Rates: $165/$185 (single/double)
Soaring above the city of Chicago, the Swissôtel Chicago is a magnificent glass hotel catering to the discriminating tastes of the business traveler. The property earned a spot on Travel & Leisure magazine's list of 500 top hotels in the world. Stylish guest rooms offer glass-topped executive desks, high-speed wireless Internet access ($9.95/day), mini bars and CD players. The Business Center fulfills all on-site business needs such as photocopying, faxing and secretarial services. If needed, computers and cell phones are available for rental. There is a fitness center and a full-service spa on site, as well as an indoor pool and Jacuzzi. The hotel has two restaurants: The Palm Restaurant, delighting patrons for three generations with its tender-aged prime beef, traditional Italian cuisine and outrageously sized lobsters; and Geneva (open for breakfast only) offering American breakfast with a European flair.

Westin Chicago River North Hotel
320 North Dearborn, Chicago, IL
Rates: $207/$227 (single/double)
Located in the heart of the business and theatre district, this is Chicago's leading upscale, downtown hotel. Guest rooms are decorated in contemporary elegance and feature Heavenly Baths with two massaging showerheads, plush bathrobes and oversized Brazilian combed-cotton bath towels. Heavenly Beds pamper guests with pillow-top mattresses, down comforters and triple sheeting. The fee-based business center features a multilingual staff trained to assist guests with business and secretarial services. High-speed Internet access is available in rooms for $9.95 per day. For a nominal fee, guests can use the WestinWORKOUT Room, an extensive health club with massage therapy, certified personal trainers and a variety of cardiovascular and strength training equipment. The hotel has three restaurants: The Ember Grille (American cuisine with fire-roasted specialties); Kamehachi (award winning sushi, sashimi and traditional Japanese); and Celebrity Café.

Westin Michigan Avenue
909 N Michigan Avenue, Chicago, IL
Rates: $197/$217 (single/double)
Located on Chicago's Magnificent Mile in the heart of a shopper's paradise, the Westin's guest rooms offer views of either the city or Lake Michigan and are decorated in contemporary elegance, featuring Heavenly Baths with two massaging showerheads and Heavenly Beds with pillow-top mattresses, down comforters and triple sheeting. Business travelers will find all the services they need in the fully staffed business center. High-speed Internet access is available in rooms for $12.95 per day. For a nominal fee, guests can use the WestinWORKOUT Room, an extensive health club with massage therapy, certified personal trainers and a variety of cardiovascular and strength training equipment. The hotel's Grille on the Alley — a mahogany-paneled steakhouse — serves classic American cuisine.

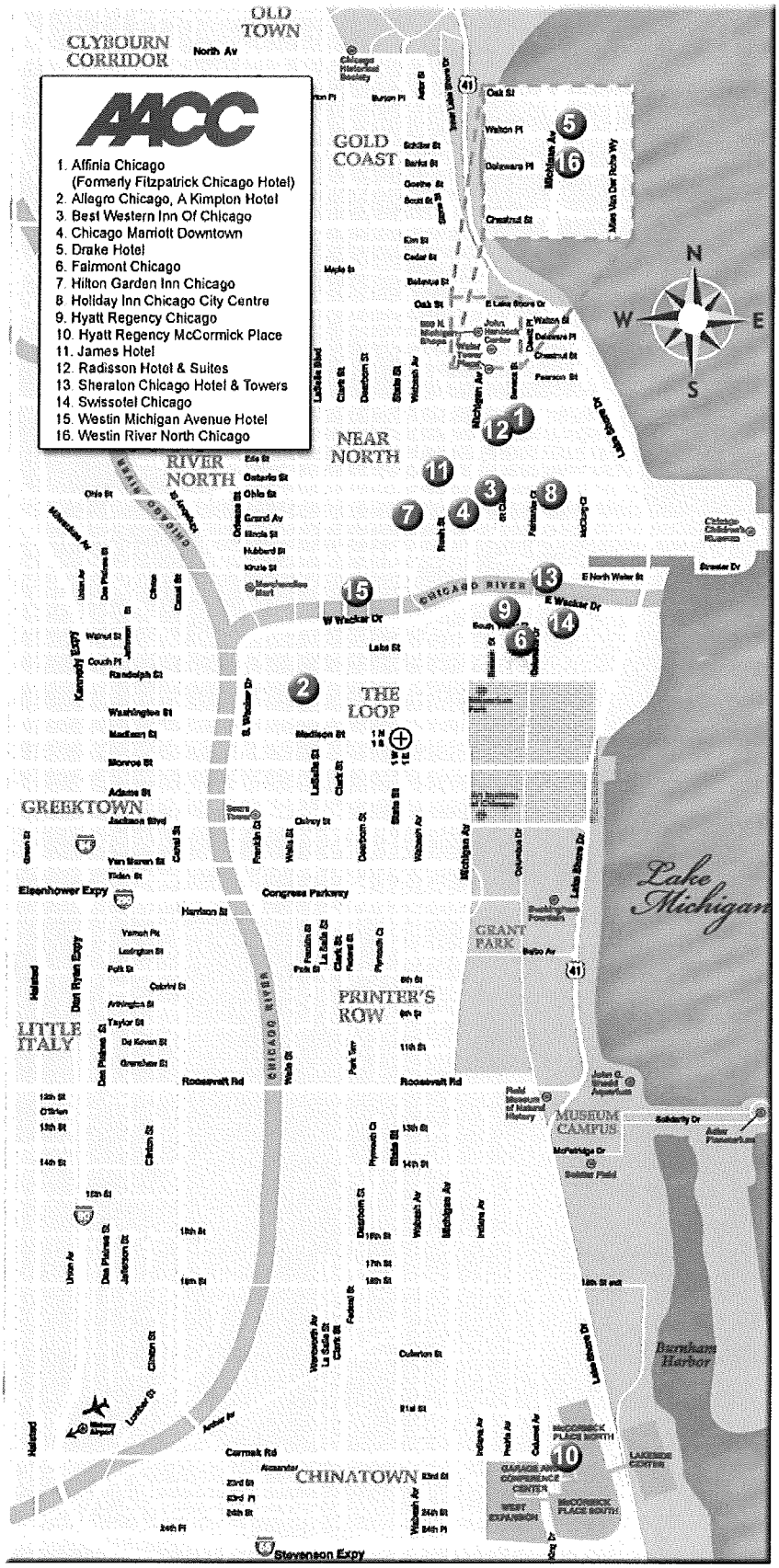
EXHIBIT 5

(Part IV of VII)

OF

DECLARATION OF GREGORY F. HEATH

Hotel Map


AACC
1. Affinia Chicago
(Formerly Fitzpatrick Chicago Hotel)
2. Allegro Chicago, A Kimpton Hotel
3. Best Western Inn Of Chicago
4. Chicago Marriott Downtown
5. Drake Hotel
6. Fairmont Chicago
7. Hilton Garden Inn Chicago
8. Holiday Inn Chicago City Centre
9. Hyatt Regency Chicago
10. Hyatt Regency McCormick Place
11. James Hotel
12. Radisson Hotel & Suites
13. Sheraton Chicago Hotel & Towers
14. Swissotel Chicago
15. Westin Michigan Avenue Hotel
16. Westin River North Chicago
OLD TOWN
CLYBOURN CORRIDOR
GOLD COAST
NEAR NORTH
RIVER NORTH
THE LOOP
GREEKTOWN
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PRINTER'S ROW
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Lake Michigan
Burnham Harbor
Chicago River
Eisenhower Expy
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Kennedy Expy
Stevenson Expy
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Attendee* Hotel Reservation Form

*Exhibitors--please go to www.wynjade.com/exhibitors/aacc06 for Exhibitor Housing Forms.

AACC 2006 ANNUAL MEETING

You may complete this form or go directly to www.aacc.org/2006am to complete your reservation request.

Today's Date _____

Name on Room _____ Share with Name _____

Arrival Date _____ Departure Date _____

Company _____

Street Address _____

City, State/Country, Postal Code _____

Phone _____ Fax _____ Email _____

HOTEL PREFERENCES

If your choices are not available, AACC Housing Services will place you in a comparable hotel.

1: _____ 4: _____

2: _____ 5: _____

3: _____ 6: _____

SUITES

All Suites must be pre-approved by AACC and are on a first come first served basis. Meeting and function space will need to be reserved through AACC directly. If a suite is desired please indicate what type of suite you're requesting. Upon receipt you will receive a call from AACC Housing Services to further define your needs.

Please circle type of suite needed: Sleeping Suite Hospitality Suite

Please note: A deposit equal to the amount of one night's room rate must accompany all reservations; the credit card provided below will be charged at time of booking.

Credit Card Used *(please circle)* American Express MasterCard Visa Confirmation Code _____

Credit Card # _____ Expiration Date _____ MM/YY

Signature _____ Date _____ MM/DD/YY

Once this form is received by AACC Housing Services, you will receive a confirmation confirming your hotel. Please call the phone number to the right if you have any questions.

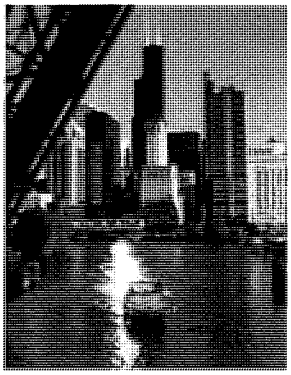
SEND COMPLETED FORM TO:
AACC Housing Services
6400 International Pkwy, Suite 2500
Plano, TX 75093
Phone: 866.546.4307 or 972.349.5423
Fax: 972.349.7715

Saturday, July 22; Sunday, July 23; Wednesday, July 26

Architectural Tour, Cruise and Lunch

9:00am – 3:00pm

Cost per person: Adult: $81.00/Child: $76.00



What better way to view Chicago's world-famous architecture than on a relaxing cruise on the Chicago River? Your specially trained architectural guide will point out the amazing array of more than 100 great architectural works. On your voyage you'll see such outstanding examples as the elegant Wrigley Tower, the world-famous Marina City, 333 Wacker with its dramatic curved glass walls, the classic Bauhaus styled IBM Building, and, of course, the Sears Tower. You'll see the work of such celebrated architects as Helmut Jahn; Holabird & Root; Skidmore, Owings & Merrill; and Ludwig Mies van der Rohe.

Lunch will be served at the Chicago Cooking Institute where a tantalizing menu has been selected for you.

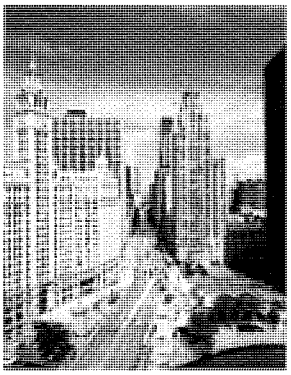
After lunch you'll continue your architectural quest on land, with the opportunity to venture inside the foyers and lobbies and other renowned interior spaces of many more marvelous edifices. Included are Frank Lloyd Wright's stunning lobby of the Rookery Building and the 1984 Marquette Building with its celebrated rotunda lobby by Louis Comfort Tiffany, and many more.

Saturday, July 22; Sunday, July 23; Monday, July 24

Chicago Highlights with Sears Tower Observatory

8:30am – 1:00pm; 12:00pm – 4:30 pm

Cost per person: Adult: $45.00/Child: $38.00



Welcome to a whirlwind peek at the remarkable world-class city of Chicago! During four hours, your guide will point out such famous landmarks as the Wrigley Building, the Picasso Sculpture, 333 N. Wacker, Marina City Towers, The Marquette and Monadnock Buildings, The Old Water Tower and Water Tower Place, the newly renovated Navy Pier and much, much more. You'll travel along the picturesque Lake Michigan while your guide points out world-renowned architecture, majestic marble museums, the Magnificent Mile with its myriad of tasteful shops. You'll stop briefly near the three lakeside museums — the Field Museum, Shedd Aquarium and the Adler Planetarium — for a quick look back at the magnificent Chicago skyline and a great 'photo-op' across Lake Michigan.

You'll also stop at the world famous Sears Tower and take a ride to the 103rd floor — the Skydeck where, on a clear day, one can see three neighboring states. And as you return downtown, you'll pass the Museum of Science and Industry, the campus of the highly revered University of Chicago, Frank Lloyd Wright's masterpiece, the Robie House, as well as the awe-inspiring gothic cathedral, the Rockefeller Chapel.

ILLUM-0158

Monday, July 24

Frank Lloyd Wright Architectural Tour with Lunch

9:30am – 3:30pm

Cost per person: Adult: $83.00/Child: $79.00

Chicago is proud of its Frank Lloyd Wright architecture. And Chicago has an abundance of his work of which to be proud. Wright began his career in Chicago and spent his first 20 years learning and developing his craft here, leaving Chicago many magnificent and exquisitely maintained examples of both his budding and then his recognized genius.

On this exclusively designed tour you'll visit three selected examples of Chicago's finest Frank Lloyd Wright designs. You'll also journey through the Frank Lloyd Wright Prairie School National Historic District surveying the world's largest concentration of Wright-designed structures, as well as a rich contrasting selection of Chicago's loveliest Victorian Homes.

You'll begin with a tour of Frank Lloyd Wright's own home and studio. Wright experimented with his own family's abode. As your guide points out items of particular interest, you'll be able to trace his attempts with several new styles and forms and identify some of the new materials for which he would eventually become so famous and so sought after.

Considered by many to be among Wright's true masterpieces, the Robie House is now owned by the University of Chicago, and is located on the campus. This house is probably the quintessential example of Wright's Prairie House style with its dramatic cantilevers and horizontal planes, lightened by long, linear art glass windows.

The Unity Temple is understood to be one of Wright's favorite commissions. Your guide will point out the bold cubist design and the extraordinary use of poured concrete — both unprecedented at the time. You'll marvel at the contrasting sense of warmth and solace you feel in the Temple's magnificent sanctuary in spite of its dramatically angular and purposely institutional design.

Relax and enjoy the architecture and a picnic-style box lunch served at the Temple.

Tuesday, July 25

Chicago's Museum of Contemporary Art & the Art Institute of Chicago

9:30am – 3:30pm

Cost per person: Adult/Child: $51.00

A specially designed tour is planned for you at the Chicago's Museum of Contemporary Art. It will be directed and guided by one of the Museum's Senior Educators. The museum's entire collection includes works representing trends in art after 1945 in all media — paintings, sculpture, works on paper, photography, video, film and books.

Your tour continues at the world-renowned Art Institute of Chicago. The Institute presents a collection spanning 5,000 years of artistic expression. The museum will be featuring an exhibition of both urban and rural Japanese pieces, a Victorian collection, and an Architectural Exhibit. Also featured will be "Harry Callahan: The Photographer at Work" and "Drawings in Dialogue: Old Masters through Modern".

Enjoy lunch on your own at the Art Institute. And don't miss the Museum Shop for that perfect memento to take back home.

Guest Program/AACC Tour Reservation Form

DEADLINE FOR PRE-REGISTRATION IS JULY 12, 2006

Complete this form (please print clearly) and return to:
AACC-Creative Events, 2166 Broadway #334, Anaheim, CA 92804 or Fax to: 714-774-1753

Name _____

Mailing Address _____

City/Province _____ State _____ Postal Code _____ Country _____

Home Phone _____ Email _____

Business Phone _____ Fax _____

Indicate method of payment:
We accept the following credit cards: ☐ Visa ☐ MasterCard ☐ American Express *(All charges on your statement will appear as Creative Events)*

NAME AS IT APPEARS ON CARD _____ EXPIRATION _____ THREE DIGIT ID NUMBER ON BACK OF CARD _____

CARD NUMBER _____ AUTHORIZED SIGNATURE _____

☐ Check enclosed, *payable to Creative Events*

	TOUR DATE		PRICE (tax inclusive)		NUMBER OF TICKETS		TOTAL COST
Architectural Tour, Cruise & Lunch (Adult)	Saturday	7/22	$ 81.00	x	_____	=	$_____
Architectural Tour, Cruise & Lunch (Child)	Saturday	7/22	$ 76.00	x	_____	=	$_____
Chicago Highlights & Sears Towers (Adult)	Saturday	7/22	$ 45.00	x	_____	=	$_____
Chicago Highlights & Sears Towers (Child)	Saturday	7/22	$ 38.00	x	_____	=	$_____
Architectural Tour, Cruise & Lunch (Adult)	Sunday	7/23	$ 81.00	x	_____	=	$_____
Architectural Tour, Cruise & Lunch (Child)	Sunday	7/23	$ 76.00	x	_____	=	$_____
Chicago Highlights & Sears Towers (Adult)	Sunday	7/23	$ 45.00	x	_____	=	$_____
Chicago Highlights & Sears Towers (Child)	Sunday	7/23	$ 38.00	x	_____	=	$_____
Frank Lloyd Wright Tour & Lunch (Adult)	Monday	7/24	$ 83.00	x	_____	=	$_____
Frank Lloyd Wright Tour & Lunch (Child)	Monday	7/24	$ 79.00	x	_____	=	$_____
Chicago Highlights & Sears Towers (Adult)	Monday	7/24	$ 45.00	x	_____	=	$_____
Chicago Highlights & Sears Towers (Child)	Monday	7/24	$ 38.00	x	_____	=	$_____
Chicago's Art Institute & Art Museum	Tuesday	7/25	$ 51.00	x	_____	=	$_____
Architectural Tour, Cruise & Lunch (Adult)	Wednesday	7/26	$ 81.00	x	_____	=	$_____
Architectural Tour, Cruise & Lunch (Child)	Wednesday	7/26	$ 76.00	x	_____	=	$_____

TOTAL ENCLOSED $_____

A confirmation letter will be sent to each participant.

All tour tickets will be held for pick-up at the Tour Desk located at McCormick Place. Please allow plenty of time to pick up your tickets.

Additional tour tickets will be available for purchase at the Tour Desk. These tickets will have a $5.00 per ticket processing fee and are limited to space available for each tour time/date.

All tours will depart from and return to McCormick Place. Please arrive at the departure area 15 minutes prior to the scheduled departure time for the tour bus loading.

If you are unable to participate, refunds will be issued less a reservation cost of $5.00 per ticket if cancellation is received by July 12, 2006. Tours not meeting minimum requirements will be canceled. A full refund will be sent.

NO REFUNDS WILL BE ISSUED ON SITE.

For special assistance and information on tours, please call 714-758-1616.

REGISTRATION HOURS

Saturday, July 22, 2006	12noon – 5:00pm
Sunday, July 23, 2006	8:00am – 6:30pm
Monday, July 24, 2006	7:00am – 5:00pm
Tuesday, July 25, 2006	7:00am – 5:00pm
Wednesday, July 26, 2006	7:00am – 5:00pm
Thursday, July 27, 2006	8:00am – 2:00pm

Registration will be located in the McCormick Place Convention Center.

ACTIVITY LOCATIONS

McCormick Place Convention Center

Educational sessions including: Plenary Sessions; Symposia; Interactive Workshops; Short Courses; Meet the Experts; Brown Bags; Posters; Chair's Invited Sessions; and Oral Abstract Presentations

Hyatt Regency McCormick Place

Opening Reception

Hyatt Regency Hotel

AACC Governance Meetings
Affiliated Organization Meetings
International Reception

Fairmont Hotel

Affiliated Organization Meetings
Industry Workshops

TRAVEL AND TRANSPORTATION

Getting to Chicago

Take advantage of special rates...

AACC has negotiated discount air fares for Annual Meeting attendees. You can:

1. Call the airlines directly and reserve using discount codes.
   American Airlines –
   Meeting Code **A3876AH** @ 1-800-433-1790

   Continental Airlines –
   Meeting Code **V70Q0J/ZFNW** @ 1-800-468-7022

   Northwest Airlines –
   Meeting Code **NYT93** @ 1-800-225-2525
2. Reserve through AACC's official travel desk at Globetrotter Travel.

   Be sure to use Group Code **AACC0706** to qualify for the special rates.

   You can make your travel arrangements by:

   Calling 1-800-236-7684; press 1 for reservations

   Visiting the travel Web site at www.GlobetrotterMgmt.com/aacc

   Emailing us at AACC@GlobetrotterMgmt.com/AACC

Getting around Chicago

Although there are cabs available for transportation in Chicago, other than the complimentary shuttle service between most of the AACC and ASCLS official hotels and the McCormick Place Convention Center, you may wish to rent a car. AACC has arranged a special discounted program with AVIS Rent a Car to help you get the car you need. Reservations can be made by calling 1-800-331-1212, or online using the www.aacc.org/2006am website or the Avis website at www.avis.com. To be eligible for your discount, be sure to register using the group number **J868723** when placing your reservation. The AACC special rates are available from July 17, 2006 until August 4, 2006.

Getting to sessions and the Clinical Lab Expo

AACC Shuttle Service

AACC provides complimentary shuttle service between most official AACC and ASCLS hotels and the McCormick Place Convention Center. The shuttle service runs from 12noon on Saturday, July 22 through afternoon on Thursday, July 27, 2006. More detailed information — including shuttle schedules for each hotel — will be available at your hotel location and at the Convention Center.

SPECIAL NOTES FOR INTERNATIONAL ATTENDEES

Apply for your Visa now.

We urge you not to delay applying for your Visa, if you need one. Experience in 2005 shows that it is taking longer to get appointments for Visa interviews, so please allow several extra months for your application. If your local Consular office requires a "Letter of Invitation" from AACC, please send a request via email to invitation@aacc.org or by fax to Annual Meeting Invitations at fax number 001 202-833-4576. All "Letter of Invitation" requests must include your full name, title, organization, address, phone and fax number and email address.

Get On-site Assistance to Improve your Conference Experience.

When you arrive at the Annual Meeting and Clinical Lab Expo, be sure to visit the International Visitors Center in the McCormick Place Convention Center. Trade specialists will be available to help you identify manufacturers who have the products you seek, and who are interested in working with international customers.

HOUSING INFORMATION

Book your hotel room at AACC discount rates

AACC has negotiated special rates at leading hotels in Chicago and appointed a company to act as our official AACC Housing Service for the Annual Meeting and Expo. AACC will provide complimentary shuttle bus service from most of the official hotels to the McCormick Place Convention Center.

Reservations Deadline: July 5, 2006

After this date, every effort will be made to accommodate your request, subject to hotel availability and rate request.

- To identify the hotel where you wish to reserve your room, turn to page 88. Rooms are assigned in the order in which reservations are received. If your first or second choice is not available, you will be assigned a room in a comparable hotel.
- *Reservations must be guaranteed.* Please include either a credit card number or a check (payable to AACC Housing Service) for the first night's deposit. Your credit card will be charged when you reservation is received.
- Written confirmation will be faxed, mailed or emailed the next business day after receipt of your request.
- Changes and cancellations should be made through the AACC Housing Service at least two weeks prior to arrival. Changes may be subject to hotel availability. If less then two weeks before arrival, please refer to your confirmation for specifics on your hotel's change and cancellation policies.
- Many hotels now impose fees for early departures. This policy is at the discretion of the individual hotel and the amount of the fee varies by hotel. To avoid an early departure charge, be sure to verify your actual date of departure at the time of check-in.

To make your hotel reservations:

Online	www.aacc.org/2006AM
Call	866-546-4307 (within the US) or 972-349-5423 (international)
Fax*	972-349-5825
Mail*	AACC Housing Service 6400 International Parkway Suite 2500 Plano, TX 75093

*When registering via mail or fax, include a completed Housing Reservation form, located on page 91.

STAYING IN CONTACT WHILE AT THE ANNUAL MEETING

Messages/Product Locator

An electronic Message Center will be located in the registration area. Monitors will be placed in various locations through the McCormick Place Convention Center and in the Expo Hall. You may leave or retrieve messages at the Message Center or from any of the remote kiosks.

Email Stations – CyberLink

AACC offers participants the opportunity to check Email via Internet terminals located in the McCormick Place Convention Center. To access email from the show site, verify the name of your server with your systems administrator. To log on you may be required to enter this information along with your email address and password. Email users who normally access their account via the Internet (i.e. Hotmail or AOL) will only need to click on the appropriate icons present on each terminal.

All information is accurate at time of printing.

A portion of your hotel room rate is used to cover association costs for housing and shuttle buses.

ILLUM-0162

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July 23-27, 2006 • Chicago, IL

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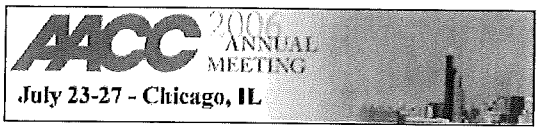
Fax: 1-202-887-5093
Email: custserv@aacc.org

OEM Lecture Series



In these brief presentations, OEM manufacturers present new technologies that may be of interest to industry scientists and R&D executives for inclusion in their new products. Admission is free—but participants must be registered for the Annual Meeting.

Tuesday, July 25, Room 403B, McCormick Place Convention Center

8:00am
The use of nanometer paramagnetic microspheres in immunoassay
Author information: Herb Chow
Organization: Magna BioSciences, LLC

8:20am
Powered by Affymetrix. Developed and Marketed by You
Author information: Cris McReynolds
Organization: Affymetrix, Inc.

8:40am
Mid-IR spectroscopic laser systems for clinical and laboratory applications
Author information: Chad B. Roller
Organization: Ekips Technologies, Inc.

9:00am
Digital Microbead Technology for Multiplex Assays
Author information: Mickie Henshall
Organization: Illumina

9:20am
Customized quality control materials
Author information: Canning, A.
Organization: Randox Laboratories Ltd.

9:40am
Antisera assay components
Author information: Dempsey, C.
Organization: Randox Laboratories Ltd.

10:00am
Innovative technology for rapid development of highly specific monoclonal antibodies
Author information: Joanne Crowe
Organization: Antibodies by Design – A Division of MorphoSys

10:20am
Introducing the LAMPIRE™ Cell Culture Bag, an elegantly simple approach to growing cells
Author information: John Malinowski
Organization: Lampire Biological Laboratories

10:40am
MagaZorb Ò , a "one kit" solution for nucleic acid isolation
Author information: Beverly A. Cormier
Organization: Cortex-Biochem

11:00am
Multiplexed genotyping of CYP450 2C9 and VKORC1 polymorphisms, associated with warfarin dosage using the INFINITI™ Analyzer.
Author information: Michael Phillips, Ram Vairavan

Organization: Genome Quebec / AutoGenomics

Wednesday, July 26, Room 403A, McCormick Place Convention Center

8:00am
ExpressPartsT offers injection molded prototype parts in days not weeks at production quality
Author information: Jenkins, S.M., O'Brien, D.J.
Organization: Metro Mold & Design, Inc.

8:20am
Full OEM manufacturing capability from development to production
Author information: Raymond Tarr
Organization: Idaho Technology

8:40am
Managing Projects From Afar: Building Strong Relationships with OEM Partners
Author information: Mary Wojtas
Organization: Abbott Laboratories

9:00am
Effect of Membrane Thickness on Assay Performance
Author information: Gupta, A., Gupta, N.K.
Organization: Advanced Microdevices Pvt. Ltd.

9:20am
A lateral flow assay format which discriminates between two antigenically similar analytes
Author information: O'Luanaigh, N., Carney, J.
Organization: BBInternational

9:40am
Improving Assay Sensitivity by Sample Preparation
Author information: Kevin Jones
Organization: Whatman Inc

10:00am
Rapid test devices – more portable, more convenient to use, and better results
Author information: Liang, G., Brown, J.V. Fan, J.C.
Organization: Acro Biotech, LLC

10:20am
A new automated QMS Ò Lamotrigine immunoassay
Author information: Melissa Wall
Organization: Seradyn, Inc.

10:40am
Verification of a new photometer system using ReagentStrip™
Author information: Ivars Jaunakais, Ray, Howard
Organization: Industrial Test Systems, Inc.

11:00am
High Volume Manufacturing of Organic Microfluidic Substrates for Point of Care Testing
Author information: Denny G. Aeschliman
Organization: 3M Electronics

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Final 2006 Exhibitor List

August 1, 2006

AACC
3M
3M Medical Diagnostics
A&T Corporation
A/C Diagnostics LLC
AAFP-Laboratory Proficiency Testing
Aalto Scientific, Ltd.
Abaxis
Abbott Diagnostics
Abbott Point of Care
Access Bio, Inc.
Accumetrics, Inc
Accumin Diagnostics, Inc.
AccuTest, Inc.
ACON Laboratories, Inc.
Acro Biotech, LLC.
Adaltis
ADEMTECH
Adeza Biomedical
Adhesives Research, Inc.
Advanced Instruments, Inc.
Advanced Microdevices Pvt. Ltd.
Aesku Diagnostics
Affymetrix, Inc.
Ahlstrom
Air Courier Dispatch, Inc.
Air Sea Atlanta, Inc.
Alfa Scientific Designs, Inc.
ALIFAX SPA
Aloka Co., Ltd.
ALPCO Diagnostics
Amano Enzyme USA Co., Ltd.
Amedica Biotech, Inc.
Ameditech, Inc.
American Bio Medica Corporation
American Biological Technologies, Inc.
American Board of Clinical Chemistry
American Diagnostica Inc.
American Medical Technologists
American Proficiency Institute
American Society for Clinical Laboratory Science
American Society for Clinical Pathology/Board of Registry
American Thermal Wizards Int'l Inc.
Ameritek USA

Amic AB
AmniSure International LLC
Analis
Analyticon Biotechnologies AG
AnaSpec, Inc.
Ani Biotech Oy & AniLabsystems Ltd
Antek HealthWare
Antibodies by Design
Applied Biosystems
Aries Filterworks, Division of ResinTech, Inc.
Arista Biologicals Inc
Arlington Scientific - ASI
Artel
ARUP Laboratories
Asahi Kasei Pharma Corporation
Aspyra
ASSEL - AMS
Astech Corporation
Asymtek
Atherotech
Audit MicroControls, Inc.
AutoGenomics Inc.
Autoimmunune Diagnostika GmbH/Cell
Avo Photonics, Inc.
Awareness Technology, Inc.
AWEX (Wallonia Export Agency)
Axis-Shield plc
AZOG, Inc.
B&E Scientific Instrument Co., Ltd.
Bayer HealthCare, Diagnostics Division
Baytree Leasing
BBI Diagnostics (A SeraCare Company)
BBInternational
BD
BD Lee Laboratories
Beaufort Advisors
Beckman Coulter, Inc.
Beijing Condor-Teco Medical
Berthold Detection Systems GmbH
BERTHOLD TECHNOLOGIES GmbH & Co. KG
Best Lab Deals, Inc.
Binding Site Inc., The
Bio Processing, Inc
Bio/Data Corporation
BioCheck, Inc.
Bio-Chem Valve and Omnifit
Biochemed Corporation
Biocode-Hycel
BIODESIGN International
BioDot, Inc.
BIOER TECHNOLOGY Co.,LTD
BioFX Laboratories, Inc.

Biogenesis
BIOHIT, Inc.
BioKit SA
Biological Specialty Corporation
BIOLYPH, LLC
Biomat
BioMed Resource Inc.
Biomedix
Biomerica, Inc.
bioMerieux, Inc.
Bio-Rad Laboratories
Biosearch Technologies, Inc.
Biosigma S.R.L.
Biosite Incorporated
Biosource
BIOSPACIFIC
BioTek Instruments, Inc.
BIOTRON DIAGNOSTICS USA
Biozyme Laboratories
BIVDA / GAMBICA
Blackhawk BioSystems, Inc.
Block Scientific, Inc.
BloodCenter of Wisconsin
BMD SA
BODITECH MED Inc.
BOMI IBERICA, S.A.
Boval Company, L.P.
Brady Medical
Bruker Daltonics Inc.
Burkert
Calbiotech Inc
Calzyme Laboratories, Inc.
Cambridge Consultants
CanAg Diagnostics
Capralogics Inc
Capricorn Products LLC
Cardinal Health
CARE Diagnostica International
Care Fusion, Inc.
Carl Zeiss MicroImaging, Inc.
Carolina Liquid Chemistries
Carville Ltd
CaseBauer
CellaVision
Cellestis, Inc.
Celliance
Centerchem Inc.
Centers for Disease Control & Prevention,TTO
Centers for Medicare & Medicaid Services-CLIA
Cepheid
Cerner Corporation
CERTEST BIOTEC S.L.

Chembio Diagnostics Systems, Inc.
Chemicon/Upstate
Childlab
Chromsystems GmbH
Ciphergen Biosystems, Inc.
CITOTEST LABWARE MANUFACTURING CO., LTD.
Clinica World Medical Technology News
Clinical & Laboratory Standards Institute
Clinical Analysis Corporation
Clinical Diagnostic Solutions, Inc.
Clinical Ligand Assay Society
CLINIQA Corporation
Cohesive Technologies Inc.
COLA
College of American Pathologists
Computype, Inc.
Conductive Technologies, Inc.
Copan Diagnostics, Inc.
Corbett Robotics
Corgenix, Inc.
Coris Bioconcept
CORMAY
CORTEX BIOCHEM
Cosmo Bio USA
Crony Instruments S.r.l.
CTK Biotech, Inc.
Custom Pack, Inc.
Cyro Industries/Degussa
Dade Behring, Inc.
Daiichi Pure Chemicals
DAS Srl
Data Comm for Business Inc.
Data Innovations, Inc.
Davco Resources LLC
David G. Rhoads Associates, Inc.
Dawning Technologies, Inc.
DCM Diagnostics LLC
Delta Industrial Services
Denka Seiken Co., Ltd
DenLine Uniforms, Inc.
Department of Veterans Affairs
Desert Biologicals/Omega Biologicals
Dexter Magnetic Technologies, Inc.
DFI Co., Ltd.
Diagam
Diagnostic Automation /Cortez Diagnostic, Inc.
Diagnostic Chemicals Limited
Diagnostic Laminations Engineering
Diagnostic Products Corp.
Diagnostica Stago, Inc.
DIALAB G.m.b.H
Diamedix Corporation

Diamics, Inc.
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DiaSys Diagnostic Systems GmbH
Diazyme Laboratories
DIBA Industries, Inc.
DIESSE Diagnostica Senese S.p.A
Dirui Industrial Co., Ltd.
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DOCRO, Inc.
DRD Diluter Corporation
Drew Scientific
DRG International, Inc.
Drucker Company, The
Drummond Scientific
Duke Scientific Corporation
DXS LIMITED
DYNEX Technologies Inc.
Ease Labs, Inc.
EastCoast Bio, Inc.
Eastern Plastics, Inc.
EFD Inc.
Egemin Automation Inc
eGene, Inc.
Ekips Technologies, Inc.
Elsevier
EMD Biosciences
EMD Chemicals, Inc.
Epocal Inc
Eppendorf AG
Eppendorf North America
EPS Bio Technology Corp.
EQUITECH-BIO, Inc.
ERBA Diagnostics Mannheim GmbH
ESA Biosciences, Inc.
Eurotrol
EVERGREEN SCIENTIFIC
EXAKT Technologies, Inc.
Excel Scientific, Inc.
Express Diagnostics Int'l, Inc.
Ferrotec (USA) Corporation
Filtrona Fibertec
Fine Care Corporation
Fisher HealthCare
Fluid Management Systems
Fluid Metering, Inc.
Focus Diagnostics
Foliage Software Systems
Fujirebio Diagnostics, Inc.
Furuno Electric Co., Ltd.
G&L Precision Die Cutting, Inc.
Gale Force Software Corporation
GE Healthcare

Gems Sensors Inc.
General Data
Genisphere, Inc.
Gen-Probe
Gentris Corporation
GenWay Biotech, Inc.
Genzyme Diagnostics
Globe Scientific Inc.
GML
Golden West Biologicals, Inc.
GONOTEC GmbH
Greiner Bio-One, Inc.
Grifols USA, Inc.
Guangzhou Improve Medical Instruments Co., Ltd.
Haemoscope Corporation
Hamamatsu Corporation
Hamilton Company
HandyLab, Inc.
Hardy Diagnostics
Harlan Bioproducts for Science
Haydon Switch & Instrument, Inc.
Headwall Photonics, Inc.
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Hitachi High Technologies America, Inc.
Hoover Precision Products, LLC
HORIBAABX Diagnostics
HRA Research
HTL-STREFA S./Lancet International, Inc.
Huayang Analyse Instrument Co., Ltd.
Hycor Biomedical Inc.
HyTest Ltd.
Idaho Technology Inc.
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Illumina, Inc.
ILS Innovative Laborsysteme GmbH
Imagene Technology Inc.
IMMCO Diagnostics
Immucor Gamma, Inc.
Immuno - Biological Laboratories, Inc. (IBL-America)
Immuno Concepts
Immunodiagnostic Systems (IDS)

Immunology Consultants Laboratory, Inc.
Immy
IMPAC Medical Systems, Inc.
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IND Diagnostic Inc.
Indiana Pathology Images
Industrial Test Systems
Inmark, Inc.
Innovacon Inc.
Inotech Biosystems International
INOVA Diagnostics, Inc.
Instrumentation Laboratory
InTec Products, Inc.
IntelliDot Corporation
International Immuno-Diagnostics
International Immunology Corporation
Inverness Medical Professional Diagnostics
Invetech
Invitrogen
IQuum, Inc.
IRIS Diagnostics
Iris Sample Processing (StatSpin)
Isensix, Inc.
ITC
IVD Research, Inc.
IVD Technology Magazine
IVEK Corporation
Iwaki America Inc.
Jackson ImmunoResearch Laboratories, Inc
JAJ International
Japan Association for Clinical Laboratory Automation
JAS Diagnostics, Inc.
Joint Commission
Jokoh Co., Ltd
Kamiya Biomedical Company
Kelly Scientific Resources
Kem-En-Tec Diagnostics
KIKKOMAN CORPORATION
Kinematic Automation Inc.
Kloehn Co. Ltd.
KMC Systems, Inc.
KRONUS, Inc.
K-Sera, Inc.
Lab Manager Magazine™
Lab Medica
LabCorp-Esoterix
LabiTec GmbH, Germany
Labnovation Technologies, Inc
Laboratory Data Systems, Inc.
Lampire Biological Laboratories
LasX-Precision Medical Converting Group
Lathrop Engineering, Inc.

Lattice Inc
Lee Company, The
Legacy Health System
Leuze Lumiflex, Inc.
LG Life Sciences, Ltd.
LifeScan Inc., a Johnson & Johnson Company
LifeSign LLC
LINCO Research, Inc.
Linear Chemicals, S.L.
LipoScience, Inc.
LPS Industries
LRE Medical, an Esterline Company
Luminex Corporation
m.u.t GmbH
Magellan Biosciences, Inc.
Magna Bio Sciences
Magsphere Inc.
Maine Biotechnology Services
Maine Standards Company
MakroMed Manufacturing (PTY) Ltd.
March Plasma Systems
Market Research.com
Mayo Medical Laboratories
McKesson
MDSS - Medical Device Safety Service
Medcompare
Medica 2006/ Messe Duesseldorf North America
Medica Corporation
MEDICAL & BIOLOGICAL LABORATORIES
Medical Automation Systems
Medical Courier Elite by Taylor Data Systems
Medical Device Consultants, Inc.
Medical Laboratory Evaluation
Medical Learning, Inc.
Medical Staffing Network Inc.
MEDIPAN GmbH
Medivative Technologies LLC
Medix Biochemica
MedMira Inc
MEDTOX Laboratories, Inc.
Medtronic Inc.
Melcor Corporation
Mercodia Inc.
Meridian Bioscience, Inc.
Metro Mold & Design, Inc.
MGM Instruments, Inc.
Michigan Diagnostics, LLC
MICROGENICS
MICROLIT
Microscan Systems, Inc.
Microsens Iseao
Midland BioProducts Corp

Millenia Diagnostics, Inc.
Millipore Corporation
Mindray Co., Ltd.
MiniGrip
Misys Healthcare Inc.
Mitsubishi Kagaku-Iatron
MLO-Medical Laboratory Observer
Monobind Inc.
Moss, Inc.
MP Biomedicals
MT Promedt Consulting GmbH
Multiplex Biosciences
Multisorb Technologies, Inc.
Nalge Nunc International
Nano-Ditech Corporation
Nanogen, Inc.
Nanosphere, Inc.
National Academy for Clinical Biochemistry
National Jewish Medical & Research Center
National Laser Services
National Registry of Certified Chemists
NCA -National Credentialing Agency for Laboratory Personnel, Inc.
Neogen Corporation
NERL Diagnostics
New England Small Tube
NICHIREI BIOSCIENCES, INC.
NIKON Instruments Inc.
NIST
Noble Medical, Inc.
NOF CORPORATION
Norgren Inc.
Nova Biomedical
NTE, S.A.
NuAire Inc.
Obelis
OEM Concepts Inc.
Olympus America, Inc.
Omega Diagnostics Ltd
OPERON S.A.
OraSure Technologies, Inc.
Orchard Software Corp
Orgenics Ltd.
Ortho-Clinical Diagnostics
Osmetech Moleculer Diagnostics
Owen Mumford Inc.
Oxonica Inc.
Oyster Bay Pump Works, Inc.
Pall Life Sciences
Parker Hannifin Corp
Parter Medical Products, Inc.
PBM-Princeton BioMeditech Corportion
PEAK-Service USA

Peripheral Resources Inc.
PerkinElmer Life and Analytical Sciences
Perlong Medical Equipment Co., Ltd.
Phadia (Pharmacia Diagnostics)
Pierce
Pierce Milwaukee
Plasmatec Laboratory Products Ltd.
Pointe Scientific, Inc.
Polymedco, Inc.
Polymer Laboratories, A Varian, Inc. Company
POLYMICROSPHERES
Polysciences, Inc/Bangs Laboratories Inc
Porex Technologies
Power Place, Inc., The
Precision Systems Inc.
PRIMUS Corporation
Prodesse, Inc
Proliant Health and Biologicals
Promega Corporation
Protedyne Corporation
Puritan Medical Products Co. LLC
PVT LabSystems LLC
QAS
QIAGEN Inc.
Quad Five
Quadra Spec, Inc.
Quantimetrix Corporation
Quantum Analytics
Quest Diagnostics Incorporated
Quidel Corporation
Quimica Clinica Aplicada, S.A.
R&D Systems, Inc.
R2 Diagnostics
Radim SpA
Radiometer America Inc.
RAM Scientific, Inc.
RANDOX LABORATORIES LTD
Rayto Life & Analytical Sciences Co, Ltd
R-Biopharm AG
RD Plastics Company
Rees Scientific Corporation
Reference Diagnostics, Inc.
Reference Laboratory, The
Remel Inc.
Research Organics, Inc.
Response Biomedical Corp
Rheodyne, LLC
RNA Medical
RND Group, Inc., The
Roche Diagnostics
Roche Diagnostics Corporation
Rocky Mountain Diagnostics, Inc.

Rotek Industries
Runbio Biotech Co., Ltd.
SA Scientific
SaatiTech
SAFC
Safe-Tec Clinical Products, Inc.
Saladax Biomedical, Inc.
Salimetrics LLC
Sapphire Engineering, Inc.
Sarstedt, Inc.
Sartorius Corporation
Scantibodies Laboratory Inc.
SCC Soft Computer
SCIMEDX Corporation
SCIPAC Ltd.
Scripps Laboratories
SDI Biomed, Inc.
Seatec/Teco
Sebia Electrophoresis
SENTINEL Diagnostics
Separation Technology, Inc. (STI)
SEPPIM - ELITECH
SeraCare Life Sciences
Seradyn, Inc.
Serion Immundiagnostica GmbH
Serotec
SFRI Diagnostics
Shamrock Scientific Specialty
Shanghai Chemtron Biotech Co., Ltd.
Shanghai Fosun Med-Tech Development co., Ltd
Shanghai SIIC Kehua Biotech Co., Ltd.
Sias AG
Sifin GmbH
SimPort Plastics Ltd
SKF USA Inc.
SLR Research Corporation
SMC Corporation of America
Softtech Health
Source Scientific, LLC
Southern Biotech
Span Diagnostics Limited
Specialty Laboratories
Spherotech Inc.
SPINREACT, SA
STANBIO LABORATORY
Standard Diagnostics, Inc.
Standard Register
STRATEC Biomedical Systems AG
Strategic Diagnostics/Strategic BioSolutions
Streck
Sud-Chemie Performance Packaging
Super Brush LLC

SurModics, Inc.
Sutter Health
Symbol Technologies
Symprotek Corporation
Syntron Bioresearch, Inc.
Sysmex
Taidoc Technology Corporation
Tecan US, Inc.
Technidata America Medical Software, LLC
Techno Medica Co. Ltd.
Teco Diagnostics
TELCOR
Tennant Packaging Corp.
Tetracore, Inc.
Thermo Electron Corporation
Third Wave Technologies
Tm Bioscience Corporation
TOKYO BOEKI LTD.
Tosoh Bioscience, Inc.
Toyobo Co., Ltd. c/o Shinko American Inc
TRINA BIOREACTIVES AG
Trinity Biotech
UCP Biosciences, Inc.
UNC Hospitals
UNICO
Uniflex
United Biotech, Inc.
Upchurch Scientific
Uritest Medical Electronic Co., Ltd
US Diagnostics
US Filter, a Siemens Business
USHIO, INC.
UTAK Laboratories, Inc.
ValuMax Protective Apparel Inc.
Varian, Inc.
VEDALAB
VIAFLO
ViraCor Laboratories
Viral Antigens, Inc.
ViraLab Inc
Vircell S.L.
ViroStat, Inc.
Vista Technology Inc.
Vital Diagnostics
Vivaproducts, Inc.
Vonco Products
VWR International
W.H.P.M. Bioresearch of Technology Co., Ltd.
Wako Diagnostics
Warde Medical Laboratory
Waters Corporation
Web Converting, Inc.

Wescor, Inc.
WesTgard QC, Inc.
Whatman
Wheaton Science Products
Wiener Laboratorios SAIC
Wolters Kluwer Health - Lippincott Williams & Wilkins
Wondfo Biotech Co., Ltd.
Worthington Biochemical Corporation
WSLH Proficiency Testing
XDX
Xiril
YD Diagnostics
Zentech
ZeptoMetrix Corporation
Zeta Corporation
ZheJiang Gongdong Medical Plastic Factory

Total Exhibiting Companies	644
Total Booths	1,764

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ILLUM-0309

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Carol	Berry	MBA	Dept of Services	Asuragen, Inc.	2150 Woo Suite-100	Austin	TX	78744	USA
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GEORGE	BERS			AFFYMETRIX	3420 CENTRAL EXPRE	SANTA CL	CA	95051	US
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Bryan L.	Betz	PhD	Dept of Pathology	University of Michiga	2910 Huro Traverwoo	Ann Arbor	MI	48105-3450	USA
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Dylan Hilm	Bird	BS	Dept Business Developmen	GenturaDx	24590 Clawiter Road	Hayward	CA	94545	
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ILLUM-0310

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ILLUM-0311

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ILLUM-0312

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ILLUM-0313

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ILLUM-0314

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ILLUM-0315

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ILLUM-0316

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ILLUM-0317

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ILLUM-0318

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ILLUM-0320

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ILLUM-0321

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ILLUM-0322

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ILLUM-0323

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ILLUM-0325

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ILLUM-0326

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ILLUM-0328

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ILLUM-0329

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ILLUM-0330

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ILLUM-0331

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ILLUM-0332

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ILLUM-0333

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ILLUM-0334

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ILLUM-0335

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ILLUM-0336

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ILLUM-0337

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ILLUM-0338

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ILLUM-0339

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ILLUM-0340

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ILLUM-0341

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ILLUM-0342

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Bill	Wyatt		Dept of Lab Med & Patholo	Allina Hospitals & Clin	800 East 28th Street	Minneapol	MN	55407	USA	
Liqiang	Xi	MD	Laboratory of Pathology	NCI/NIH	10 Center I Bldg 10 Ro	Bethesda	MD	20892-1500	USA	
Yagang	Xie	MD PhD	Molecular Genetics Lab/Lat	Memorial University c	300 Prince Rm-1J418	St. John	NF	A1B 3V6	CANADA	
Ling	Xu	MS MD	Dept of R&D	Canon U.S. Life Scienc	9800 Medi Suite-A-10	Rockville	MD	20850	USA	
Ruliang	Xu	MD PhD	Dept of Pathology	NYU School of Medici	550 First Avenue	New York	NY	10016	USA	
Rinat	Yacobi			Medison - Pharmatop	10 Hashilo ISRAEL	Petach-Tik	NA	49170	IS	
Yosuke	Yamamoto			JSR Micro	1280 N Mathilda Ave	Sunnyvale	CA	94107	USA	

ILLUM-0343

Shi	Yang	MD	Dept of Pathology & Lab M	Mallory Pathology As	670 Alban	Room 346	Boston	MA	2118	USA
Wendy	Yang	MD		Genoptix, In c	2110 Rutherford Rd		Carlsbad	CA	92008	USA
Joseph	Yao			Mayo Clinic	200 First St. Sw, Sdsc		Rochester	MN	55905-0002	USA
Kimberley	Ybarra		Dept Molecular Pathology	Scott and White	2401 S. 31	Room 36B	Temple	TX	76508	US
Fei	Ye	PhD	Dept of Molecular Patholog	Mount Sinai School of	1425 Madison Ave		New York	NY	10029	USA
Hongtao	Ye			Royal National Ortho	Hongtao.ye@cancer.u		London	NA	HA7 4LP	UK
Joanne Mu	Yeakley	PhD	Diagnostic Assay Developm	Illumina, Inc.	9885 Towne Centre D		San Diego	CA	92121	USA
Cindy J.	Yee	PhD		Prometheus Laborato	9410 Carroll Park Driv		San Diego	CA	92121	USA
Garland	Yee	BS	Molecular Diagnostics Labo	Univ Texas MD Ander	8515 Fannin Street, M		Houston	TX	77054	USA
Belinda	Yen-Lieberman	PhD	Clinical Pathology	Cleveland Clinic Foun	Departmer 9500 Euclid		Cleveland	OH	44195-5140	USA
Ivy	Yeung	MS	Dept of Microbiology	TPMG Kaiser Perman	1725 Eastshore Highw		Berkeley	CA	94710	USA
Cecilia Chi	Yeung	MD			6169 Pers	Apt-3W	St Louis	MO	63112	USA
Chen	Yi-Lin	MT	Dept of Pathology	Cheng Kung Universit	138 Sheng Li Road		Tainan		70403	Taiwan
Priscilla	Yim			Life Technologies	850 Lincoln Centre Dr		Foster City	CA	94404	US
Soo Jin	Yoo	MD PhD	Laboratory Medicine	Sanggye Paik Hospital	761-1 Sanggye 7-dong		Seoul		139-707	Republic of Ko
Young Ho	Yoon	MD PhD	Laboratory Medicine	Eone Reference Lab	19-6 Noryangjin Dong		Seoul		156-800	Republic of Ko
Denis Fran	York	PhD	Molecular Diagnostics	Molecular Diagnostics	6 Ribston Place		Westville,	KZN	3630	South Africa
Stephen	Young	PhD	Dept of Pathology	University of New Me	1 Universit Msc 08 46		Albuquerq	NM	87131-0001	USA
Keith	Young	BS	Product Development	Celera	1401 Harbor Bay Park		Alameda	CA	94502	USA
Judy	Yu	PhD	Scientific Affairs/Global Ma	Abbott Molecular, Inc	1300 E Touhy		Des Plaine	IL	60018	USA
Min	Yu	MD	HLA Lab	Children's Memorial H	2300 Child Rm-M055		Chicago	IL	60614	USA
Shihui	Yu	PhD	Dept of Microarray Laborat	Children's Mercy Hos	2401 Gillham Road		Kansas City	MO	64108	USA
Jar-fee	Yung			NeoGenomics	12701 Commonwealt		Fort Myers	FL	33913	US
Irina	Zaytseva			Cureline BioPathology	290 Utah Ave Suite 3C		South San	CA	94080	US
Barbara	Zehentner	PhD	Molecular Analysis	HematoLogics Inc	3161 Elliot Suite 200		Seattle	WA	98121	USA
Barbara	Zehnbauer	PhD		Centers for Disease C	1600 Clifto Mail Stop C		Atlanta	GA	30329	USA
Shimin	Zhang	MD PhD	Scientific Laboratory	Armed Forces Institut	14th St & Alaska Ave,		Washingto	DC	20817	USA
Tong	Zhang	MT	Dept of Molecular Diagnost	University Health Net	200 Elizabeth St, Eato		Toronto	ON	M5G 2C4	CANADA
E Katherin	Zhang	MS	Applied Molecular Profiling	Toronto General Hosp	11-NU111	200 Elizabe	Toronto	ON	M5G 2C4	Canada
David	Zhang	MD PhD	Dept of Pathology	Mount Sinai School of	1425 Madi	Rm 952	New York	NY	10029	USA
Shengle	Zhang	MD	Dept of Pathology	SUNY Upstate Medica	750 E Adams Street, L		Syracuse	NY	13210	USA
Kejian	Zhang	MD MBA	Division of Human Genetics	Cincinnati Children	3333 Burn	MI 4006	Cincinnati	OH	45229	USA
Qing	Zhang	MD PhD	Medical & Molecular Genet	Indiana Univ School o	975 W. Wa	IB 130	Indianapol	IN	46202	USA
Gloria	Zhang	MD MS	Dept Pathology & Lab Medi	The Cleveland Clinic	9500 Euclid	L25	Cleveland	OH	44139	USA

ILLUM-0344

Hongwei	Zhang	PhD	Research & Early Developm	Luminex Corporation	439 University Ave	Toronto	ON	M5G 1Y8	Canada
Weiwei	Zhao	MS MLS(ASCP)		Kingmed Diagnostics	9407 Sunray Dr	Lenexa	KS	66227	USA
Weiqiang (	Zhao	MD PhD	Dept of Human Tissue Reso	Ohio State Univ Med	2001 Polar Room 206	Columbus	OH	43240	USA
Xiaofeng	Zhou			Kaiser permanente	5755 Cottle Road, Bui	San Jose	CA	95123	US
Lan	Zhou	MD PhD	Dept of Pathology	Case Western Reserv	2103 Cornell Rd, Wols	Cleveland	OH	44106	USA
Lei	Zong			Key Tech	40 East Cross Street	Baltimore	MD	21230	
kathy	zoumberos			Moffitt Cancer Center	12901 Magnolia Dr	Tampa	FL	33612	US
Markus	Zumbansen	PhD	Dept R&D	Miltenyi Biotec GmbH	Friedrich-Ebert-Strass	Bergisch Gladbach		51429	Germany

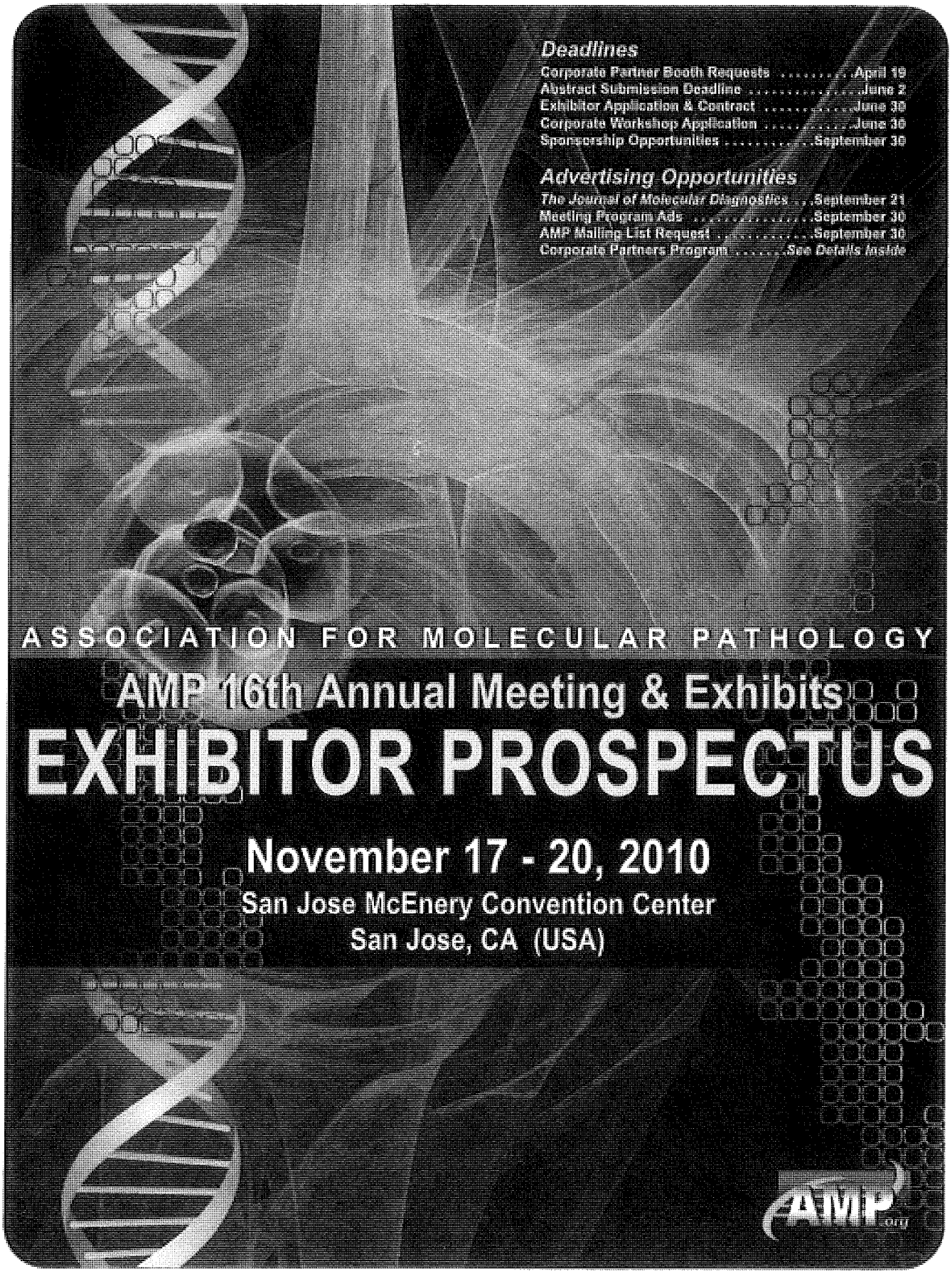
ILLUM-0345

EXHIBIT 5

(Part V of VII)

OF

DECLARATION OF GREGORY F. HEATH


Deadlines
Corporate Partner Booth Requests . . . . . April 19
Abstract Submission Deadline . . . . . June 2
Exhibitor Application & Contract . . . . . June 30
Corporate Workshop Application . . . . . June 30
Sponsorship Opportunities . . . . . September 30
Advertising Opportunities
The Journal of Molecular Diagnostics . . . September 21
Meeting Program Ads . . . . . September 30
AMP Mailing List Request . . . . . September 30
Corporate Partners Program . . . . . See Details Inside
ASSOCIATION FOR MOLECULAR PATHOLOGY
AMP 16th Annual Meeting & Exhibits
EXHIBITOR PROSPECTUS
November 17 - 20, 2010
San Jose McEnery Convention Center
San Jose, CA (USA)
AMP.org

Association for Molecular Pathology

2010 Annual Meeting and Exhibits

November 17-20, 2010

San Jose McEnery Convention Center, San Jose, CA

Association for Molecular Pathology

The Association for Molecular Pathology (AMP) is committed to the advancement of clinical molecular diagnostic and prognostic medicine through education and training of practitioners, physicians, laboratory and industrial scientists, and health care professionals involved in patient care and management. AMP supports the development of new technologies in molecular biology to be used in laboratory medicine, including diagnosis, treatment, and prognosis of genetic disorders, cancer, infectious diseases, identity and histocompatibility.

About the Membership

The membership of AMP includes individuals interested in the educational, medical, scientific, economic, and regulatory aspects of molecular diagnostics, including pathologists, clinical laboratory scientists, clinicians and other health care personnel, government employees - especially those involved in regulation of the field - and professionals in the *in vitro* diagnostics industry.

AMP members are involved in every aspect of molecular diagnostics: performance, interpretation, and reporting of molecular diagnostic tests, assay development and validation, and medical education. Many members participate in research aimed at broadening the understanding of gene/protein structure and function, disease processes, and developing new technologies. AMP aims to inform and educate its members as well as other professionals interested in molecular pathology through its annual meeting, publications, website, listserv, and other venues.

Important Dates and Deadlines!

Corporate Partner Booth Requests	April 19
Abstract Submission Deadline	June 2
Exhibitor Application and Contract Form	June 30
Corporate Workshop Application Form	June 30
Exhibitor Service Kits Mailed	August 13
Sponsorship Opportunities Form	September 30
Advertising Opportunities:	
The Journal of Molecular Diagnostics	September 21
Meeting Program	September 30
AMP Mailing List Request	September 30
AMP Corporate Partners Program	*(See details on pages 10-12)*

The Association for Molecular Pathology will host its 16th Annual Meeting and Exhibits November 18-20 at the San Jose McEnery Convention Center in San Jose, CA.

This four-day event starts on November 17 with a day of corporate-sponsored workshops. A keynote lecture presented by **Patrick O. Brown, PhD, Stanford School of Medicine,** the distinguished recipient of the **2010 AMP Award for Excellence in Molecular Diagnostics**, launches the scientific program on November 18.

Programming includes poster sessions and invited speakers for workshop and plenary sessions in each of the four major areas of clinical molecular diagnostics:

- **Hematopathology**
- **Infectious diseases**
- **Inherited genetic diseases**
- **Solid tumors**

The meeting also includes several technical workshops. Corporate exhibits, working lunch meetings, and casual social gatherings offer opportunities for networking and further exchange with molecular laboratory professionals.

Enclosed is your **2010 Exhibitor Prospectus**. Additional opportunities for Exhibitors include **Corporate Workshops, Dining Event Sponsorships** and **Scientific and Educational Activity Sponsorships**. Our **Corporate Partners** program offers our Exhibitors additional opportunities for high visibility to the molecular pathology community.

Mark Your Calendars...

Association for Molecular Pathology

AMP 2011 Annual Meeting & Exhibits

November 16-19, 2011

Gaylord Texan Resort & Convention Center

Grapevine, TX

ILLUM-0386

Exhibitor Information

Exhibitor Information & Application Forms on the Web

The Exhibitor Prospectus is available in its entirety at: www.amp.org/2010/exhibits.htm

- Preliminary Program
- Rules and Regulations for Exhibiting
- General Information
- Exhibitor Application and Contract
- Corporate Partners Program Information
- Sponsorship/Advertising Opportunities
- Mailing List Information
- Services and Official Contractor
- Union Regulations
- Corporate Workshop Information and Application
- Exhibitor Badges Form
- Current Exhibiting Companies/Booth Assignments

Exhibit Space Rental

All booths are 10' x 10' or 20' x 20'. The maximum height in the exhibit area is 30 feet. Rental includes 8 ft. high back drapes, 3 ft. high side dividers and a standard (7" X 44") identification sign with company name. Exhibiting companies are **required** to purchase carpeting for their booth area.

Booth Fees

10 X 10 Inline	$4,000
10 X 10 Corner	$4,750
20 X 20 Island	$19,000
10 x 10 Non-Profit Inline	$2,000

Please submit your completed **Exhibitor Application and Contract** (page 7) by **June 30, 2010**.

Exhibitor Registration Hours

Tuesday, November 17	12:00 pm - 6:00 pm
Wednesday, November 18	7:00 am - 6:00 pm
Thursday, November 19	7:00 am - 5:00 pm
Friday, November 20	7:00 am - 5:00 pm
Saturday, November 21	7:00 am - 5:00 pm

Exhibit Installation

Wednesday, November 17	8:00 am - 4:00 pm

Exhibit Hours

Thursday, November 18	1:00 pm - 5:00 pm
Friday, November 19	9:00 am - 5:00 pm
Saturday, November 20	9:00 am - 5:00 pm

Dismantling of Exhibits

Saturday, November 20	5:00 pm - 9:00 pm

*No packing or dismantling of exhibits will be permitted until **5:00 pm, Saturday, November 20.** Early departure will result in the company or group being penalized including being banned from future tradeshows. When planning your dismantling and departure to follow the show, please allow no less than 3 hours for return of all empty shipping materials from storage. We strongly recommend that you advise your staff to make appropriate departure plans; i.e. plan to depart late Saturday evening or Sunday morning and to not count on being able to depart on Saturday afternoon.*

Exhibitor Rules & Regulations

- **Electronic Lead Retrieval**
  Attendees at the 2010 AMP Annual Meeting will carry electronic cards. Lead retrieval services will be provided by Trade Show Leads. Exhibitors will have the opportunity to rent lead retrieval services as part of their exhibit booth package.
- **Exhibitor Badges**
  Exhibitor badges must be worn at all times, and allow access to the Exhibit Hall and Plenary Sessions ***only.*** Exhibitors will receive 6 badges per 10' x 10' booth space, 12 badges per 10' x 20' booth space, and 24 badges per 20' X 20' booth space; additional Exhibitor badges will be available at a fee of $50.00/each. Additionally, each exhibiting company will be entitled to six Guest of Exhibitor badges; the Guest badges will be available for pick up at registration by the designated company representative. Exhibitor name badge requests must be submitted through the AMP Website at www.amp.org/meetings/2010/login.cfm
- **Promotional Items and Activities**
  Companies wishing to conduct contests or drawings should contact the AMP office at 301-634-7400 for guidelines and permission. Exhibiting companies are permitted to distribute promotional materials and other items at their Exhibit Booth location only. All items distributed must be useful to the professional activities of the meeting attendees, and be made available to all meeting attendees as long as supplies last.
  No soliciting of registrants is permitted in the aisles or in other exhibitor's booths, or in any other area of the hotel. No distribution of literature or other promotional items at hotel guestrooms, or in any other public or private area of the hotel is permitted.
- **Subletting Exhibit Space**
  Subletting any part of the exhibit space by an exhibitor is prohibited.
- **Sale of Goods**
  The sale of goods or services of any kind in the exhibit area in connection with the Annual Meeting is prohibited. Order taking is permitted.
- **Booth Relocation**
  AMP reserves the right to relocate space to areas other than that selected by the exhibitor. Relocations will be made only upon notification to the exhibitor by Exhibit Management. Management strives for, but cannot guarantee, that a company will not be located near a competitor.
- **Exhibit Space Cancellation**
  All exhibit space cancellations must be received in writing by AMP Exhibit Management.
- Cancellations received on or before **August 18, 2010**, qualify for a 90% refund of all monies paid for booth space rental.
- Any company cancelling its booth space between **August 19, 2010** and **September 18, 2010**, will forfeit 50% of the total cost of exhibit space rental.
- Any company cancelling after **September 18, 2010**, will forfeit full exhibit space payment.

ILLUM-0387

Exhibitor Information

Ancillary and Satellite Events

AMP encourages ancillary meetings and events during the annual meeting provided that they are not scheduled while ***any*** official AMP scientific sessions or sponsored social events are scheduled.

Individuals who wish to schedule an ancillary event (non-AMP event held during the AMP Annual Meeting dates of November 17-20), or a satellite event (non-AMP event to be held during dates immediately before or immediately after the official AMP dates) should contact Maricel Herrera in the AMP Administrative office (*mherrera@amp.org*) by May 10.

Rules which apply to Ancillary and Satellite events:

1. All ancillary and satellite events must be cleared through the AMP Administrative Office. The title, time and location of all approved events will be included in the Meeting Program and Website. Space may be leased from AMP at each of the contracted hotels on a first-come, first-served basis. There will be an administrative fee for any space released by AMP. Should the purpose for any function be misrepresented to the AMP administrative office, the group sponsoring such function will be penalized by AMP, including being suspended from participation in future AMP events.

2. Ancillary events must not overlap with AMP scientific sessions as outlined in the preliminary meeting schedule. (AMP is not responsible for subsequent schedule changes made by the Program Committee and will inform organizers if their requested time must be changed).

3. AMP does not assist with the planning, funding, or management of ancillary or satellite events. Organizers will be responsible for all arrangements and costs associated with their events which may include: room rental, audio-visual equipment, food and beverages. Ancillary and satellite events scheduled by September 15, 2010 will be listed in printed program information and on the AMP Annual Meeting Web site.

4. AMP will not release or assign any of its meeting space to commercial companies that are not already contracted to exhibit at the Annual Meeting.

5. Ancillary and Satellite organizers are not permitted to display signs or brochures in any of the public areas of the Convention Center/Hotel. Signs can be displayed outside the meeting room on the day of the event.

6. Organizers will be informed of their confirmed room assignment in September.

Contact Information

Exhibit Management
Maricel M. Herrera, CMP CEM
Director of Meetings & Exhibits
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7400 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org

Travel Information

Hotel Accommodations

Accommodations are available for exhibitors and attendees at three contracted hotels. The Fairmont Hotel located across the street from the convention center and the Hilton San Jose and San Jose Marriott which are connected to the center. For rates, location and reservation information please visit www.amp.org/meetings/2010/hotel.cfm. (Reservations will be accepted beginning Wednesday, May 5th)

Note regarding exhibitor hotel reservations:
As a result of the large number of last minute cancellations and no-shows, **a full, non-refundable prepayment is required on all reservations for non-registered meeting attendees.** Hotel property will charge credit card account 30 days before arrival.

Air Travel Discounts

The city of San Jose is serviced by three airports. The Norman Y. Mineta San Jose International Airport (SJC) is just three miles from downtown San Jose. Additionally, the Oakland International airport and the San Francisco International airport are 35 miles north of the city.

American Airlines is offering a discount of up to 10% on airfare, plus other travel discount options to and from the AMP Annual Meeting. The percentage discount can be booked online at www.aa.com for AA/AE flights or at 1-800-221-2255 through the AA Group Sales Reservation Desk. Please mention the star file **AN#A72N9AD** for our group (AMP Annual Meeting) to receive your special fare.

JetBlue Airways is offering a 5% discount off the lowest available fare by simply booking online at the JetBlue website! Go to www.jetblue.com/promo and enter our event code **AFMP10** to take advantage of this discount.

Ground Transportation & Car Rentals

Avis Rent a Car will be providing rental discounts to our group for ground transportation. To make rental car reservations, call the Avis Rent A Car Convention Desk directly at 1-800-331-1600. The desk is available to assist you twenty four hours a day, but you must reference the group file **AWD#D086607** to obtain the best possible car rental rates available. The Convention Center has a daily fee of $18.00 for Self Parking.

For full Ground Transportation information from the three local airports please see:

Mineta San Jose Airport - www.sjc.org/travelers.php

San Francisco International Airport - http://www.flysfo.com/web/page/tofrom/transp-serv/

Oakland International Airport - http://www.flyoakland.com/ground_transportation.shtml

ILLUM-0388

Workshop & Sponsorship Opportunities

Sponsoring activities at the Annual Meeting is an ideal way to get your company noticed by attendees. All functions may be either fully or partially sponsored; companies providing sponsorship will be individually recognized in the Meeting Program and signage at the event.

We offer an exciting opportunity for those who provide significant support to be recognized as "Corporate Partners." *Complete details of the AMP Corporate Partners Program is located at the end of this Prospectus.*

Sponsorship Opportunities

Activity Sponsorships will be individually recognized in the Meeting Program. Activities available for sponsorship include: Plenary Sessions, Workshops, Continental Breakfasts, Morning Coffee Breaks, Lunch, Afternoon Coffee Breaks, Trainee Registration Support, and support for other AMP activities. Sponsorship of educational activities requires an unrestricted educational grant. If you are interested in sponsoring an activity, please fax your completed **Sponsorship Opportunities Form** to Maricel Herrera by **September 30**.

Corporate Workshops Day

A full day of corporate sponsored workshops will take place on Wednesday, November 17. Meeting rooms have been reserved for workshop presenters at the Fairmont San Jose Hotel. The fee for each workshop is $3,500 per hour and includes basic audio visual setup. Catering arrangements should be made directly with the hotel and will be billed directly to you. Workshops will run concurrently during the morning and afternoon sessions.

Deadline for submitting the completed **Corporate Workshop Application Form** (page 8) and description is **June 30** so that we can work with you to arrange a schedule that most benefits presenters and attendees (minimizing topic overlaps or other conflicts). This will also allow us to provide early notification to our membership and meeting attendees about your workshop for early registration and travel planning purposes. We can also put you in touch with our contact at the Fairmont San Jose Hotel for other necessary arrangements.

A schedule and full description of Corporate Workshops will be posted on the AMP website at www.amp.org, and in the Fall 2010 *AMP Newsletter*.

Corporate Partners

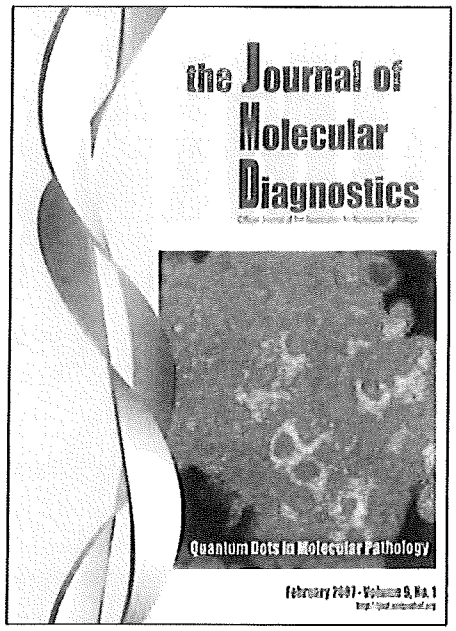
The AMP Corporate Partners Program is designed to provide our corporate supporters with additional high-visibility opportunities to highlight their company at the annual meeting, at other AMP educational events, and on the AMP website. See complete information in the Corporate Partnerships section at the end of this Prospectus (see pages 10-12).

2009 Annual Meeting Demographics

Total Scientific Attendees - 1010
Exhibitors - 116

2009 Exhibitors

AAB Proficiency Testing Service
Abbott Molecular, Inc.
Acrometrix
Affymetrix, Inc
Althea Technologies, Inc
American Society for Clinical Pathology
Analytical Genetics Technology Centre
Applied Imaging/Genetix
Argene, Inc
ARTEL
ARUP Laboratories
Asuragen, Inc
Attostar LLC
Aurora Biomed Inc
AutoGen, Inc.
Autogenomics, Inc
Avero Diagnostics
BioArray Solutions
BD Diagnostics
Beckman Coulter, Inc.
BioHelix Corporation
bioMerieux, Inc.
Bioplastics Cyclertest, Inc
Biosearch Technologies, Inc
Biotage
BioTrove
BioView, Inc
Cepheid Inc
Cerner Corporation
City of Hope National Medical Center
Cleveland Clinic Reference Laboratory
Clinical and Laboratory Standards Institute
College of American Pathologists
Combimatrix Molecular Diagnostics (CMDX)
Copan Diagnostics, Inc
Corbett Robotics, Inc
Cytocell,Ltd./Rainbow Scientific, Inc
DiagnoCure, Inc
DNA Genotek, Inc.
DxS Limited
Elsevier/Saunders/Mosby
Emory Genetics Laboratory
EpigenDx, Inc
Eppendorf North America
Eragen Biosciences
Eurogentec North America
Fisher HealthCare
Fluidigm Corporation
Focus Diagnostics
GenomeWeb LLC
Genomic Health, Inc
GenPath
Gen-Probe Inc.
Genvault Corporation
HandyLab
Idaho Technology, Inc
Ikonisys, Inc
Illumina, Inc
Innogenetics, Inc
InVivoScribe Technologies, LLC
IPSOGEN
Laboratory for Personalized Molecular Medicine
Lippincott Williams & Wilkins
Luminex Corporation
Maine Molecular Quality Controls, Inc
MetaSystems Group, Inc
Miltenyi Biotec, Inc
MP Biomedicals, LLC
Nanogen, Inc.
Nanosphere, Inc.
NorDiag
Olympus America Inc.
OpGen
Osmetech Molecular Diagnostics
ParagonDx, LLC
Pathwork Diagnostics, Inc.
PreAnalytiX
PrimeraDx
Prodesse
Promega Corporation
QIAGEN, INC
Roche Applied Science
Roche Diagnostics Corporation
Sci Gene
Sequenom, Inc
SeraCare Life Sciences, Inc
Siemens Healthcare Diagnostics
Signature Genomic Laboratories, LLC
Skyline Diagnostics LLC
SoftGenetics, LLC
Spartan Bioscience, Inc
StemCell Technologies, Inc
Sysmex
Tepnel Lifecodes Corporation
Tetracore, Inc
Thermo Scientific/Nanodrop
Third Wave Technologies
TIB Molbiol
Transgenomic, Inc
TriCore Reference Laboratories
Trim Gen Corporation
ViraCor
Xceed Molecular
ZeptoMetrix Corporation



The Journal of Molecular Diagnostics

Editor-in-Chief: Timothy J. O'Leary, MD, PhD
Veterans Health Administration, Washington, DC

The Journal of Molecular Diagnostics (JMD), the official publication of the Association for Molecular Pathology, co-published with the American Society for Investigative Pathology, publishes high-quality original papers on scientific advances in the translation and validation of molecular discoveries in medicine into the clinical diagnostic setting, and the description and application of technological advances in the field of molecular diagnostic medicine.

Annual Meeting/Abstracts Issue: November 2010
Insertion orders and materials due:
September 21, 2010
Circulation: 3,500 Paid Subscribers

One complementary copy of the November 2010 issue of *The Journal of Molecular Diagnostics* will be distributed to each meeting attendee and Exhibit Booth.

Rate Card online at:
www.amp.org/Advertising/RateCard.pdf

To advertise in *JMD*, contact:
Robyn Engelson
FASEB AdNet
9650 Rockville Pike, Bethesda, MD 20814
Tel: 800-43-FASEB ext 7103
Email: *rengelson@faseb.org*

Meeting Program

Special Offer to *JMD* Advertisers: Purchase your full-page ad in the November 2010 issue of *JMD* and receive 50% rebate off the pricing below for ads placed in the Meeting Program.

Display Advertising

Back Cover of Meeting Program - Color, 7" x 10"	$2,875
Inside Front or Back Cover - color, 7" x 10"	$2,015
Inside Front or Back Cover - b/w, 7" x 10"	$1,350
Full page b/w only, 7" x 10"	$1,100
Page Horizontal - b/w only, 7" x 4.75"	$ 850
1/2 Page Vertical - b/w only, 3.25" x 10"	$ 850
1/4 Page Vertical - b/w only, 3.25" x 4.75"	$ 500

Specifications
Color Ad: PDF (embed fonts), jpg, or tif
Black and White Ads: 300 dpi tif, pcx, or PDF (embed fonts)

Program insertion orders and materials due:
September 21, 2010

Send materials to:
Laurie Menser
Director of Marketing,
The American Society for Investigative Pathology
9650 Rockville Pike
Bethesda, MD 20814-3993
Tel: 301-634-7943; Fax: 301-634-7961
Email: *lmenser@asip.org*

Promotional Opportunities Included with your AMP Exhibitor Contract:

Program Listing
A floor plan of the Exhibit Hall and a list of all confirmed exhibiting companies will be included in the Meeting Program. The Meeting program will be distributed to all meeting attendees. Additionally, the information will be posted online at www.amp.org.

On-Site Program
Exhibitors must provide a 60-word product description to be included in the Exhibit Guide. This guide is distributed to all meeting attendees. This opportunity to advertise your products and services is complimentary and is available only to AMP's exhibitors and supporters. Product description must be submitted by **June 30.**

Registration List
AMP will provide a complete registration list to exhibitors within 30 days of the annual meeting or by December 22, 2010. The registration list will be a read-only PDF file and does not include email addresses. The information is the sole property of AMP and cannot be reproduced in any form without express written permission.

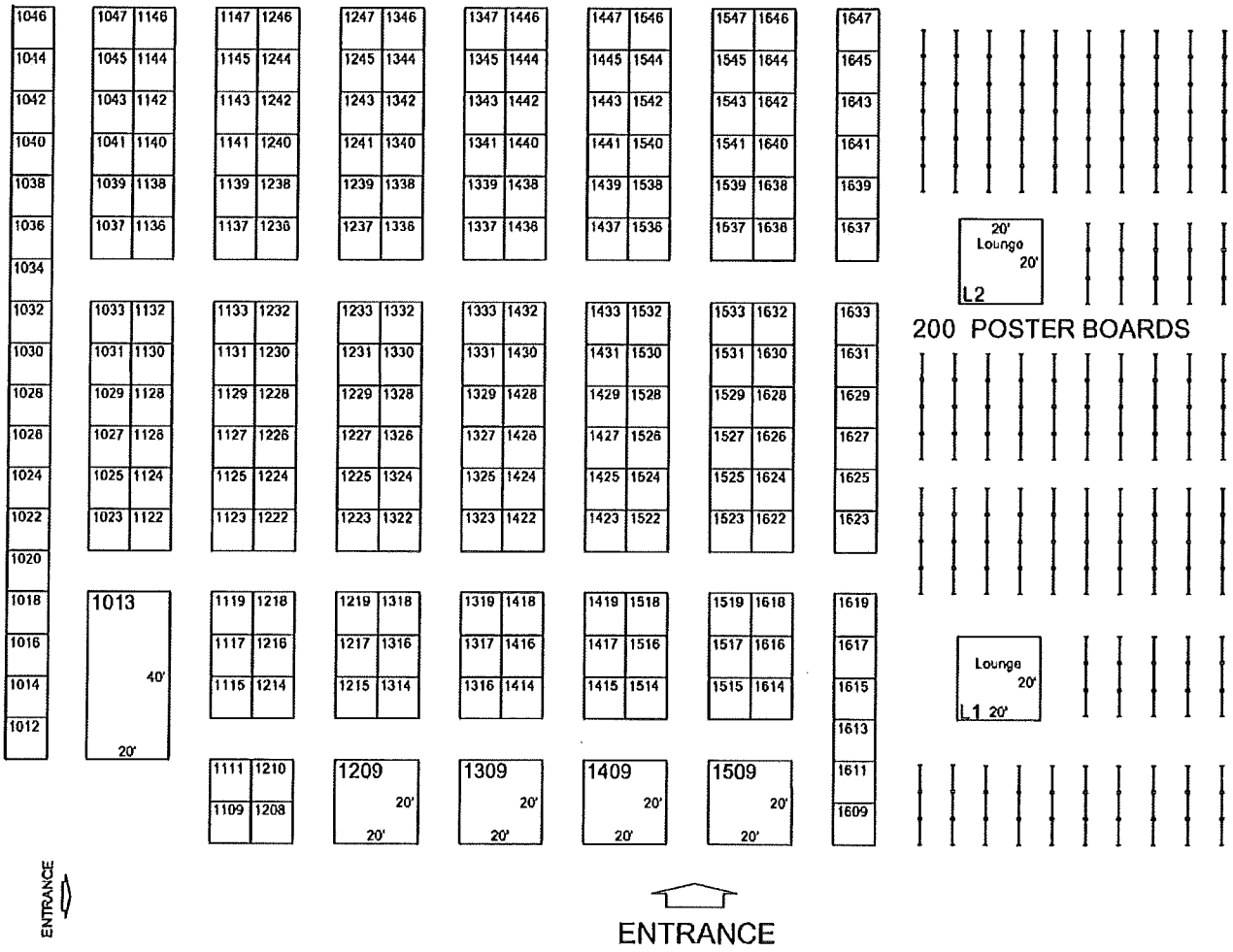
AMP Membership List
Exhibitors are entitled to a 50% discount for a one-time use of the AMP Membership Mailing List (approximately 1,600 names & addresses) for use in advertising their products and services. (Email addresses are not provided.) Requests must be made via email to Maricel Herrera at *mherrera@amp.org* no later than **September 30**.

ILLUM-0390

Exhibit Hall & Booth Floor Plan

Exhibit Schedule – San Jose McEnery Convention Center, Exhibition Hall 2/3

Thursday, November 18 1:00 pm – 5:00 pm
Friday, November 19 9:00 am – 5:00 pm
Saturday, November 20 9:00 am – 5:00 pm



ILLUM-0391

2010 Association for Molecular Pathology 16th Annual Meeting and Exhibits
November 17-20, 2010, San Jose McEnery Convention Center

Exhibitor Application and Contract

Exhibit Days: November 18-20, 2010
Deadline: June 30, 2010

Company Name: *(Please list company name as you would like it to appear in the AMP 2010 program, exhibitor badges and any required signage)*			
Contact Individual: *(This person will receive all AMP 2010 exhibitor correspondence)*			
Address:			Telephone:
City:	State/Province:		Fax:
Zip/Postal Code	Country:		Email:
Booth Choices: 1._____ 2._____ 3._____ 4._____	Total Square Footage:	List any exhibitor(s) you wish to be near: List any exhibitor(s) you do not wish to be near:	

Signage

❑ NO, We do not require an identification sign ❑ YES, We do require an identification sign

Product Description

A 60-word description of products or services must be submitted with your application for inclusion in the Program. Descriptions exceeding 60 words may be edited by the AMP administrative office. Please submit online at www.amp.org/2010/exhibitdesc.asp.
❑ 60-word Product Description submitted at www.amp.org by **June 30, 2010**.

Payment of Fees

Full payment must accompany the Exhibitor Application and Contract Form or it will not be processed. Payment may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:

❑ MC ❑ VISA ❑AMEX Credit Card Account #: Expiration Date: *Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.*	❑ Inline 10' x 10', **$4,000** ❑ Corner 10' x 10', **$4,750** ❑ Island 20' x 20', **$19,000** ❑ Non-Profit Inline 10' x 10', **$2,000** ❑ Other : Size Requested Size : _____ Cost : _____
Name on Card:	Signature: Date:

In accordance with the terms, conditions and regulations governing exhibits of the AMP 2010 Annual Meeting at the San Jose McEnery Convention Center, November 17-20, 2010 the undersigned hereby makes application for exhibit space(s) that, when accepted by AMP Exhibit Management, becomes a contract. All rules and regulations as outlined in the AMP Annual Meeting Exhibitor Prospectus, as well as any amendments published by AMP, are part of this contract. Failure to abide by such rules and regulations results in forfeiture of all monies paid AMP Exhibit Management under terms of this agreement.

Signature:	Date:

Deadline for Exhibitor Application and Contracts, description of products or services, and payment: June 30 2010
Space will be sold on a first-come, first-served basis. Slots will be verified upon receipt of completed application including full payment and description of products or services. IMPORTANT: No booths will be held or assigned with out required full pre-payment & company description. Submit your 60-word description of products and services at www.amp.org/2010/exhibitdesc.asp

Please submit completed Exhibitor Application and Contract with payment to:

Maricel M. Herrera, CMP, CEM
Director of Meetings & Exhibits
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7400 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org

Exhibit Space Cancellation Policy: All exhibit space cancellations must be received in writing by AMP Exhibit Management (Maricel M. Herrera, CMP).

- Cancellations received on or before **August 18, 2010** qualify for a 90% refund of all monies paid for booth space rental.
- Any company cancelling its booth space between **August 19, 2010** and **September 18, 2010**, will forfeit 50% of the total cost of exhibit space rental.
- Any company cancelling after **September 18, 2010** will forfeit full exhibit space payment

2010 Association for Molecular Pathology 16th Annual Meeting and Exhibits
November 17-20, 2010, San Jose McEnery Convention Center

Corporate Workshop Application Form

Corporate Workshops Day: Wednesday, November 17, 2010
Deadline: June 30, 2010

A full day of corporate sponsored workshops will take place on Wednesday, November 17, 2010. Meeting rooms have been reserved for workshop presenters at the San Jose Fairmont Hotel in San Jose, CA. The fee for each workshop is $3,500 per hour. This fee includes basic audiovisual setup for the room. Catering arrangements should be made directly with the hotel and will be billed directly to you. Up to four workshops will run concurrently during the morning and afternoon sessions. **Please fax your completed Corporate Workshop Application Form to Maricel Herrera by June 30 so that we can work with you to arrange a schedule that most benefits presenters and attendees (minimizing topic overlaps or other conflicts).** This will allow us to provide early notification to our membership and meeting attendees about your workshop for early registration and travel planning purposes. We can also put you in touch with our contact at the San Jose Fairmont Hotel for other necessary arrangements.

Company:	
Contact Individual(s):	
Address:	Telephone: Fax: Email:
Title of Workshop you are interested in presenting:	
Maximum number of attendees:	Targeted number of attendees:
How long will the workshop last? (NOTE: $3,500 per hour -includes a basic audio visual setup (Screen, LCD Projector, Podium Mike) ❑ 1 Hour ❑ 2 Hours ❑ 3 Hours	
Format you prefer (please check one below): ❑ Classroom ❑ Theater ❑ Demonstration w/6 ft tables ❑ Include _____ Head table(s)	Requested Time Slot:
Special Requirements (electricity, sink, etc.) and Other Information (these requirements will be forwarded to the contact person at the convention services department so they can coordinate with you): **IMPORTANT: Final arrangements must be confirmed directly with the hotel representative.**	
Full payment must accompany this application form for consideration. Payments for Corporate Workshops may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:	
❑ MC ❑ VISA ❑ AMEX	Credit Card Account #: Expiration Date: *Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.*
	❑ 1 Hour Workshop, **$3,500** ❑ 2 Hour Workshop, **$7,000** ❑ 3 Hour Workshop, **$10,500**
Name on Card:	Signature: Date:

A one paragraph description of your workshop (~100 words) must be submitted online at www.amp.org/2010/wkdesc.asp **by June 30, 2010.** This description will be used for distribution to AMP members, posting on the AMP website's meeting section, in the AMP Newsletter, and publication in the meeting program.

Space will be sold on a first-come, first-served basis. Slots will be verified upon receipt of completed application including full payment and workshop description. Preliminary schedule/assigned time slot will be provided approximately 30 days after submission deadline.

Please submit the completed Corporate Workshop Application Form to:
Maricel M. Herrera, CMP, CEM
Director of Meetings & Exhibits
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7400 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org

Corporate Workshop Cancellation Policy: All corporate workshop cancellations must be received in writing by AMP Meeting Management (Maricel M. Herrera, CMP).

- Cancellations received on or before **August 18, 2010** qualify for a 90% refund of all monies paid for workshop time slot.
- Any company canceling its workshop time slot between **August 19, 2010** and **September 18, 2010**, will forfeit 50% of the total cost of their corporate workshop payment.
- Any company canceling after **September 18, 2010** will forfeit full corporate workshop payment.

ILLUM-0393

2010 Association for Molecular Pathology 16th Annual Meeting and Exhibits
November 17-20, 2010, San Jose McEneary Convention Center

Sponsorship Opportunities Form

Deadline: September 30, 2010

Activity sponsorship will be individually recognized in the meeting program, on the AMP website, and on signage. NOTE: All sponsorships for the following activities are credited toward your Corporate Partnership.
Some activities may be fully or partially sponsored. Activities available for sponsorship include:

Event		Full Sponsorship	Partial Sponsorship
Dining Events Sponsorship	Continental Breakfast – Thurs 11/18, Fri 11/19, Sat 11/20	☐ $ 5,000 each COMMITTED	☐ $ 2,500
	Morning Coffee Break – Thursday, 11/18	☐ $ 2,000	☐ $ 1,000
	Morning Coffee Break – Friday, 11/19	☐ $ 2,000	☐ $ 1,000
	Morning Coffee Break – Saturday, 11/20	☐ $ 2,000	☐ $ 1,000
	Lunch – Thursday, 11/18	☐ $12,000	☐ $ 6,000
	Lunch – Friday, 11/19	☐ $12,000	☐ $ 6,000
	Lunch – Saturday, 11/20	☐ $12,000	☐ $ 6,000
	Afternoon Coffee Break – Thurs 11/18, Fri 11/19, Sat 11/20	☐ $ 2,000 each COMMITTED	☐ $ 1,000
Event/Activity		**Full Sponsorship**	**Partial Sponsorship**
Scientific Session Sponsorship *The Annual Meeting Preliminary Program is available online at www.amp.org* *Note: You may choose to sponsor a specific Workshop or Special Topics Plenary. Sponsorship of educational activities requires an unrestricted educational grant.* *Contact Maricel Herrera at mherrera@amp.org*	Plenary Session – Genetics	☐ $ 5,000 COMMITTED	☐ $ 2,500
	Plenary Session – Hematopathology	☐ $ 5,000 COMMITTED	☐ $ 2,500
	Plenary Session – Infectious Diseases	☐ $ 5,000 COMMITTED	☐ $ 2,500
	Plenary Session – Solid Tumors	☐ $ 5,000 COMMITTED	☐ $ 2,500
	Plenary Session – Special Topics	☐ $ 5,000	☐ $ 2,500
	Workshop – Genetics	☐ $ 2,500 COMMITTED	☐ $ 1,500
	Workshop – Hematopathology	☐ $ 2,500 COMMITTED	☐ $ 1,500
	Workshop – Infectious Diseases	☐ $ 2,500 COMMITTED	☐ $ 1,500
	Workshop – Solid Tumors	☐ $ 2,500 COMMITTED	☐ $ 1,500
	Workshop – Technical Topics	☐ $ 2,500 COMMITTED	☐ $ 1,500
Description		**Sponsorship**	
Education Grant	Unrestricted Education Grant to Sponsor AMP Activities	☐ $_____ (no minimum)	
Pathology Outreach Course	☐ $10,000 Supporter - COMMITTED		
Cyber Café, Hotel Keycards, Lanyards, Pens Pads and Social Event	Cyber Café	☐ $15,000	
	Bottled Water Sponsorship	☐ $15,000 COMMITTED	
	Lanyard Sponsorship	☐ $10,000 COMMITTED	
	Hotel Room Keycard Sponsorship	☐ $10,000 COMMITTED	
	Notepads	☐ $10,000	
	Pens	☐ $10,000	
	Social Event	☐ $1,500 for one table	☐ $5,000 for five tables

Company:

Contact Individual:

Address:

Telephone:

Fax:

Email:

Payment may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:

☐ MC ☐ VISA ☐ AMEX Credit Card Account #: Expiration Date:

Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.

Name on Card:

Signature: Date:

Thank you for sponsoring an activity at the AMP Annual Meeting. Please send the completed Sponsorship Opportunities Form and payment by September 30, 2010 to:

Maricel M. Herrera, CMP, CEM
Director of Meetings & Exhibits
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7400 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org

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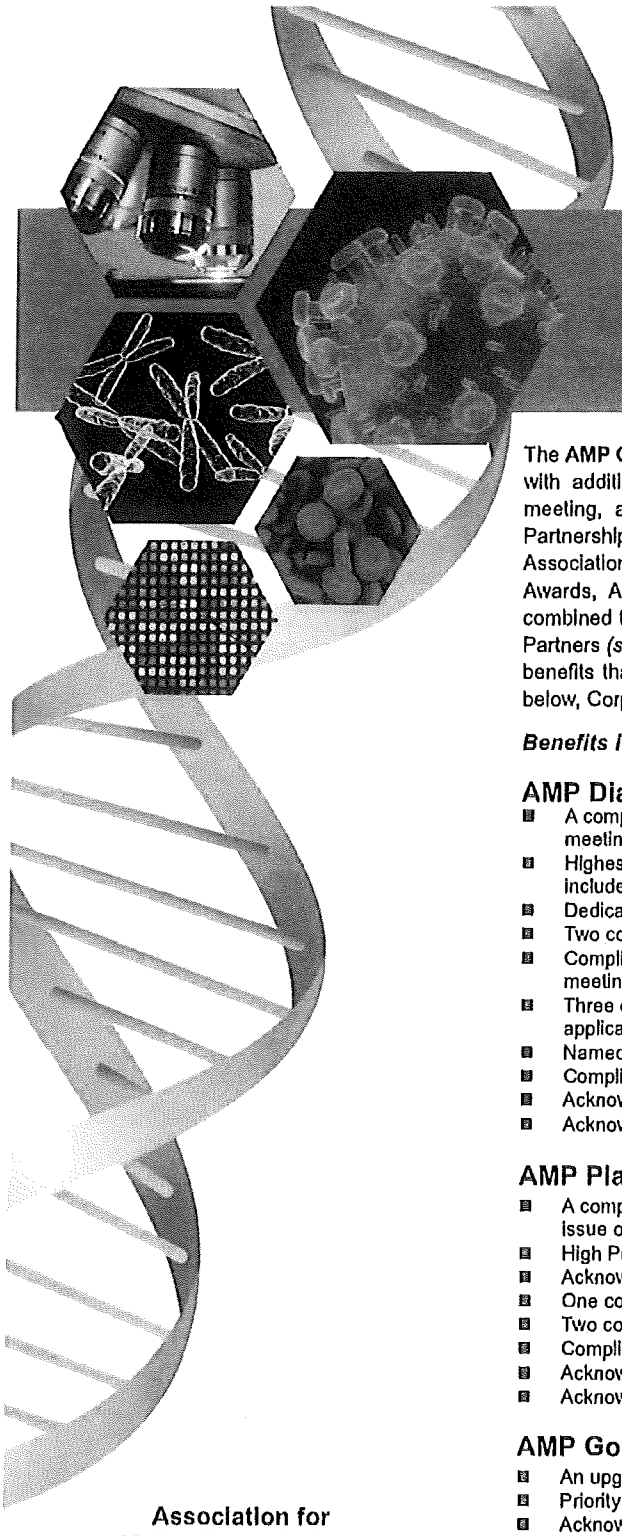

Highlighting Your Products and Services to Molecular Laboratory Professionals

ASSOCIATION FOR MOLECULAR PATHOLOGY

2010 AMP Corporate Partners Program

The **AMP Corporate Partners Program** is designed to provide our corporate supporters with additional high-visibility opportunities to highlight their company at the annual meeting, at other AMP educational events, and on the AMP website. Corporate Partnerships are renewable each year and support the educational initiatives of the Association. Contributions received for support of activities at the Annual Meeting, Awards, AMP Test Directory, and Educational or General Unrestricted Grants are combined to qualify those with significant interest and investment in AMP as Corporate Partners *(see the following page for details)*. AMP Corporate Partners receive significant benefits that elevate their visibility to AMP members. In addition to the benefits listed below, Corporate Partners are given first notification of selected support opportunities.

Benefits include:

AMP Diamond Level Corporate Partner ($75,000)

- A complimentary four-color, full page, priority placement ad in the annual meeting issue of *JMD* (November)
- Highest Priority booth space location for the following year's Annual Meeting and includes one division or subsidiary that exhibits in a separate booth
- Dedicated acknowledgement signage at the Annual Meeting
- Two complimentary attendee registrations to the Annual Meeting
- Complimentary meeting room for internal company meetings during the annual meeting
- Three complimentary tickets to the annual meeting banquet/social event (if applicable)
- Named supporter of an unreserved activity at no extra fee
- Complimentary use of the member mail list twice during the year
- Acknowledgement in the annual meeting review issue of the AMP Newsletter
- Acknowledgement on the AMP website, with logo, and link to company website

AMP Platinum Level Corporate Partner ($50,000)

- A complimentary four-color, full page, priority placement ad in any non-meeting issue of *JMD*
- High Priority booth space location for the following year's Annual Meeting
- Acknowledgement on signage at the Annual Meeting
- One complimentary attendee registration to the Annual Meeting
- Two complimentary tickets to the annual meeting banquet/social event (if applicable)
- Complimentary one-time use of the member mail list
- Acknowledgement in the annual meeting review issue of the AMP Newsletter
- Acknowledgement on the AMP website, with logo, and link to company website

AMP Gold Level Corporate Partner ($30,000)

- An upgrade ad placement in any non-meeting issue of *JMD*
- Priority booth space location for the following year's Annual Meeting
- Acknowledgement in the annual meeting review issue of the AMP Newsletter
- Acknowledgement on the AMP website, with logo, and link to company website

AMP Silver Level Corporate Partner ($15,000)

- Preferred booth space location for the following year's Annual Meeting
- Acknowledgement in the annual meeting review issue of the AMP Newsletter
- Acknowledgement on the AMP website, with logo, and link to company website

Association for Molecular Pathology
Mary Steele Williams, MNA, MT(ASCP)SM
COO, Director of Scientific Programs
9650 Rockville Pike
Bethesda, MD 20814-3993 (USA)
Tel: 301-634-7921
Fax: 301-634-7990
Email: *mwilliams@amp.org*
www.amp.org

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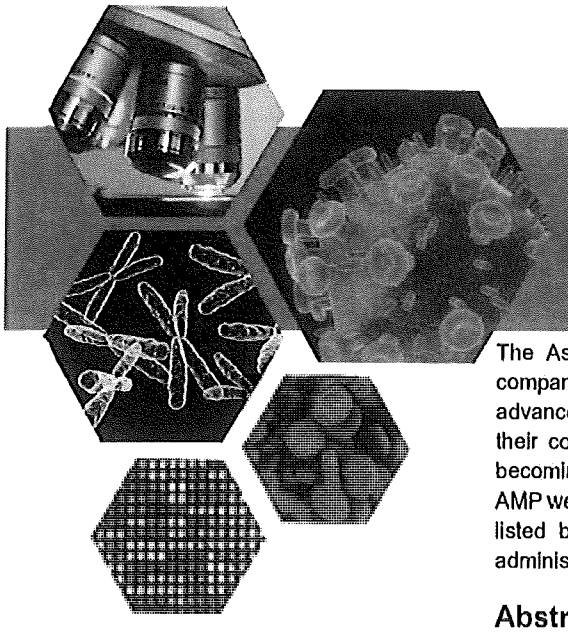

Highlighting Your Products and Services to Molecular Laboratory Professionals

ASSOCIATION FOR MOLECULAR PATHOLOGY

Corporate Support Opportunities

AMP's primary mission is to advance the practice of clinical molecular laboratory medicine. We welcome all suggestions for additional programs that will help AMP members better serve the health of people around the world.

The Association for Molecular Pathology appreciates the financial support that companies provide for AMP programs. There are numerous opportunities for you to advance the field of molecular diagnostics through AMP. Companies may express their commitment to AMP members and the Association's educational mission by becoming Corporate Partners. Whatever the amount of your resources, however, AMP welcomes your support. Educational activities that receive corporate support are listed below along with the contact information of the AMP staff member who administers the activity.

Abstract Submission Service

AMP contracts with an online abstract submission service. Your support will help defray the cost of this service. Sponsorship is in three-year cycles.

Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

Annual Meeting

The AMP Annual Meeting is the Association's most important educational event. Numerous sponsorship opportunities exist to support the scientific sessions, receptions, meeting bags, program book, lead retrieval service, lanyards, internet café, lunches, and breaks.

Contact: Maricel Herrera at *mherrera@amp.org* or (301) 634-7400

Awards

AMP honors individuals at various stages of their careers through several prestigious awards: The AMP Award for Excellence in Molecular Diagnostics, AMP Leadership Award, Young Investigator Award, and Technologist Award. Sponsorship is in three-year cycles.

Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

Pathology Outreach

The AMP Training & Education Committee hosts educational initiatives for non-molecular laboratory professionals. These are exciting opportunities to facilitate the growth of molecular diagnostics in mainstream laboratory services. The **Pathology Outreach Course** is a full-day course scheduled one day prior to the AMP Annual Meeting.

Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

Webinars

Web-based presentations covering topics in molecular pathology. These are exciting opportunities to facilitate the growth of molecular diagnostics in mainstream laboratory services.

Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

Molecular Case Studies

Web-based presentations intended to develop differential diagnostic skills. This program offers a unique opportunity to reach out to molecular and non-molecular laboratory professionals.

Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

Association for Molecular Pathology
Mary Steele Williams, MNA, MT(ASCP)SM
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Fax: 301-634-7990
Email: *mwilliams@amp.org*
www.amp.org

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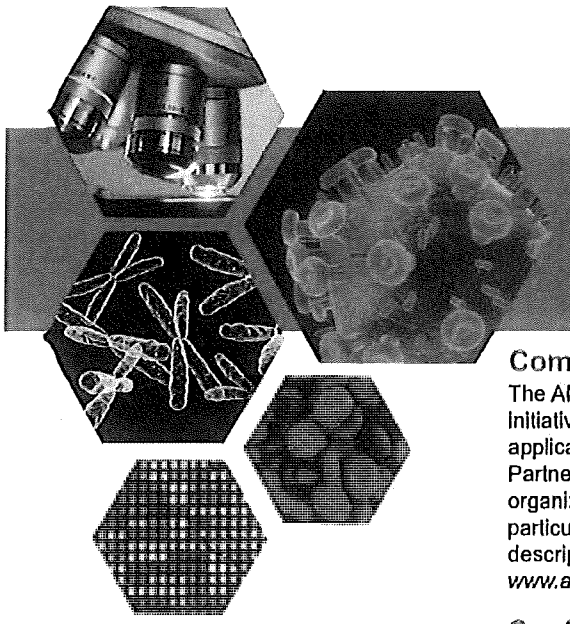

Highlighting Your Products and Services to Molecular Laboratory Professionals

ASSOCIATION FOR MOLECULAR PATHOLOGY

2010 AMP Corporate Partners Program

Commitment Form

The AMP Corporate Partners Program supports the Association and its educational initiatives through unrestricted educational grants. A completed and approved application with payment is required to begin implementation of benefits. Corporate Partner contracts are renewable each year. AMP is a 501(c)3 not-for-profit organization. Contributions may be designated to support specific activities such as particular activities at the annual meeting and/or other education events. Complete descriptions of support opportunities are available on the AMP website at *www.amp.org.*

Select Your 2010 Corporate Partnership Level:

- ❑ Diamond Partnership, $75,000/year
- ❑ Platinum Partnership, $50,000/year
- ❑ Gold Partnership, $30,000/year
- ❑ Silver Partnership, $15,000/year

Select Your Payment Plan:

- ❑ Full Payment Enclosed
- ❑ Four (4) Payment Plan:

Please include the first payment with this form.
#1 - 25% due 3/31/2010

AMP will invoice you one month prior to the payment-due date for the following 3 payments. Invoice will be sent to the contact name listed at right.
#2 - 25% - payment due 5/31/2010
#3 - 25% - payment due 7/31/2010
#4 - 25% - payment due 10/31/2010

Association for Molecular Pathology
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Bethesda, MD 20814-3993 (USA)
Tel: 301-634-7921
Fax: 301-634-7990
Email: *mwilliams@amp.org*
www.amp.org

Contact Information:

Organization/Company_____

Contact Name_____

Address_____

City_____ State/Province_____ Zip_____

Country_____

Tel_____

Fax_____

Email_____

Payment: *(please indicate desired partnership level and payment plan at left)*

❑ Check enclosed *(made payable to "Association for Molecular Pathology" or "AMP")*

Charge my credit card* Amount $_____

❑ VISA ❑ MasterCard ❑ American Express

Credit Card #_____ Exp Date_____

Card Holder Name *(please print)*_____

Signature_____ Date_____

Credit Card Billing Address_____

City_____ State_____ ZIP_____ Country_____

*IMPORTANT: If paying by credit card, the charge on your credit card statement will be from the American Society for Investigative Pathology (ASIP). AMP is a constituent society of the office of the American Society for Investigative Pathology and uses the ASIP credit card processing system.

ILLUM-0397

Support AMP Webinars and gain visibility for your company!

ASSOCIATION FOR MOLECULAR PATHOLOGY
2010 WEBINAR SERIES
Presented by the AMP Training & Education Committee

Become a Supporter of AMP Webinars

2010 Webinar Support:

☐ $2,500 **per webinar; exclusive supporter**
(Attention AMP Corporate Partners: Webinar support counts towards your Partnership commitment)

2010 Webinar Topics:
(select the topic(s) you would like to support)

- ☐ **Molecular Testing in AML with Normal Cytogenetics** - April 29, 2010
- ☐ **Interpretation of Copy Number Changes** - May 20, 2010
- ☐ **Screening for Hospital Acquired Infections** - June 2010 (Supported by Illumina)
- ☐ **Pandemic California H1N1 - Lessons Learned** - August 30, 2010 (Supported by Nanosphere)
- ☐ **Coding and Billing 101** - September 30, 2010
- ☐ **Genomic Arrays in Pediatric Oncology** - December 9, 2010 (Supported by iKaryos Diagnostics)

Supporter Benefits:

- ☐ **Exclusive Supporter** *(only one supporter per webinar)*
- ☐ **Acknowledgement on the AMP Website**
- ☐ **Acknowledgement on the webinar announcement and invitation**
- ☐ **Acknowledgement during the webinar**

For More Information, contact:

Association for Molecular Pathology
Mary Steele Williams, MNA, MT(ASCP)SM
COO, Director of Scientific Programs
9650 Rockville Pike
Bethesda, MD 20814-3993 (USA)
Tel: 301-634-7921
Fax: 301-634-7990
Email: *mwilliams@amp.org*
www.amp.org

Contact Information:

Organization/Company_____

Contact Name_____

Address_____

City_____

State/Province_____ Zip_____

Country_____

Tel_____

Fax_____

Email_____

Payment:

☐ We are an AMP Corporate Partner and would like to support this as part of our commitment *(AMP Corporate Partners do NOT need to provide payment information on this form)*

☐ Check enclosed *(made payable to "Association for Molecular Pathology")*

Charge my credit card* Amount $_____

☐ VISA ☐ MasterCard ☐ American Express

Credit Card #_____ Exp Date_____

Card Holder Name *(please print)*:

_____

Signature_____ Date_____

Credit Card Billing Address_____

City_____ State_____ ZIP_____

Country_____

***IMPORTANT:** If paying by credit card, the charge on your credit card statement will be from the American Society for Investigative Pathology (ASIP). AMP is a constituent society of the office of the American Society for Investigative Pathology and uses the ASIP credit card processing system.

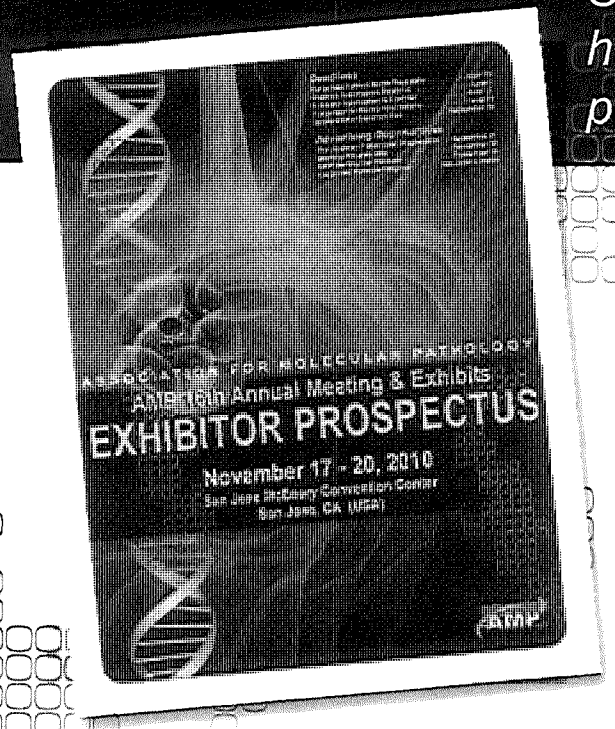
www.amp.org

Association for
Molecular Pathology
9650 Rockville Pike
Bethesda, MD 20814 (USA)

ASSOCIATION FOR MOLECULAR PATHOLOGY

AMP 16th Annual Meeting & Exhibits

Showcase your products and services to hundreds of molecular laboratory professionals!



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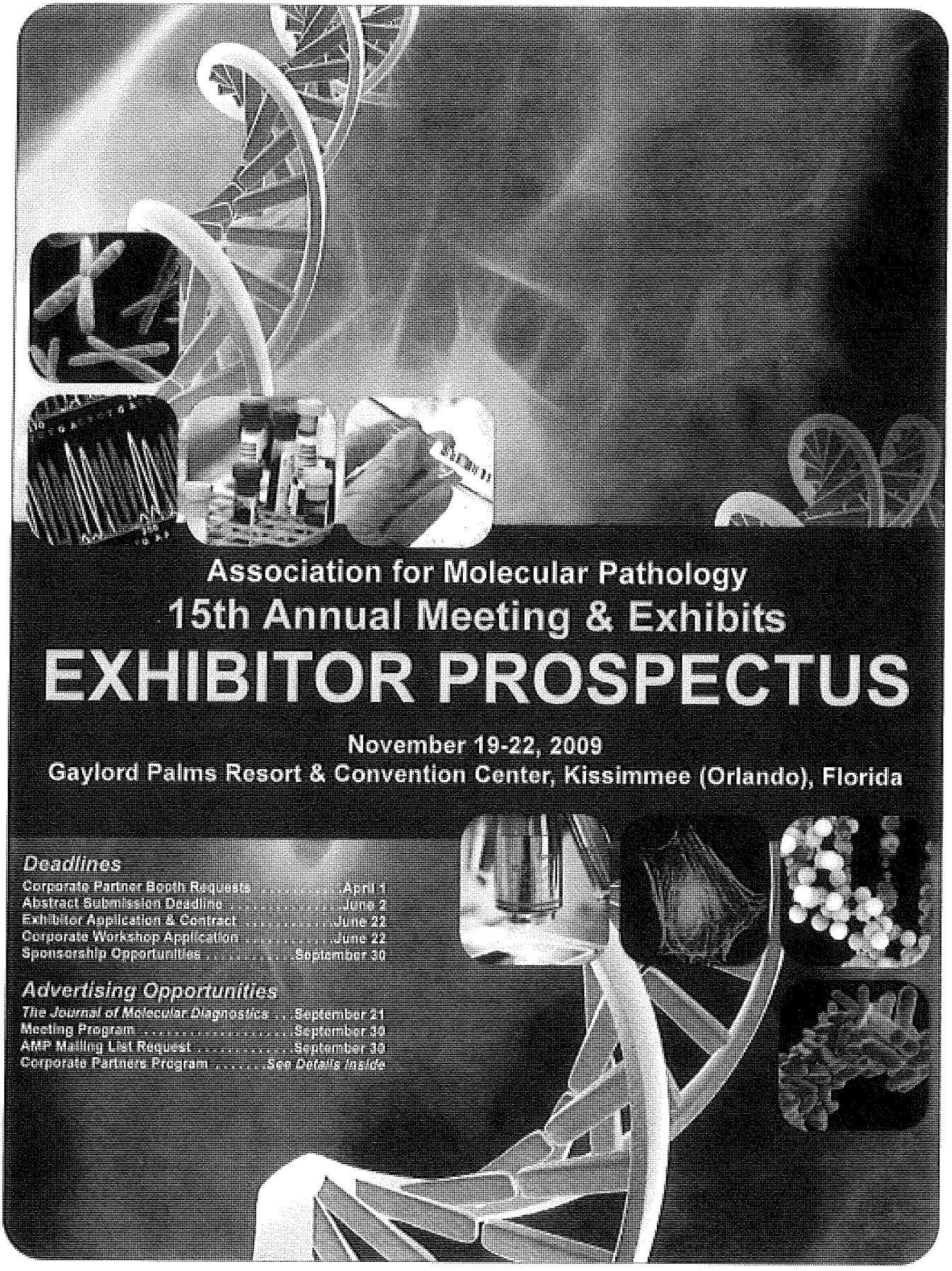


Association for Molecular Pathology

15th Annual Meeting & Exhibits

EXHIBITOR PROSPECTUS

November 19-22, 2009

Gaylord Palms Resort & Convention Center, Kissimmee (Orlando), Florida

Deadlines

Corporate Partner Booth Requests . . . . . April 1
Abstract Submission Deadline . . . . . June 2
Exhibitor Application & Contract . . . . . June 22
Corporate Workshop Application . . . . . June 22
Sponsorship Opportunities . . . . . September 30

Advertising Opportunities

The Journal of Molecular Diagnostics . . . September 21
Meeting Program . . . . . September 30
AMP Mailing List Request . . . . . September 30
Corporate Partners Program . . . . . *See Details Inside*

Association for Molecular Pathology

2009 Annual Meeting and Exhibits

November 19-22, 2009

Gaylord Palms Resort & Convention Center, Kissimmee (Orlando), Florida

Association for Molecular Pathology

The Association for Molecular Pathology (AMP) is committed to the advancement of clinical molecular diagnostic and prognostic medicine through education and training of practitioners, physicians, laboratory and industrial scientists, and health care professionals involved in patient care and management. AMP supports the development of new technologies in molecular biology to be used in laboratory medicine, including diagnosis, treatment, and prognosis of genetic disorders, cancer, infectious diseases, identity and histocompatibility.

About the Membership

The membership of AMP includes individuals interested in the educational, medical, scientific, economic, and regulatory aspects of molecular diagnostics, including pathologists, clinical laboratory scientists, clinicians and other health care personnel, government employees - especially those involved in regulation of the field - and professionals in the *in vitro* diagnostics industry.

AMP members are involved in every aspect of molecular diagnostics: performance, interpretation, and reporting of molecular diagnostic tests, assay development and validation, and medical education. Many members participate in research aimed at broadening the understanding of gene/protein structure and function, disease processes, and developing new technologies. AMP aims to inform and educate its members as well as other professionals interested in molecular pathology through its annual meeting, publications, website, listserv, and other venues.

Important Dates and Deadlines!

Corporate Partner Booth Requests	April 1
Abstract Submission Deadline	June 2
Exhibitor Application and Contract Form	June 22
Corporate Workshop Application Form	June 22
Exhibitor Service Kits Mailed	August 1
Sponsorship Opportunities Form	September 30
Advertising Opportunities:	
The Journal of Molecular Diagnostics	September 21
Meeting Program	September 30
AMP Mailing List Request	September 30
AMP Corporate Partners Program	*(See details on pages 10-12)*

The Association for Molecular Pathology will host its 15th Annual Meeting and Exhibits November 19-22, at the Gaylord Palms Resort & Convention Center in Kissimmee (Orlando), Florida.

This four-day event starts on November 19 with a day of corporate-sponsored workshops. A keynote lecture presented by **Kay Davies, PhD, University of Oxford**, the distinguished recipient of the **2009 AMP Award for Excellence in Molecular Diagnostics**, launches the scientific program on November 20.

Programming includes poster sessions and invited speakers for workshop and plenary sessions in each of the four major areas of clinical molecular diagnostics:

- **Hematopathology**
- **Infectious diseases**
- **Inherited genetic diseases**
- **Solid tumors**

The meeting also includes several technical workshops. Corporate exhibits, working lunch meetings, and casual social gatherings offer opportunities for networking and further exchange with molecular laboratory professionals.

Enclosed is your **2009 Exhibitor Prospectus**. Additional opportunities for Exhibitors include **Corporate Workshops, Dining Event Sponsorships** and **Scientific and Educational Activity Sponsorships**. Our **Corporate Partners** program offers our Exhibitors additional opportunities for high visibility to the molecular pathology community.

Mark Your Calendars...

Association for Molecular Pathology

AMP 2010 Annual Meeting & Exhibits

November 17-20, 2010
San Jose McEnery Convention Center
San Jose, CA

Exhibitor Information

Exhibitor Information & Application Forms on the Web

The Exhibitor Prospectus is available in its entirety at: www.amp.org/2009/exhibits.htm

- Preliminary Program
- Rules and Regulations for Exhibiting
- General Information
- Exhibitor Application and Contract
- Corporate Partners Program Information
- Sponsorship Opportunities
- Advertising Opportunities
- Mailing List Information
- Services and Official Contractor
- Union Regulations
- Corporate Workshop Information and Application
- Exhibitor Badges Form
- Current Exhibiting Companies and Booth Assignments

Exhibit Space Rental

All booths are 10' x 10' or 20' x 20'. The maximum height in the exhibit area is 24 feet. Rental includes 8 ft. high back drapes, 3 ft. high side dividers and a standard (7" X 44") identification sign with company name.

Booth Fees

10 X 10 Inline	$3,900
10 X 10 Corner	$4,500
20 X 20 Island	$18,000
10 x 10 Non-Profit Inline	$1,800

Please submit your completed **Exhibitor Application and Contract** (page 7) by **June 22, 2009**.

Exhibitor Registration Hours

Wednesday, November 18	2:00 pm - 6:00 pm
Thursday, November 19	8:00 am - 6:00 pm
Friday, November 20	8:00 am - 6:00 pm
Saturday, November 21	8:00 am - 6:00 pm

Exhibit Installation

Thursday, November 19	8:00 am - 4:00 pm

Exhibit Hours

Friday, November 20	9:00 am - 5:00 pm
Saturday, November 21	9:00 am - 5:00 pm

Dismantling of Exhibits

Saturday, November 21	5:00 pm - 9:00 pm

*No packing or dismantling of exhibits will be permitted until **5:00 pm, Saturday, November 21**. Early departure will result in the company or group being penalized including being banned from future tradeshows. When planning your dismantling and departure to follow the show, please allow no less than 3 hours for return of all empty shipping materials from storage. We strongly recommend that you advise your staff to make appropriate departure plans; i.e. plan to depart late Saturday evening or Sunday morning and to not count on being able to depart on Saturday afternoon.*

Exhibitor Rules & Regulations

- **Electronic Lead Retrieval**
  Attendees at the 2009 AMP Annual Meeting will carry electronic cards. Lead retrieval services will be provided by Trade Show Leads. Exhibitors will have the opportunity to rent lead retrieval services as part of their exhibit booth package.
- **Exhibitor Badges**
  Exhibitors badges must be worn at all times, and allow access to the Exhibit Hall and Plenary Sessions ***only.*** Exhibitors will receive 6 badges per 10' x 10' booth space, 12 badges per 10' x 20' booth space, and 24 badges per 20' X 20' booth space; additional Exhibitor badges will be available at a fee of $50.00/each. Additionally, each exhibiting company will be entitled to six Guest of Exhibitor badges; the Guest badges will be available for pick up at registration by the designated company representative. Exhibitor name badge requests must be submitted through the AMP Website at www.amp.org/2009/exhibits.htm
- **Promotional Items and Activities**
  Companies wishing to conduct contests or drawings should contact the AMP office at 301-634-7400 for guidelines and permission. Exhibiting companies are permitted to distribute promotional materials and other items at their Exhibit Booth location only. All items distributed must be useful to the professional activities of the meeting attendees, and be made available to all meeting attendees as long as supplies last.
  No soliciting of registrants is permitted in the aisles or in other exhibitor's booths, or in any other area of the hotel. No distribution of literature or other promotional items at hotel guestrooms, or in any other public or private area of the hotel is permitted.
- **Subletting Exhibit Space**
  Subletting any part of the exhibit space by an exhibitor is prohibited.
- **Sale of Goods**
  The sale of goods or services of any kind in the exhibit area in connection with the Annual Meeting is prohibited. Order taking is permitted.
- **Booth Relocation**
  AMP reserves the right to relocate space to areas other than that selected by the exhibitor. Relocations will be made only upon notification to the exhibitor by Exhibit Management. Management strives for, but cannot guarantee, that a company will not be located near a competitor.
- **Exhibit Space Cancellation**
  All exhibit space cancellations must be received in writing by AMP Exhibit Management.
- Cancellations received on or before **August 20, 2009**, qualify for a 90% refund of all monies paid for booth space rental.
- Any company cancelling its booth space between **August 21, 2009** and **September 20, 2009**, will forfeit 50% of the total cost of exhibit space rental.
- Any company cancelling after **September 20, 2009**, will forfeit full exhibit space payment.

Exhibitor Information

Ancillary and Satellite Events

AMP encourages ancillary meetings and events during the annual meeting provided that they are not scheduled while *any* official AMP scientific sessions or sponsored social events are scheduled.

Individuals who wish to schedule an ancillary event (non-AMP event held during the AMP Annual Meeting dates of November 19-22), or a satellite event (non-AMP event to be held during dates immediately before or immediately after the official AMP dates) should contact Maricel Herrera in the AMP Administrative office (*mherrera@amp.org*) by June 1.

Rules which apply to Ancillary and Satellite events:

1. All ancillary and satellite events must be cleared through the AMP Administrative Office. The title, time and location of all approved events will be included in the Meeting Program and Website. Space may be available at the Gaylord Palms on a first-come, first-served basis. There will be an administrative fee for any space released by AMP. Should the purpose for any function be misrepresented to the AMP administrative office, the group sponsoring such function will be penalized by AMP, including being suspended from participation in future AMP events.

2. Ancillary events must not overlap with AMP scientific sessions as outlined in the preliminary meeting schedule. (AMP is not responsible for subsequent schedule changes made by the Program Committee and will inform organizers if their requested time must be changed).

3. AMP does not assist with the planning, funding, or management of ancillary or satellite events. Organizers will be responsible for all arrangements and costs associated with their events which may include: room rental, audio-visual equipment, food and beverages. Ancillary and satellite events scheduled by September 15, 2009 will be listed in printed program information and on the AMP Annual Meeting Web site.

4. AMP will not release or assign any of its meeting space to commercial companies that are not already contracted to exhibit at the Annual Meeting.

5. Ancillary and Satellite organizers are not permitted to display signs or brochures in any of the public areas of the Convention Center/Hotel. Signs can be displayed outside the meeting room on the day of the event.

6. Organizers will be informed of their confirmed room assignment in August.

Contact Information

Exhibit Management
Maricel M. Herrera, CMP
Director of Meetings
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7400 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org

Travel Information

Hotel Accommodations

Accommodations are available for exhibitors and attendees at the Gaylord Palms Resort & Convention Center where sessions and exhibits will be held. The 65 acre property is located just 1.5 miles from the main gate of WALT DISNEY WORLD® Resort. AMP has negotiated a special rate of $199 standard single/double rooms. Room block opens May 1st for reservations. **Be sure to make reservations by October 18**; afterward the discounted room rate may not apply. To make reservations please follow the link at www.amp.org (Reservations will be accepted beginning Monday, May 4th)

Note regarding exhibitor hotel reservations:
As a result of the large number of last minute cancellations and no-shows, **a full, non-refundable prepayment is required on all reservations at time of booking for non-registered meeting attendees.**

For general information, visit the Gaylord Palms Resort & Convention Center hotel website at:
http://www.gaylordhotels.com/gaylord-palms/

Air Travel Discounts

AirCanada is offering a discount of 10% off the lowest available fare by simply booking online at the AirCanada website! Go to www.aircanada.com and enter our event code **X6JXWCX1** in the search panel to take advantage of this discount.

American Airlines is offering a discount of up to 10% on airfare, plus other travel discount options to and from the AMP Annual Meeting. The percentage discount can be booked online at www.aa.com for AA/AE flights or at 1-800-221-2255 through the AA Group Sales Reservation Desk. Please mention the star file **AN#A72N9AD** for our group (AMP Annual Meeting) to receive your special fare.

JetBlue Airways is offering a 5% discount off the lowest available fare by simply booking online at the JetBlue website! Go to www.jetblue.com/promo and enter our event code **AFMP09** to take advantage of this discount.

Ground Transportation & Car Rentals

Avis Rent a Car will be providing rental discounts to our group for ground transportation. To make rental car reservations, call the Avis Rent A Car Convention Desk directly at 1-800-331-1600. The desk is available to assist you twenty four hours a day, but you must reference the group file **AWD#D086607** to obtain the best possible car rental rates available. The Gaylord Palms has a daily fee of $12.00 for Self Parking and $20.00 for Valet service.

Mears Transportation has teamed up with Gaylord Palms Resort & Convention Center to provide a seamless guest experience, which begins the moment a guest arrives at the airport. Mears Transportation provided 24-hour shuttle service to and from the Orlando International Airport. Please call the 24-hour reservations line at (407) 423-5566.

Workshop & Sponsorship Opportunities

Sponsoring activities at the Annual Meeting is an ideal way to get your company noticed by attendees. All functions may be either fully or partially sponsored; companies providing sponsorship will be individually recognized in the Meeting Program and signage at the event.

We offer an exciting opportunity for those who provide significant support to be recognized as "Corporate Partners." *Complete details of the AMP Corporate Partners Program is located at the end of this Prospectus.*

Sponsorship Opportunities

Activity Sponsorships will be individually recognized in the Meeting Program. Activities available for sponsorship include: Plenary Sessions, Workshops, Continental Breakfasts, Morning Coffee Breaks, Lunch, Afternoon Coffee Breaks, Trainee Registration Support, and support for other AMP activities. Sponsorship of educational activities requires an unrestricted educational grant. If you are interested in sponsoring an activity, please fax your completed **Sponsorship Opportunities Form** to Maricel Herrera by **September 30**.

Corporate Workshops Day

A full day of corporate sponsored workshops will take place on Thursday, November 19. Meeting rooms have been reserved for workshop presenters at the Gaylord Palms Resort & Convention Center. The fee for each workshop is $3,500 per hour and includes basic audio visual setup. Catering arrangements should be made directly with the hotel and will be billed directly to you. Workshops will run concurrently during the morning and afternoon sessions.

Deadline for submitting the completed **Corporate Workshop Application Form** (page 8) and description is **June 22** so that we can work with you to arrange a schedule that most benefits presenters and attendees (minimizing topic overlaps or other conflicts). This will also allow us to provide early notification to our membership and meeting attendees about your workshop for early registration and travel planning purposes. We can also put you in touch with our contact at the Gaylord Palms Resort & Convention Center for other necessary arrangements.

A schedule and full description of Corporate Workshops will be posted on the AMP website at www.amp.org, and in the Fall 2009 *AMP Newsletter*.

Corporate Partners

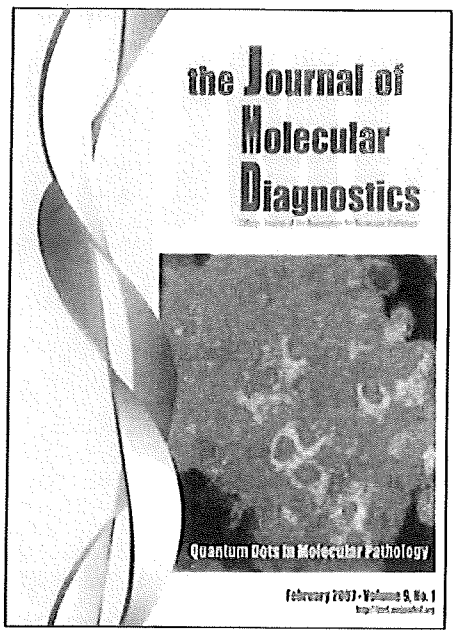
The AMP Corporate Partners Program is designed to provide our corporate supporters with additional high-visibility opportunities to highlight their company at the annual meeting, at other AMP educational events, and on the AMP website. See complete information in the Corporate Partnerships section at the end of this Prospectus (see pages 10-12).

2008 Annual Meeting Demographics

Total Scientific Attendees - 1010
Exhibitors - 116

2008 Exhibitors

AAB Proficiency Testing Service
Abbott Molecular, Inc.
Acrometrix
Affymetrix, Inc
Althea Technologies, Inc
American Society for Clinical Pathology
Analytical Genetics Technology Centre
Applied Imaging/Genetix
Argene, Inc
ARTEL
ARUP Laboratories
Asuragen, Inc
Attostar LLC
Aurora Biomed Inc
AutoGen, Inc.
Autogenomics, Inc
Avero Diagnostics
BioArray Solutions
BD Diagnostics
Beckman Coulter, Inc.
BioHelix Corporation
bioMerieux, Inc.
Bioplastics Cyclertest, Inc
Biosearch Technologies, Inc
Biotage
BioTrove
BioView, Inc
Cepheid Inc
Cerner Corporation
City of Hope National Medical Center
Cleveland Clinic Reference Laboratory
Clinical and Laboratory Standards Institute
College of American Pathologists
Combimatrix Molecular Diagnostics (CMDX)
Copan Diagnostics, Inc
Corbett Robotics, Inc
Cytocell,Ltd./Rainbow Scientific, Inc
DiagnoCure, Inc
DNA Genotek, Inc.
DxS Limited
Elsevier/Saunders/Mosby
Emory Genetics Laboratory
EpigenDx, Inc
Eppendorf North America
Eragen Biosciences
Eurogentec North America
Fisher HealthCare
Fluidigm Corporation
Focus Diagnostics
GenomeWeb LLC
Genomic Health, Inc
GenPath
Gen-Probe Inc.
Genvault Corporation
HandyLab
Idaho Technology, Inc
Ikonisys, Inc
Illumina, Inc
Innogenetics, Inc
InVivoScribe Technologies, LLC
IPSOGEN
Laboratory for Personalized Molecular Medicine
Lippincott Williams & Wilkins
Luminex Corporation
Maine Molecular Quality Controls, Inc
MetaSystems Group, Inc
Miltenyi Biotec, Inc
MP Biomedicals, LLC
Nanogen, Inc.
Nanosphere, Inc.
NorDiag
Olympus America Inc.
OpGen
Osmetech Molecular Diagnostics
ParagonDx, LLC
Pathwork Diagnostics, Inc.
PreAnalytiX
PrimeraDx
Prodesse
Promega Corporation
QIAGEN, INC
Roche Applied Science
Roche Diagnostics Corporation
Sci Gene
Sequenom, Inc
SeraCare Life Sciences, Inc
Siemens Healthcare Diagnostics
Signature Genomic Laboratories, LLC
Skyline Diagnostics LLC
SoftGenetics, LLC
Spartan Bioscience, Inc
StemCell Technologies, Inc
Sysmex
Tepnel Lifecodes Corporation
Tetracore, Inc
Thermo Scientific/Nanodrop
Third Wave Technologies
TIB Molbiol
Transgenomic, Inc
TriCore Reference Laboratories
Trim Gen Corporation
ViraCor
Xceed Molecular
ZeptoMetrix Corporation



The Journal of Molecular Diagnostics

Editor-in-Chief: Karen L. Kaul, MD, PhD
Evanston Hospital/Northwestern University Medical School

The Journal of Molecular Diagnostics (JMD), the official publication of the Association for Molecular Pathology, co-published with the American Society for Investigative Pathology, publishes high-quality original papers on scientific advances in the translation and validation of molecular discoveries in medicine into the clinical diagnostic setting, and the description and application of technological advances in the field of molecular diagnostic medicine.

Annual Meeting/Abstracts Issue: November 2009
Insertion orders and materials due:
September 21, 2009
Circulation: 3,500 Paid Subscribers

One complementary copy of the November 2009 issue of *The Journal of Molecular Diagnostics* will be distributed to each meeting attendee and Exhibit Booth.

Rate Card online at:
www.amp.org/Advertising/RateCard.pdf

To advertise in *JMD*, contact:
Robyn Engelson
FASEB AdNet
9650 Rockville Pike, Bethesda, MD 20814
Tel: 800-43-FASEB ext 7103
Email: *rengelson@faseb.org*

Meeting Program

Special Offer to *JMD* Advertisers: Purchase your full-page ad in the November 2009 issue of *JMD* and receive 50% rebate off the pricing below for ads placed in the Meeting Program.

Display Advertising

Back Cover of Meeting Program - Color, 7" x 10"	$2,875
Inside Front or Back Cover - color, 7" x 10"	$2,015
Inside Front or Back Cover - b/w, 7" x 10"	$1,350
Full page b/w only, 7" x 10"	$1,100
Page Horizontal - b/w only, 7" x 4.75"	$ 850
1/2 Page Vertical - b/w only, 3.25" x 10"	$ 850
1/4 Page Vertical - b/w only, 3.25" x 4.75"	$ 500

Specifications
Color Ad: PDF (embed fonts), jpg, or tif
Black and White Ads: 300 dpi tif, pcx, or PDF (embed fonts)

Program Insertion orders and materials due:
September 21, 2009

Send materials to:
Laurie Menser
Director of Marketing,
The American Society for Investigative Pathology
9650 Rockville Pike
Bethesda, MD 20814-3993
Tel: 301-634-7943; Fax: 301-634-7961
Email: *lmenser@asip.org*

Promotional Opportunities Included with your AMP Exhibitor Contract:

Program Listing
A floor plan of the Exhibit Hall and a list of all confirmed exhibiting companies will be included in the Meeting Program. The Meeting Program will be distributed to all meeting attendees. Additionally, the information will be posted online at www.amp.org.

On-Site Program
Exhibitors must provide a 60-word product description to be included in the Exhibit Guide. This guide is distributed to all meeting attendees. This opportunity to advertise your products and services is complimentary and is available only to AMP's exhibitors and supporters. Product description must be submitted by **June 22.**

Registration List
AMP will provide a complete registration list to exhibitors within 30 days of the annual meeting or by December 22, 2009. The registration list will be a read-only PDF file and does not include email addresses. The information is the sole property of AMP and cannot be reproduced in any form without express written permission.

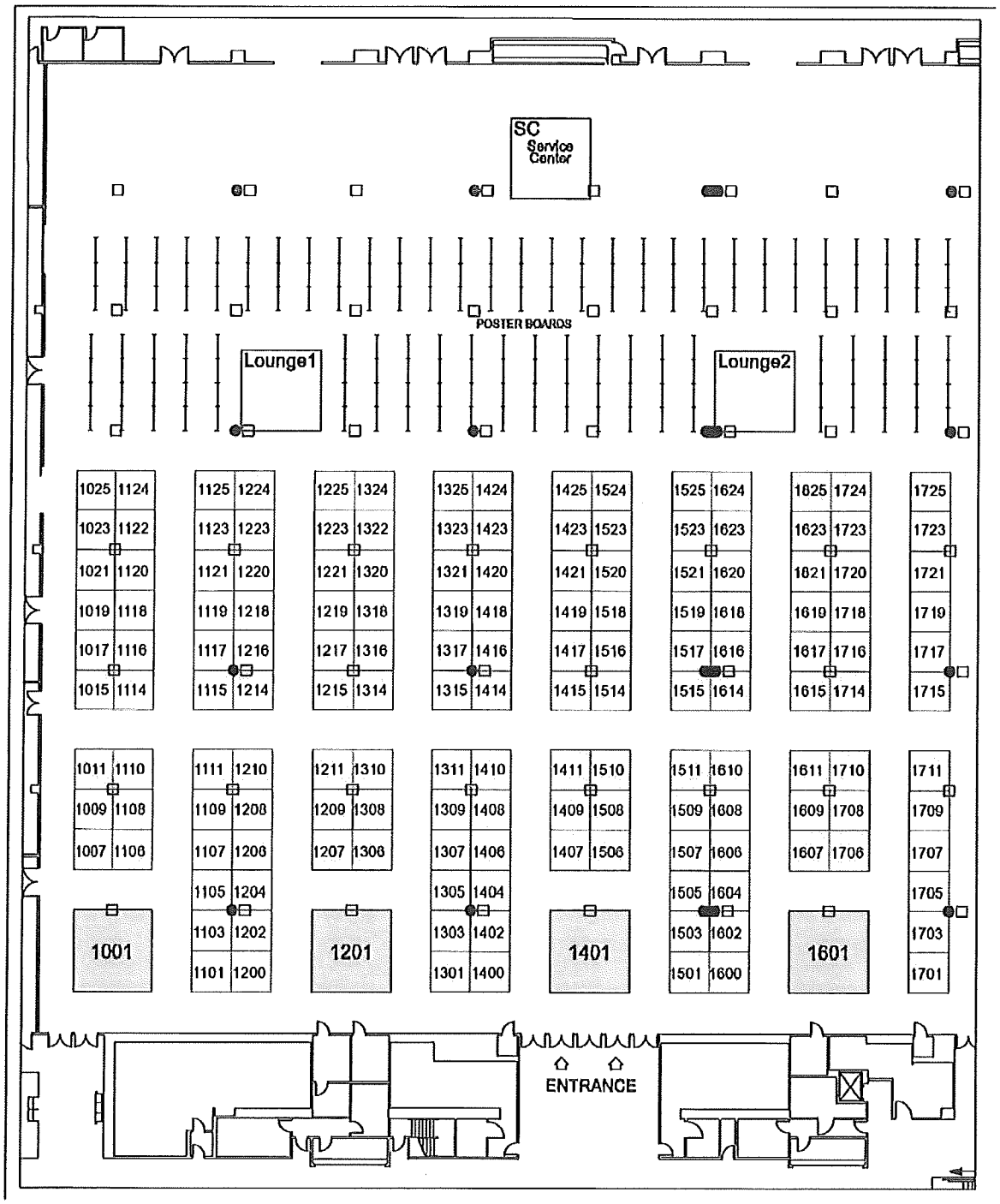
AMP Membership List
Exhibitors are entitled to a 50% discount for a one-time use of the AMP Membership Mailing List (approximately 1,500 names & addresses) for use in advertising their products and services. (Email addresses are not provided.) Requests must be made via email to Maricel Herrera at *mherrera@amp.org* no later than **September 30**.

Exhibit Hall & Booth Floor Plan

Exhibit Schedule – Florida Exhibition Hall

Friday, November 20 9:00 am – 5:00 pm

Saturday, November 21 9:00 am – 5:00 pm



2009 Association for Molecular Pathology 15th Annual Meeting and Exhibits
November 19-22, 2009, Gaylord Palms Resort & Convention Center

Exhibitor Application and Contract

Exhibit Days: November 20-21, 2009
Deadline: June 22, 2009

Company Name: *(Please list company name as you would like it to appear in the AMP 2009 program, exhibitor badges and any required signage)*		
Contact Individual: *(This person will receive all AMP 2009 exhibitor correspondence)*		
Address:		Telephone:
City:	State/Province:	Fax:
Zip/Postal Code	Country:	Email:

Booth Choices: 1._____ 2._____ 3._____ 4._____	Total Square Footage:	List any exhibitor(s) you wish to be near: List any exhibitor(s) you do not wish to be near:

Signage

❑ NO, We do not require an identification sign
❑ YES, We do require an identification sign

Product Description

A 60-word description of products or services must be submitted with your application for inclusion in the Program. Descriptions exceeding 60 words may be edited by the AMP administrative office. Please submit online at www.amp.org/2009/exhibitdesc.asp.
❑ 60-word Product Description submitted at www.amp.org by **June 22, 2009**.

Payment of Fees

Full payment must accompany the Exhibitor Application and Contract Form or it will not be processed. Payment may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:

❑ MC ❑ VISA ❑AMEX Credit Card Account #: Expiration Date: *Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.*	❑ Inline 10' x 10', **$3,900** ❑ Corner 10' x 10', **$4,500** ❑ Island 20' x 20', **$18,000** ❑ Non-Profit Inline 10' x 10', **$1,800**
Name on Card:	Signature: Date:

In accordance with the terms, conditions and regulations governing exhibits of the AMP 2009 Annual Meeting at the Gaylord Palms Resort & Convention Center, November 19-22, 2009, the undersigned hereby makes application for exhibit space(s) that, when accepted by AMP Exhibit Management, becomes a contract. All rules and regulations as outlined in the AMP Annual Meeting Exhibitor Prospectus, as well as any amendments published by AMP, are part of this contract. Failure to abide by such rules and regulations results in forfeiture of all monies paid AMP Exhibit Management under terms of this agreement.

Signature:	Date:

Deadline for Exhibitor Application and Contracts, description of products or services, and payment: June 22, 2009
Space will be sold on a first-come, first-served basis. Slots will be verified upon receipt of completed application including full payment and description of products or services. IMPORTANT: No booths will be held or assigned with out required full pre-payment & company description. Submit your 60-word description of products and services at www.amp.org/2009/exhibitdesc.asp

Please submit completed Exhibitor Application and Contract with payment to:
Maricel M. Herrera, CMP
Director of Meetings
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7400 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org

Exhibit Space Cancellation Policy: All exhibit space cancellations must be received in writing by AMP Exhibit Management (Maricel M. Herrera, CMP).

- Cancellations received on or before **August 20, 2009** qualify for a 90% refund of all monies paid for booth space rental.
- Any company cancelling its booth space between **August 21, 2009** and **September 20, 2009**, will forfeit 50% of the total cost of exhibit space rental.
- Any company cancelling after **September 20, 2009** will forfeit full exhibit space payment

15th ANNIVERSARY

2009 Association for Molecular Pathology 16th Annual Meeting and Exhibits
November 19-22, 2009, Gaylord Palms Resort & Convention Center

Corporate Workshop Application Form

Corporate Workshops Day: Thursday, November 19, 2009
Deadline: June 22, 2009

A full day of corporate sponsored workshops will take place on Thursday, November 19, 2009. Meeting rooms have been reserved for workshop presenters at the Gaylord Palms Resort & Convention Center, in Kissimmee, Florida. The fee for each workshop is $3,500 per hour. This fee includes basic audiovisual setup for the room. Catering arrangements should be made directly with the hotel and will be billed directly to you. Up to four workshops will run concurrently during the morning and afternoon sessions. **Please fax your completed Corporate Workshop Application Form to Maricel Herrera by June 22 so that we can work with you to arrange a schedule that most benefits presenters and attendees (minimizing topic overlaps or other conflicts).** This will allow us to provide early notification to our membership and meeting attendees about your workshop for early registration and travel planning purposes. We can also put you in touch with our contact at the Gaylord Palms Resort & Convention Center for other necessary arrangements.

Company:	
Contact Individual(s):	
Address:	Telephone: Fax: Email:
Title of Workshop you are interested in presenting:	
Maximum number of attendees:	Targeted number of attendees:
How long will the workshop last? (NOTE: $3,500 per hour -includes a basic audio visual setup (Screen, LCD Projector, Podium Mike) ❑ 1 Hour ❑ 2 Hours ❑ 3 Hours	
Format you prefer (please check one below): ❑ Classroom ❑ Theater ❑ Demonstration w/6 ft tables ❑ Include _____ Head table(s)	Requested Time Slot:
Special Requirements (electricity, sink, etc.) and Other Information (these requirements will be forwarded to the contact person at the convention services department so they can coordinate with you): **IMPORTANT: Final arrangements must be confirmed directly with the hotel representative.**	
Full payment must accompany this application form for consideration. Payments for Corporate Workshops may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:	
❑ MC ❑ VISA ❑ AMEX Credit Card Account #: Expiration Date: *Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.*	❑ 1 Hour Workshop, **$3,500** ❑ 2 Hour Workshop, **$7,000** ❑ 3 Hour Workshop, **$10,500**
Name on Card:	Signature: Date:

A one paragraph description of your workshop (~100 words) must be submitted online at www.amp.org/2009/wkdesc.asp by June 22, 2009. This description will be used for distribution to AMP members, posting on the AMP website's meeting section, in the AMP Newsletter, and publication in the meeting program.

Space will be sold on a first-come, first-served basis. Slots will be verified upon receipt of completed application including full payment and workshop description. Preliminary schedule/assigned time slot will be provided approximately 30 days after submission deadline.

Please submit the completed Corporate Workshop Application Form to:
Maricel M. Herrera, CMP
Director of Meetings
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7400 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org

Corporate Workshop Cancellation Policy: All corporate workshop cancellations must be received in writing by AMP Meeting Management (Maricel M. Herrera, CMP).

- Cancellations received on or before **August 20, 2009** qualify for a 90% refund of all monies paid for workshop time slot.
- Any company cancelling its workshop time slot between **August 21, 2009** and **September 20, 2009,** will forfeit 50% of the total cost of their corporate workshop payment.
- Any company cancelling after **September 20, 2009** will forfeit full corporate workshop payment.

2009 Association for Molecular Pathology 15th Annual Meeting and Exhibits
November 19-22, 2009, Gaylord Palms Resort & Convention Center

Sponsorship Opportunities Form

Deadline: September 30, 2009

Activity sponsorship will be individually recognized in the meeting program, on the AMP website, and on signage.
NOTE: All sponsorships for the following activities are credited toward your Corporate Partnership.
Some activities may be fully or partially sponsored. Activities available for sponsorship include:

Event		Full Sponsorship	Partial Sponsorship
Dining Events Sponsorship	Continental Breakfast – Friday, 11/20	❑ $ 5,000	❑ $ 2,500
	Continental Breakfast – Saturday, 11/21	❑ $ 5,000	❑ $ 2,500
	Continental Breakfast – Sunday, 11/22	❑ $ 5,000	❑ $ 2,500
	Morning Coffee Break – Friday, 11/20	❑ $ 2,000	❑ $ 1,000
	Morning Coffee Break – Saturday,11/21	❑ $ 2,000	❑ $ 1,000
	Morning Coffee Break – Sunday, 11/22	❑ $ 2,000	❑ $ 1,000
	Lunch – Friday, 11/20	❑ $12,000	❑ $ 6,000
	Lunch – Saturday, 11/21	❑ $12,000	❑ $ 6,000
	Afternoon Coffee Break – Friday, 11/20	❑ $ 2,000	❑ $ 1,000
	Afternoon Coffee Break – Saturday, 11/21	❑ $ 2,000	❑ $ 1,000
Event/Activity		**Full Sponsorship**	**Partial Sponsorship**
Scientific Session Sponsorship *The Annual Meeting Preliminary Program is available online at www.amp.org* *Note: You may choose to sponsor a specific Workshop or Special Topics Plenary. Sponsorship of educational activities requires an unrestricted educational grant.* *Contact Maricel Herrera at mherrera@amp.org*	Plenary Session – Genetics	❑ $ 5,000	❑ $ 2,500
	Plenary Session – Hematopathology	❑ $ 5,000	❑ $ 2,500
	Plenary Session – Infectious Diseases	❑ $ 5,000	❑ $ 2,500
	Plenary Session – Solid Tumors	❑ $ 5,000	❑ $ 2,500
	Plenary Session – Special Topics	❑ $ 5,000	❑ $ 2,500
	Plenary Session – Technical Topics	❑ $ 5,000	❑ $ 2,500
	Workshop – Genetics	❑ $ 2,500	❑ $ 1,500
	Workshop – Hematopathology	❑ $ 2,500	❑ $ 1,500
	Workshop – Infectious Diseases	❑ $ 2,500	❑ $ 1,500
	Workshop – Solid Tumors	❑ $ 2,500	❑ $ 1,500
	Workshop – Special Topics	❑ $ 2,500	❑ $ 1,500
	Workshop – Technical Topics	❑ $ 2,500	❑ $ 1,500
Description		**Sponsorship**	
Trainee Support	Trainee Registration Support	❑ $ 1,000	
Education Grant	Unrestricted Education Grant to Sponsor AMP Activities	❑ $_____ (no minimum)	
Pathology Outreach Course	❑ $10,000 Supporter - COMMITTED		
Cyber Café, Badges, Lanyards, and Hotel Keycards	Cyber Café	❑ $15,000	
	Bottled Water Sponsorship	❑ $15,000	
	Lanyard Sponsorship	❑ $10,000	
	Hotel Room Keycard Sponsorship	❑ $10,000	

Company:	
Contact Individual:	
Address:	Telephone:
	Fax:
	Email:

Payment may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:

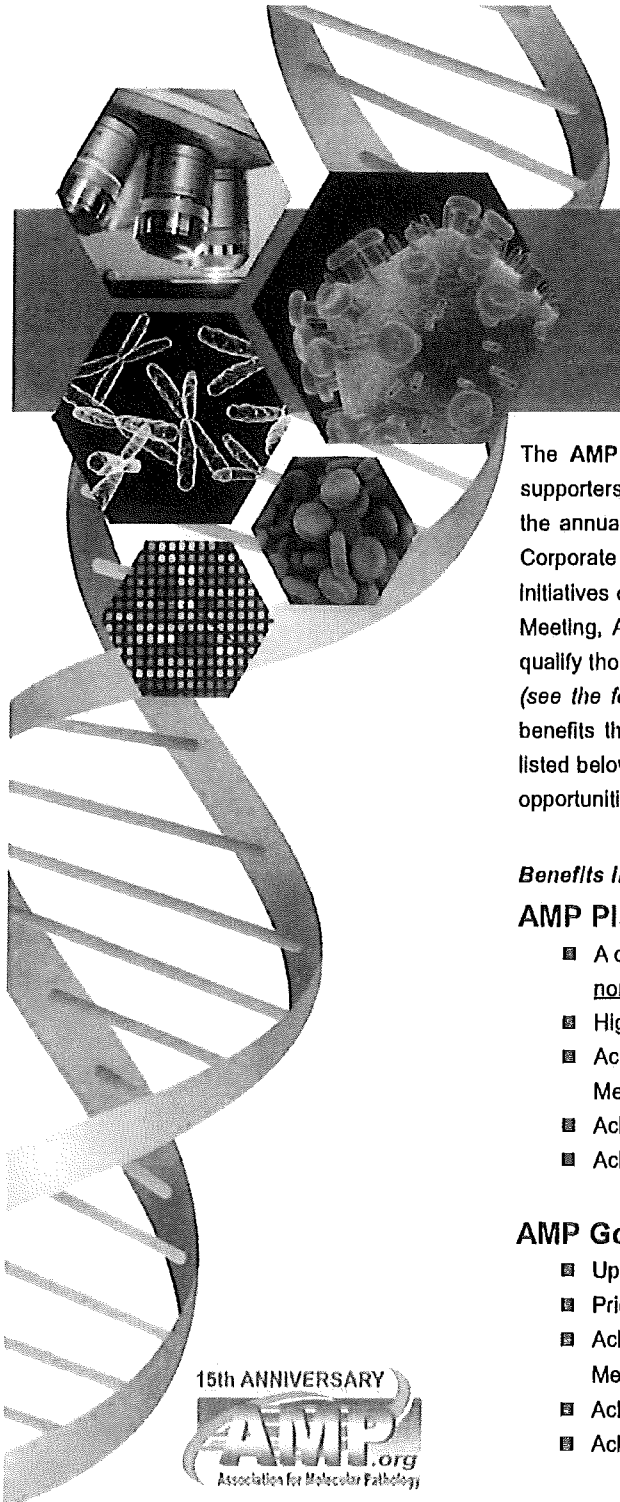
❑ MC ❑ VISA ❑ AMEX Credit Card Account #: Expiration Date:

Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.

Name on Card:	Signature: Date:

Thank you for sponsoring an activity at the AMP Annual Meeting. Please send the completed Sponsorship Opportunities Form and payment by September 30, 2009 to:

Maricel M. Herrera, CMP
Director of Meetings
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7400 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org



Highlighting Your Products and Services to Molecular Laboratory Professionals

ASSOCIATION FOR MOLECULAR PATHOLOGY

2009 AMP Corporate Partners Program

The **AMP Corporate Partners Program** is designed to provide our corporate supporters with additional high-visibility opportunities to highlight their company at the annual meeting, at other AMP educational events, and on the AMP website. Corporate Partnerships are renewable each year and support the educational initiatives of the Association. Contributions received for sponsorship of the Annual Meeting, Awards, AMP Test Directory, and Educational Grants are combined to qualify those with significant interest and investment in AMP as Corporate Partners *(see the following page for details)*. AMP Corporate Partners receive significant benefits that elevate their visibility to AMP members. In addition to the benefits listed below, Corporate Partners are given first notification of selected sponsorship opportunities.

Benefits Include:

AMP Platinum Level Corporate Partner ($30,000)

- A complimentary four-color, full page, priority placement ad in any non-meeting issue of *The Journal of Molecular Diagnostics (JMD).*
- High Priority booth space location for the Annual Meeting.
- Acknowledgement in advertisements for the Annual Meeting and in the Meeting Program.
- Acknowledgement on the AMP website.
- Acknowledgement in the *AMP Newsletter.*

AMP Gold Level Corporate Partner ($20,000)

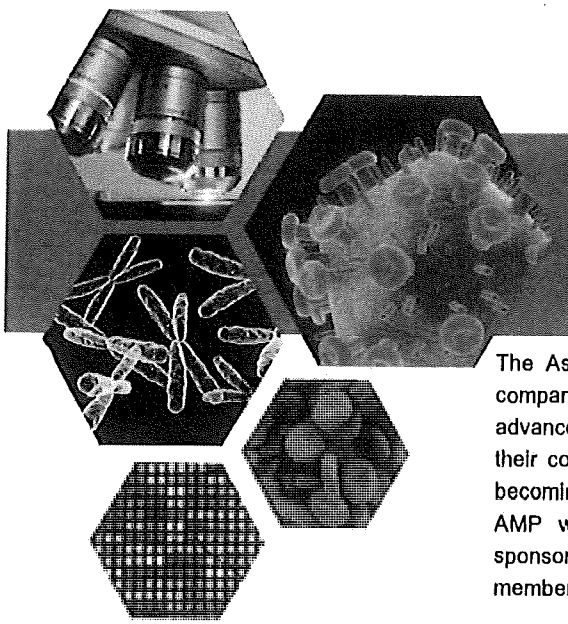
- Upgrade ad placement in any non-meeting issue of *JMD.*
- Priority booth space location for the Annual Meeting.
- Acknowledgement in advertisements for the Annual Meeting and in the Meeting Program.
- Acknowledgement on the AMP website.
- Acknowledgement in the *AMP Newsletter.*

AMP Silver Level Corporate Partner ($10,000)

- Preferred booth space location for the Annual Meeting.
- Acknowledgement in advertisements for the Annual Meeting and in the Meeting Program.
- Acknowledgement on the AMP website.
- Acknowledgement in the *AMP Newsletter.*

15th ANNIVERSARY AMP.org Association for Molecular Pathology

Association for Molecular Pathology
Mary Steele Williams, MT(ASCP)SM
COO, Director of Scientific Programs
9650 Rockville Pike
Bethesda, MD 20814-3993 (USA)
Tel: 301-634-7921
Fax: 301-634-7990
Email: *mwilliams@amp.org*
www.amp.org



Highlighting Your Products and Services to Molecular Laboratory Professionals

ASSOCIATION FOR MOLECULAR PATHOLOGY

Sponsorship Opportunities

The Association for Molecular Pathology appreciates the financial support that companies provide for AMP programs. There are numerous opportunities for you to advance the field of molecular diagnostics through AMP. Companies may express their commitment to AMP members and the Association's educational mission by becoming Corporate Partners. Whatever the amount of your resources, however, AMP welcomes your support. Educational activities that receive corporate sponsorship are listed below along with the contact information of the AMP staff member who administers the activity.

AMP's primary mission is to advance the practice of clinical molecular laboratory medicine. We welcome all suggestions for additional programs that will help AMP members better serve the health of people around the world.

Abstract Submission Service

AMP contracts with an online abstract submission service. Your support will help defray the cost of this service. Sponsorship is in three-year cycles.

Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

Annual Meeting

The AMP Annual Meeting is the Association's most important educational event. Numerous sponsorship opportunities exist to support the scientific sessions, receptions, meeting bags, program book, lanyards, internet café, lunches, and breaks. Sponsorship of scientific sessions will be in the form of an unrestricted educational grant.

Contact: Maricel Herrera at *mherrera@amp.org* or (301) 634-7400

Awards

AMP honors individuals at various stages of their careers through several prestigious awards: The AMP Award for Excellence in Molecular Diagnostics, AMP Leadership Award, Young Investigator Award, and Technologist Award. Sponsorship is in three-year cycles.

Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

Pathology Outreach

The AMP Training & Education Committee hosts educational initiatives for non-molecular laboratory professionals. These are exciting opportunities to facilitate the growth of molecular diagnostics in mainstream laboratory services. The **Pathology Outreach Course** is a full-day course scheduled one day prior to the AMP Annual Meeting. Sponsorship will be in the form of an unrestricted educational grant.

Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

AMP Webinars

Web-based courses covering topics in molecular pathology. These are exciting opportunities to facilitate the growth of molecular diagnostics in mainstream laboratory services.

Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

15th ANNIVERSARY

AMP.org
Association for Molecular Pathology

Association for Molecular Pathology
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Tel: 301-634-7921
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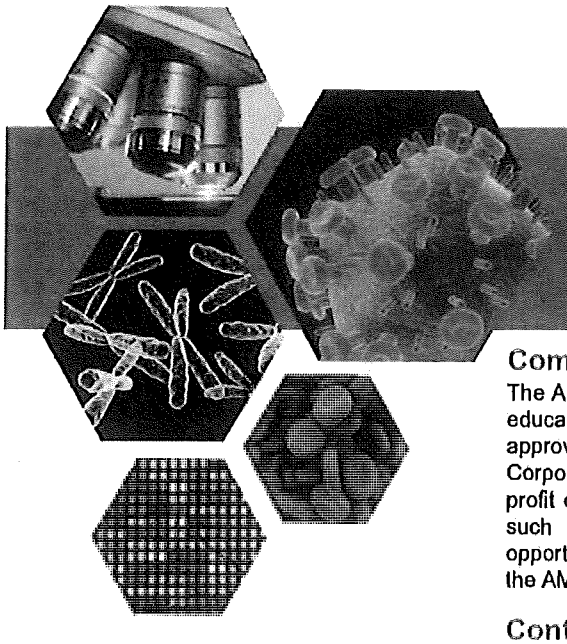
www.amp.org



Highlighting Your Products and Services to Molecular Laboratory Professionals

ASSOCIATION FOR MOLECULAR PATHOLOGY

2009 AMP Corporate Partners Program

Commitment Form

The AMP Corporate Partners Program is a sponsorship of the Association and its educational initiatives through unrestricted educational grants. A completed and approved application with payment is required to begin implementation of benefits. Corporate Partner contracts are renewable each year. AMP is a 501(c)3 not-for-profit organization. Contributions may be designated to support specific activities such as particular sessions at the annual meeting and/or other sponsorship opportunities. Complete descriptions of sponsorship opportunities are available on the AMP website at *www.amp.org*.

Select Your 2009 Corporate Partnership Level:

- ❑ Platinum Partnership, $30,000/year
- ❑ Gold Partnership, $20,000/year
- ❑ Silver Partnership, $10,000/year

Select Your Payment Plan:

- ❑ Full Payment Enclosed
- ❑ Four (4) Payment Plan:

Please include the first payment with this form.
#1 - 25% due 3/31/2009

AMP will invoice you one month prior to the payment-due date for the following 3 payments. Invoice will be sent to the contact name listed at right.
#2 - 25% - payment due 6/31/2009
#3 - 25% - payment due 7/31/2009
#4 - 25% - payment due 10/31/2009

15th ANNIVERSARY
AMP.org
Association for Molecular Pathology

Association for Molecular Pathology
Mary Steele Williams, MT(ASCP)SM
COO, Director of Scientific Programs
9650 Rockville Pike
Bethesda, MD 20814-3993 (USA)
Tel: 301-634-7921
Fax: 301-634-7990
Email: *mwilliams@amp.org*
www.amp.org

Contact Information:

Organization/Company_____

Contact Name_____

Address_____

City_____ State/Province_____ Zip_____

Country_____

Tel_____

Fax_____

Email_____

Payment: *(please indicate desired partnership level and payment plan at left)*

❑ Check enclosed *(made payable to "Association for Molecular Pathology" or "AMP")*

Charge my credit card* Amount $_____

❑ VISA ❑ MasterCard ❑ American Express

Credit Card #_____ Exp Date_____

Card Holder Name *(please print)*_____

Signature_____ Date_____

Credit Card Billing Address_____

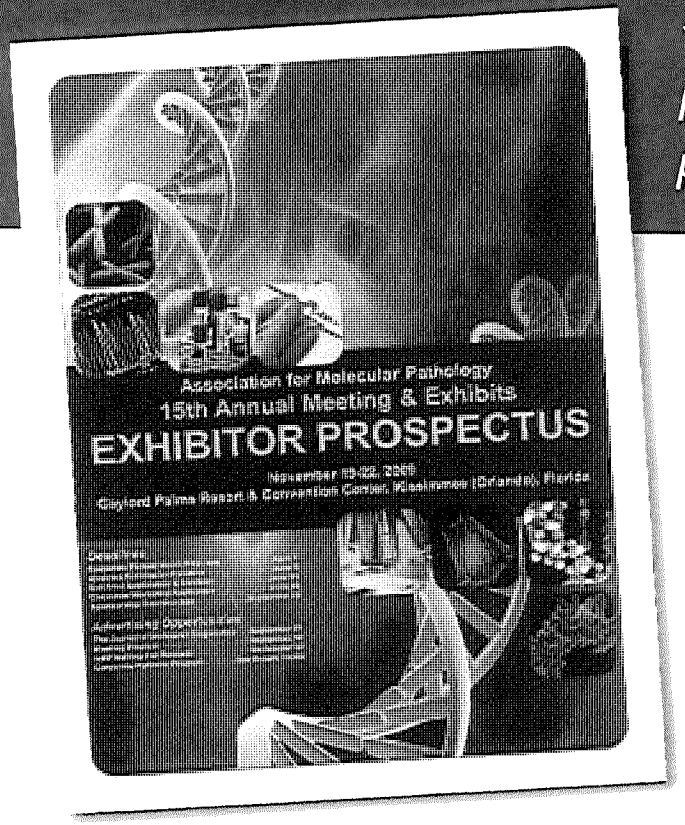
City_____ State_____ ZIP_____ Country_____

*IMPORTANT: If paying by credit card, the charge on your credit card statement will be from the American Society for Investigative Pathology (ASIP). AMP is a constituent society of the office of the American Society for Investigative Pathology and uses the ASIP credit card processing system.

15th ANNIVERSARY
AMP.org
Association for Molecular Pathology

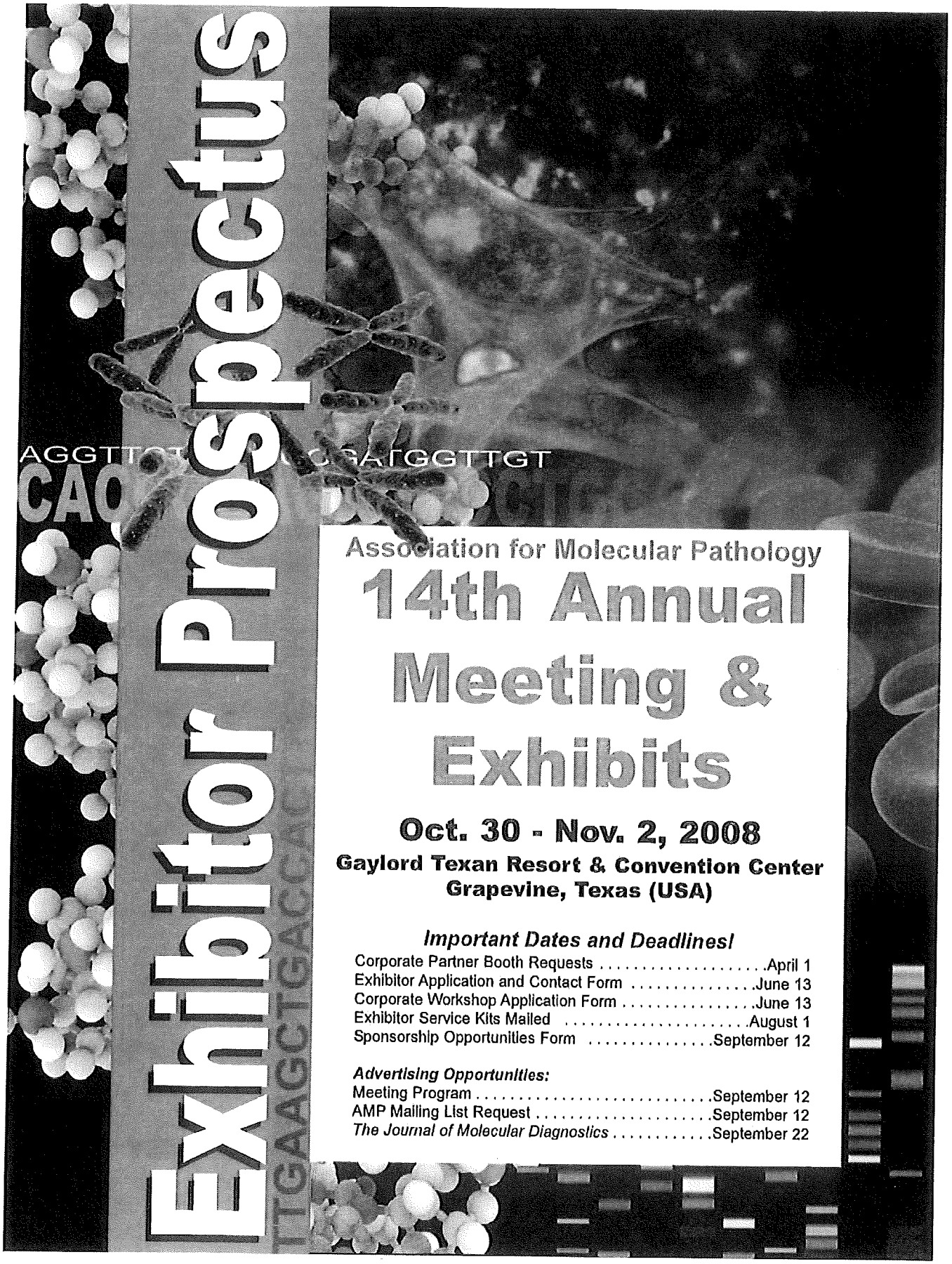
Association for Molecular Pathology
9650 Rockville Pike
Bethesda, MD 20814 (USA)
www.amp.org

AMP 15th Annual Meeting & Exhibits



Your single best opportunity to reach hundreds of molecular laboratory professionals!

ILLUM-0415



Association for Molecular Pathology

14th Annual Meeting & Exhibits

Oct. 30 - Nov. 2, 2008

Gaylord Texan Resort & Convention Center
Grapevine, Texas (USA)

Important Dates and Deadlines!

Corporate Partner Booth Requests	April 1
Exhibitor Application and Contact Form	June 13
Corporate Workshop Application Form	June 13
Exhibitor Service Kits Mailed	August 1
Sponsorship Opportunities Form	September 12

Advertising Opportunities:

Meeting Program	September 12
AMP Mailing List Request	September 12
The Journal of Molecular Diagnostics	September 22

EXHIBIT 5

(Part VI of VII)

OF

DECLARATION OF GREGORY F. HEATH

Association for Molecular Pathology

2008 Annual Meeting and Exhibits

October 30 - November 2, 2008

Gaylord Texan Resort & Convention Center, Grapevine, Texas

Association for Molecular Pathology

The Association for Molecular Pathology (AMP) is committed to the advancement of clinical molecular diagnostic and prognostic medicine through education and training of practitioners, physicians, laboratory and industrial scientists, and health care professionals involved in patient care and management. AMP supports the development of new technologies in molecular biology to be used in laboratory medicine, including diagnosis, treatment, and prognosis of genetic disorders, cancer, infectious diseases, identity and histocompatibility.

About the Membership

The membership of AMP includes individuals interested in the educational, medical, scientific, economic, and regulatory aspects of molecular diagnostics, including pathologists, clinical laboratory scientists, clinicians and other health care personnel, government employees - especially those involved in regulation of the field - and professionals in the *in vitro* diagnostics industry.

AMP members are involved in every aspect of molecular diagnostics: performance, interpretation, and reporting of molecular diagnostic tests, assay development and validation, and medical education. Many members participate in research aimed at broadening the understanding of gene/protein structure and function, disease processes, and developing new technologies. AMP aims to inform and educate its members as well as other professionals interested in molecular pathology through its annual meeting, publications, website, listserv, and other venues.

Important Dates and Deadlines!

Corporate Partner Booth Requests	April 1
Abstract Submission Deadline	June 2
Exhibitor Application and Contract Form	June 13
Corporate Workshop Application Form	June 13
Exhibitor Service Kits Mailed	August 1
Sponsorship Opportunities Form	September 12
Advertising Opportunities:	
Meeting Program	September 12
AMP Mailing List Request	September 12
The Journal of Molecular Diagnostics	September 22
AMP Corporate Partners Program	*(See details on pages 13-15)*

The Association for Molecular Pathology will host its 14th Annual Meeting and Exhibits October 30-November 2, at the Gaylord Texan Resort & Convention Center in Grapevine, Texas.

This four-day event starts on October 30 with a day of corporate-sponsored workshops. A keynote lecture presented by **Carl Wittwer, MD, PhD, ARUP Laboratories**, the distinguished recipient of the **2008 AMP Award for Excellence in Molecular Diagnostics**, launches the scientific program on October 31.

Programming includes poster sessions and invited speakers for workshop and plenary sessions in each of the four major areas of clinical molecular diagnostics:

- **Hematopathology**
- **Infectious diseases**
- **Inherited genetic diseases**
- **Solid tumors**

The meeting also includes several technical workshops. Corporate exhibits, working lunch meetings, and casual social gatherings offer opportunities for networking and further exchange with molecular laboratory professionals.

Enclosed is your **2008 Exhibitor Prospectus**. Additional opportunities for Exhibitors include **Corporate Workshops, Dining Event Sponsorships** and **Scientific and Educational Activity Sponsorships**. Our **Corporate Partners** program offers our Exhibitors additional opportunities for high visibility to the molecular pathology community.

Mark Your Calendars...

Association for Molecular Pathology

AMP 2009 Annual Meeting & Exhibits

November 19-22, 2009
Gaylord Palms Resort & Convention Center
Orlando, Florida

Exhibitor Information

Exhibitor Information & Application Forms on the Web

The Exhibitor Prospectus is available in its entirety at: www.amp.org/Meetings/exhibit.htm

- Preliminary Program
- Rules and Regulations for Exhibiting
- General Information
- Exhibitor Application and Contract
- Corporate Partners Program Information
- Sponsorship Opportunities
- Advertising Opportunities
- Mailing List Information
- Services and Official Contractor
- Union Regulations
- Corporate Workshop Information and Application
- Exhibitor Badges Form
- Current Exhibiting Companies and Booth Assignments

Exhibit Space Rental

All booths are 10' x 10' or 20' x 20'. The maximum height in the exhibit area is 24 feet. Rental includes 8 ft. high back drapes, 3 ft. high side dividers and a standard (7" X 44") identification sign with company name.

Booth Fees

10 X 10 Inline	$3,900
10 X 10 Corner	$4,500
20 X 20 Island	$18,000
10 x 10 Non-Profit Inline	$1,800

Please submit your completed **Exhibitor Application and Contract** (page 7) by **June 13, 2008**.

Exhibitor Registration Hours

Wednesday, October 29	1:00 pm - 6:00 pm
Thursday, October 30	8:00 am - 6:00 pm
Friday, October 31	8:00 am - 6:00 pm
Saturday, November 1	8:00 am - 6:00 pm

Exhibit Installation

Thursday, October 30	8:00 am - 4:00 pm

Exhibit Hours

Friday, October 31	9:00 am - 5:00 pm
Saturday, November 1	9:00 am - 5:00 pm

Dismantling of Exhibits

Saturday, November 1	5:00 pm - 9:00 pm

*No packing or dismantling of exhibits will be permitted until **5:00 pm, Saturday, November 1**. Early departure will result in the company or group being penalized including being banned from future tradeshows. When planning your dismantling and departure to follow the show, please allow no less than 3 hours for return of all empty shipping materials from storage. We strongly recommend that you advise your staff to make appropriate departure plans; I.e. plan to depart late Saturday evening or Sunday morning and to not count on being able to depart on Saturday afternoon.*

Exhibitor Rules & Regulations

- **Electronic Lead Retrieval**
  Attendees at the 2008 AMP Annual Meeting will carry electronic cards. Lead retrieval services will be provided by Trade Show Leads. Exhibitors will have the opportunity to rent lead retrieval services as part of their exhibit booth package.
- **Exhibitor Badges**
  Exhibitors badges must be worn at all times, and allow access to the Exhibit Hall and Plenary Sessions only. Exhibitors will receive 6 badges per 10' x 10' booth space, 12 badges per 10' x 20' booth space, and 24 badges per 20' X20' booth space. Additional Exhibitor badges will be available at $50.00/each. Exhibitor name badge requests may be submitted through the AMP Website at www.amp.org/meetings/exhibit.htm.
- **Promotional Items and Activities**
  Companies wishing to conduct contests or lotteries should contact the AMP office at 301-634-7939 for guidelines and permission. Exhibiting companies are permitted to distribute promotional materials and other items at their Exhibit Booth location only. All items distributed must be useful to the professional activities of the meeting attendees, and be made available to all meeting attendees as long as supplies last.
  No soliciting of registrants is permitted in the aisles or in other exhibitor's booths, or in any other area of the hotel. No distribution of literature or other promotional items at hotel guestrooms, or in any other public or private area of the hotel is permitted.
- **Subletting Exhibit Space**
  Subletting any part of the exhibit space by an exhibitor is prohibited.
- **Sale of Goods**
  The sale of goods or services of any kind in the exhibit area in connection with the Annual Meeting is prohibited. Order taking is permitted.

Booth Relocation

- AMP reserves the right to relocate space to areas other than that selected by the exhibitor. Relocations will be made only in the exhibitor's best interest and upon notification to the exhibitor by Exhibit Management. Management strives for, but cannot guarantee, that a company will not be located near a competitor.

Exhibit Space Cancellation

- All exhibit space cancellations must be received in writing by AMP Exhibit Management (Maricel M. Herrera, CMP).
- Cancellations received on or before **July 30, 2008**, qualify for a 90% refund of all monies paid for booth space rental.
- Any company cancelling its booth space between **July 31, 2008** and **August 29, 2008**, will forfeit 50% of the total cost of exhibit space rental.
- Any company cancelling after **August 29, 2008** will forfeit full exhibit space payment.

Exhibitor Information

Ancillary and Satellite Events

AMP encourages ancillary meetings and events during the annual meeting provided that they are not scheduled while any official AMP scientific sessions or sponsored social events are scheduled.

Individuals who wish to schedule an ancillary event (e.g., meeting, social dinner) during the AMP Annual Meeting dates (October 30 - November 2), or a satellite event (dates immediately before or immediately after the official AMP dates) should contact Maricel M. Herrera in the AMP Administrative office (*mherrera@amp.org*) as soon as possible.

All ancillary and satellite events must be cleared through the AMP Administrative Office. The title, time and location of all approved events will be included in The Meeting Program and Website. Space may be available at the Gaylord Texan on a first-come, first-served basis. There will be an administrative fee for any space released by AMP. Should the purpose for any function be misrepresented to the AMP administrative office, the group sponsoring such function will be penalized by AMP, including being suspended from participation in future AMP events.

AMP does not assist with the planning, funding, or management of ancillary or satellite events. Organizers will be responsible for all arrangements and costs associated with their events which may include: room rental, audio-visual equipment, food and beverages. Ancillary and satellite events scheduled by September 12, 2008 will be listed in printed program information and on the AMP Annual Meeting Web site.

Contact Information

Exhibit Management
Maricel M. Herrera, CMP
Director, Meetings and Membership Services
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7939 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org

Travel Information

Hotel Accommodations

Accommodations will be provided for exhibitors and attendees at the Gaylord Texan Resort & Convention Center where sessions and exhibits will be held. AMP has negotiated a special rate of $189 standard single/double rooms. Room block opens April 1st for reservations. **Be sure to make reservations by October 1st**; afterward the discounted room rate may not apply. It is important to identify yourself as an AMP attendee when you contact the reservations desk. To make reservations please dial 1-817-778-1000.

Gaylord Texan Resort & Convention Center
1501 Gaylord Trail
Grapevine, TX 76051
Telephone: (817) 778-1000
Guest fax: (817) 778-1001

For general information, visit the Gaylord Texan Resort & Convention Center hotel website at:
http://www.gaylordhotels.com/gaylordtexan/

Note regarding group hotel reservations:
As a result of the large number of last minute cancellations and no-shows, a **two night, non-refundable deposit is required on all reservations** and will be charged on Friday, September 5, 2008 to the credit card on file. The amount charged will be a total of two nights at the rate of $189 per night plus $15.00 resort fee and a 12% tax. All reservations made on or after September 5 will be automatically charged a two-night non-refundable deposit.

Air Travel Discounts

American Airlines is offering a discount of up to 10% on airfare, plus other travel discount options to and from the AMP Annual Meeting. The percentage discount can be booked online at www.aa.com for AA/AE flights or at 1-800-221-2255 through the AA Group Sales Reservation Desk. Please mention the star file **AN#A24H8AE** for our group (AMP Annual Meeting) to receive your special fare.

To learn more about the discounts available to you, or to book your reservation, please call American Airlines today!

Ground Transportation & Car Rentals

Avis Rent a Car will be providing rental discounts to our group for ground transportation. To make rental car reservations, call the Avis Rent A Car Convention Desk directly at 1-800-331-1600. The desk is available to assist you twenty four hours a day, but you must reference the group file **AWD#D086607** to obtain the best possible car rental rates available.

SuperShuttle provides 24 hour transportation between the airport and the hotel. Door to door shuttle service is available by reservation. AMP Meeting attendees are entitled to a discount off their regular rate. Reservations may be made by calling 800-258-3826 or online at:
http://www.supershuttle.com/default.aspx?GC=6R72M

Workshop & Sponsorship Opportunities

Sponsoring activities at the Annual Meeting is an ideal way to get your company noticed by attendees. All functions may be either fully or partially sponsored; companies providing sponsorship will be individually recognized in the meeting program and signage at the event.

We offer an exciting opportunity for those who provide significant support to be recognized as "Corporate Partners." *Complete details of the AMP Corporate Partners Program is located at the end of this Prospectus.*

Sponsorship Opportunities

Activity Sponsorships will be individually recognized in the meeting program. Activities available for sponsorship include: Plenary Sessions, Workshops, Continental Breakfasts, Morning Coffee Breaks, Lunch, Afternoon Coffee Breaks, Trainee Registration Support, and support for other AMP activities. If you are interested in sponsoring an activity, please fax your completed **Sponsorship Opportunities Form** (page 11) to Maricel Herrera by **September 12**.

Corporate Workshops Day

A full day of corporate sponsored workshops will take place on Thursday, October 30. Meeting rooms have been reserved for workshop presenters at the Gaylord Texan Resort & Convention Center. The fee for each workshop is $3,500 per hour and includes basic audio visual setup. Catering arrangements should be made directly with the hotel and will be billed directly to you. Workshops will run concurrently during the morning and afternoon sessions.

Deadline for submitting the completed **Corporate Workshop Application Form** (page 9) is **June 13** so that we can work with you to arrange a schedule that most benefits presenters and attendees (minimizing topic overlaps or other conflicts). This will also allow us to provide early notification to our membership and meeting attendees about your workshop for early registration and travel planning purposes. We can also put you in touch with our contact at the Gaylord Texan Resort & Convention Center for other necessary arrangements.

A schedule and full description of Corporate Workshops will be posted on the AMP website at www.amp.org, and in the Fall 2008 *AMP Newsletter*.

Corporate Partners

The AMP Corporate Partners Program is designed to provide our corporate supporters with additional high-visibility opportunities to highlight their company at the annual meeting, at other AMP educational events, and on the AMP website. See complete information in the Corporate Partnerships section at the end of this Prospectus (see pages 13-15).

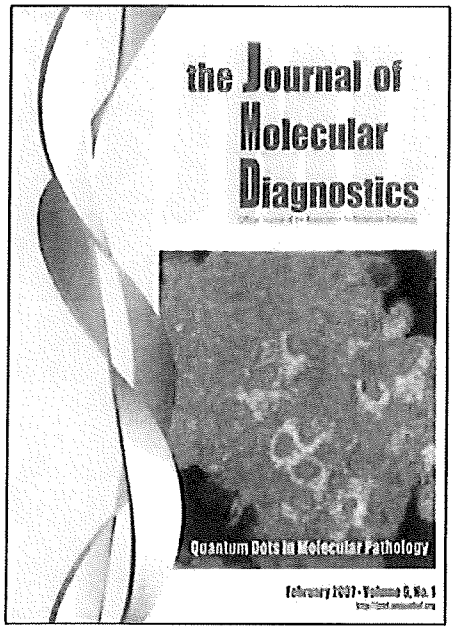
2007 Annual Meeting Demographics

Total Scientific Attendees - 1046
Exhibitors - 67

2007 Exhibitors

Abbott Molecular, Inc.
Acrometrix
Affymetrix, Inc.
Althea Technologies, Inc.
American Society for Clinical Pathology
ARTEL
ARUP Laboratories
Asuragen, Inc.
Attostar LLC
AutoGen, Inc.
Autogenomics, Inc.
Beckman Coulter, Inc.
BioArray Solutions
Biosearch Technologies, Inc.
BioTrove
Cepheid Inc.
Cleveland Clinic Reference Laboratory
College of American Pathologists
Combimatrix Molecular Diagnostics (CMDX)
Corbett Robotics, Inc.
DxS Limited
Elsevier/Saunders/Mosby
Eppendorf North America
EraGen Biosciences
Expression Analysis, Inc.
Focus Diagnostics
Genomic Health, Inc.
Gen-Probe
Genzyme
HandyLab, Inc.
Idaho Technology, Inc.
Ikonisys, Inc.
Illumina, Inc.
Invitrogen
InVivoScribe Technologies, LLC
IPSOGEN
Laboratory for Personalized Molecular Medicine
Lippincott Williams & Wilkins
Luminex Corporation
Maine Molecular Quality Controls, Inc.
MetaSystems Group, Inc
Miltenyi Biotec, Inc.
MolecularMD
Nanogen, Inc.
Olympus America Inc.
Osmetech Molecular Diagnostics
Pathwork Diagnostics
PreAnalytiX
Prodesse
Promega Corporation
QIAGEN, INC.
Rainbow Scientific, Inc.
Roche Applied Science
Roche Diagnostics Corporation
SciGene
Sequenom, Inc.
SeraCare Life Sciences, Inc.
Siemens Medical Solutions Diagnostics
Tepnel Lifecodes Corporation
Third Wave Technologies
TIB Molbiol
TrimGen Corporation
US Labs
Veridex, a Johnson & Johnson Company
Xceed Molecular
ZeptroMetrix Corporation

Advertising and Promotional Opportunities



The Journal of Molecular Diagnostics

Editor-in-Chief: Karen L. Kaul, MD, PhD
Evanston Hospital/Northwestern University Medical School

The Journal of Molecular Diagnostics (JMD), the official publication of the Association for Molecular Pathology, co-published with the American Society for Investigative Pathology, publishes high-quality original papers on scientific advances in the translation and validation of molecular discoveries in medicine into the clinical diagnostic setting, and the description and application of technological advances in the field of molecular diagnostic medicine.

Annual Meeting/Abstracts Issue: November 2008
Insertion orders and materials due:
September 22, 2008
Circulation: 3,500 Paid Subscribers

One complementary copy of the November 2008 issue of *The Journal of Molecular Diagnostics* will be distributed to each meeting attendee and Exhibit Booth.

Rate Card online at:
www.amp.org/Advertising/RateCard.pdf

To advertise in *JMD*, contact:
Robyn Engelson
FASEB AdNet
9650 Rockville Pike, Bethesda, MD 20814
Tel: 800-43-FASEB ext 7103
Email: *rengelson@faseb.org*

Meeting Program

Special Offer to *JMD* Advertisers: Purchase your full-page ad in the November 2008 issue of *JMD* and receive 50% rebate off the pricing below for ads placed in the Meeting Program.

Display Advertising

Back Cover of Meeting Program - Color, 7" x 10"	$2,875
Inside Front or Back Cover - color, 7" x 10"	$2,015
Inside Front or Back Cover - b/w, 7" x 10"	$1,350
Full page b/w only, 7" x 10"	$1,100
Page Horizontal - b/w only, 7" x 4.75"	$ 850
1/2 Page Vertical - b/w only, 3.25" x 10"	$ 850
1/4 Page Vertical - b/w only, 3.25" x 4.75"	$ 500

Specifications
Color Ad: PDF (embed fonts), jpg, or tif
Black and White Ads: 300 dpi tif, pcx, or PDF (embed fonts)

Program Insertion orders and materials due:
September 12, 2008

Send materials to:
Laurie Menser
Marketing Manager,
The American Society for Investigative Pathology
9650 Rockville Pike
Bethesda, MD 20814-3993
Tel: 301-634-7943; Fax: 301-634-7961
Email: *lmenser@asip.org*

Promotional Opportunities Included with your AMP Exhibitor Contract:

Program Listing
A floor plan of the Exhibit Hall and a list of all confirmed exhibiting companies will be included in the Meeting Program. The Meeting Program will be distributed to all meeting attendees. Additionally, the information will be posted online at www.amp.org.

On-Site Program
Exhibitors must provide a 60-word product description to be included in the Meeting Program. This guide is distributed to all meeting attendees. This opportunity to advertise your products and services is complimentary and is available only to AMP's exhibitors and supporters.

Registration List
AMP will provide a complete registration list to exhibitors within 30 days of the annual meeting. The registration list will be a read-only PDF file and does not include email addresses. The information is the sole property of AMP and cannot be reproduced in any form without express written permission.

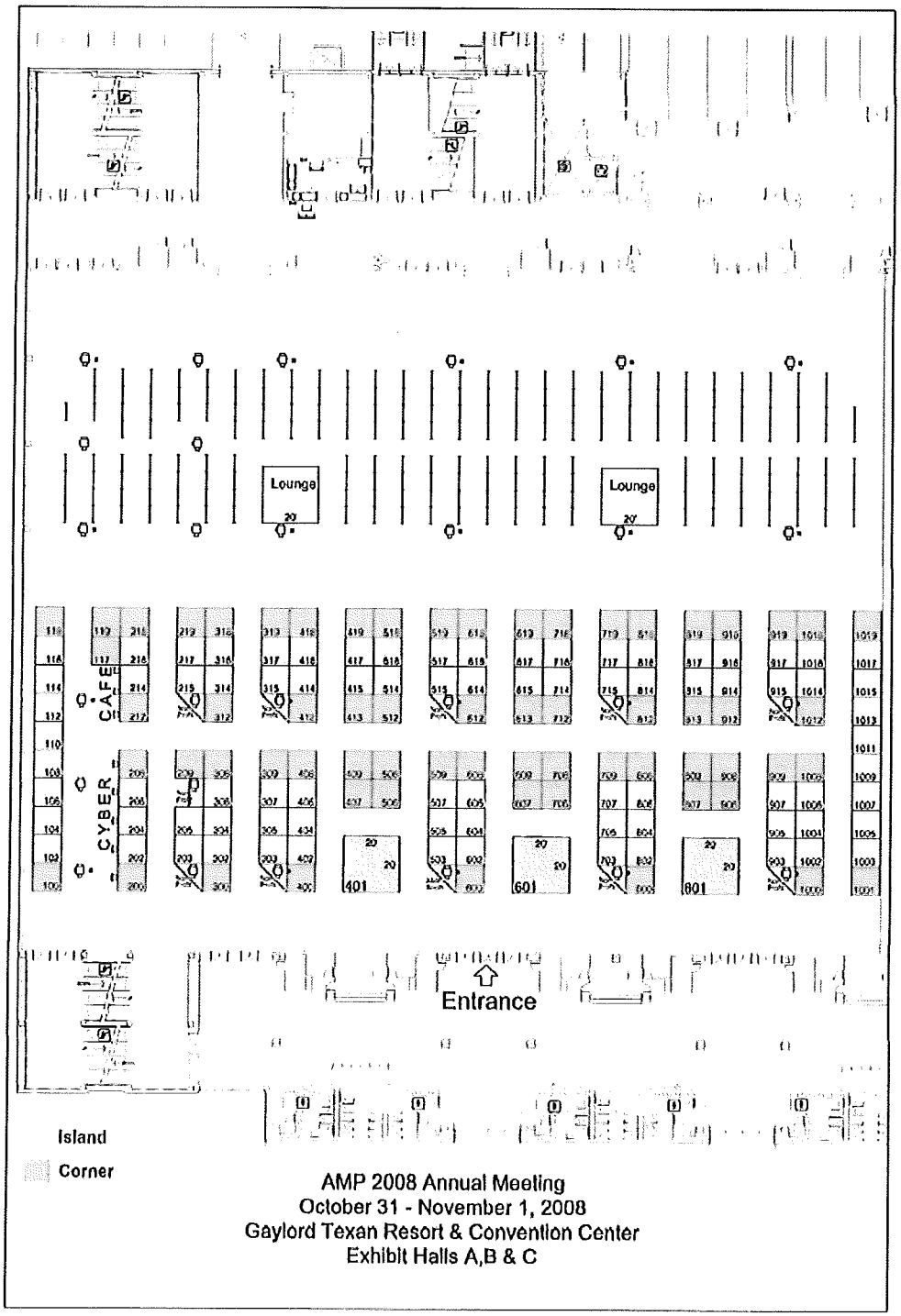
AMP Membership List
Exhibitors are entitled to a 50% discount for a one-time use of the AMP Membership Mailing List (approximately 1,500 names & addresses) for use in advertising their products and services. (Email addresses are not provided.) Requests must be made via email to Maricel Herrera at *mherrera@amp.org* no later than **September 12**.

Exhibit Hall & Booth Floor Plan

Exhibit Schedule – Longhorn Exhibit Hall

Friday, October 31 9:00 am – 5:00 pm

Saturday, November 1 9:00 am – 5:00pm



AMP 2008 Annual Meeting
October 31 - November 1, 2008
Gaylord Texan Resort & Convention Center
Exhibit Halls A,B & C

2008 Association for Molecular Pathology 14th Annual Meeting and Exhibits
October 30 - November 2, 2008, Gaylord Texan Resort & Convention Center

Exhibitor Application and Contract

Exhibit Days: October 31-November 1, 2008
Deadline: June 13, 2008

Company Name: *(Please list company name as you would like it to appear in the AMP 2008 program, exhibitor badges and any required signage)*		
Contact Individual: *(This person will receive all AMP 2008 exhibitor correspondence)*		
Address:		Telephone:
City:	State/Province:	Fax:
Zip/Postal Code	Country:	Email:

Booth Choices: 1._____ 2._____ 3._____ 4._____	Total Square Footage:	List any exhibitor(s) you wish to be near: List any exhibitor(s) you do not wish to be near:

Signage

❑ NO, We do not require an identification sign
❑ YES, We do require an identification sign

Product Description

A 60-word description of products or services must be submitted with your application for inclusion in the Program. Descriptions exceeding 60 words may be edited by the AMP administrative office. Please submit online at www.amp.org/2008/exhibitdesc.asp.
❑ 60-word Product Description submitted at www.amp.org by **June 13, 2008**.

Payment of Fees

Full payment must accompany the Exhibitor Application and Contract Form or it will not be processed. Payment may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:

❑ MC ❑ VISA ❑AMEX Credit Card Account #: Expiration Date: *Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.*	❑ Inline 10' x 10', **$3,900** ❑ Corner 10' x 10', **$4,500** ❑ Island 20' x 20', **$18,000** ❑ Non-Profit Inline 10' x 10', **$1,800**
Name on Card:	Signature: Date:

In accordance with the terms, conditions and regulations governing exhibits of the AMP 2008 Annual Meeting at the Gaylord Texan Resort & Convention Center, October 30-November 2, 2008, the undersigned hereby makes application for exhibit space(s) that, when accepted by AMP Exhibit Management, becomes a contract. All rules and regulations as outlined in the AMP Annual Meeting Exhibitor Prospectus, as well as any amendments published by AMP, are part of this contract. Failure to abide by such rules and regulations results in forfeiture of all monies paid AMP Exhibit Management under terms of this agreement.

Signature:	Date:

Deadline for Exhibitor Application and Contracts, description of products or services, and payment: June 13, 2008
Space will be sold on a first-come, first-served basis. Slots will be verified upon receipt of completed application including full payment and description of products or services. IMPORTANT: No booths will be held or assigned with out required full pre-payment & company description. Submit your 60-word description of products and services at www.amp.org/2008/exhibitdesc.asp

Please submit completed Exhibitor Application and Contract with payment to:
Maricel M. Herrera, CMP
Director, Meetings and Membership Services
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7939 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org

Exhibit Space Cancellation Policy: All exhibit space cancellations must be received in writing by AMP Exhibit Management (Maricel M. Herrera, CMP).

- Cancellations received on or before **July 30, 2008** qualify for a 90% refund of all monies paid for booth space rental.
- Any company cancelling its booth space between **July 31, 2008** and **August 29, 2008**, will forfeit 50% of the total cost of exhibit space rental.
- Any company cancelling after **August 29, 2008** will forfeit full exhibit space payment

2008 Association for Molecular Pathology 14th Annual Meeting and Exhibits
October 30 - November 2, 2008, Gaylord Texan Resort & Convention Center

Corporate Workshop Application Form

Corporate Workshops Day: Thursday, October 30, 2008
Deadline: June 13, 2008

A full day of corporate sponsored workshops will take place on Thursday, October 30, 2008. Meeting rooms have been reserved for workshop presenters at the Gaylord Texan Resort & Convention Center, in Grapevine, Texas. The fee for each workshop is $3,500 per hour. This fee includes basic audiovisual setup for the room. Catering arrangements should be made directly with the hotel and will be billed directly to you. Up to four workshops will run concurrently during the morning and afternoon sessions. **Please fax your completed Corporate Workshop Application Form to Maricel Herrera by June 13 so that we can work with you to arrange a schedule that most benefits presenters and attendees (minimizing topic overlaps or other conflicts).** This will allow us to provide early notification to our membership and meeting attendees about your workshop for early registration and travel planning purposes. We can also put you in touch with our contact at the Gaylord Texan Resort & Convention Center for other necessary arrangements.

Company:	
Contact Individual(s):	
Address:	Telephone:
	Fax:
	Email:
Title of Workshop you are interested in presenting:	
Maximum number of attendees:	Targeted number of attendees:
How long will the workshop last? (NOTE: $3,500 per hour -includes a basic audio visual setup (Screen, LCD Projector, Podium Mike) ❑ 1 Hour ❑ 2 Hours ❑ 3 Hours	
Format you prefer (please check one): Requested Time Slot: ❑ Classroom ❑ Theater ❑ Demonstration w/6 ft tables ❑ Include _____ Head table(s)	
Special Requirements (electricity, sink, etc.) and Other Information (these requirements will be forwarded to the contact person at the convention services department so they can coordinate with you): **IMPORTANT: Final arrangements must be confirmed directly with the hotel representative.**	
Full payment must accompany this application form for consideration. Payments for Corporate Workshops may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:	
❑ MC ❑ VISA ❑ AMEX	Credit Card Account #: Expiration Date: *Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.*
	❑ 1 Hour Workshop, **$3,500** ❑ 2 Hour Workshop, **$7,000** ❑ 3 Hour Workshop, **$10,500**
Name on Card:	Signature: Date:

A one paragraph description of your workshop (~100 words) must be submitted online at www.amp.org/2008/wkdesc.asp by June 13, 2008. This description will be used for distribution to AMP members, posting on the AMP website's meeting section, in the AMP Newsletter, and publication in the meeting program.

Space will be sold on a first-come, first-served basis. Slots will be verified upon receipt of completed application including full payment and workshop description. Preliminary schedule/assigned time slot will be provided approximately 30 days after submission deadline.

Please submit the completed Corporate Workshop Application Form to:
Maricel M. Herrera, CMP
Director, Meetings and Membership Services
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7939 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org

Exhibit Space Cancellation Policy: All exhibit space cancellations must be received in writing by AMP Exhibit Management (Maricel M. Herrera, CMP).

- Cancellations received on or before July 30, 2008 qualify for a 80% refund of all monies paid for booth space rental.
- Any company cancelling its booth space between July 31, 2008 and August 29, 2008, will forfeit 50% of the total cost of exhibit space rental.
- Any company cancelling after August 29, 2008 will forfeit full exhibit space payment

2008 Association for Molecular Pathology 14th Annual Meeting and Exhibits
October 30 - November 2, 2008, Gaylord Texan Resort & Convention Center

Sponsorship Opportunities Form

Deadline: September 12, 2008

Activity sponsorship will be individually recognized in the meeting program, on the AMP website, and on signage.
NOTE: All sponsorships for the following activities are credited toward your Corporate Partnership.
Some activities may be fully or partially sponsored. Activities available for sponsorship include:

Event		Full Sponsorship	Partial Sponsorship
Dining Events Sponsorship	Continental Breakfast – Friday, 10/31	☐ $ 5,000	☐ $ 2,500
	Continental Breakfast – Saturday, 11/1	☐ $ 5,000	☐ $ 2,500
	Continental Breakfast – Sunday, 11/2	☐ $ 5,000	☐ $ 2,500
	Morning Coffee Break – Friday, 10/31	☐ $ 2,000	☐ $ 1,000
	Morning Coffee Break – Saturday, 11/1	☐ $ 2,000	☐ $ 1,000
	Morning Coffee Break – Sunday, 11/2	☐ $ 2,000	☐ $ 1,000
	Lunch – Friday, 10/31	☐ $12,000	☐ $ 6,000
	Lunch – Saturday, 11/1	☐ $12,000	☐ $ 6,000
	Afternoon Coffee Break – Friday, 10/31	☐ $ 2,000	☐ $ 1,000
	Afternoon Coffee Break – Saturday, 11/1	☐ $ 2,000	☐ $ 1,000
Event/Activity		**Full Sponsorship**	**Partial Sponsorship**
Scientific Session Sponsorship *The Annual Meeting Preliminary Program is available online at www.amp.org* *Note: You may choose to sponsor a specific Workshop or Special Topics Plenary. Contact Maricel Herrera at mherrera@amp.org*	Plenary Session - Genetics	☐ $ 5,000	☐ $ 2,500
	Plenary Session – Hematopathology	☐ $ 5,000	☐ $ 2,500
	Plenary Session – Infectious Diseases	☐ $ 5,000	☐ $ 2,500
	Plenary Session – Solid Tumors	☐ $ 5,000	☐ $ 2,500
	Plenary Session – Special Topics	☐ $ 5,000	☐ $ 2,500
	Plenary Session – Technical Topics	☐ $ 5,000	☐ $ 2,500
	Workshop – Genetics	☐ $ 2,500	☐ $ 1,500
	Workshop – Hematopathology	☐ $ 2,500	☐ $ 1,500
	Workshop – Infectious Diseases	☐ $ 2,500	☐ $ 1,500
	Workshop – Solid Tumors	☐ $ 2,500	☐ $ 1,500
	Workshop – Special Topics	☐ $ 2,500	☐ $ 1,500
	Workshop – Technical Topics	☐ $ 2,500	☐ $ 1,500
Description		**Sponsorship**	
Trainee Support	Trainee Registration Support	☐ $ 1,000	
Education Grant	Unrestricted Education Grant to Sponsor AMP Activities	☐ $_____ (no minimum)	
Pathology Outreach Course	☐ $10,000 Premier Sponsor - COMMITTED	☐ $ 5,000 Sustaining ☐ $2,500 Supporting	
Cyber Café, Badges, Lanyards, and Hotel Keycards	Cyber Café	☐ $15,000	
	Bottled Water Sponsorship	☐ $15,000	
	Lanyard Sponsorship	☐ $10,000	
	Hotel Room Keycard Sponsorship	☐ $10,000	

Company:

Contact Individual:

Address:

Telephone:

Fax:

Email:

Payment may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:

☐ MC ☐ VISA ☐ AMEX Credit Card Account #: Expiration Date:

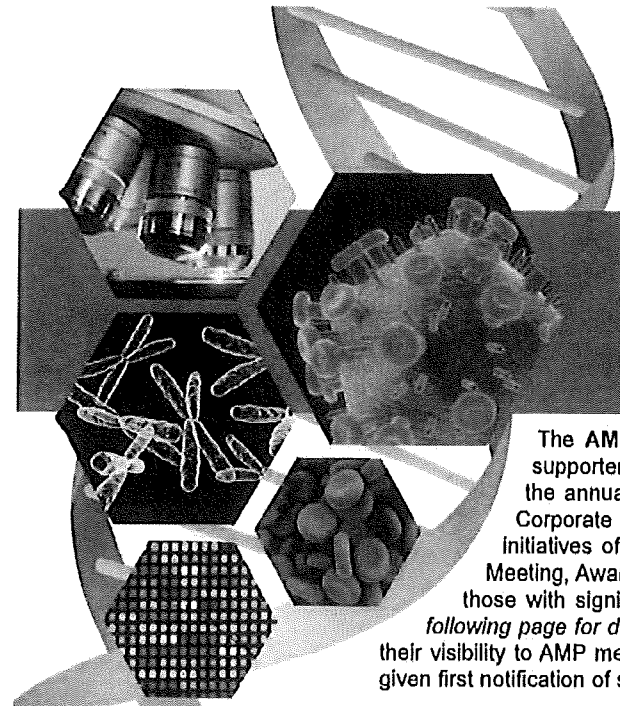
Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.

Name on Card:

Signature: Date:

Thank you for sponsoring an activity at the AMP Annual Meeting. Please send the completed Sponsorship Opportunities Form and payment by September 12, 2008 to:

Maricel M. Herrera, CMP
Director, Meetings and Membership Services
Association for Molecular Pathology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7939 • Fax: 301-634-7990
Email: *mherrera@amp.org* • Web: www.amp.org



Highlighting Your Products and Services to Molecular Laboratory Professionals

ASSOCIATION FOR MOLECULAR PATHOLOGY

AMP Corporate Partners Program

The **AMP Corporate Partners Program** is designed to provide our corporate supporters with additional high-visibility opportunities to highlight their company at the annual meeting, at other AMP educational events, and on the AMP website. Corporate Partnerships are renewable each year and support the educational initiatives of the Association. Contributions received for sponsorship of the Annual Meeting, Awards, AMP Test Directory, and Educational Grants are combined to qualify those with significant interest and investment in AMP as Corporate Partners *(see the following page for details)*. AMP Corporate Partners receive significant benefits that elevate their visibility to AMP members. In addition to the benefits listed below, Corporate Partners are given first notification of selected sponsorship opportunities.

Benefits Include:

AMP Platinum Level Corporate Partner ($30,000)

- A complimentary four-color, full page, priority placement ad in any non-meeting issue of *The Journal of Molecular Diagnostics (JMD)*.
- High Priority booth space location for the Annual Meeting.
- Acknowledgement in advertisements for the Annual Meeting and in the Meeting Program.
- Acknowledgement on the AMP website.
- Acknowledgement in the *AMP Newsletter.*

AMP Gold Level Corporate Partner ($20,000)

- Upgrade ad placement in any non-meeting issue of *JMD*.
- Priority booth space location for the Annual Meeting.
- Acknowledgement in advertisements for the Annual Meeting and in the Meeting Program.
- Acknowledgement on the AMP website.
- Acknowledgement in the *AMP Newsletter.*

AMP Silver Level Corporate Partner ($10,000)

- Preferred booth space location for the Annual Meeting.
- Acknowledgement in advertisements for the Annual Meeting and in the Meeting Program.
- Acknowledgement on the AMP website.
- Acknowledgement in the *AMP Newsletter.*

Current Corporate Partners *(as of 3/10/2008)*

Premium Platinum Level

Roche Diagnostics

Platinum Level

Abbott Molecular

Luminex

Gold Level

Beckman Coulter

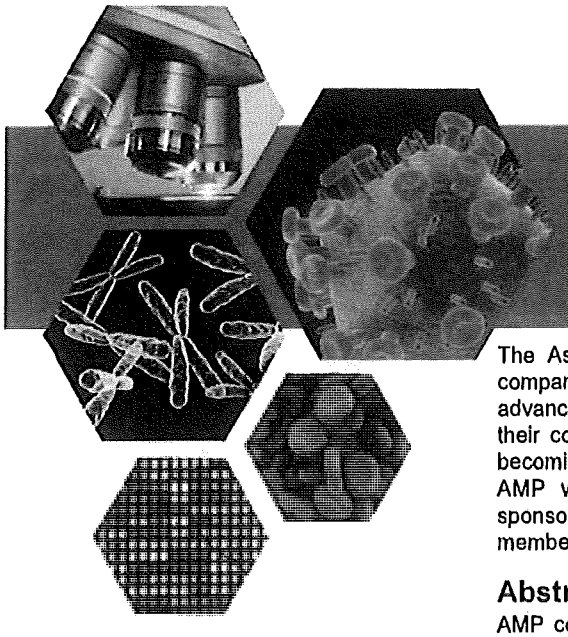
Silver Level

Asuragen

Nanosphere

SEQUENOM

Third Wave Technologies



Highlighting Your Products and Services to Molecular Laboratory Professionals

ASSOCIATION FOR MOLECULAR PATHOLOGY

Sponsorship Opportunities

AMP's primary mission is to advance the practice of clinical molecular laboratory medicine. We welcome all suggestions for additional programs that will help AMP members better serve the health of people around the world.

The Association for Molecular Pathology appreciates the financial support that companies provide for AMP programs. There are numerous opportunities for you to advance the field of molecular diagnostics through AMP. Companies may express their commitment to AMP members and the Association's educational mission by becoming Corporate Partners. Whatever the amount of your resources, however, AMP welcomes your support. Educational activities that receive corporate sponsorship are listed below along with the contact information of the AMP staff member who administers the activity.

Abstract Submission Service

AMP contracts with an online abstract submission service. Your support will help defray the cost of this service. Sponsorship is in three-year cycles.
Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

Annual Meeting

The AMP Annual Meeting is the Association's most important educational event. Numerous sponsorship opportunities exist to support the scientific sessions, receptions, meeting bags, program book, lead retrieval service, lanyards, Internet café, lunches, and breaks.
Contact: Maricel Herrera at *mherrera@amp.org* or (301) 634-7400

Awards

AMP honors individuals at various stages of their careers through several prestigious awards: The AMP Award for Excellence in Molecular Diagnostics, AMP Leadership Award, Young Investigator Award, and Technologist Award. Sponsorship is in three-year cycles.
Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

Pathology Outreach

The AMP Training & Education Committee hosts educational initiatives for non-molecular laboratory professionals. These are exciting opportunities to facilitate the growth of molecular diagnostics in mainstream laboratory services.
Programs include:

- Directory of AMP member speakers for local seminars. (support the directory and/or local seminars)
- Pathology Outreach Course, scheduled just prior to the Annual Meeting.

Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

AMP Test Directory

www.amptestdirectory.org

The AMP Test Directory is a popular online directory of molecular tests. Sponsorship is in two-year cycles.
Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

Molecular Pathology Essentials: Principles and Practice

This 2½ day course will focus on the essential knowledge and current practice of clinical molecular pathology, with an emphasis on case-based examples and technologies. Topics to be presented include molecular diagnostic testing for genetic disorders, cancer, infectious diseases, pharmacogenetics, identity testing, and laboratory regulations and management.
Contact: Mary Steele Williams at *mwilliams@amp.org* or (301) 634-7921

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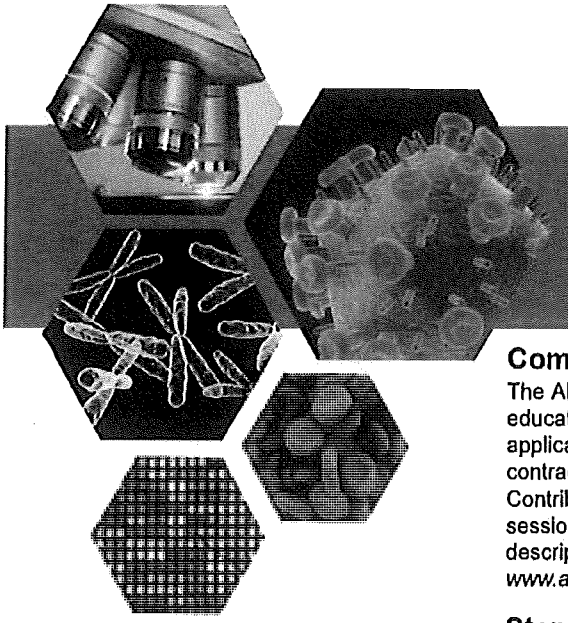
www.amp.org



Highlighting Your Products and Services to Molecular Laboratory Professionals

ASSOCIATION FOR MOLECULAR PATHOLOGY

AMP Corporate Partners Program

Commitment Form

The AMP Corporate Partners Program is a sponsorship of the Association and its educational initiatives through educational grants. A completed and approved application is required to begin implementation of benefits. Corporate Partners contracts are renewable each year. AMP is a 501(c)3 not-for-profit organization. Contributions may be designated to support specific activities such as particular sessions at the annual meeting and/or other sponsorship opportunities. Complete descriptions of sponsorship opportunities are available on the AMP website at *www.amp.org.*

Step 1

Provide contact information and choose your Corporate Partnership Level:

Organization/Company_____

Contact Name_____

Address_____

City_____State/Province_____Zip_____

Country_____

Tel_____

Fax_____

Email_____

Please Select Your Corporate Partnership Level:

- ❑ Platinum Partnership, $30,000/year
- ❑ Gold Partnership, $20,000/year
- ❑ Silver Partnership, $10,000/year

Signature_____ Date_____

Step 2

Send this application to Mary Steele Williams *(see address/fax at left).* She will be your primary contact at AMP and will arrange a time to discuss your preferred sponsorship activities.

Do you have questions regarding the AMP Corporate Partners Program?
To discuss activities available for sponsorship or how to best designate your Corporate Partner contribution, contact Mary Steele Williams, Tel: (301) 634-7921 or Email: *mwilliams@amp.org.*

Association for Molecular Pathology
9650 Rockville Pike
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www.amp.org

AMP 14th Annual Meeting & Exhibits

Oct. 30 - Nov. 2, 2008 - Grapevine, Texas (USA)

Your single best opportunity to reach hundreds of molecular laboratory professionals!

ILLUM-0435

First Name	Last Name	Title	Company	Phone	Mobile Phone	Fax	Email
Richard	Scuderi		Pacific Rim Pathologists	(858) 337-7174			ricscu@gmail.com
Arturo	Mendoza		Sharp Memorial Hospital	(858) 939-3660		(858) 939-3647	art.mendoza@sharp.com
Mike	Armstrong		Pacific Rim	(619) 295-0964		(619) 295-0853	marmstrong8@dcox.net
Mark	Lovell		The Children's Hospital	(720) 777-5468		(720) 777-7119	lovell.mark@tchden.org
Paula	Revell		Texas Children's Hospital Baylor College of Med	(832) 824-1873		(832) 825-0164	parevell@texaschildrens.org
Ruth Ann	Luna		Baylor College of Medicine				raluna@bcm.tmc.edu
Su	Chen		M D Anderson Cancer Center	(713) 792-2576		(713) 794-4773	sschen@mdanderson.org
Kasinathan	Muralidharan		Quest Diagnostics-Nichols Institute	(703) 802-7172		(703) 802-7172	kasinathan.x.muralidharan@questdiagnostics.com
John	Jessup		National Cancer Institute	(301) 435-9010		(301) 402-7819	jessupj@mail.nih.gov
Ross	Haynes		NIST	(301) 975-4469		(301) 975-8505	ross.haynes@nist.gov
William	Benjamin Jr.		U Alabama at Birmingham Medical Center	(205) 934-6421		(205) 975-4468	bbenjami@uab.edu
Voncia	Arterberry		Quest Diagnostic Nichols Institute	(703) 802-6900		(703) 802-7153	voncia.x.arterberry@questdiagnostics.com
Jeffrey	Hung		SABiosciences				jhung@sabiosciences.com
Michael	Hafez		Johns Hopkins University Hospital	(410) 955-1438		(410) 614-7440	mjhafez@aol.com
Mark	Raffeld		NIH NCI	(301) 496-1569		(301) 402-2415	mraff@box-m.nih.gov
Donna	Wolk		University of Arizona	(520) 626-3676		(520) 694-7329	dwolk@email.arizona.edu
Marilyn	Owens		Caris Diagnostics	(562) 818-1567			marilynowens@earthlink.net
Yuan	Xue		UCLA	(310) 206-3945			yxue@mednet.ucla.edu
Wilbur	Franklin		Univ of Colorado	(303) 274-3080		(303) 274-3096	wilbur.franklin@uchsc.edu
Lawrence	Crolla		Northwest Community Hospital	(847) 618-6157		(847) 618-6159	lcrolla@nch.org
Christine	Curtis		Case Western Reserve University	(216) 983-1130		(216) 983-1150	christine.curtis@uhhospitals.org
Michael	Wang		University of Missouri	(573) 882-1276		(573) 882-5206	wangmx@health.missouri.edu
Yasuhiro	Otomo		Sysmex	(078) 991-1919			otomo.yasuhiro@sysmex.co.jp
John Greg	Howe		Yale University School of Medicine	(203) 737-4237		(203) 688-7340	john.howe@yale.edu
Lei	Li		Pfizer Global Research & Development CT				lei.li@pfizer.com
Ivan	Brandslund	Manager for Laboratorie Centre	Vejle Sygehus	+45 7940 6500			ivan.brandslund@slb.regionsyddanmark.dk

ILLUM-0346

Vivianna	Van Deerlin		University of Pennsylvania	(215) 662-6550	(215) 662-7529	vivianna@mail.med.upenn.edu
Metin	Taskin		The Valley Hospital	(201) 447-8242	(201) 447-8657	mtaskin@yahoo.com
Cynthia	Jackson		Rhode Island Hospital Brown University	(401) 444-4370	(401) 444-8514	cjackson@lifespan.org
Mai	He		Women & Infants Hospital of Rhode Island	(862) 242-6092		mhe@wihri.org
Oana	Vele		Lenox Hill Hospital	(917) 499-9708		ovele@hotmail.com
Jeremy	Segal		New York Presbyterian Hospital-Cornell	(917) 509-7176		jp2001@ayp.org
Marlene	Sabbath-Solitare		St Barnabas Medical Center	(973) 322-8248	(973) 322-8917	msabbath@sbhcs.com
Marina	Nikiforova		Univ of Pittsburgh	(412) 802-6092	(412) 802-6799	nikiforovamn@upmc.edu
Connie	McGregor		Royal University Hospital	(306) 655-2184	(306) 655-2223	connie.mcgregor@saskatoonhealthregion.ca
Roberta	Madej		[not provided]	(510) 610-0982		rmadej@comcast.net
Narasimhan	Nagan		Genzyme Genetics	(508) 389-8351	(508) 389-5548	narasimhan.nagan@genzyme.com
Joseph	Pulliam		University of Kentucky	(859) 323-5425		joe.pulliam@uky.edu
Steven	Schichman	Assistant Professor	Central Arkansas Veterans Healthcare System Research Service	(501) 257-1000	(501) 257-6441	schichmanstevena@uams.edu
Alain	Troesch		Biomerieux	+33 478 87 7482	+33 478 87 7476	alain.troesch@eu.biomerieux.com
Raymond	Widen		Tampa General Hospital	(813) 844-7882	(813) 844-1312	rwiden@verizon.net
Antonia	Sepulveda	Associate Professor of Pathology	University of Pennsylvania	(215) 615-1752	(215) 614-1988	asepu@mail.med.upenn.edu
Lei Po	Wong		Hong Kong Sanatorium & Hospital			chrislpw@hkucc.hku.hk
Stephanie	Hallam		Allegro Diagnostics	(617) 414-2313	(617) 358-5001	sehallam01@hotmail.com
Judy	Yu		Abbott Molecular, Inc.	(224) 361-7291	(224) 361-7578	judy.yu@abbott.com
Scott	Shell		TMD Quintiles	(630) 203-6223	(630) 789-3765	scott.shell@quintiles.com
Slava	Elagin		Meridian Bioscience	(513) 271-3700	(513) 271-0744	slava.elagin@meridianbioscience.com
Dimitris	Agamanolis		Akron Children's Hospital			dagamanolis@chmca.org
E	Zhang		Princess Margaret Hospital	(416) 340-4800	(416) 340-3596	katzhang@uhnres.utoronto.ca
Jin	Li		Dana-Farber Cancer Institute Harvard Medical School	(617) 632-4119	(617) 582-8213	jli@lroc.harvard.edu

ILLUM-0347

Firstname	Lastname	Addrmsa	Department	Orgname	Address1	Address2	City	Statecd	Zip	Country
Klara	Abravaya	PhD	R&D	Abbott Mole	1300 E. Touhy Avenue		DesPlaines	IL	60018	USA
Vipin	Adhlakha	MS	Dept Marke	Canon Life	9800 Medic	100	Rockville	MD	20850	USA
Daniel	Adlerstein	PhD	Nerviano R	Diasorin SP	Viale Pasteur 10		Nerviano (MI)		20014	ITALY
Mohammad R	Afunian	PhD	Dept of Patl	University o	900 University Ave		Riverside	CA	92507	USA
Dimitris	Agamanolis	MD	Dept of Patl	Akron Child	One Perkins Square		Akron	OH	44308-1062	USA
Sally	Agersborg			Associated	33608 Orte	Bldg A, Executive Area	San Juan Capistran	CA	92675	USA
Arshad	Ahsanuddin	MD	Dept of Patl	Diagnostic	Health Scie	820 Sherbrook St	Winnipeg	MB	R3C 3H3	Canada
Stefanie	Akselrod	MT	Microbiolog	Food Drug	2098 Gaither Road		Rockville	MD	20850	USA
Serhan	Alkan	MD	Dept of Patl	Loyola Univ	2160 S First Ave		Maywood	IL	60153	USA
Jeffrey K	Allen	PhD	Sales and M	BD	7948 Grado El Tupelo		Carlsbad, Ca	CA	92009	USA
Patrice	Allibert	PhD		BD Diagnos	2050 Boul. Rene-Levesque W		Quebec	QC	G1V 2K8	Canada
Mitual	Amin			William Bea	4715 Walden Drive		Troy	MI	48098	USA
Caroline	An			Clarian Hea	7042 Bluffridge Blvd.		Indianapolis	IN	46278	USA
Caroline	An			Clarian Hea	7042 Bluffridge Blvd.		Indianapolis	IN	46278	USA
Bharathi	Anekella	PhD	Molecular B	SeraCare B	217 Perry Parkway		Gaithersburg	MD	20877	USA
M Qasim	Ansari	MD	Dept of Patl	University o	5323 Harry Hines Blvd		Dallas	TX	75390	USA
Mohammad Ali	Ansari-Lari	MD PhD	Pathology C	Memorial H	3501 Johnson Street		Hollywood	FL	33021	USA
Angela	Archer			Novation	125 E John 15th Floor		Irving	TX	75062	USA
Maria	Arcila	MD		Memorial Sl	1233 York / Apt 6J		New York	NY	10065	USA
Catherine	Arnoldi			ViraCor	1001 HW Technology Drive		Lees Summit	MO	64086	USA
Sharon	Arnoldi	BS	Scientific Af	ViraCor Lat	1001 Nw Technology Drive		Lees Summit	MO	64086	USA
Lindsey	Aspden	BS	Dept of Ana	UPMC/Pres	200 Lothrop	S752 Scaife Hall	Pittsburgh	PA	15213	USA
Caroline	Astbury	PhD	Cytogenetic	Nationwide	700 Children's Drive		Columbus	OH	43205	USA
Valerie	August	BS MLT		Valerie Aug	609 West 114th St, Suite 54		New York	NY	10025	USA
Erik	Avaniss-Aghajani	PhD		Primex Clini	16742 Van Nuys, Suite 120		Van Nuys	CA	91406	USA
Carmen	Azurin			New York P	525 E 68th Street		NY	NY	10021	USA
Yosuke	Baba	MS	Life Science	Sysmex Co	1-2-2 Osaki, Shinagawatan		Tokyo		141-0032	Japan
Michael	Babcock	MS MP(AS(	Molecular P	Dahl Chase	428 Essex Street		Bangor	ME	4401	USA
Jonathan F	Baden	MS	Technology	Veridex, A	33 Technology Drive		Warren	NJ	7059	USA
Kenneth	Bahl	PhD		Lurie Invest	440 West Ontario		Chicago	IL	60610	USA
David	Bahler	MD PhD	Dept of Patl	University o	Jmr Building	15 North Medical Drive	Salt Lake City	UT	84112	USA
Yu	Bai	MD PhD	Dept of Patl	U Texas He	6431 Fannii	Msb2.136	Houston	TX	77030	USA
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ILLUM-0348

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ILLUM-0349

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ILLUM-0350

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ILLUM-0351

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ILLUM-0353

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ILLUM-0354

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ILLUM-0355

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ILLUM-0356

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ILLUM-0357

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ILLUM-0358

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ILLUM-0359

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Bevoline	Nwachukwu	BSc MT	Dept of Mol	University H	200 Elizabeth St, Eaton 11-444	Toronto	ON	M5G 2C4	CANADA	
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ILLUM-0360

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ILLUM-0361

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ILLUM-0362

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ILLUM-0363

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ILLUM-0364

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ILLUM-0365

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ILLUM-0366

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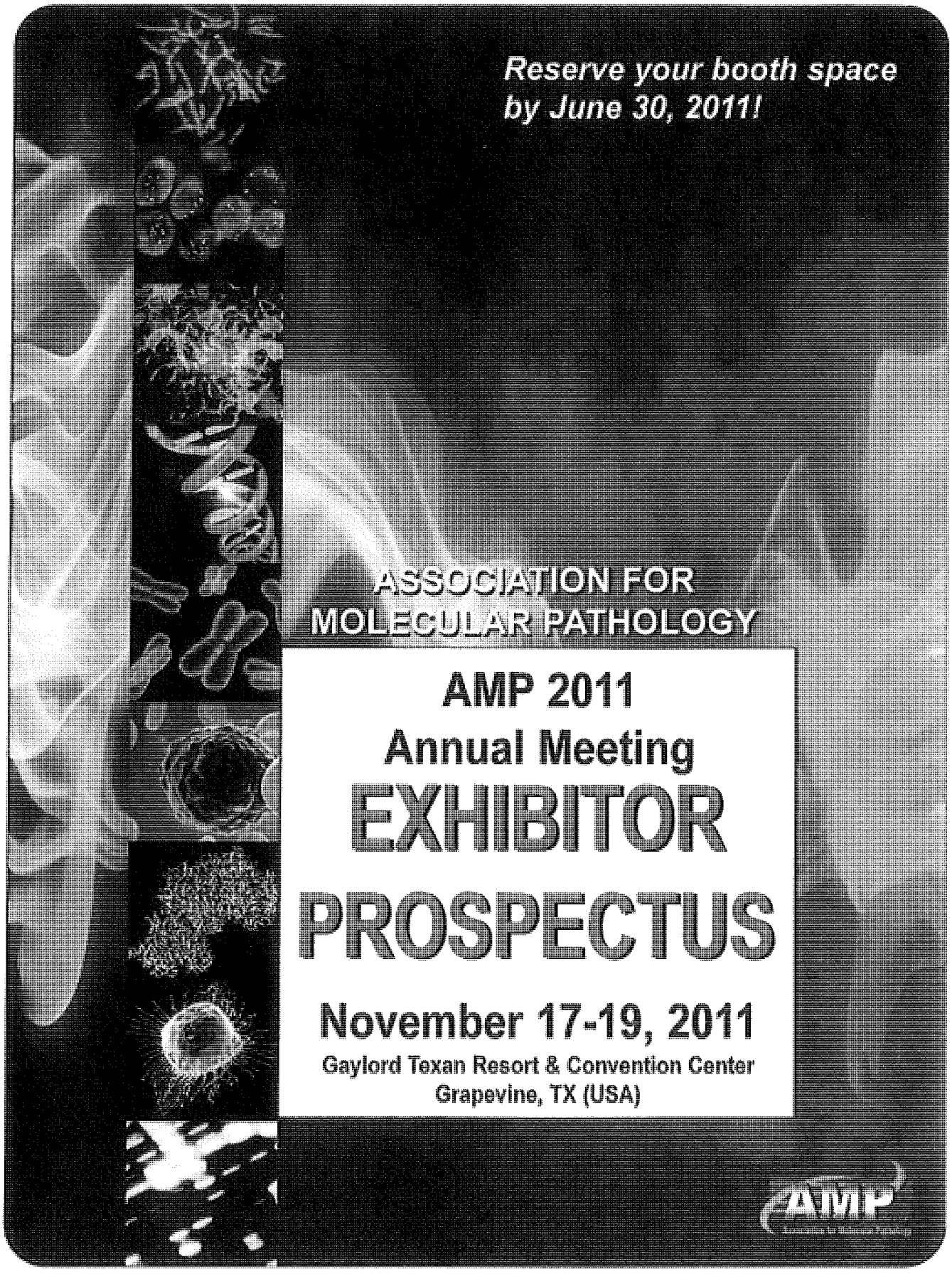
ILLUM-0367

EXHIBIT 5

(Part VII of VII)

OF

DECLARATION OF GREGORY F. HEATH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Corporate Partners Program Commitment	See Form

Booth Fees

10' x 10' Inline *(bounded by front aisle only)*	$ 4,000
10' x 10' Corner *(bounded by a front and side aisle)*	$ 4,750
10' x 20' Inline *(bounded by front aisle only)*	$ 8,000
10' x 20' End Cap *(bounded by aisles on three sides)*	$12,000
20' x 20' Island	$19,000
30' x 30' Island	$39,000
10' x 10' Non-Profit *(inline only)*	$ 2,000

Add $4,000 for each additional inline and $4,750 for each additional corner booth space (10' x 10')

Exhibit Installation

Wednesday, November 16	8:00 am - 4:00 pm
Thursday, November 17*	8:00 am - 10:00 am

**Internal booth work only, no freight delivery*

Exhibit Hours

Thursday, November 17	1:00 pm - 5:00 pm
Friday, November 18	9:00 am - 5:00 pm
Saturday, November 19	9:00 am - 5:00 pm

Exhibitor Registration

Tuesday, November 15	12:00 pm - 6:00 pm
Wednesday, November 16	7:00 am - 6:00 pm
Thursday, November 17	7:00 am - 5:00 pm
Friday, November 18	7:00 am - 5:00 pm
Saturday, November 19	7:00 am - 5:00 pm

Exhibit Dismantling*

Saturday, November 19	5:00 pm - 9:00 pm

* *No packing or dismantling of exhibits will be permitted until **5:00 pm, Saturday, November 19**. Early departure will result in the company or group being penalized including being banned from future AMP Events. When planning your dismantling and departure, please allow no less than three hours for return of all empty shipping materials from storage. AMP strongly recommends that Exhibit Hall staff make appropriate departure plans; i.e. plan to depart on Sunday morning, not Saturday evening.*

HELPFUL LINKS and CONTACT INFORMATION...

AMP Main Website
www.amp.org

AMP 2011 Annual Meeting Website
www.amp.org/meetings/2011

Product Description Form – Due June 30
http://www.amp.org/meetings/2011/exhibit_description.cfm

Corporate Workshop Application Form – Due June 30
http://www.amp.org/meetings/2011/corporate_workshops_descriptions_form.cfm

Exhibitor Badge Form – Due November 1
http://www.amp.org/meetings/2011/exhibits/exhibitor_badges.cfm

Unless otherwise noted, complete and return all forms, and direct all inquiries regarding exhibits, sponsorships, partnerships, and support opportunities to:

Catherine Davidge
Marketing & Web Communications Manager
Association for Molecular Pathology (AMP)
9650 Rockville Pike
Bethesda, MD 20814-3993 (USA)
Phone: 301-634-7400
Fax: 301-634-7990
Email: cdavidge@amp.org

TABLE of CONTENTS...

Prices, Dates, and Deadlines	*Page 1*
Helpful Links and Contact Information	*Page 1*
2010 AMP Annual Meeting Exhibitors	*Page 2*
Booth Reservations and Specifications	*Page 3*
Exhibitor Services and Booth Activities	*Page 4*
Complimentary Promotional Opportunities	*Page 4*
Additional Promotional Opportunities	*Page 4*
Corporate Sponsorship, Workshop, Partner, and Support Opportunities	*Page 5*
Ancillary and Sotellite Events	*Page 6*
Hotel and Travel Information	*Page 6*
Exhibit Hall Floor Plan	*Page 7*
FORMS	
Exhibitor Application and Contract	*Page 8*
Application Checklist	*Page 9*
Corporate Workshop Application	*Page 10*
Sponsorship Opportunities	*Page 12*
Webinar Support Commitment	*Page 13*
Corporate Partner Commitment	*Page 14*

ILLUM-0369

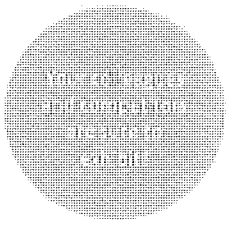
The AMP 2011 Annual Meeting is the only opportunity to connect with more than 1,200 key decision makers involved in every aspect of molecular diagnostics, including:

- Interpretation & Reporting of Molecular Diagnostic Tests
- Assay Development, Validation & Performance
- Translational Research
- Medical Education

AMP Members and Meeting Attendees are Pathologists, Doctoral Laboratory Scientists, Clinicians & Other Health Care Personnel. They are government employees – primarily regulators in the field, and professionals in the in vitro *diagnostics industry.*

AMP Members and Meeting Attendees are experts in the specialty areas of

- Genetic Disorders
- Hematopathology
- Infectious Diseases
- Solid Tumors



Visit *www.amp.org/meetings/2011* for details about this unique event!

2010 AMP ANNUAL MEETING EXHIBITORS...

5 PRIME
Abbott Molecular * ***2010 DIAMOND PARTNER!***
Access Genetics, LLC
Advanced Cell Diagnostics, Inc.
AdvanDx
Affymetrix
Agilent Technologies, Inc
American Society for Clinical Pathology
Applied BioCode, Inc.
Applied Spectral Imaging
Argene Inc
Arista Laboratories
ARUP Laboratories
Asuragen * ***2010 SILVER PARTNER!***
Aurora Biomed, Inc
AutoGenomics, Inc.
Baylor College of Medicine, Medical Genetics Laboratories
BD Diagnostics - Infectious Disease
bioMerieux, Inc.
Bio-Rad Laboratories
Biosearch Technologies
BioView USA Inc.
CBLPath Inc.
Cellay, Inc.
Cepheid
Cerner Corporation
Chemagen USA, Inc
City of Hope - Molecular Diagnostic Lab
Cleveland Clinic Laboratories
Clinical and Laboratory Standards Institute
Clontech Laboratories, Inc.
College of American Pathologists
College of American Pathologists Periodicals
CombiMatrix Diagnostics
CymoGen Dx
Cytocell/RainbowScientific, Inc.
Data Unlimited International, Inc.
Diatherix Laboratories
Elsevier/Saunders/Mosby
Emory Genetics Laboratory
EntroGen Inc.
EPOCH Biosciences, a Division of Wescor, Inc
Eppendorf
EraGen Biosciences
Eurogentec North America, Inc.
Exact Sciences
Exiqon, Inc.
Fisher HealthCare
Focus Diagnostics
Geneuity CRS
Genisphere
GenMark Diagnostics, Inc.
Gen-Probe
GenturaDx
GenVault Corporation
High Throughput Genomics, Inc.
HOLOGIC * ***2010 GOLD PARTNER!***
Idaho Technology, Inc.
iKaryos Diagnostics
Illumina,Inc. * ***2010 SILVER PARTNER!***
IncellDx, Inc.
Innogenetics, Inc
Integrated DNA Technologies
Invivoscribe Technologies
Ion Torrent
IPSOGEN
Laboratory for Personalized Molecular Medicine
Lathrop Engineering Inc.
Life Technologies
Luminex Corporation * ***2010 PLATINUM PARTNER!***
Maine Molecular Quality Controls, Inc.
Mayo Medical Laboratories
Meridian Bioscience, Inc.
MetaSystems
Miltenyi Biotec, Inc
MolecularMD Corp.
MP Biomedicals
MRC-Holland
Nanosphere, Inc. * ***2010 SILVER PARTNER!***
NanoString Technologies
NorDiag, Inc
Omega Bio-tek, Inc
OpGen, Inc
PCPGM - Laboratory for Molecular Medicin
Pathwork Diagnostics
Pharmigene, Inc
PreAnalytiX
PrimeraDx
Promega Corporation
Prometheus Laboratories Inc.
QIAGEN, Inc. * ***2010 GOLD PARTNER!***
QuantaLife
Quidel Corporation
Response Genetics
Rheonix, Inc
Roche Applied Science
Roche Diagnostics * ***2010 DIAMOND PARTNER!***
Sequenom
SeqWright, Inc.
SeraCare Life Sciences, Inc.
Siemens Healthcare Diagnostics * ***2010 PLATINUM PARTNER!***
Signature Genomics
Skyline Diagnostics
SoftGenetics, LLC
STEMCELL Technologies Inc.
STRATEC Biomedical Systems AG
Therapak Corporation
Thermo Scientific NanoDrop Products
TIB Molbiol, LLC
Transgenomic, Inc
TriLink BioTechnologies, Inc.
TrimGen Corporation
University of Washington Reference Lab
Wafergen Biosystems
WI, Inc.
ZeptoMetrix Corporation

BOOTH RESERVATIONS and SPECIFICATIONS...

Exhibit Space Rental
All booths are 10' x 10', 20' x 20' or 30'x 30'. A combination of inline and corner booths may be secured to create an inline booth size larger than 10' x 10' or an end cap booth. Exhibitors wishing to create their own island booths or requesting island space other than those islands that pre-exist on the exhibit floor plan will be charged the full cost of any booths deleted to create such an island (if approved by Exhibit Management and Fire Marshall regulations).

Booth Design
Booths must be designed so that they can be installed and completely removed during published installation and dismantling hours. Failure to comply will result in fees for labor, liability and insurance as determined by Exhibit Management. Any booth design, configuration, and/or height not expressly permitted in this Prospectus requires advance written permission from Exhibit Management.

Each exhibit space will have an 8' high back wall and 3' high side dividers defining the sides of the space. A booth identification sign measuring 7" x 44" and showing only the company name will also be supplied with all booths.

IMPORTANT:

- Exhibiting companies are required to purchase carpeting for their booth area.
- Inline booths are arranged in a straight line. The back wall of any construction in a linear booth shall not exceed 8' in height including signage. All display material is restricted to a maximum height of 4' in the front half or front 5' of the booth and a maximum of 8' in the rear half or the rear 5' of the booth. Side dividers are 3' high.
- Maximum height for all island booths, including signage is 16'. Excessive visual obstructions are prohibited at the discretion of Exhibit Management.
- All displays, booth elements, and other exhibit materials including roofing and floor covering, must be contained within the confines of the booth dimensions. No exhibit may span or extend into an aisle.

Booth Space Reservations
Booth spaces may only be reserved by receipt of completed Exhibitor Application & Contract and full payment for booth space.

Reserve your booth space by June 30!

Subletting / Sharing Exhibit Space
Subletting or sharing any part of the exhibit space by an exhibitor is prohibited.

Co-Marketing
If two or more companies wish to be assigned exhibit space adjacent to one another, *each company* must include a written request along with the completed Exhibitor Application and Contract form. Space application forms and written requests to co-market must be submitted as one packet, not individually by each company.

Exhibit Management will review and approve or deny applications for co-marketing on a case-by-case basis based on the best use of overall floor space. Applications that arrive separately or after the deadline of **June 30, 2011** will not be honored.

If two or more divisions of a company wish to exhibit in one booth space, they must exhibit under one company name. All badges and Exhibitor Guide listings will be conducted in one name only. Multiple listings for one booth space are not permitted.

Non-Contracted Exhibit Space
Persons, companies or organizations that have not contracted with AMP to occupy space in the Exhibit Hall will not be permitted to display or demonstrate products, processes, or services, solicit orders, or distribute advertising materials in the Gaylord Texan Hotel & Convention Center, parking lots or any hotel contracted by AMP.

Exhibit Hall Reconfiguration and Booth Relocation
Generally, Exhibit Management does not reconfigure the Exhibit Hall but reserves the right to do so. AMP reserves the right to relocate booth space to areas other than that selected by the exhibitor. Relocations will be made only upon notification to the exhibitor by Exhibit Management. Management strives for, but cannot guarantee, that a company will not be located near a competitor.

Booth Space Cancellation or Space Reductions

- All notifications of exhibit space cancellations or reductions must be received in writing by Exhibit Management.
- Cancellations received on or before **August 15, 2011**, qualify for a 75% refund of all monies paid for booth space rental.
- Any company cancelling its booth space between **August 16, 2011** and **September 15, 2011**, will forfeit 50% of the total cost of exhibit space rental.
- Any company cancelling after **September 15, 2011**, will forfeit full exhibit space payment.

Note: Reduction of island space dimensions after assignment has been confirmed may result in relocation of the exhibit booth. AMP may cancel exhibitor rooms and room blocks held by a company cancelling or reducing booth space.

EXHIBITOR SERVICES and BOOTH ACTIVITIES...

Official Services Contractor
The Expo Group has been selected as the official services contractor for the AMP 2011 Annual Meeting. Exhibitor Service Kits will be mailed to all exhibitors in August 2011. They may be contacted at 5931 West Campus Circle Drive, Irving, TX 75063 USA Phone: 972-580-9000 FAX 972-465-1187. Those using the services other than those provided by The Expo Group must notify Exhibit Management no later than **September 15, 2011**.

Electronic Lead Retrieval
Attendees at the AMP 2011 Annual Meeting will carry electronically coded name badges. Lead retrieval services will be provided by Trade Show Leads. Lead retrieval service order forms will be included in the Expo Group Exhibitor Service Kit.

Exhibitor Badges
Exhibitor badges must be worn at all times and allow access to the Exhibit Hall and Plenary Sessions *only*. Exhibiting companies will receive six badges per 10' x 10' booth space. Additional Exhibitor badges will be available at a fee of $50.00 each. Exhibitor name badge requests must be submitted via the online form at www.amp.org/meetings/2011/exhibits/exhibitor_badges.cfm.

Guest of Exhibitor Badges
Each exhibiting company will be entitled to six Guest of Exhibitor badges; the Guest badges will be available for pick up at registration by the designated company representative. Guest of Exhibitor badges allow for access to the Exhibit Hall, *only*.

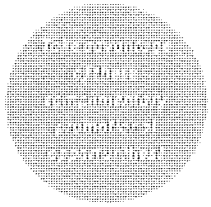
Giveaways and Booth Activities
Exhibiting companies are permitted to distribute promotional materials (giveaways) and other items at their assigned Exhibit Booth location only. All items distributed must be useful to the professional activities of the meeting attendees, have a value of $10.00 or less per item and be made available to all meeting attendees as long as supplies last.

Companies wishing to conduct contests or drawings should contact the Exhibit Management by email at cdavidge@amp.org or by phone at 301-634-7400 for guidelines and permission. No soliciting of registrants is permitted in the aisles, at other exhibitor's booths, or in any other area of the meeting and exhibit facility. No distribution of literature or other promotional items at hotel guestrooms, or in any other public or private area of the hotel is permitted.

Sale of Goods
The sale of goods or services of any kind in the Exhibit Hall in connection with the Annual Meeting is prohibited. Order taking is permitted.

COMPLIMENTARY PROMOTIONAL OPPORTUNITIES...

On-Site Program Listing
Exhibitors must provide a 60-word product description to be included in the Exhibit Guide. This guide is distributed to all meeting attendees. The opportunity to advertise your products and services is complimentary and is available only to AMP's exhibitors. Product description must be submitted by **June 30, 2011.**



Post-Meeting Registration List
AMP will provide a complete registration list to exhibitors within 30 days of completion of the Annual Meeting. This list will be available through **December 15, 2011**. The registration list will be a read-only PDF file and does not include email addresses. The information is the sole property of AMP and cannot be reproduced in any form without express written permission. Pre-registration lists are not available.

ADDITIONAL PROMOTIONAL OPPORTUNITIES...

The Journal of Molecular Diagnostics (JMD)
Editor-in-Chief: Timothy J. O'Leary, MD, PhD, Veterans Health Administration, Washington, DC
JMD is the official publication of the Association for Molecular Pathology, co-published with the American Society for Investigative Pathology, publishes high-quality original papers on scientific advances in the translation and validation of molecular discoveries in medicine into the clinical diagnostic setting, and the description and application of technological advances in the field of molecular diagnostic medicine.

JMD Annual Meeting/Abstracts Issue: November 2011. *This issue is distributed to every AMP Attendee and Exhibitor!* Insertion orders and materials are due September 27, 2011. View the rate card online at http://mediakits.elsevier.com/journalDetail.php?jrn_id=00000575

To advertise in *JMD*, contact Aileen Rivera, Integrated Sales Representative, Elsevier, Tel: 212-633-3721, Fax: 212-633-3820, Email: a.rivera@elsevier.com.

Additional Promotional Opportunities continued...

AMP Membership List

Exhibitors are entitled to a 50% discount for a one-time use of the AMP Membership Mailing List (approximately 1,700 names & addresses) for use in advertising their products and services. (Email addresses are not provided.) Requests must be made via email to Catherine Davidge at *cdavidge@amp.org* no later than **September 30, 2011.**

Meeting Program Book Display Advertising

Reach every attendee while they are at the 2011 AMP Annual Meeting and long after the close of the event! Program Book display ads are a great way to keep your product or service "top of mind."

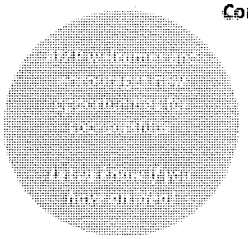
Program Book Ad Rates	Standard Rate	*Discounted as Noted*
Back Cover of Meeting Program - Color, 7" x 10"	$3,000	$1,500
Inside Front or Back Cover - color, 7" x 10"	$2,300	$1,150
Full page b/w only, 7" x 10"	$1,250	$ 750
Page Horizontal - b/w only, 7" x 4.75"	$1,000	$ 500
1/2 Page Vertical - b/w only, 3.25" x 10"	$1,000	$ 500
1/4 Page Vertical - b/w only, 3.25" x 4.75"	$ 750	$ 375

Specifications

Color Ad: PDF (embed fonts), jpg, or tif
Black and White Ads: 300 dpi tif, pcx, or PDF (embed fonts)

Program Insertion orders and materials due September 15, 2011

CORPORATE SPONSORSHIP, WORKSHOP, PARTNER, and SUPPORT OPPORTUNITIES...



Corporate Sponsorships

Expand your company's reach by sponsoring activities, events, and sessions at the AMP Annual Meeting! Sponsorship opportunities include dining events, coffee breaks, plenaries, symposia, and workshops. Also available for sponsorship are attendee services, such as an iPod App, notepads, pens, and social events. Companies providing sponsorship will be individually recognized in the AMP Meeting Program, on the AMP Website, and via signage at the event. To sponsor an activity or service at AMP 2011 Annual Meeting, complete and return the Sponsorship Opportunities Form (page 11) with payment no later than **September 30, 2011.**

Corporate Workshops

A full day of Corporate Workshops will take place on Wednesday, **November 16, 2011.** Meeting rooms have been reserved for these gatherings at the Gaylord Texan Hotel & Convention Center. The cost to host a workshop is $3,500 per hour and includes basic audio visual setup. Catering arrangements should be made directly with the hotel and will be billed directly to you. Workshops will run concurrently during the morning and afternoon AMP sessions.

Deadline for submitting the completed **Corporate Workshop Application Form** on page 10 including the title and description is **June 30, 2011.** AMP aims to collaborate with your company by creating a program that most benefits presenters and attendees (minimizing topic duplications or other conflicts). By submitting the completed Corporate Workshop Application Form by **June 30, 2011** AMP will be able to provide early notification to our membership and meeting attendees about your workshop for early registration and travel planning purposes. We can also put you in touch with our contact at the Gaylord Texan Hotel & Convention Center for other necessary arrangements. A schedule and full description of Corporate Workshops will be posted on the AMP website at www.amp.org, and in the Fall 2011 *AMP Newsletter.*

Corporate Partners

The AMP Corporate Partners Program is designed to provide our corporate supporters with additional high-visibility opportunities to further promote their company at the annual meeting, other AMP educational events, and on the AMP Website.

Benefits of corporate partnership include preferred or priority booth assignments, special recognition on the AMP Website with your company's logo and a link to the website, as well as acknowledgement in the AMP Annual Meeting review issue of the AMP Newsletter. These benefits are just the beginning. Refer to the Corporate Partners Commitment form on page 14 of the Exhibitor Prospectus, or contact Catherine Davidge at AMP by email at cdavidge@amp.org or by phone at 301-634-7400. *See page 11 for details about the Corporate Partners Program.*

Corporate Supporters

AMP invites and appreciates the financial support that companies provide for AMP programs. Corporate support opportunities include the abstract submission service, awards, pathology outreach, and webinars. Contact Catherine Davidge for details about AMP's Corporate Support Opportunities.

ILLUM-0373

ANCILLARY and SATELLITE EVENTS...

Ancillary events are non-AMP events held immediately before or after the AMP Annual Meeting dates of November 17-19, 2011. Satellite events are non-AMP events held during the AMP Annual Meeting dates, in either the morning or evening - before or after the official AMP sessions and social events of the day.

Individuals and organizations are welcome to host ancillary and satellite events provided they *do not conflict* with any official AMP scientific sessions or sponsored social events. Refer to the schedule online at www.amp.org/meetings/2011 for the most current AMP schedule.

To host an ancillary or satellite event, contact Catherine Davidge at AMP by email at cdavidge@amp.org or by phone at 301-634-7400. Requests must be received no later than June **30, 2011.**

Ancillary and Satellite Event Rules and Regulations:

1. All ancillary and satellite events must be approved in advance by Exhibit Management.
2. AMP will not assist with the planning, funding, or management of ancillary or satellite events. Hosts are responsible for all arrangements and costs associated with their events which may include: room rental, audiovisual equipment, food and beverages.
3. Space *may* be leased from AMP at the contracted hotel(s) on a first-come, first-served basis. There will be an administrative fee charged to the host for any space released by AMP for an ancillary or satellite event. Note – commercial companies requesting space from AMP must be contracted to exhibit at the AMP 2011 Annual Meeting. Space will not be released to non-exhibiting companies.
4. Cancellation of Exhibit Booth space will result in automatic cancellation of ancillary or satellite event.
5. Should the purpose for any ancillary or satellite event be misrepresented to Exhibit Management, the sponsoring organization will be penalized by AMP, including being suspended from participation in future AMP events.
6. Ancillary events must not conflict with the timing of AMP scientific sessions as outlined in the preliminary meeting schedule. (AMP is not responsible for subsequent schedule changes made by the Program Committee and will inform organizers if their requested time must be changed).
7. To be listed in the AMP 2011 Meeting Program and on the AMP Website, all details including the title, time, date, and location must be provided to AMP no later than **September 15, 2011.**
8. Signs, brochures, and other advertising materials are not permitted in any of the public areas of the convention center or hotel. Any such signage will be removed. Signs can be displayed outside the meeting room on the day of the event.
9. Organizers will be informed of their confirmed room assignment in September 2011.

HOTEL and TRAVEL INFORMATION...

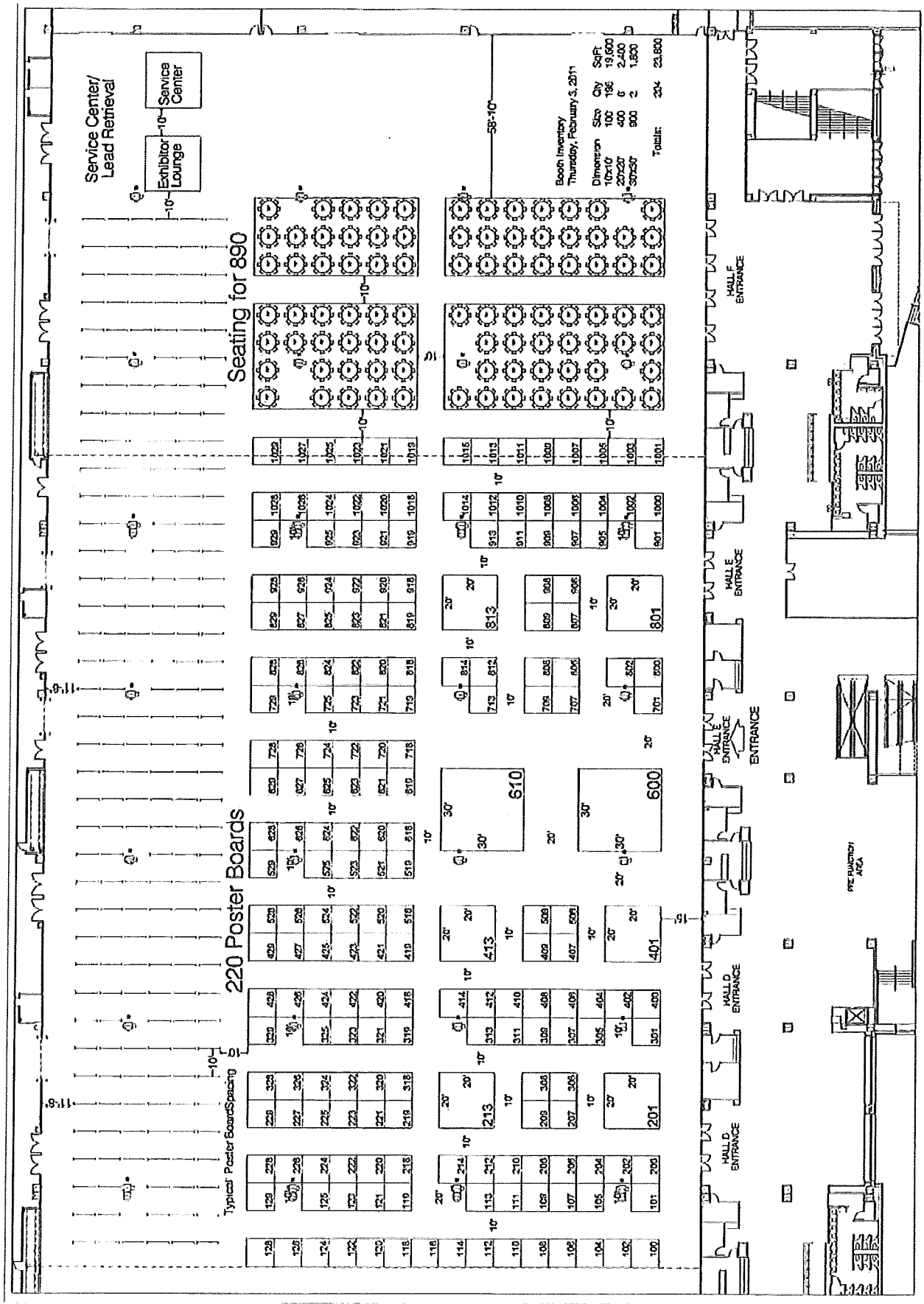
Hotel Accommodations
Accommodations will be provided for exhibitors and attendees at the Gaylord Texan Hotel & Convention Center (where sessions will be held) located at 1501 Gaylord Trail, Grapevine, TX 76051. For rates, availability, location and reservation information please visit www.amp.org/meetings/2011/hotel.cfm. For general information, visit the Gaylord Texan Hotel & Convention Center Website at: http://www.gaylordhotels.com/gaylordtexan/.

NOTE: Full payment is due upon reservation for all rooms and nights. This requirement has become necessary due to room cancellations by exhibitors in the past, resulting in many thousands of dollars in attrition penalties for AMP. We appreciate your cooperation and understanding.

Air Travel Discounts
The Gaylord Texan Resort & Convention Center is located in Grapevine, TX a short ten minute ride from the Dallas-Fort Worth International Airport. American Airlines is offering a discount of up to 10% on airfare, plus other travel discount options to and from the AMP Annual Meeting. The percentage discount can be booked online at www.aa.com/group or by phone at 800-433-1790 through the AA Group Sales Reservation Desk. Please mention the star file **A63N1AU** (AMP Annual Meeting) to receive your special fare.

Ground Transportation & Car Rentals
Avis Rent-A-Car will be providing rental discounts to our group for ground transportation. To make rental car reservations, call the Avis Convention Desk directly at 888-754-8878. The desk is available to assist you twenty-four hours a day. Please mention the group file **AWD# D086607** to obtain the best possible car rental rates available.

The Gaylord is just minutes from Dallas-Fort Worth International Airport. Cab fare to the hotel from the airport is roughly $30.00. Shuttle service is available as well for $15.00. Visit the Gaylord Texan Hotel & Convention Center Website at http://www.gaylordhotels.com/gaylordtexan/ for more information.


Service Center/
Lead Retrieval
Service Center
Exhibitor Lounge
Seating for 890
220 Poster Boards
Typical Poster BoardSpacing
Booth Inventory
Thursday, February 3, 2011
Dimension
Size
Qty
SqFt
10x10
100
196
19,600
20x20
400
6
2,400
30x30
900
2
1,800
Totals:
234
23,800
58'-10"
HALL F ENTRANCE
HALL E ENTRANCE
HALL D ENTRANCE
ENTRANCE
PRE FUNCTION AREA
610
600
813
801
413
401
213
201

Exhibitor Application and Contract

Exhibit Days: November 17-19, 2011
Deadline: June 30, 2011

Company Name: *(Please list company name as you would like it to appear in the AMP 2011 program, exhibitor badges and any required signage)*		
Primary Contact Individual: *(This person will receive all AMP 2011 exhibitor correspondence)*		
Address:		Telephone:
City:	State/Province:	Fax:
Zip/Postal Code:	Country:	Email:
Booth Choices: 1._____ 2._____ 3._____ 4._____	Alternate Contact Person (Name and Email)	
❑ We plan to Co-Market with:_____(company name). We wish to be placed in adjacent booth spaces. Letters of request attached.	List any exhibitor(s) you wish to be near:	
❑ Special booth configuration request attached.	List any exhibitor(s) you do not wish to be near:	

Signage ❑ NO, we do not require an identification sign ❑ YES, we do require an identification sign

Product Description

❑ A 60-word description of products or services is requested for inclusion in the Meeting Program. Descriptions exceeding 60 words may be edited by AMP. Submit online at www.amp.org/meetings/2011/exhibit_description.cfm by **June 30, 2011.**

Booth Fees *(Refer to Exhibit Hall Floor Plan)*

- ❑ 10' x 10' Inline.....$ 4,000 *(bounded by front aisle only)*
- ❑ 10' x 10' Corner.....$ 4,750 *(bounded by a front and side aisle)*
- ❑ 10' x 20' Inline.....$ 8,000 *(bounded by front aisle only)*
- ❑ 10' x 20' End Cap.....$ 12,000 *(bounded by aisles on three sides)*
- ❑ 20' x 20' Island.....$19,000
- ❑ 30' x 30' Island.....$39,000
- ❑ 10' x 10' Non-Profit *(Inline only)* $ 2,000
- ❑ Other *(Size and Cost)*_____

Add $4,000 for each additional inline and $4,750 for each additional corner booth space (10' x 10')

Payment of Fees

Full payment must accompany the Exhibitor Application and Contract Form or it will not be processed. Payment may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:

❑ MC ❑ VISA ❑ AMEX Expiration Date:

Account #:

Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.

Name on Card:	Signature:	Date:

In accordance with the terms, conditions and regulations governing exhibits of the AMP 2011 Annual Meeting at the Gaylord Texan Resort and Convention Center in Grapevine, TX November 17-19, 2011 the undersigned hereby makes application for exhibit space(s) that, when accepted by AMP Exhibit Management, becomes a contract. All rules and regulations as outlined in the AMP Annual Meeting Exhibitor Prospectus, as well as any amendments published by AMP, are part of this contract. Failure to abide by such rules and regulations results in forfeiture of all monies paid AMP Exhibit Management under terms of this agreement.

By signing below, I confirm that I have read, understand, and accept these terms, conditions, and regulations.

Signature:	Date:

Deadline for Exhibitor Application and Contracts, description of products or services, and payment: June 30, 2011
Space will be sold on a first-come, first-served basis. Booth space will be verified upon receipt of completed application including full payment and description of products or services. IMPORTANT: No booths will be held or assigned without required full pre-payment & company description. Submit your 60-word description of products and services at www.amp.org/meetings/2011/exhibit_description.cfm.

Please submit completed Exhibitor Application and Contract with payment to:

Catherine Davidge
Marketing & Web Communications Manager
Association for Molecular Pathology
Suite E133
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7400 • Fax: 301-634-7990
Email: *cdavidge@amp.org* • Web: www.amp.org

Exhibit Space Cancellation Policy: All exhibit space cancellations must be received in writing by AMP Exhibit Management (Catherine Davidge).

- Cancellations received on or before **August 15, 2011** qualify for a 75% refund of all monies paid for booth space rental.
- Any company cancelling its booth space between **August 16, 2011** and **September 15, 2011**, will forfeit 50% of the total cost of exhibit space rental.
- Any company cancelling after **September 15, 2011** will forfeit full exhibit space payment

Exhibitor Application and Contract Checklist

The following items must be completed prior to submission:

- ❑ **Full company name** to be published on all materials is clearly noted (please print clearly or type to omit any errors)
- ❑ **One primary and one alternate contact persons** are noted on your application for AMP to communicate all necessary information regarding the meeting and exhibits
- ❑ **60 word Product Description** has been submitted: www.amp.org/meetings/2011/exhibit_description.cfm
- ❑ **Preferred booth space selection(s)** and booth type have been noted
- ❑ **Full payment** is provided either by credit card information listed on application or accompanying check
- ❑ **Corporate Workshop Application** submitted (if applicable)
- ❑ **Sponsorship Opportunities Request submitted** (if applicable)

Corporate Workshop Application Checklist

The following items must be completed prior to submission:

- ❑ Full **workshop title** has been included on application form
- ❑ **One primary and one alternate contact persons** are noted on your application for AMP to communicate all necessary information regarding the meeting and exhibits
- ❑ **Workshop topic descriptor** has been identified
- ❑ 100 word workshop topic description has been submitted online via http://www.amp.org/meetings/2011/corporate_workshops_descriptions_form.cfm
- ❑ **Workshop length and preferred room size** has been noted
- ❑ **Full payment** is provided either by credit card information listed on application or accompanying check
- ❑ **Sponsorship Application submitted** (if applicable)

Forward all completed forms with payment to:

Catherine Davidge
Marketing & Web Communications Manager
Association for Molecular Pathology
Suite E133
9650 Rockville Pike, Bethesda, MD
20814

Tel: 301-634-7400 * Fax: 301-634-7990
Email: cdavidge@amp.org * Web:
www.amp.org

Corporate Workshop Application Form

Corporate Workshops Day: Wednesday, November 16, 2011
Deadline: June 30, 2011

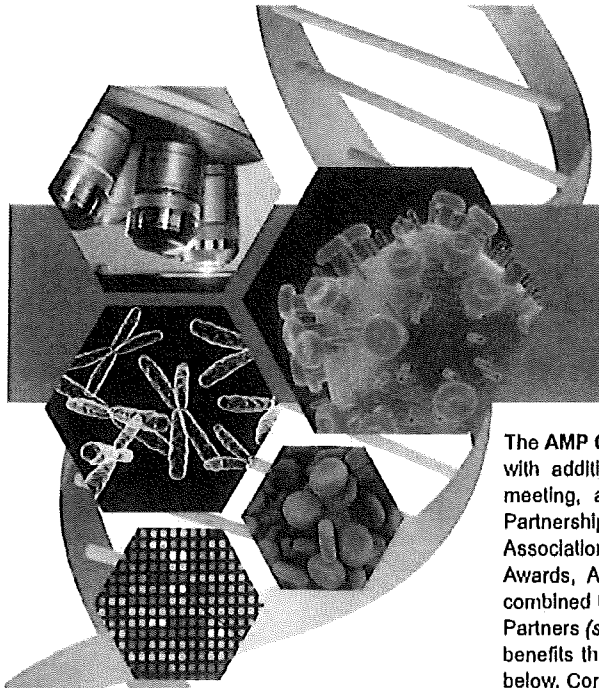
A full day of corporate presented workshops will take place on Wednesday, November 16, 2011. For exhibiting companies, only, meeting rooms have been reserved for workshop presenters at the Gaylord Texan Resort and Convention Center in Grapevine, TX. The fee for each workshop is $3,500 per hour. This fee includes basic audiovisual setup for the room. Catering arrangements should be made directly with the hotel and will be billed directly to you. Up to four workshops will run concurrently during the morning and afternoon sessions. **Please submit your completed Corporate Workshop Application Form to Catherine Davidge by June 30 so that we can work with you to arrange a schedule that most benefits presenters and attendees (minimizing topic duplications or other conflicts).** This will allow us to provide early notification to our membership and meeting attendees about your workshop for early registration and travel planning purposes. We can also put you in touch with our contact at the Gaylord Texan Resort and Convention Center for other necessary arrangements. **If you plan to host more than one workshop, please submit a separate form for each workshop (payment may be combined).**

Company:	
Contact Individual(s):	
Address:	Telephone: Fax: Email:
Workshop Content Descriptors – *Select one that most closely identifies the workshop topic* ❑ Extraction / Purification ❑ Genetics / Cytogenetics ❑ Infectious Diseases - General ❑ Informatics ❑ Microarrays ❑ Multiplex Assays	❑ Mutation Analysis ❑ Pharmacogenetics/Pharmacogenomics ❑ QC / Validation ❑ Sequencing / Next Generation Sequencing ❑ Viral Assays ❑ Other: (please specify) _____
Title of Workshop you are interested in presenting:	Requested Time Slot:
Maximum number of attendees:	Targeted number of attendees:
How long will the workshop last? ❑ 1 Hour ❑ 2 Hours ❑ 3 Hours	
Format you prefer ❑ Classroom ❑ Theater ❑ Demonstration w/6 ft tables ❑ Include ____ Head table(s) ❑ Schedule all of our workshops as back-to-back and in the same meeting room	
NOTE: $3,500 per hour -includes a basic audio visual setup (Screen, LCD Projector, Podium Mike), only. Special Requirements (electricity, sink, etc.) and Other Information (these requirements will be forwarded to the contact person at the convention services department so they can coordinate with you): **IMPORTANT: Final arrangements must be confirmed directly with the hotel representative.**	
Full payment must accompany this application form for consideration. Payments for Corporate Workshops may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:	
❑ MC ❑ VISA ❑ AMEX	Credit Card Account #: Expiration Date: *Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.*
	❑ 1 Hour Workshop..... **$3,500** ❑ 2 Hours of Workshops..... **$7,000** ❑ 3 Hours of Workshops... **$10,500**
Name on Card:	Signature: Date:

A one paragraph description of your workshop (~100 words) must be submitted online by June 30 at http://www.amp.org/meetings/2011/corporate_workshops_descriptions_form.cfm
This description will be used for distribution to AMP members; posting on the AMP website's meeting section, in the AMP Newsletter, and publication in the meeting program. Space will be sold on a first-come, first-served basis. Workshop times will be verified upon receipt of completed application including full payment and workshop description. Preliminary schedule/assigned time slot will be provided approximately 30 days after submission deadline.

Please submit the completed Corporate Workshop Application Form to:
Catherine Davidge
Marketing & Web Communications Manager
Association for Molecular Pathology – Suite E133
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7400 • Fax: 301-634-7990
Email: *cdavidge@amp.org* • Web: www.amp.org

Corporate Workshop Cancellation Policy: All corporate workshop cancellations must be received in writing by AMP Meeting Management (Catherine Davidge).
- Cancellations received on or before **August 16, 2011** qualify for a 75% refund of all monies paid for workshop time slot.
- Any company cancelling its workshop time slot between **August 16, 2011** and **September 16, 2011,** will forfeit 50% of the total cost of their corporate workshop payment.
- Any company cancelling after **September 16, 2011** will forfeit full corporate workshop payment.
- Cancellation of exhibit booth will result in automatic cancellation of corporate workshop.



Highlighting Your Products and Services to Molecular Laboratory Professionals

ASSOCIATION FOR MOLECULAR PATHOLOGY

2011 AMP Corporate Partners Program

The **AMP Corporate Partners Program** is designed to provide our corporate supporters with additional high-visibility opportunities to highlight their company at the annual meeting, at other AMP educational events, and on the AMP website. Corporate Partnerships are renewable each year and support the educational initiatives of the Association. Contributions received for support of activities at the Annual Meeting, Awards, AMP Test Directory, and Educational or General Unrestricted Grants are combined to qualify those with significant interest and investment in AMP as Corporate Partners *(see the following page for details)*. AMP Corporate Partners receive significant benefits that elevate their visibility to AMP members. In addition to the benefits listed below, Corporate Partners are given first notification of selected support opportunities.

Benefits Include:

AMP Diamond Level Corporate Partner ($75,000)

- A complimentary four-color, full page, priority placement ad in the annual meeting issue of *JMD* (November)
- Highest Priority booth space location for the following year's Annual Meeting and includes one division or subsidiary that exhibits in a separate booth
- Dedicated acknowledgement signage at the Annual Meeting
- Two complimentary attendee registrations to the Annual Meeting
- Complimentary meeting room for internal company meetings during the annual meeting
- Three complimentary tickets to the annual meeting banquet/social event (if applicable)
- Named supporter of an unreserved activity at no extra fee
- Complimentary use of the member mail list twice during the year
- Acknowledgement in the annual meeting review issue of the AMP Newsletter
- Acknowledgement on the AMP website, with logo, and link to company website

AMP Platinum Level Corporate Partner ($50,000)

- A complimentary four-color, full page, priority placement ad in any non-meeting issue of *JMD*
- High Priority booth space location for the following year's Annual Meeting
- Acknowledgement on signage at the Annual Meeting
- One complimentary attendee registration to the Annual Meeting
- Two complimentary tickets to the annual meeting banquet/social event (if applicable)
- Complimentary one-time use of the member mail list
- Acknowledgement in the annual meeting review issue of the AMP Newsletter
- Acknowledgement on the AMP website, with logo, and link to company website

AMP Gold Level Corporate Partner ($30,000)

- An upgrade ad placement in any non-meeting issue of *JMD*
- Priority booth space location for the following year's Annual Meeting
- Acknowledgement in the annual meeting review issue of the AMP Newsletter
- Acknowledgement on the AMP website, with logo, and link to company website

AMP Silver Level Corporate Partner ($15,000)

- Preferred booth space location for the following year's Annual Meeting
- Acknowledgement in the annual meeting review issue of the AMP Newsletter
- Acknowledgement on the AMP website, with logo, and link to company website

Association for Molecular Pathology
Marketing, Development & Web Communications Manager
9650 Rockville Pike
Bethesda, MD 20814-3993 (USA)
Tel: 301-634-7400
Fax: 301-634-7990
Email: *cdavidge@amp.org*
www.amp.org

Sponsorship Opportunities Form

Deadline: September 30, 2011

Activity sponsorship will be individually recognized in the meeting program, on the AMP website, and on signage.
All sponsorships for the following activities are credited toward your Corporate Partnership. Sponsorship opportunities sell quickly! Act now to secure your sponsorship. Activities and services available for sponsorship include:

Event		Sponsorship
Dining Events Sponsorship	Continental Breakfast – Thurs 11/17	☐ $ 5,000
	Continental Breakfast – Fri 11/18	☐ $ 5,000
	Continental Breakfast – Sat 11/19	☐ $ 5,000
	Morning Coffee Break – Thurs 11/17	☐ $ 2,000
	Morning Coffee Break – Fri 11/18	☐ $ 2,000
	Morning Coffee Break – Sat 11/19	☐ $ 2,000
	Lunch – Thurs 11/17	☐ $12,000
	Lunch – Fri 11/18	☐ $12,000
	Lunch – Sat 11/19	☐ $12,000
	Afternoon Coffee Break – Thurs 11/1719	☐ $ 2,000
	Afternoon Coffee Break – Fri 11/1819	☐ $ 2,000
	Afternoon Coffee Break – Sat 11/19	☐ $ 2,000
Event		**Sponsorship**
Scientific Session Support *The number of topic sessions may be changed by the Program Committee.* *The Annual Meeting Preliminary Program is available online at www.amp.org*	Plenary Sessions (6) # of Sessions to Sponsor (1-6) _____	☐ $ 5,000 x # of Sessions to Sponsor _____
	Symposia (4) # of Symposia to Sponsor (1-4) _____	☐ $ 5,000 x # of Symposia to Sponsor _____
	Workshops (12) # of Workshops to Sponsor (1-12) _____	☐ $ 2,500 x # of Workshops to Sponsor _____
	There will be six Plenary Sessions, four Symposia and 12 workshops. For topic/title of each programmed session please see www.amp.org/2011/program or contact Catherine Davidge at cdavidge@amp.org *Note: You may choose to support a specific Workshop, Symposium, or Plenary. Support of educational activities requires an unrestricted educational grant and completion of a Commercial Agreement Letter.*	
Description		**Sponsorship**
Education Grant	Unrestricted Education Grant for AMP Activities	☐ $ _____ (no minimum)
Pathology Outreach Course	Supporter	☐ $10,000
Charging Station, Hotel Keycards, iPOD App, Lanyards, Pens Pads, Social Event, and other Attendee Services	Meeting Bags	☐ $15,000
	Power2Go Charging Station	☐ $10,000
	iPhone / iPAD App	☐ $10,000
	Electronic Signage	☐ $30,000
	Lanyards	☐ $10,000
	Hotel Room Keycards	☐ $10,000
	Notepads	☐ $10,000
	Pens	☐ $10,000
	Social Event	☐ $5,000 for five tables ☐ $1,500 for one table
	Other Attendee Services	*Contact Catherine Davidge at AMP cdavidge@amp.org*

Company:	
Contact Individual:	
Address:	Telephone:
	Fax:
	Email:

Payment may be made by check in U.S. dollars drawn on a U.S. bank, or MC, VISA, AMEX by completing the following credit card information:

☐ MC ☐ VISA ☐ AMEX	Credit Card Account #: Expiration Date: *Note: Credit Card payments are processed through the American Society for Investigative Pathology (ASIP) and your credit card invoice will reflect this.*

Name on Card:	Signature:	Date:

Thank you for sponsoring an activity at the AMP Annual Meeting. Please send the completed Sponsorship Opportunities Form and payment by **September 30, 2011.**

AMP encourages and welcomes your ideas for additional sponsorship opportunities! Please contact Catherine to discuss your ideas.

Catherine Davidge
Marketing & Web Communications Manager
Association for Molecular Pathology
Suite E133
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301-634-7400 • Fax: 301-634-7990
Email: *cdavidge@amp.org* • Web: www.amp.org

Support AMP Webinars and gain visibility for your company!

ASSOCIATION FOR MOLECULAR PATHOLOGY
2011 WEBINAR SERIES
Presented by the AMP Training & Education Committee

Become a Supporter of AMP Webinars

2011 Webinar Support:
$2,500 per webinar; exclusive supporter
(Attention AMP Corporate Partners: Webinar support counts towards your Partnership commitment)

2011 Webinar Topics:
Webinar topics and speakers are selected by the AMP Training & Education Committee. A list of future webinars can be found on the AMP website, under the "Education" tab. Please indicate the topic areas and number of webinars you wish to support below. We will send you the webinar titles in the topic area(s) you choose.

# Webinars	Topic Area
_____	Genetics
_____	Hematopathology
_____	Infectious Diseases
_____	Management/Regulatory/ Reimbursement

Supporter Benefits:
- **Exclusive Supporter** *(only one supporter per webinar)*
- **Acknowledgement on the AMP Website**
- **Acknowledgement on the webinar announcement and invitation**
- **Acknowledgement during the webinar**

Association for Molecular Pathology
Marketing, Development & Web Communications Manager
9650 Rockville Pike
Bethesda, MD 20814-3993 (USA)
Tel: 301-634-7400
Fax: 301-634-7990
Email: *cdavidge@amp.org*
www.amp.org

Contact Information:
Organization/Company_____

Contact Name_____

Address_____

City_____

State/Province_____ Zip_____

Country_____

Tel_____

Fax_____

Email_____

Payment:
☐ We are an AMP Corporate Partner and would like to support this as part of our commitment *(AMP Corporate Partners do NOT need to provide payment information on this form)*

☐ Check enclosed *(made payable to "Association for Molecular Pathology")*

Charge my credit card* Amount $_____

☐ VISA ☐ MasterCard ☐ American Express

Credit Card #_____ Exp Date_____

Card Holder Name *(please print)*:

_____

Signature_____ Date_____

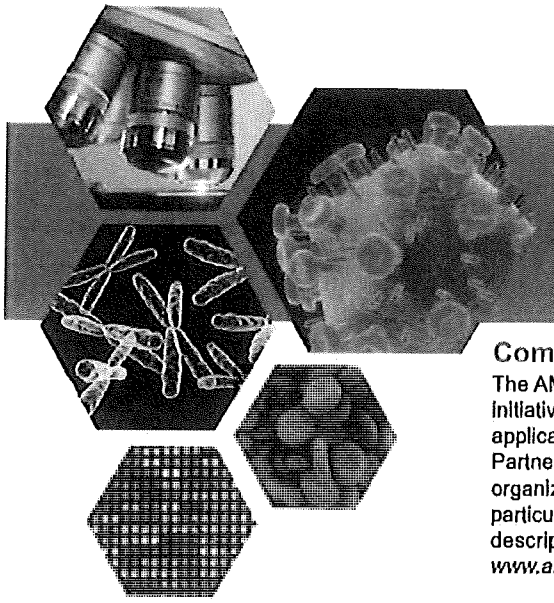
Credit Card Billing Address_____

City_____ State_____ ZIP_____

Country_____

*IMPORTANT: If paying by credit card, the charge on your credit card statement will be from the American Society for Investigative Pathology (ASIP). AMP is a constituent society of the office of the American Society for Investigative Pathology and uses the ASIP credit card processing system.

www.amp.org



Highlighting Your Products and Services to Molecular Laboratory Professionals

ASSOCIATION FOR MOLECULAR PATHOLOGY

2011 AMP Corporate Partners Program

Commitment Form

The AMP Corporate Partners Program supports the Association and its educational initiatives through unrestricted educational grants. A completed and approved application with payment is required to begin implementation of benefits. Corporate Partner contracts are renewable each year. AMP is a 501(c)3 not-for-profit organization. Contributions may be designated to support specific activities such as particular activities at the annual meeting and/or other education events. Complete descriptions of support opportunities are available on the AMP website at *www.amp.org*.

Select Your 2011 Corporate Partnership Level:

- ☐ Diamond Partnership, $75,000/year
- ☐ Platinum Partnership, $50,000/year
- ☐ Gold Partnership, $30,000/year
- ☐ Silver Partnership, $15,000/year

Select Your Payment Plan:

- ☐ Full Payment Enclosed
- ☐ Four (4) Payment Plan:

Please include the first payment with this form.
#1 - 25% due 3/31/2011

AMP will invoice you one month prior to the payment-due date for the following 3 payments. Invoice will be sent to the contact name listed at right.
#2 - 25% - payment due 5/31/2011
#3 - 25% - payment due 7/31/2011
#4 - 25% - payment due 10/1/2011

Association for Molecular Pathology
Marketing, Development & Web Communications Manager
9650 Rockville Pike
Bethesda, MD 20814-3993 (USA)
Tel: 301-634-7400
Fax: 301-634-7990
Email: *cdavidge@amp.org*
www.amp.org

Contact Information:

Organization/Company_____

Contact Name_____

Address_____

City_____ State/Province_____ Zip_____

Country_____

Tel_____

Fax_____

Email_____

Payment: *(please indicate desired partnership level and payment plan at left)*

☐ Check enclosed *(made payable to "Association for Molecular Pathology" or "AMP")*

Charge my credit card* Amount $_____

☐ VISA ☐ MasterCard ☐ American Express

Credit Card #_____ Exp Date_____

Card Holder Name *(please print)*_____

Signature_____ Date_____

Credit Card Billing Address_____

City_____ State_____ ZIP_____ Country_____

***IMPORTANT:** If paying by credit card, the charge on your credit card statement will be from the American Society for Investigative Pathology (ASIP). AMP is a constituent society of the office of the American Society for Investigative Pathology and uses the ASIP credit card processing system.

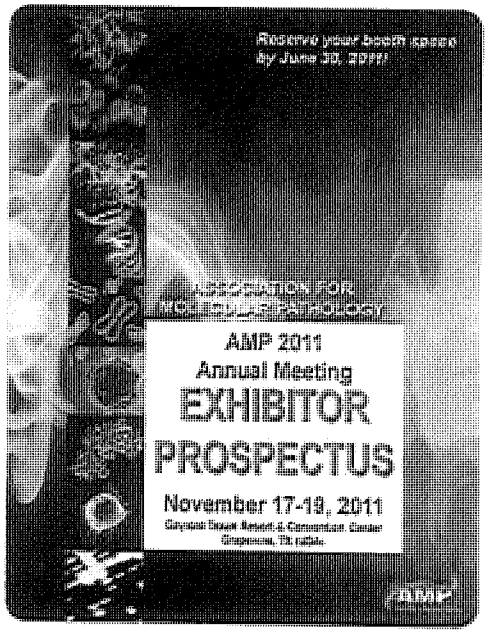
ILLUM-0382

Association for
Molecular Pathology
9650 Rockville Pike
Bethesda, MD 20814 (USA)

ASSOCIATION FOR MOLECULAR PATHOLOGY

AMP 2011 Annual Meeting

Your single best opportunity to reach hundreds of molecular laboratory professionals!



ILLUM-0383

First Name	Last Name	Title	Company	Address St	Email Addr	Address Ci	Address St	Address Pc	Address Cc	Phone	Fax	Description
Dimitris	Agamanolis		Akron Chil	One Perkir	dagamano	Akron	OH	44308-106	United States			
Ivan	Brandslund		Lillebaelt H	25 Kabbelt	ivan.brand	Vejle		DK-7100	Denmark			interest in
Su	Chen		M D Ander	1515 Holc	sschen@m	Houston	TX	77030	United Sta	(713) 792-	(713) 794-	interested
Lawrence	Crolla		Northwest	800 W Cen	lcrolla@nc	Arlington H	IL	60005	United Sta	(847) 618-	(847) 618-	veracode t
Christine	Curtis		Case West	10524 Euc	christine.c	Cleveland	OH	44106	United Sta	(216) 983-	(216) 983-	gpr beads i
Wilbur	Franklin		Univ of Col	Mail Stop F	wilbur.fran	Aurora	CO	80045	United Sta	(303) 274-	(303) 274-3096	
Michael	Hafez		Johns Hopl	600 N Wol	mjhafez@a	Baltimore	MD	21287	United Sta	(410) 955-	(410) 614-7440	
Stephanie	Hallam		Allegro Dia	650 Alban	sehallam0	Boston	MA	2118	United Sta	617 414 2	617 358 5	startup wa
John Greg	Howe		Yale Unive	333 Cedar	john.howe	New Have	CT	06520-803	United Sta	(203) 737-	(203) 688-	gpr univers
Jeffrey	Hung		SABiosciences		jhung@sabiosciences.com				United States			
Lei	Li		Pfizer	213 Long V	lei.li@pfiz	Mystic	CT	6355	United States			
Mark	Lovell		The Childr	13123 E. 1	lovell.mark	Aurora	CO	80045	United Sta	(720) 777-	(720)777-7119	
Ruth Ann	Luna		Baylor Coll	6621 Fann	raluna@bc	Houston	TX	77030	United States			
Roberta	Madej			700 Begier	rmadej@c	San Leandı	CA	94577	United Sta	(510) 610	-0982	gpr beads
Narasimha	Nagan		Genzyme (	3400 Com	narasimha	Westboro	MA	1581	United Sta	(508) 389-	(508) 389-	higlhy inte
Marina	Nikiforova		Univ of Pitt	200 Lothro	nikiforovar	Pittsburgh	PA	15213	United Sta	(412) 802-	(412) 802-6799	
Yasuhiro	Otomo		Sysmex	Kobe Taka	otomo.yas	Kobe		651-2271	Japan	078-991-1919		have rep c
Joseph	Pulliam		University	800 Rose S	joe.pullian	Lexington	KY	40536	United Sta	8.59E+09		interested
Mark	Raffeld		NCI	9000 Rock	mraff@bo	Bethesda	MD	20892	United Sta	(301) 496-	(301) 402-2415	
Paula	Revell		Texas Chil	6621 Fann	parevell@t	Houston	TX	77030	United Sta	(832) 824-	(832) 825-0164	
Marlene	Sabbath-Solitare		St Barnaba	94 Old Sho	msabbath	Livingston	NJ	7039	United Sta	(973) 322-	(973) 322-	running a e
Steven	Schichman		Central Ark	4300 W 7t	schichman	Little Rock	AR	72205	United Sta	(501) 257-	(501) 257-	adme inte
Jeremy	Segal		New Yourk	435 E. 70t	jp2001@a	New York	NY	10021	United Sta	917-509-7176		
Antonia	Sepulveda		U Pennsylv	3400 Spru	Sepulveda	Philadelph	PA	19104	United Sta	(215) 615-	(215) 614-1988	
Alain	Troesch		Biomerieu	5, Rue Des	alain.troes	Grenoble		38024	France	+33 478 87	+33 478 87	9nterested
Oana	Vele		Lenox Hill	100 East 7	ovele@ho	New York	NY	10075	United Sta	(917) 499-9708		starting m
Michael	Wang		University	115 Busine	wangmx@	Columbia	MO	65203	United Sta	(573) 882-	(573) 882-	gpr beads
Raymond	Widen		Tampa Ge	PO Box 12	rwiden@v	Tampa	FL	33601	United Sta	(813) 844-	(813) 844-	eragen cyt
Lei Po	Wong		Hong Kong	Village Roa	chrislpw@	Hong Kong	NA	HKSAR	CHINA			has lumine
Yuan	Xue		UCLA	1000 Vete	yxue@me	Los Angele	CA	90024	United Sta	310-206-3945		
Mike	Armstrong		Pacific Rim	5325 Metr	marmstror	San Diego	CA	92110	United Sta	619-295-0	619-295-0853	
Voncia	Arterberry		Quest Diag	14225 Nev	voncia.x.A	Chantilly	VA	20153-084	United Sta	(703) 802-	(703) 802-7153	
William	Benjamin Jr.		U Alabama	619 S 19th	bbenjami	Birmingha	AL	35249	United Sta	(205) 934-	(205) 975-	he is a 23 a

ILLUM-0436

Industry	Sub-indust	Budget	Next Steps	Contact M	Questions	Lead Statu	Cancer res	Cytogeneti	Diagnostic	Disease re	Gene Cont	Gene Expr
Academic	Hospital/Path Lab			1		Marketing			1			
Commerci	Dx or Refe	Other		1		Marketing						
Academic	University	Other	Customer	1		Marketing						
Academic	Hospital/P	Other	Customer	1		Marketing			1			
Commerci	Dx or Refe	Other		1		Marketing						
Academic	Hospital/P	Grant (Available Fund		1		Marketing	1			1		
Academic	Hospital/Path Lab		Customer	1		Marketing		1	1	1		
Commerci	Dx or Reference Lab		Customer	1		Marketing						
Academic	Hospital/Path Lab			1		Marketing						
Commerci	Service Provider/Core		Customer	1		Marketing	1					
Commerci	Pharma		Customer	1		Marketing	1		1			1
Other			Customer	1		Marketing			1			
Academic	Hospital/Path Lab			1		Marketing						
Other				1		Marketing			1	1		
Commerci	Biotech	Other	Customer	1		Marketing			1			
Other			Customer	1		Marketing						
Commerci	Dx or Refe	Other		1		Marketing						
Academic	Hospital/P	Other	Customer	1		Marketing			1	1		
Governme	Human Re	Other		1		Marketing			1			
Academic	Hospital/Path Lab			1		Marketing						
Commerci	Service Provider/Core		Customer	1		Marketing	1					
Other				1		Marketing						
Other			Customer	1		Marketing						
Other			Customer	1		Marketing	1		1			1
Commerci	Pharma	Other	Customer	1		Marketing		1	1			
Commerci	Dx or Refe	Grant (Available Fund		1		Marketing			1			
Commerci	Pharma	Other		1		Marketing			1			
Commerci	Dx or Refe	Grant (Available Fund		1		Marketing						
Commerci	Dx or Reference Lab			1		Marketing						
Academic	Hospital/Path Lab		Customer	1		Marketing		1	1			
Other						Marketing	1		1			
Other						Marketing					1	1
Academic	University	Other	Customer requested product infc			Marketing						

ILLUM-0437

Genotypin	Sequencin	Systems	Record Owner
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	1		Illumina Lead Queue

ILLUM-0438

Slava	Elagin	Meridian B	3471 River	slava.elagi	Cincinnati	OH	45244	United Sta	513-271-3	513-271-0744
Ross	Haynes	NIST	100 Bureai	ross.hayne	Gaithersbu	MD	20899-831	United Sta	(301) 975-	(301) 975- didn't kno
Mai	He	Women &	101 Dudle	mhe@wih	Providence	RI	2905	United Sta	(862) 242-6092	
Mridula	Iyer	QIAGEN, Inc.						United States		asked info
Cynthia	Jackson	Rhode Isla	Apc12	cjackson@	Providence	RI	2903	United Sta	401-444-4	401-444-8514
John	Jessup	National C	6130 Exec	jessupj@n	Bethesda	MD	20892	United Sta	(301) 435-	(301) 402-7819
Susannah	Kennedy	Aurora Biomed Inc						United States		
Jin	Li	Dana-Farb	44 Binney	jli@lroc.ha	Boston	MA	2115	United Sta	(617) 632-	(617) 582-8213
Robert	Lloyd	ViveBio						United States		
Connie	McGregor	Royal Univ	103 Hospit	connie.mc	Saskatoon	SK	S7N 0W8	Canada	(306) 655-	(306) 655-2223
Arturo	Mendoza	Sharp Men	7901 Frost	art.mendo	San Diego	CA	92014	United Sta	858-939-3	858-939-3647
Kasinathar	Muralidharan	Quest Diag	14225 Nev	kasinathan	Chantilly	VA	20151	United Sta	(703) 802-	703-802-7 cftr interes
Marilyn	Owens	Caris Diagr	8400 Ester	marilynow	Irving	TX	75063	United Sta	(562) 818-1567	
Richard	Scuderi	Pacific Rim	Pathologis	ricscu@gn	San Diego	CA	92122	United Sta	858-337-7174	
Scott	Shell	TMD Quint	610 Oakm	scott.shell	Westmont	IL	60559	United Sta	(630) 203-	(630) 789- targeted s
Metin	Taskin	The Valley	223 N Van	mtaskin@	Ridgewooc	NJ	7450	United Sta	(201) 447-	(201) 447- beadxpres
Vivianna	Van Deerlin	University	3400 Spru	vivianna@	Philadelph	PA	19104	United Sta	(215) 662-	(215) 662-7529
Donna	Wolk	University	1501 N Ca	dwolk@en	Tucson	AZ	85724-505	United Sta	(520) 626-	(520) 694- add to mai
Judy	Yu	Abbott Mo	1300 E Tot	judy.yu@a	Des Plaine	IL	60018	United Sta	(224) 361-	(224) 361-7578
E	Zhang	Princess M	610 Univer	katzhang@	Toronto	ON	M5G 2M9	Canada	(416) 340-	(416) 340-3596

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Date	First Name	Last Name	Company I	Address St	Address St	Address Pc	Address Ci	Address Cc	Phone Nur	Fax Numbe	Email Addr	Agricultura
11/17/2010	Karen	Kaul	NorthShor	IL	2650 Ridge	60201-178	Evanston		847-570-2052		kkaul@northshore.org	
11/17/2010	Peggy	Ruymbeec	Innogenetics									
11/17/2010	Brian	Lester	Manning &	NY	290 Wood	14450	Fairport		585-325-6880			
11/17/2010	Franklin	Cockerill	Mayo Clini	MN	200 First St	55905	Rochester		507-284-2901		cockerill.franklin@ma	
11/17/2010	Zheng	Li	Novartis	CA	4560 Horto	94608	Emeryville		510-923-7877		zheng.li@novartis.com	
11/17/2010	Dave	Craford	Pathwork Diagnostics									
11/17/2010	Thomas	Monroe	Spectrum I	MI	145 Michig	49503	Grand Rapids		616-486-6264		thomas.monroe@spe	
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11/17/2010	Paul D	Neuwald	Halteres A	CA	5858 Horto	94608	Emeryville		925-586-0486		pneuwald@halteresas	
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11/17/2010	Brian H.	Taylor	Crowing Cc	MD	20271 Gol	20876	Germanto	USA	240-678-0525		btaylor@growingcos.c	
11/17/2010	Donna	Roscoe	FDA	MD	10903 Nev	20993	Silver Spring		301-796-6183		donna.roscoe@fda.hh	
11/17/2010	Karen	Bijwaard	FDA/CDRH	MD	10903 Nev	20993-000	Silver Spring		301-796-6162		karen.bijwaard@fda.h	
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11/17/2010	Suzanne K.	Coberly	Amgen	CA	1120 Vete	94080	So San Francisco	650-244-2697	scoberly@amgen.com
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11/17/2010	Zeyu (Davi	Jiang	Ventana M	AZ	1910 E. Inr	85755	Tucson	520-229-3848	david.jiang.dj1@venta
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11/17/2010	Carol	Berry	Asuragen						
11/17/2010	Karen	Mann	Emory Uni	GA	1364 Clifto	30322	Atlanta	404-712-1264	kmann@emory.edu
11/17/2010	Carl	Millward	Genomic H	CA	301 Penob	94063	Burlingame	650-569-2491	cmillward@genomich
11/17/2010	Yosuke	Yamamoto	JSR Micro	CA	1280 N Ma	94107	Sunnyvale	408-543-8976	yyamamoto@jsrmicro
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11/17/2010	Vineet	Bansal	Life Technologies						
11/17/2010	Ruby	Galderab	Affymetrix						
11/17/2010	Seela	Nattanmai	Albany Me	NY	43 New Sc	12208	Albany	518-262-3483	nattans@mail.amc.ed
11/17/2010	Kathleen	Stellrecht	Albany Me	NY	43 New Sc	12208	Albany	518-262-3587	stellrk@mail.amc.edu
11/17/2010	Yao-shi	Fu	Genzyme C	CA	16483 Oldl	91436	Encino	310-482-5025	yao-shi.fu@genzyme.c
11/17/2010	Nikolay	Sergeev	LifeTech	CA	350 Lincoln Centre. Di		Foster City		nikolay.sergeev@lifet
11/17/2010	Jinseok	Kang	LG Life Sciences		104-1, Munji-dong		Daejeon Korea	82-10-3310-7319	friendsse@lgls.com
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11/17/2010	James	Gale	TriCore Re	NM	1001 Woo	87102	Albuquerque	505-938-8427	james.gale@tricore.or
11/17/2010	Nora Kristi	Leos	Children's	TX	1935 Medi	75235	Dallas	214-456-3273	nora.leos@childrens.c
11/17/2010	Shama	Khan Khok	Children's	TX	1935 Medi	75235	Dallas		shakho@childrens.cor
11/17/2010	Brandon	Williams	JSR Micro,	CA	1280 N. M	94089	Sunnyvale	408-543-8718	bwilliams@jsrmicro.cc
11/17/2010	Chris	Bird	Roche						
11/17/2010	Steve	Harrison	Roche Mol	WA	5202 Narb	98203	Everett	425-220-6439	steve.harrison@roche
11/17/2010	Daniel	Farkas	Sequenom	MI	301 Michig	49503	Grand Rapids	616-284-3737	dan@scmmlab.com
11/17/2010	Zeba N.	Singh	U Arkansas	AR	4301 West	72205	Little Rock	501-526-7511	zebaniazi@gmail.com

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11/17/2010	Jessica	Parra	Affymetrix						
11/17/2010	Ling	Xu	Canon U.S.	MD	9800 Medi	20850	Rockville	301-762-2755	lilng.xu@canon.uslifes
11/17/2010	Teresa Anr	Smolarek	Cincinnati	OH	3333 Burn	45229-303	Cincinnati	513-636-4474	teresa.smolarek@cchi
11/17/2010	Anjali	Seth	Univ of Me	NJ	185 South	7103	Newark	908-230-3542	sethan@umdnj.edu
11/17/2010	Lyle	Arnold	Lyle Arnol	CA	15638 Bou	92064	Poway	619-851-8923	ljarnold@cox.net
11/17/2010	Padma	Sundar	Affymetrix	CA	1126 Lafay	94087	Sunnyvale	510-717-8015	padma_sundar@affyn
11/17/2010	Laurie	Kessler	Roche						
11/17/2010	Shinji	Mori	Canon US I	MD	9800 Medi	20850	Rockville	301-517-8793	shinji.mori@canon.usl
11/17/2010	Mastan	Chintalapu	Moffitt Ca	FL	12902 Mag	33612-941	Tampa	813-745-8799	mastan.chintalapudi@
11/17/2010	Lynne	Whetsell	Saint Franc	OK	6465 S Yal	74136	Tulsa	918-502-1730	lhwhetsell@saintfranc
11/17/2010	Myrna M.	Mantaring	Walter Ree	DC	6900 Geor	20307	Washington	202-782-8429	mmantari@aol.com
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11/17/2010	So Youn	Shin	So Youn Shin		86 Asanby	138-736	Seoul	Republic o +82 10 6484 3244	leukoso@hanmail.net
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11/17/2010	Mark A.	Lovell	The Childr	CO	13123 E. 1	80045	Aurora	720-777-5468	lovell.mark@tchden.o
11/17/2010	Shoba	Anantha	EraGen Bic	WI	918 Demin	53717	Madison	608-512-5608	sanantha@eragen.cor
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11/17/2010	Kenneth	Ward	Axial Biote	UT	2749 E Par	84109	Salt Lake City	801-487-6000	ken.ward.hi@mac.con
11/17/2010	Vaidehi	Jobanputra	Columbia U	NY	3959 Broa	10032	New York	212-305-7373	vj2004@columbia.edu
11/17/2010	Yun-fu	Hu	FDA	MD	10993 Nev	20993	Silver Spring	301-796-6170	yun-fu.hu@fda.hhs.go
11/17/2010	Jim	Forrester	EraGen Biosciences						
11/17/2010	Kathleen	Shelton	Roche						
11/17/2010	Minbong	Park	PhileKorea	NA	1303~130	153802	Seoul	KR 821-044-433300	pioneer@philekorea.c
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11/17/2010	Katrin	Stapleton	Affymetrix	CA	3170 Haml	94598	Walnut Cre	USA	925 639 0543	katrin_stapleton@affy
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11/17/2010	Anna G.	Dobretsov	Northside	GA	1000 Johns	30342	Atlanta		404-303-3871	anna.dobretsova@nor
11/17/2010	Chris	Badger	Abbott Lab	IL	1300 E. To	60018	Des Plaine	USA		christopher.badger@a
11/17/2010	Michelle	Tabb	Focus Diag	CA	11331 Vall	90630	Cypress		714-822-6756	mtabb@focusdx.com
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11/17/2010	Amanda	Stafford	Johns Hopl	MD	600 North	21287	Baltimore		410-955-1438	astaffo2@jhmi.edu
11/17/2010	Suvas	Desai	Memorial S	NY	1275 York	10021	New York		212-639-5141	desais@mskcc.org
11/17/2010	Bejan	Shahbahra	Neo Genor	CA	6 Morgan	92618	Irvine		949-554-9890	bejan@att.net
11/17/2010	Ming	Chou Lee	PrimeraDx							
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11/17/2010	Harmeet	Arora	Life Techn	CA	601 Garon	93036	Foster City		805-205-4416	
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11/17/2010	David	Barton	National Centre for M		Our Lady's	12	Dublin	IRELAND	+3531 409 6749	david.barton@olchc.ie
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11/17/2010	Doug	Lunderville	QIAGEN, Inc.							
11/17/2010	Jeff	Ares	Goldman S	NY			New York			jeff.ares@gs.com
11/17/2010	Katie	Beierl	Johns Hopl	MD	600 N Wol	21287	Baltimore		410-955-1438	kbeierl1@jhmi.edu
11/17/2010	Erik	Avaniss-Ag	Primex Clir	CA	16742 Stag	91406	Van Nuys		818-779-0496	eerik@primexlab.com

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11/17/2010	Nargol	Faravashi	Affymetrix								
11/17/2010	Anniek	De Witte	Agilent Tec	CA	5301 Steve	95051	Santa Clara	USA	408-553-3325	anniek_de-witte@agil	
11/17/2010	Jonathan	Earle	Hartford P	CT	Hartford H	6102	Hartford		917-348-9343	jearle@harthosp.org	
11/17/2010	Joan	Gordon	Maine Mol	ME	10 Southga	4074	Scarborough		207-885-1072	jgordon@mmqci.com	
11/17/2010	Katherine	Tynan	Tynan Con	CA	825 Somer	94070	San Carlos		650-637-0491	tynankm@yahoo.com	
11/17/2010	Jene	Choi	Asan Medical Center		Departmer	138-736	Seoul	Republic o	822-301-04555	jenec@amc.seoul.kr	
11/17/2010	Jung-sun	Kim	Sungkyunk	NA	Dept Of Pa	135-710	Seoul	KR	822-341-02767	jsunkim@skku.edu	
11/17/2010	Laila O	Mnayer	Hartford H	CT	80 Seymou	6102	Hartford		860-545-3589	lmnayer@clpct.com	
11/17/2010	Katherine	Hodges	Hartford H	CT	80 Seymou	06102-503	Hartford		860-545-3409	khodges@clpct.com	
11/18/2010	Ronald	Lam	Northwest	IL	800 West (	60005	Arlington H		847-618-6141	rlam@nch.	FALSE
11/18/2010	Ramanath	Majumdar	Mayo Clini	MN	200 First St	55905	Rochester		507-284-4169	majumdar.	FALSE
11/18/2010	TuDung T	Nguyen	Washingto	MO	660 S Eucli	63110	St. Louis		314-747-4329	nguyen_tu	FALSE
11/18/2010	Bill	Howell		CA	935 Sandp	94303	Palo ALto	USA	650-384-5002	w_d_howe	FALSE
11/18/2010	Lisa	Farwell	Harvard Pa	MA	65 Landsdo	2139	Cambridge		617-768-8443	lfarwell@p	FALSE
11/18/2010	George	Corpus	Florida Ho	FL	601 East R	32803	Orlando		407-303-9499	george.cor	FALSE
11/18/2010	Mark	Rabin	Mira Dx	CT	30 George	6511	New Haver		203-789-9000	rabinm@n	FALSE
11/18/2010	Donna	Wolk	University	AZ	1501 N Cai	85724-505	Tucson		520-626-3676	dwolk@email.arizona.	
11/18/2010	Thomas	Wilson	Univ of Mi	MI	109 Zina Pi	48109-220	Ann Arbor		734-764-2212	wilsonte@	FALSE
11/18/2010	Gurunatha	Murugesar	Cleveland (	OH	9500 Euclid	44195	Cleveland		216-444-9484	murugeg@	FALSE
11/18/2010	Dahui	Qin	Moffitt Cai	FL	12902 Mag	33612	Tampa		813-745-1883	dahuiqin@	FALSE
11/18/2010	Carol	Saunders	Children's	MO	2401 Gillha	64108	Kansas City		816-346-1325	csaunders(	FALSE
11/18/2010	Jordan	Laser	North Shor	NY	155 Foxwo	11753	Jericho		516-562-2910	jlaser@nsh	FALSE
11/18/2010	Steven	Quay	Atossa Genetics, Inc.							Steven.Qu	FALSE
11/18/2010	Shuko Y	Harada	Johns Hopl	MD	600 N Wol	21287	Baltimore		410-955-1438	shukohara	FALSE
11/18/2010	Timothy	O'Leary	Departmer	MD	703 Herml	20902	Silver Sprir		202-461-1666	timothy.ol	FALSE
11/18/2010	Mike	Steele	SeraCare Life Science, Inc.							msteele@s	FALSE
11/19/2010	Gorm	Lisby	QuantiBac		Kettleguar		Hvidovre	Denmark	45 406 33787	gorm.lisby	FALSE
11/19/2010	Helen D.	Fernandes	UMDNJ-Ne	NJ	185 S Oran	07103-271	Newark		973-972-6555	fernande@	FALSE
11/19/2010	Yiu-lian	Fong	Novartis	MA	250 Mass A	2139	Cambridge		617-871-8250	yiu-lian.for	FALSE
11/19/2010	Ramakrish	Sasi	Northern M	MI	3711 West	49855	Marquette		906-227-2663	rsasi@nmu	FALSE
11/19/2010	Jelveh	Lameh	Genoptix M	CA	2110 Ruth	92008	Carlsbad		760-431-6122	jlameh@ge	FALSE
11/19/2010	Kara	Kilbourne	CHOC Hos	CA	455 S. Mai	92868	Orange		714-289-4060	kkilbourne	FALSE
11/19/2010	Long Phi	Le	Massachus	MA	55 Fruit St	2114	Boston		857-413-0593	lple@partr	FALSE
11/19/2010	Ivy	Yeung	TPMG Kais	CA	1725 Easts	94710	Berkeley		510-559-5030	ivy.c.yeung	FALSE

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FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	Commerci
FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Academic
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FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Academic
FALSE	FALSE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	Academic
FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	Commerci
TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Commerci

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FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	Academic
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TRUE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	Commerci
FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Academic
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FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Commerci
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FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Commerci
TRUE	FALSE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	Other
FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Academic
FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Commerci

ILLUM-0455

							TRUE		
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							TRUE		
							TRUE		
							TRUE		
Dx or Reference Lab		FALSE	FALSE	FALSE	FALSE	Send seq literature			TRUE
Hospital/P:	Other	FALSE	FALSE	TRUE	FALSE	Carrier screening via biochem/enzyme meto			TRUE
Hospital/P:	Other	FALSE	FALSE	TRUE	FALSE	Pathology. Hematology			TRUE
Hospital/P:	Other	FALSE	FALSE	FALSE	TRUE				TRUE
Service Provider/Core		FALSE	TRUE	FALSE	FALSE				TRUE
Dx or Refe	Other	FALSE	TRUE	FALSE	FALSE	Wants presentation on seq and pharmacoge			TRUE
Biotech	Other	FALSE	FALSE	FALSE	FALSE	Wants info on BX. Ha:	TRUE		TRUE
									TRUE
Hospital/P:	Other	FALSE	FALSE	TRUE	FALSE	MDx. Faster seq tat.			TRUE
Hospital/P:	Other	FALSE	TRUE	FALSE	FALSE				TRUE
Service Prc	Grant - Fur	FALSE	FALSE	FALSE	FALSE		TRUE		TRUE
	Other	FALSE	TRUE	FALSE	FALSE	Veracode gggt basic slides to carol			TRUE
	Other	FALSE	FALSE	TRUE	FALSE				TRUE
Biotech	Grant - Fur	FALSE	TRUE	TRUE	FALSE	Full Dx development. Ask Brett for details			TRUE
Hospital/Path Lab		FALSE	FALSE	FALSE	TRUE		TRUE		TRUE
Other	Grant - Fur	FALSE	TRUE	FALSE	FALSE	Wants to buy 10 HiSeqs Boston, Palo Alto, Li			TRUE
		FALSE	FALSE	FALSE	TRUE	Needs to touch base with BD and Dave Smitl			TRUE
Dx or Refe	Other	FALSE	FALSE	FALSE	TRUE	Biz dev please contact			TRUE
Hospital/P:	Other	FALSE	TRUE	FALSE	FALSE		TRUE		TRUE
Pharma	Other	FALSE	FALSE	TRUE	FALSE	Send next gen lit	TRUE		TRUE
Hospital/P:	Grant - Fur	FALSE	TRUE	FALSE	FALSE	Oncology, postnatal			TRUE
Dx or Refe	Other	FALSE	FALSE	FALSE	TRUE	Prenatal screening with U Wisconsin?			TRUE
		FALSE	TRUE	TRUE	FALSE	Have Brett contact for	TRUE		TRUE
Hospital/P:	Grant - Fur	FALSE	TRUE	FALSE	FALSE	Using snapshot. Wants to do pilot run for on			TRUE
Dx or Refe	Other	FALSE	FALSE	FALSE	TRUE	rand DInfectious disea	TRUE		TRUE

ILLUM-0456

11/19/2010	Jen S	Shieh	TPMG, Kai:	CA	1725 Easts	94710	Berkeley	510-231-5696	jen.shieh@ FALSE
11/20/2010	Shimin	Zhang	Armed For	DC	14th St & /	20817	Washingto	202-782-1768	zhangs@af FALSE
11/20/2010	Deborah	Sun	South Ben	IN	530 N. Lafa	46601	South Ben	574-234-4176	dsun@sbm FALSE
11/20/2010	Nehad	Mohamed	Ohio State	OH	2001 Polar	43240	Columbus	614-293-0665	nehad.mol FALSE
11/20/2010	Linda	Cook	University	WA	1616 Eastl	98102-102	Seattle	USA 206 685 7384	lincoo@ao FALSE
11/20/2010	Edward	Ginns	U Mass Me	MA	222 Maple	1545	Shrewsbur	508-856-8134	edward.ginns@umass
11/20/2010	Marzena M	Galdzicka	Umass Me	MA	222 Maple	1545	Shrewsbur	508-856-4384	marzena.g FALSE
11/20/2010	Fernanda	Sabato	Virginia Co	VA	403 N 13th	23298	Richmond	804-828-9564	msabatoch FALSE
11/20/2010	Ted	Schutzban	Covance C	IN	8211 Scico	46214	Indianapol	317-273-7988	ted.schutzl FALSE
11/20/2010	Harold H.	Harrison	Geisinger I	PA	100 North	17822	Danville	570-271-7443	hhharrison FALSE
11/20/2010	Martin	Adelson	Medical Di	NJ	2439 Kusel	8690	Hamilton	609-570-1015	madelson(FALSE
11/20/2010	Deborah V	Spencer	Emory Uni	GA	1115 Nortl	30033	Decatur	404-712-1875	deborahvs FALSE

FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Commerci
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TRUE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	Commerci
FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	Academic
FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	Academic
TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	Academic

Dx or Refe	Other	FALSE	FALSE	FALSE	TRUE				TRUE
Other	Other	FALSE	TRUE	FALSE	FALSE				TRUE
Service Prc	Other	FALSE	FALSE	TRUE	FALSE				TRUE
Hospital/P	Other	FALSE	FALSE	TRUE	FALSE				TRUE
Hospital/P	Other	FALSE	FALSE	TRUE	FALSE				TRUE
Other	Other	FALSE	TRUE	TRUE	FALSE	Need sales rep, interested in HiSeq need site			TRUE
Hospital/P	Grant - Fur	FALSE	TRUE	FALSE	FALSE				TRUE
Dx or Refe	Other	FALSE	TRUE	TRUE	FALSE	Wants to genotype clinical samples soon. Ne			TRUE
Hospital/P	Grant - Fur	FALSE	TRUE	FALSE	FALSE	Low complexity			TRUE
Hospital/P	Other	FALSE	TRUE	FALSE	FALSE	Looking at cyto array systems. Have aysel co			TRUE
University	Grant - Fur	FALSE	FALSE	TRUE	FALSE	Send NGS	TRUE	TRUE	TRUE

ILLUM-0459

First Name	Last Name	Title	Company	Address St	Email Addr	Address Ci	Address St	Address Pc	Address Cc	Phone	Fax	Description
Dimitris	Agamanolis		Akron Chil	One Perkir	dagamano	Akron	OH	44308-106	United States			
Ivan	Brandslund		Lillebaelt H	25 Kabbelt	ivan.brand	Vejle		DK-7100	Denmark			interest in
Su	Chen		M D Ander	1515 Holcc	sschen@m	Houston	TX	77030	United Sta	(713) 792-	(713) 794-	interested
Lawrence	Crolla		Northwest	800 W Cen	lcrolla@nc	Arlington H	IL	60005	United Sta	(847) 618-	(847) 618-	veracode t
Christine	Curtis		Case West	10524 Euc	christine.c	Cleveland	OH	44106	United Sta	(216) 983-	(216) 983-	gpr beads i
Wilbur	Franklin		Univ of Col	Mail Stop F	wilbur.fran	Aurora	CO	80045	United Sta	(303) 274-	(303) 274-3096	
Michael	Hafez		Johns Hopl	600 N Wol	mjhafez@a	Baltimore	MD	21287	United Sta	(410) 955-	(410) 614-7440	
Stephanie	Hallam		Allegro Dia	650 Albany	sehallam0	Boston	MA	2118	United Sta	617 414 2	617 358 5(	startup wa
John Greg	Howe		Yale Unive	333 Cedar	john.howe	New Haver	CT	06520-803	United Sta	(203) 737-	(203) 688-	gpr univers
Jeffrey	Hung		SABiosciences		jhung@sabiosciences.com				United States			
Lei	Li		Pfizer	213 Long V	lei.li@pfize	Mystic	CT	6355	United States			
Mark	Lovell		The Childr	13123 E. 1	lovell.mark	Aurora	CO	80045	United Sta	(720) 777-	(720)777-7119	
Ruth Ann	Luna		Baylor Coll	6621 Fann	raluna@bc	Houston	TX	77030	United States			
Roberta	Madej			700 Begier	rmadej@c	San Leandı	CA	94577	United Sta	(510) 610	-0982	gpr beads
Narasimha	Nagan		Genzyme (	3400 Com	narasimha	Westboroı	MA	1581	United Sta	(508) 389-	(508) 389-	higlhy inte
Marina	Nikiforova		Univ of Pit	200 Lothro	nikiforovar	Pittsburgh	PA	15213	United Sta	(412) 802-	(412) 802-6799	
Yasuhiro	Otomo		Sysmex	Kobe Taka	otomo.yas	Kobe		651-2271	Japan	078-991-1919		have rep c
Joseph	Pulliam		University	800 Rose S	joe.pullian	Lexington	KY	40536	United Sta	8.59E+09		interested
Mark	Raffeld		NCI	9000 Rock	mraff@bo	Bethesda	MD	20892	United Sta	(301) 496-	(301) 402-2415	
Paula	Revell		Texas Chil	6621 Fann	parevell@t	Houston	TX	77030	United Sta	(832) 824-	(832) 825-0164	
Marlene	Sabbath-Solitare		St Barnaba	94 Old Sho	msabbath(	Livingston	NJ	7039	United Sta	(973) 322-	(973) 322-	running a
Steven	Schichman		Central Ar	4300 W 7t	schichman	Little Rock	AR	72205	United Sta	(501) 257-	(501) 257-	adme inte
Jeremy	Segal		New Yourk	435 E. 70t	jp2001@a	New York	NY	10021	United Sta	917-509-7176		
Antonia	Sepulveda		U Pennsylv	3400 Spru	Sepulveda	Philadelph	PA	19104	United Sta	(215) 615-	(215) 614-1988	
Alain	Troesch		Biomerieu	5, Rue Des	alain.troes	Grenoble		38024	France	+33 478 87	+33 478 87	9nterested
Oana	Vele		Lenox Hill	100 East 7	ovele@hot	New York	NY	10075	United Sta	(917) 499-9708		starting m
Michael	Wang		University	115 Busine	wangmx@	Columbia	MO	65203	United Sta	(573) 882-	(573) 882-	gpr beads
Raymond	Widen		Tampa Ger	PO Box 12	rwiden@v	Tampa	FL	33601	United Sta	(813) 844-	(813) 844-	eragen cyt
Lei Po	Wong		Hong Kong	Village Roa	chrislpw@	Hong Kong	NA	HKSAR	CHINA			has lumine
Yuan	Xue		UCLA	1000 Vete	yxue@me	Los Angele	CA	90024	United Sta	310-206-3945		
Mike	Armstrong		Pacific Rim	5325 Metr	marmstror	San Diego	CA	92110	United Sta	619-295-0	619-295-0853	
Voncia	Arterberry		Quest Diag	14225 Nev	voncia.x.A	Chantilly	VA	20153-084	United Sta	(703) 802-	(703) 802-7153	
William	Benjamin Jr.		U Alabama	619 S 19th	bbenjami	Birminghar	AL	35249	United Sta	(205) 934-	(205) 975-	he is a 23 a

ILLUM-0460

Industry	Sub-indust	Budget	Next Steps	Contact M	Questions	Lead Statu	Cancer res	Cytogeneti	Diagnostic	Disease re	Gene Cont	Gene Expr
Academic	Hospital/Path Lab			1		Marketing			1			
Commerci	Dx or Refe	Other		1		Marketing						
Academic	University	Other	Customer	1		Marketing						
Academic	Hospital/P	Other	Customer	1		Marketing			1			
Commerci	Dx or Refe	Other		1		Marketing						
Academic	Hospital/P	Grant (Available Fund		1		Marketing	1			1		
Academic	Hospital/Path Lab		Customer	1		Marketing		1	1	1		
Commerci	Dx or Reference Lab		Customer	1		Marketing						
Academic	Hospital/Path Lab			1		Marketing						
Commerci	Service Provider/Core		Customer	1		Marketing	1					
Commerci	Pharma		Customer	1		Marketing	1		1			1
Other			Customer	1		Marketing			1			
Academic	Hospital/Path Lab			1		Marketing						
Other				1		Marketing			1	1		
Commerci	Biotech	Other	Customer	1		Marketing			1			
Other			Customer	1		Marketing						
Commerci	Dx or Refe	Other		1		Marketing						
Academic	Hospital/P	Other	Customer	1		Marketing			1	1		
Governme	Human Re	Other		1		Marketing			1			
Academic	Hospital/Path Lab			1		Marketing						
Commerci	Service Provider/Core		Customer	1		Marketing	1					
Other				1		Marketing						
Other			Customer	1		Marketing						
Other			Customer	1		Marketing	1		1			1
Commerci	Pharma	Other	Customer	1		Marketing		1	1			
Commerci	Dx or Refe	Grant (Available Fund		1		Marketing			1			
Commerci	Pharma	Other		1		Marketing			1			
Commerci	Dx or Refe	Grant (Available Fund		1		Marketing						
Commerci	Dx or Reference Lab			1		Marketing						
Academic	Hospital/Path Lab		Customer	1		Marketing		1	1			
Other						Marketing	1		1			
Other						Marketing					1	1
Academic	University	Other	Customer requested product info			Marketing						

ILLUM-0461

Genotypin	Sequencin	Systems	Record Owner
			Illumina Lead Queue
			Illumina Lead Queue
			Illumina Lead Queue
1			Illumina Lead Queue
1		1	Illumina Lead Queue
	1		Illumina Lead Queue
1		1	Illumina Lead Queue
1		1	Illumina Lead Queue
			Illumina Lead Queue
			Illumina Lead Queue
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1		1	Illumina Lead Queue
	1		Illumina Lead Queue

ILLUM-0462

Slava	Elagin	Meridian B	3471 River	slava.elagi	Cincinnati	OH	45244	United Sta	513-271-3	513-271-0744	
Ross	Haynes	NIST	100 Bureai	ross.hayne	Gaithersbu	MD	20899-831	United Sta	(301) 975-	(301) 975-	didn't kno
Mai	He	Women &	101 Dudle	mhe@wih	Providence	RI	2905	United Sta	(862) 242-6092		
Mridula	Iyer	QIAGEN, Inc.						United States			asked info
Cynthia	Jackson	Rhode Isla	Apc12	cjackson@	Providence	RI	2903	United Sta	401-444-4	401-444-8514	
John	Jessup	National C	6130 Exec	jessupj@n	Bethesda	MD	20892	United Sta	(301) 435-	(301) 402-7819	
Susannah	Kennedy	Aurora Biomed Inc						United States			
Jin	Li	Dana-Farb	44 Binney	jli@lroc.ha	Boston	MA	2115	United Sta	(617) 632-	(617) 582-8213	
Robert	Lloyd	ViveBio						United States			
Connie	McGregor	Royal Univ	103 Hospit	connie.mc	Saskatoon	SK	S7N 0W8	Canada	(306) 655-	(306) 655-2223	
Arturo	Mendoza	Sharp Men	7901 Frost	art.mendo	San Diego	CA	92014	United Sta	858-939-3	858-939-3647	
Kasinathar	Muralidharan	Quest Diag	14225 Nev	kasinathan	Chantilly	VA	20151	United Sta	(703) 802-	703-802-7	cftr interes
Marilyn	Owens	Caris Diagr	8400 Ester	marilynow	Irving	TX	75063	United Sta	(562) 818-1567		
Richard	Scuderi	Pacific Rim	Pathologis	ricscu@gm	San Diego	CA	92122	United Sta	858-337-7174		
Scott	Shell	TMD Quint	610 Oakm	scott.shell	Westmont	IL	60559	United Sta	(630) 203-	(630) 789-	targeted se
Metin	Taskin	The Valley	223 N Van	mtaskin@	Ridgewooc	NJ	7450	United Sta	(201) 447-	(201) 447-	beadxpres
Vivianna	Van Deerlin	University	3400 Spru	vivianna@	Philadelph	PA	19104	United Sta	(215) 662-	(215) 662-7529	
Donna	Wolk	University	1501 N Ca	dwolk@en	Tucson	AZ	85724-505	United Sta	(520) 626-	(520) 694-	add to mai
Judy	Yu	Abbott Mo	1300 E Tot	judy.yu@a	Des Plaine	IL	60018	United Sta	(224) 361-	(224) 361-7578	
E	Zhang	Princess M	610 Univer	katzhang@	Toronto	ON	M5G 2M9	Canada	(416) 340-	(416) 340-3596	

		Marketing	1	1		1				
Government	Customer requested product infc	Marketing	1							
Other		Marketing			1					
Commercial	Customer requested product infc	Marketing			1					
Government	Customer requested product infc	Marketing								
Other	Customer requested product infc	Marketing								
Other		Marketing	1							
Other	Customer requested product infc	Marketing	1				1			
Other		Marketing								
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ILLUM-0464

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EXHIBIT III

OF

OPPOSER/PETITIONER'S MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT THEREOF

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Serial Number: 77982582 Assignment Information Trademark Document Retrieval

Registration Number: 4053668

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ILLUMINADX

(words only): ILLUMINADX

Standard Character claim: Yes

Current Status: Registered. The registration date is used to determine when post-registration maintenance documents are due.

Date of Status: 2011-11-08

Filing Date: 2009-05-28

Transformed into a National Application: No

Registration Date: 2011-11-08

Register: Principal

Law Office Assigned: LAW OFFICE 102

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 650 -Publication And Issue Section

Date In Location: 2011-10-06

LAST APPLICANT(S)/OWNER(S) OF RECORD

1. Illumina, Inc.

Address:
Illumina, Inc.

5200 Illumina Way
San Diego, CA 92122
United States
Legal Entity Type: Corporation
State or Country of Incorporation: Delaware

GOODS AND/OR SERVICES

International Class: 005
Class Status: Active
Clinical diagnostic reagents, reagent kits, and beads with attached biomolecules, comprised primarily of oligonucleotides and other nucleic acids, natural and modified nucleotides, buffers, labels, and substrates, for clinical diagnostic purposes
Basis: 1(a)
First Use Date: 2010-03-19
First Use in Commerce Date: 2010-03-19

ADDITIONAL INFORMATION

Prior Registration Number(s):
2471539
2632507
2756703

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2012-03-08 - Applicant/Correspondence Changes (Non-Responsive) Entered

2012-03-08 - TEAS Change Of Owner Address Received

2011-11-08 - Registered - Principal Register

2011-10-07 - Notice Of Acceptance Of Statement Of Use E-Mailed

2011-10-06 - Law Office Registration Review Completed

2011-09-30 - Allowed for Registration - Principal Register (SOU accepted)

2011-09-20 - Notice Of Pseudo Mark Mailed

2011-09-19 - Statement Of Use Processing Complete

2011-09-16 - Use Amendment Filed

2011-09-19 - Divisional processing completed

2011-09-16 - Divisional request received

2011-09-16 - TEAS Request To Divide Received

2011-09-16 - TEAS Statement of Use Received

2011-08-16 - Notice Of Approval Of Extension Request E-Mailed

2011-08-15 - Extension 2 granted

2011-08-02 - Extension 2 filed

2011-08-15 - Case Assigned To Intent To Use Paralegal

2011-08-02 - TEAS Extension Received

2011-02-03 - Notice Of Approval Of Extension Request E-Mailed

2011-02-01 - Extension 1 granted

2011-02-01 - Extension 1 filed

2011-02-01 - TEAS Extension Received

2010-08-03 - NOA E-Mailed - SOU Required From Applicant

2010-06-08 - Official Gazette Publication Confirmation E-Mailed

2010-06-08 - Published for opposition

2010-04-30 - Law Office Publication Review Completed

2010-04-30 - Approved For Pub - Principal Register

2010-04-30 - Examiner's Amendment Entered

2010-04-30 - Notification Of Examiners Amendment E-Mailed

2010-04-30 - EXAMINERS AMENDMENT E-MAILED

2010-04-30 - Examiners Amendment -Written

2010-04-23 - Assigned To Examiner

2010-04-23 - Previous Allowance Count Withdrawn

2010-04-16 - Withdrawn From Pub - Og Review Query

2010-04-07 - Law Office Publication Review Completed

2010-04-07 - Assigned To LIE

2010-03-21 - Approved For Pub - Principal Register

2010-02-24 - Teas/Email Correspondence Entered

2010-02-23 - Communication received from applicant

2010-02-23 - TEAS Response to Office Action Received

2009-09-04 - Notification Of Non-Final Action E-Mailed

2009-09-04 - Non-final action e-mailed

2009-09-04 - Non-Final Action Written

2009-08-27 - Assigned To Examiner

2009-06-02 - Notice Of Pseudo Mark Mailed

2009-06-01 - New Application Office Supplied Data Entered In Tram

2009-06-01 - New Application Entered In Tram

ATTORNEY/CORRESPONDENT INFORMATION

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United States Patent and Trademark Office

Assignments on the Web > Trademark Query

No assignment has been recorded at the USPTO

For Serial Number: 77982582

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Web interface last modified: Jan 26, 2012 v.2.3.1

EXHIBIT IV

OF

OPPOSER/PETITIONER'S MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT THEREOF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc.,	)	
	)	Opp. No. 91194218 (SN 77768176) (Parent)
Opposer/Petitioner,	)	
	)	Opp. No. 91194219 (SN 77775316)
v.	)	
	)	Can. No. 92053479 (RN 3887164)
Meridian Bioscience, Inc.,	)	
	)	Can. No. 92053482 (RN 3868081)
Applicant/Registrant.	)	

DECLARATION OF CALVIN FAN

I, Calvin Fan, declare as follows:

1. I am a Senior Patent Attorney with Illumina, Inc. ("Illumina"). In my current role with the company, I am responsible for managing Illumina's trademark portfolio. I have reviewed the relevant documents and make this declaration based on my personal knowledge.

2. Attached hereto as Exhibit 1 are true and correct copies of print-outs from Meridian Bioscience, Inc.'s website, www.meridianbioscience.com.

3. Attached hereto as Exhibit 2 is a true and correct copy of a February 1, 2010 article containing an interview of Meridian's CEO Jack Kraeutler, published in MedCity News.

4. Attached hereto as Exhibit 3 is a true and correct excerpt from Meridian's 2010 Annual Report, which is available on Meridian Bioscience, Inc.'s website at http://investor.meridianbioscience.com/phoenix.zhtml?c=117257&p=irol-reportsannual.

5. Attached hereto as Exhibit 4 are true and correct copies of the FDA's 510(k) Substantial Equivalence Determination Decision Summary Assay And Instrument Combination Template for the ILLUMIGENE *C. difficile* assay and the Technical Data Sheet for the DisplaceAce™ DNA Polymerase used in the ILLUMIGENE *C. difficile* assay.

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 29th day of May 2012

Calvin Fan

EXHIBIT 1

OF

DECLARATION OF CALVIN FAN

Get to Know Us

Get to know Meridian Bioscience.

Meridian Bioscience is a fully integrated life science company that manufactures, markets and distributes a broad range of innovative diagnostic test kits, purified reagents and biopharmaceutical enabling technologies that help deliver answers. Our products provide accuracy, simplicity and speed for the early diagnosis and treatment of common medical conditions, such as *C. difficile*, *H. pylori*, foodborne diseases and respiratory infections.

In addition, we develop and manufacture a variety of biological and non-biological materials used in proficiency testing programs. Learn more about our Proficiency & Controls business unit.

Meridian diagnostic products are used outside of the human body and require little or no special equipment. We design our products to enhance the well being of the patient—while reducing the total outcome costs of healthcare.

Meridian has strong market positions in the areas of gastrointestinal infections, serology, parasitology and fungal disease diagnosis. We actively market our products to hospitals, reference laboratories, research centers, physician offices and diagnostics manufacturers in more than 60 countries around the world.

Our shares are traded on the NASDAQ National Market, symbol VIVO. Learn why Meridian Bioscience is a company to watch.

Learn more about our mission and core values.

Meridian Team

Meridian's Board of Directors and Management Team are committed to providing value to all of our stakeholders —our shareholders, our customers, and our employees.

Meet the Board

News & Alerts

Access industry-specific news, product features, and Meridian company information.

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illumigene®

THE PROMISE OF illumigene® Molecular Simplified

The Promise of *illumigene*® empowers your lab with the speed and accuracy of molecular testing.

***illumigene*®** delivers the power of molecular technology in a simplified and affordable format. Meridian Bioscience has employed Loop-Mediated Isothermal Amplification (LAMP) technology to design and manufacture the ***illumipro-10*™**, a compact, automated detection system with a very simple assay process that is the heart of ***illumigene*®**. Based on feedback from hundreds of laboratory professionals, ***illumigene*®** is the molecular diagnostic system clinical labs have been waiting for.

Learn more about innovative LAMP technology

***illumigene*® is:**

- Simple procedure with a smaller footprint
- Faster and More Flexible
- More cost-effective

***illumigene*®** makes it possible for any laboratory—regardless of space, personnel, or budget limitations—to implement molecular diagnostic capabilities.

Simpler and Smaller
The simple 7-step sample preparation process takes less than 2 minutes of hands-on time per sample. The ***illumipro-10*™** offers walk-away automation. When you place the sample into the ***illumipro-10*™** and press the "run" button, your work is done.

With *illumigene*® there is:

- No centrifugation, precision pipetting
- No thermal cycling
- No gel electrophoresis

The *illumipro-10*™:

- Has a very small footprint—approximately the size of an 8.5" x 11" sheet of paper
- Internal and external keyboard as well as an internal bar code reader for flexible sample ID entry
- Provides continuous access while running up to 10 samples at a time in 2 independent 5-sample chambers
- Does not require an auxiliary computer

Learn more about the *illumipro-10*™ instrument

Learn more about the *illumigene*® *C. difficile* 7-step process

Faster and More Flexible
Because there is no thermal cycling, ***illumigene*®** can provide **results for up to 10 samples in less than an hour.** Results are displayed directly on the ***illumipro-10*™** LED readout screen and can be printed out on the system printer. ***illumigene*®** integrates easily into any facility, regardless of work volume or staff experience:

- Flexibility to stop and restart the assay procedure
- Adaptable to single sample or batch processing
- Optional work station adapts to any user or work flow

More Cost Effective
***illumigene*®** allows your lab to add molecular diagnostics without additional costs for labor, training, and capital equipment. In your lab, ***illumigene*®** means:

- Less then 2 minutes hands-on time per sample
- Minimal labor requirement
- Low maintenance with no additional service costs and 24-hour equipment replacement
- Reduced waste disposal costs from environmentally friendly, mercury-free process

Add *illumigene*® Capability to Your Lab
***illumigene*®** is revolutionary technology that is simple, fast, and affordable. It puts molecular diagnostics within the reach of every lab.

Product Information

illumigene® System Brochure

Product Sheet: *illumipro-10*™

Sell Sheet: *C. difficile* Assay

Product Sheet: *illumigene*® work station

Sell Sheet: Lamp Process

Sell Sheet: LAMP vs PCR

Sell Sheet: Pediatric

Video: *illumigene*® Assay Procedure

Video: LAMP Technology

Clinical Literature

ASM Abstract 1: A Novel New Molecular Approach for the Detection of *Clostridium difficile*

ASM Abstract 2: Reactivity of *Clostridium difficile* Toxinotypes with the *illumigene*™ *C. difficile* Molecular Assay

ASM Abstract 3: A New Molecular Approach for the Detection of *Clostridium difficile*

CVS Abstract: A New Molecular Approach for the Detection of *Clostridium difficile*

YAHOO! FINANCE

Meridian Bioscience Receives FDA Clearance for New Molecular Test: illumigene® Group B Streptococcus

Press Release: Meridian Bioscience, Inc. – Mon, Dec 12, 2011 9:30 AM EST

CINCINNATI--(BUSINESS WIRE)-- Meridian Bioscience, Inc., Cincinnati, Ohio (NASDAQ: VIVO - News) today announced that it has received FDA clearance for a new molecular diagnostic test for Group B *Streptococcus* (GBS) on the ***illumi**gene*® platform. This innovative test is a strong addition to the ***illumi**gene* platform. Group B *Streptococcus,* or GBS, continues to be a major perinatal pathogen, for both mothers and their infants, and is associated with significant morbidity and mortality. The CDC recommendations for GBS, published in November of 2010, indicated that a universal culture-based screening method should be performed at 35 to 37 weeks of gestation. (MMWR Vol 59 NoRR-10) The ***illumi**gene* GBS test allows laboratories to comply with the CDC recommendations while benefitting from a simplified workflow and greater sensitivity for early diagnosis and proper management. Donna Mayne, Supervisor of the Microbiology, Serology and Molecular Laboratories at Sacred Heart Hospital in Pensacola, Florida states, "***illumi**gene* GBS fully complies with the CDC guidelines for the detection of Group B *Streptococcus* (GBS) and is the most sensitive test on the market. Broth enrichment plus ***illumi**gene* GBS empowers my laboratory to provide the highest standard of care for my patients. The simplified procedure will allow my laboratory to report accurate, definitive results in less time than culture."

The ***illumi**gene* GBS test utilizes loop-mediated isothermal DNA amplification (LAMP) technology to detect *Streptococcus agalactiae* in enriched cultures of samples from women. The test procedure is remarkably simple, highly sensitive, and yields results in less than one hour. It requires no expensive capital equipment. The test relies upon a simple procedure that includes heat treatment, amplification and detection. The entire amplification is isothermal and results are read on the ***illumi**pro-10*™ instrument. All reagents and disposables are contained in the test kit and can be stored at room temperature. Meridian believes that the "point-of-care" simplicity of this technology, along with its cost efficiency, make this innovative test ideal for helping in early diagnosis and proper management of this preventable disease, especially in those instances where there is a low level of the biological target.

Richard Eberly, Chief Commercial Officer stated, "***illumi**gene* GBS is a key addition to the ***illumi**gene* platform given the importance of early detection of GBS to prevent serious disease in infants. This new test begins the expansion of the ***illumi**gene* platform and provides a molecular technology that is affordable, simple, and quick. Our technology continues to appeal to any size acute care laboratory that is seeking molecular amplification capability with no capital investment and the ultimate in simplicity and accuracy."

FORWARD LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as "estimates", "anticipates", "projects", "plans", "seeks", "may", "will", "expects", "intends", "believes", "should" and similar expressions or the negative versions thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. The Company assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors that could cause actual results to differ materially, including, without limitation, the following:

Meridian's continued growth depends, in part, on its ability to introduce into the marketplace enhancements of existing products or new products that incorporate technological advances, meet customer requirements and respond to products developed by Meridian's competition. While Meridian has introduced a number of internally developed products, there can be no assurance that it will be successful in the future in introducing such products on a timely basis. Meridian relies on proprietary, patented and licensed technologies and the Company's ability to protect its intellectual property rights, as well as the potential for intellectual property litigation, would impact its results. Ongoing consolidations of reference laboratories and formation of multi-hospital alliances may cause adverse changes to pricing and distribution. Recessionary pressures on the economy and the markets in which our customers operate, as well as adverse trends in buying patterns from customers can change expected results. Costs and difficulties in complying with laws and regulations, including those administered by the United States Food and Drug Administration, can result in unanticipated expenses and delays and interruptions to the sale of new and existing products. The international scope of Meridian's operations, including changes in the relative strength or weakness of the U.S. dollar, can make results difficult to predict. One of Meridian's main growth strategies is the acquisition of companies and product lines. There can be no assurance that additional acquisitions will be consummated or that, if consummated, will be successful and the acquired businesses will be successfully integrated into Meridian's operations. There may be risks that acquisitions may disrupt operations and may pose potential difficulties in employee retention and there may be additional risks with respect to Meridian's ability to recognize the benefits of acquisitions, including potential synergies and cost savings or the failure of acquisitions to achieve their plans and objectives. The Company cannot predict the possible effects of recently-enacted United States healthcare legislation and any similar initiatives in other countries on its results of operations. In addition to the factors described in this paragraph, Part I, Item 1A Risk Factors of our Form 10-K contains a list and description of uncertainties, risks and other matters that may affect the Company.

Meridian is a fully integrated life science company that manufactures, markets and distributes a broad range of innovative diagnostic test kits, purified reagents and related products and offers biopharmaceutical enabling technologies. Utilizing a variety of methods, these products and diagnostic tests provide accuracy, simplicity and speed in the early diagnosis and treatment of common medical conditions, such as gastrointestinal, viral and respiratory infections. Meridian's diagnostic products are used outside of the human body and require little or no special equipment. The Company's products are designed to enhance patient well-being while reducing the total outcome costs of healthcare. Meridian has strong market positions in the areas of gastrointestinal and upper respiratory infections, serology, parasitology and fungal disease diagnosis. In addition, Meridian is a supplier of rare reagents, specialty biologicals and related technologies used by biopharmaceutical companies engaged in research for new drugs and vaccines. The Company markets its products and technologies to hospitals, reference laboratories, research centers, veterinary testing centers, diagnostics manufacturers and biotech companies in more than 60 countries around the world. The Company's shares are traded through NASDAQ's Global Select Market, symbol VIVO. Meridian's website address is www.meridianbioscience.com.

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EXHIBIT 2

OF

DECLARATION OF CALVIN FAN

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MedCity News Q&A: Meridian Bioscience CEO Jack Kraeutler

February 1, 2010 by *MedCity News*

Meridian Bioscience CEO Jack Kraeutler on how his diagnostics company is making the big jump into molecular tests for bacteria.

By Mary Vanac

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CINCINNATI, Ohio — Over the years, Meridian Bioscience Inc. has gotten good at making diagnostic test kits that detect bugs like *C. difficile* and *H. pylori*, both bacteria that can wreak havoc in the digestive tract — or worse.

The longtime Cincinnati-based life sciences company also knows a lot about testing for upper-respiratory infections, antibodies in the blood, and even for parasites and fungi, as well as supplying big laboratories with the proteins they need to do their work.

Now, the company that sells most of its tests to hospitals, reference laboratories, research centers, doctors' offices and veterinary testing centers is getting into molecular testing — tests that are so sensitive they can spot a single bacterium or virion in a tiny sample.

CEO Jack Kraeutler talked with MedCity News about the promise of this new generation of diagnostic tests — and potential acquisitions – for his company.

MedCity News: In January, Meridian Bioscience started clincial trials of its molecular test for *C. difficile*, which like other future molecular tests will will go by the brand name "Illumigene." What's the development strategy behind this new platform technology?

Jack Kraeutler: As we move into molecular, there are a couple of detection goals that we have. One is, if it's a single-point detection, let's say you're looking for a virus, that uses a simpler technology. Now, if you're looking for a virus or a bacteria that might be resistant to a particular drug, now you need to have multi-analyte capability. With the current generation of Illumigene, you could do multi-analyte testing, but it would require two different tests. In the future, we'll be able to do it in the same test.

MedCity News: So what's the market opportunity for Illumigene?

JK: For us, the ability to go into molecular gives us, not necessarily a displacement technology, but a technology that augments all of the immunoassays that we sell. The first platform of *C. difficile* – and that's the one we expect to launch later this year — is capable of producing somewhere in the range of $10 to $20 million annually. The second

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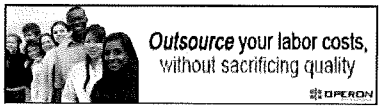

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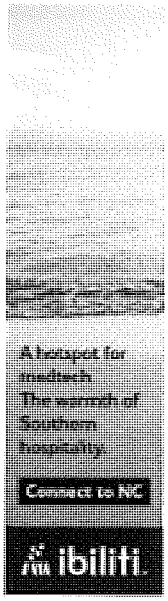
SIMILAR ENTRIES

- Meridian Bioscience lands FDA clearance for C. difficile test
- Meridian seeks FDA nod for Illumigene test
- Meridian rebounds slightly after cutting guidance



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generation of Illumigene, which will probably start to go into clinical trials later this fiscal year, should be able to do even more than that.

MedCity News: Is Illumigene part of the medical industry's move toward personalized medicine?

JK: Many of the most rapidly growing tests are the ones that can be done in 10 or 15 minutes. Most people tend to think of these tests as doctor-office tests. But when you're dealing with acute diseases, hospitals need to be able to run these tests 24-7 so the right therapies can be selected. That happens to be a type of personalized medicine in the acute-care market.

The interesting thing about Illumigene is that most molecular assays that are in the market are very cumbersome because they're based on a technology called "polymerase chain reaction." With PCR, you have to raise and lower the temperature of the sample several times to amplify it so that it can be tested. It usually requires large pieces of capital equipment to do PCR.

Our product is run at a constant temperature, and it is simple enough to be run one at a time. There's no capital equipment associated with it. So it does have a much greater reach.

MedCity News: Tell me about the amplification technology you licensed from Japan that enables you to run samples without thermo-cycling them.

JK: The technology was developed for oyster farmers who were concerned about norovirus contaminating their oyster beds. So they needed a very sensitive technology that would measure down to a single virion in a water sample. And they came up with the LAMP technology, it's loop-amplification, and we've adapted it to human samples.

MedCity News: Now, sales of your current generation of *C. difficile* test were flat in the fiscal first quarter because of increasing competition. It strikes me that Illumigene could re-energize your test line for this bacteria.

JK: That's actually been our history. We've been detecting *C. difficile* for almost 20 years now. Every 18 to 24 months, we introduce a new product. So, we've had about seven evolutions over the last 20 years. And this, of course, is a major step up. I think Illumigene is a platform that will change the perception of Meridian as being just a little kit company to being a company that is a player with advanced technologies.

MedCity News: What are the major challenges that Meridian Bioscience will face in 2010?

JK: One of the nice things about the business is because it's built around infectious diseases, it doesn't ebb and flow because of economic conditions. And in virtually every case, our products help the patient get better faster with the right therapy. So it's a stable business.

What's impacting us today is so many companies have tried to go for the high-volume diagnostics. They're beginning to open their eyes to see our space, which has largely been populated with Meridian and three or four other companies.

The problem is, the technologies these other companies want to bring into our space are extremely expensive. My worry is these companies

- Despite poor earnings, Meridian Bioscience touts purchase of British firm
- Meridian Bioscience dives on "disappointing" Q4 results

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are going to do stupid things in terms of pricing their products and other taking market share other ways. And it's going to be disruptive. But this is a fast-moving business, and we can deal with it.

MedCity News: What are the biggest opportunities your company has this year?

JK: One is to increase sales outside the United States. For the first quarter, for example, our international sales were up 17 percent, which was a good number for us. Our international sales increases had been running around 9 or 10 percent. We think we can increase international sales by fine-tuning some of our distributor partnerships. We made some changes in Canada, Australia, Argentina and Israel recently. We're looking at two other markets.

We also have new product lines, like one that tests for the bacteria that causes most stomach ulcers, *H. pylori*. And food-borne infections like *E. coli* and *Campylobacter* are emerging markets for us that are growing very fast.

There is no silver bullet. This year is about balanced opportunities and making sure that we maximize those opportunities.

MedCity News: Your company has zero debt. What gives?

JK: Any time that we've raised debt or borrowed money, we've paid it off quickly. And that makes us a shopper this year. We are looking for opportunities. But because we've got a financially efficient business, we're not going to buy something and make our shareholders wait three years for the payback. It has to be accretive in the first year.

MedCity News: Is there a certain type of company that you're looking for?

JK: We're looking at businesses that we can bolt into our life sciences business. To make it clear, our life science business is one that supplies the biggest automated diagnostic companies like Abbott, Roche, Johnson & Johnson with their essential proteins. So it's a limited customer market, it's a highly technical sale, and the more components and biologics you can offer them, the better that business will grow. So, small, private businesses ... $5, $10, $15 million in revenue are excellent bolt-ons for us.

And then there are a number of diagnostic opportunities, either carve-outs that are non-strategic for bigger businesses, or a number of smaller [firms], both public and private, that have been wandering for years and could use a good home.

Business/Financial News, News Well, Diagnostics

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Meridian Bioscience Inc.

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GE Healthcare unit inks deal with Theragenics | Deals roundup

The MassDevice Weekly Checkup: April 18, 2011

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Tod Loofbourrow out at iRobot | Personnel moves

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more

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- Wrong-site surgery: The problem continues
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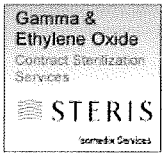
- Should scientists write editorials about their own published work?
- Weekly Wireless Roundup: Myomo launches Android-supported robotic stroke rehab device
- Three- and four-point bend testing of semiconductor devices

more



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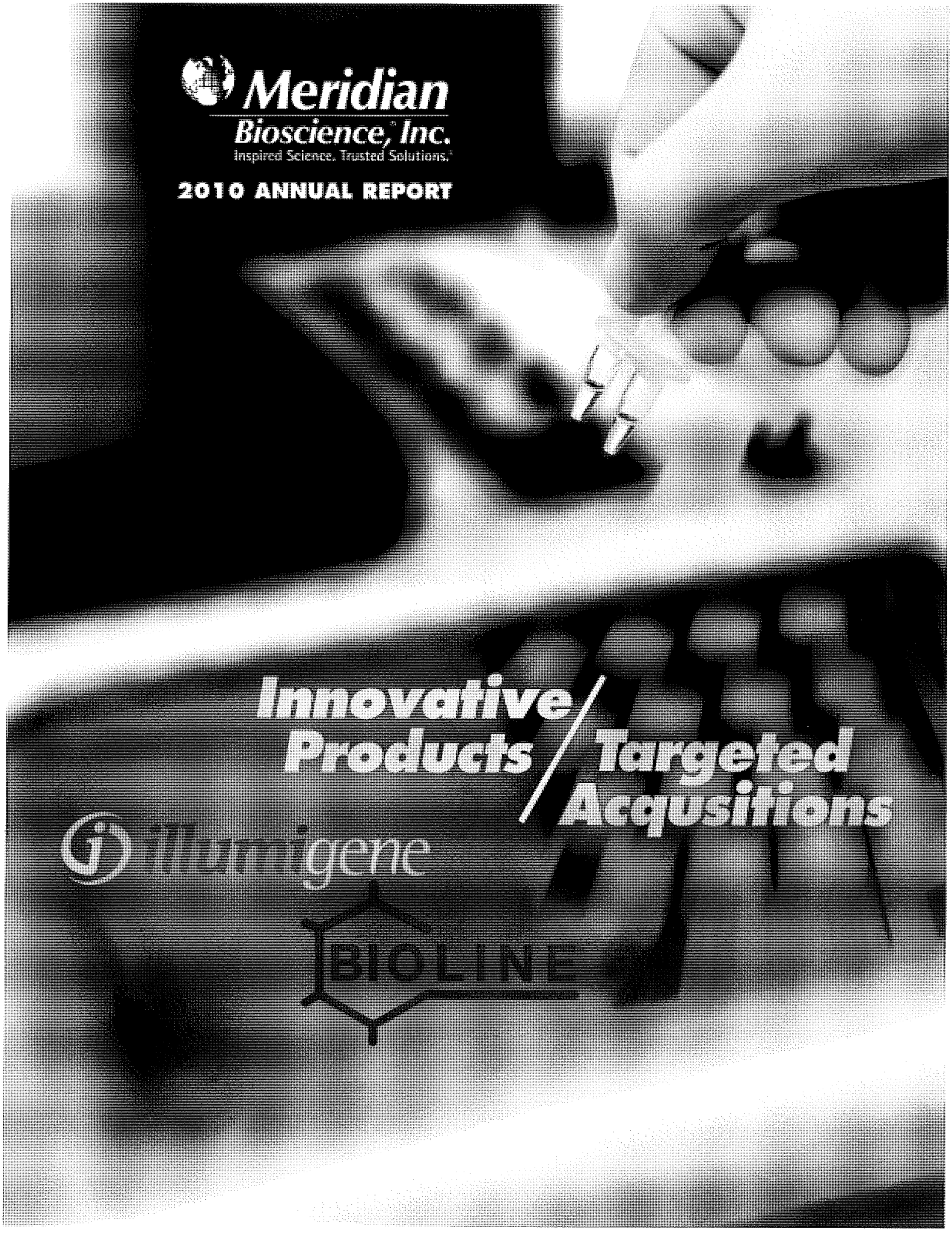
Built on an AdaptiveTheme using Drupal by Michael Knapp mknapp

EXHIBIT 3

OF

DECLARATION OF CALVIN FAN


Meridian
Bioscience, Inc.
Inspired Science. Trusted Solutions.
2010 ANNUAL REPORT
Innovative Products / Targeted Acquisitions
Immunogene
BIOLINE

SELECTED FINANCIAL DATA

Income Statement Information *(Amounts in thousands, except per share data)*

	FY 2010	FY 2009	FY 2008	FY 2007	FY 2006
Net sales	$143,000	$148,274	$139,639	$122,963	$108,413
Gross profit	88,475	92,783	86,480	74,940	64,684
Operating income	41,138	48,779	44,350	35,030	26,894
Net earnings	26,647	32,759	30,202	26,721	18,333
Basic earnings per share	$ 0.66	$ 0.81	$ 0.75	$ 0.67	$ 0.47
Diluted earnings per share	$ 0.65	$ 0.80	$ 0.74	$ 0.66	$ 0.46
Cash dividends declared per share	$ 0.74	$ 0.65	$ 0.53	$ 0.40	$ 0.28
Book value per share	$ 3.38	$ 3.40	$ 3.19	$ 2.83	$ 2.40

Balance Sheet Information

	FY 2010	FY 2009	FY 2008	FY 2007	FY 2006
Current assets	$94,020	$117,147	$99,458	$93,745	$80,742
Current liabilities	14,147	16,752	16,061	17,067	20,617
Total assets	154,785	155,997	146,431	132,698	120,528
Long-term debt obligations	-	-	-	-	1,803
Shareholders' equity	137,361	137,905	128,489	112,948	94,350

FORWARD LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as "estimates", "anticipates", "projects", "plans", "seeks", "may", "will", "expects", "intends", "believes", "should" and similar expressions or the negative versions thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. The Company assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors that could cause actual results to differ materially, including, without limitation, the following:

Meridian's continued growth depends, in part, on its ability to introduce into the marketplace enhancements of existing products or new products that incorporate technological advances, meet customer requirements and respond to products developed by Meridian's competition. While Meridian has introduced a number of internally developed products, there can be no assurance that it will be successful in the future in introducing such products on a timely basis. Ongoing consolidations of reference laboratories and formation of multi-hospital alliances may cause adverse changes to pricing and distribution. Recessionary pressures on the economy and the markets in which our customers operate, as well as adverse trends in buying patterns from customers can change expected results. Costs and difficulties in complying with laws and regulations administered by the United States Food and Drug Administration can result in unanticipated expenses and delays and interruptions to the sale of new and existing products. Changes in the relative strength or weakness of the U.S. dollar can also change expected results. One of Meridian's main growth strategies is the acquisition of companies and product lines. There can be no assurance that additional acquisitions will be consummated or that, if consummated, will be successful and the acquired businesses will be successfully integrated into Meridian's operations. There may be risks that acquisitions may disrupt operations and may pose potential difficulties in employee retention and there may be additional risks with respect to Meridian's ability to recognize the benefits of acquisitions, including potential synergies and cost savings or the failure of acquisitions to achieve their plans and objectives. The Company cannot predict the possible impact of recently-enacted United States healthcare legislation and any similar initiatives in other countries on its results of operations. In addition to the factors described in this paragraph, Part I, Item 1A Risk Factors of our Form 10-K contains a list and description of uncertainties, risks and other matters that may affect the Company.

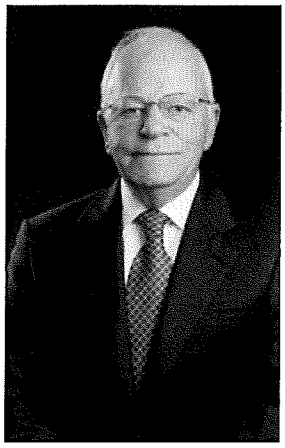
CORPORATE PROFILE

Meridian is a fully integrated life science company that manufactures, markets and distributes a broad range of innovative diagnostic test kits, purified reagents and related products and offers complementary enabling technologies. Utilizing a variety of methods, these products and diagnostic tests provide accuracy, simplicity and speed in the early diagnosis and treatment of common medical conditions, such as gastrointestinal, viral and respiratory infections. Meridian's diagnostic products are used outside of the human body and require little or no special equipment. The Company's products are designed to enhance patient well being while reducing the total outcome costs of healthcare. Meridian has strong market positions in the areas of gastrointestinal and upper respiratory infections, serology, parasitology and fungal disease diagnosis. In addition, Meridian is a supplier of rare reagents, specialty biologicals and related technologies used by biopharmaceutical companies engaged in research for new drugs and vaccines. The Company markets its products and technologies to hospitals, reference laboratories, research centers, veterinary testing centers, diagnostics manufacturers and biotech companies in more than 60 countries around the world. The Company's shares are traded through NASDAQ's Global Select Market, symbol: VIVO. Meridian's website address is *www.meridianbioscience.com*.

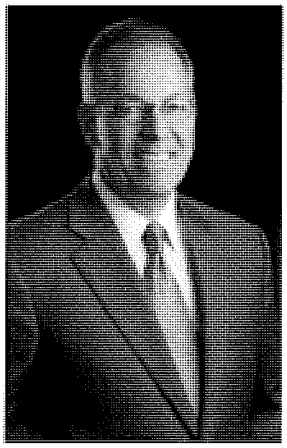
TO OUR SHAREHOLDERS

Following nearly a decade of uninterrupted growth, fiscal 2010 could be described as a "reset" year for Meridian Bioscience. During the past year, our Diagnostics businesses faced an environment in which testing for influenza virtually disappeared when the H1N1 pandemic abruptly ended and "seasonal" flu, which normally strikes during the first calendar quarter, never arrived. In addition, our core franchise in hospital acquired infections was challenged by new test offerings from our traditional competitors and new testing technologies from new competitors that were beginning to encroach into the infectious disease labs. More broadly, the impact of a weak employment picture continued to erode healthcare utilization rates as coverage lapsed for the unemployed. However, during this difficult period our focus on future growth continued and the strategic achievements we made during this challenging year will provide the tools and technologies to recapture Meridian's traditional growth trajectory.

Our work to expand the transition of lab customers to our rapid tests for foodborne infections intensified and produced excellent results. We continued to leverage our managed care and reference lab relationships to drive physician practices towards ordering our HpSA® stomach ulcer tests prior to prescribing drugs that only mask the symptoms of gastritis. We accelerated the expansion of our Life Science business through a strategic acquisition and optimized efforts with our key industrial customers. Finally, we introduced our simple and novel molecular testing platform, ***illumigene***®, globally in the latter part of the year. We believe that these actions have produced sustainable opportunities for growth and that Meridian is on track for another long run of successes.



William J. Motto

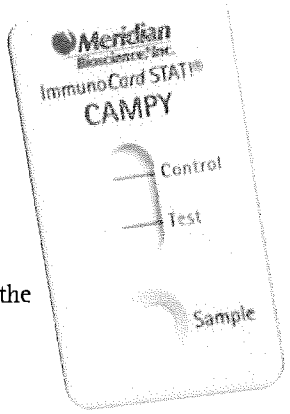


John A. Kraeutler

On a macro level, opportunities for growth in medical diagnostics continue to increase based upon factors including: (i) an aging population that will require and seek more physician interaction resulting in greater utilization of healthcare services; (ii) the same aging population that is living longer and will therefore be more susceptible to conditions that require diagnosis and treatment; (iii) advances in molecular biology that have made the human genome a powerful and predictive target for diagnosing acute and chronic diseases as well as aiding in selecting appropriate therapies; and (iv) regardless of its final form, the impact of healthcare reform which is likely to drive greater utilization of related products and services. At Meridian, therefore, our mission is to drive innovation, develop simple but powerful tests and utilize technologies that enable labs to be leaders in rapidly diagnosing disease causes while helping reduce overall costs and improving patient well-being. Our focus is three-fold. First, we develop improved methods that reduce labor and turnaround time compared to results associated with current testing procedures. Second, we target emerging diseases and build testing demand by educating and motivating physicians to order new diagnostic tests as they strive to better manage and treat their patients. Finally, we use our strong balance sheet to make accretive strategic acquisitions that complement Meridian's diagnostics and life science businesses.

INCREASING SHAREHOLDER RETURN THROUGH GROWTH AND DIVIDENDS

On the diagnostic side of the business, we completed product development for our first molecular amplification technology, ***illumigene***. Historically, Meridian has been built upon simple technologies for detecting specific proteins, or antigens and antibodies, which are produced by disease-causing pathogens or as a result of the body's response to these pathogens. We utilize a variety of simple technologies as the basis for our diagnostic tests based upon antigen-antibody binding such as Premier™, ImmunoCard®, ImmunoCard STAT!®, and more recently, TRU. All of these technologies use "immunoassay" principles to help create a detectable color change or other evident change based on binding or aggregation. More recently, a new DNA based technology was introduced into the clinical laboratory market. This new technology, PCR, was so sensitive that it could isolate a single DNA fragment from a human sample and then amplify that DNA via elaborate chemistry to make it detectable by sophisticated instrumentation. Due to the complexity of PCR, expensive instrumentation was required to help simplify the technology for routine laboratory usage. As a result, the initial markets that embraced PCR were typically high volume applications such as blood unit screening for viruses and STD testing.



Early on, Meridian recognized that DNA testing technology should be developed or acquired as a future core technology. The needs of our customer base, however, were not likely to support high volume testing, as the infectious disease labs tend to work with single or small volumes of patient samples. Therefore, we needed a special type of DNA amplification technology that could be performed as easily on one sample as on ten or twenty. Further, all other DNA technologies required expensive capital equipment to be justified and maintained by the customer. Meridian's DNA technology would have to have minimal or no capital equipment requirement. We evaluated numerous technologies in the early years of our quest. Ultimately we licensed a technology termed "LAMP", loop-mediated isothermal amplification. After licensing LAMP, our product development teams raced to perfect the technology and to design a simple reader that would fit the workflow and daily demands of our microbiology and virology lab customers. We chose *Clostridium difficile*, an important hospital associated pathogen and our largest product category, as the initial target. Following successful pilot studies during the second quarter of fiscal 2010 we completed formal clinical trials and, in March, we submitted our regulatory application to the FDA. ***illumigene*** *C. difficile* was launched to non-U.S. markets in late May, and in July we received clearance to market in the U.S. Although we are still in the early stages of market release, ***illumigene*** has already been very well received. Our scientists and outside collaborators have published strong supporting studies that have been peer reviewed and

EXHIBIT 4

OF

DECLARATION OF CALVIN FAN

EPICENTRE®
Biotechnologies

DisplaceAce™ DNA Polymerase

Cat. No. ***D090710K***

DisplaceAce™ DNA Polymerase* is a recombinant enzyme derived from a thermophilic bacterium that has been altered by truncation to remove the 5'→3' exonuclease activity of the full-length enzyme. It has strong strand-displacing DNA polymerase activity, similar to that of *Bacillus* DNA polymerases. The DNA-dependent DNA polymerase activity is optimal at approximately 65°C. It also has RNA-dependent DNA polymerase activity. The enzyme can be inactivated by incubation at 80°C for 20 minutes. Thus, if thermal denaturation of a DNA substrate is intended (>75°C), the enzyme must be added after this step to ensure activity.

DisplaceAce DNA Polymerase is provided in a 10,000-units size (100 U/µl) along with 10X DisplaceAce Reaction Buffer. Please inquire for other package sizes or concentrations.

Product Specifications

Storage: Store only at –20°C in a freezer without a defrost cycle.

Storage Buffer: DisplaceAce DNA Polymerase is supplied in a 50% glycerol solution containing 50 mM Tris-HCl (pH 7.5), 0.1 M NaCl, 0.1 mM EDTA, 1 mM dithiothreitol, and 0.1% Triton® X-100.

Unit Definition: One unit converts 10 nmol of dNTPs into acid-insoluble material in 30 minutes at 65°C.

Activity Assay: The activity assay is performed in a 50-µl reaction containing 25 mM TAPS (pH 9.3), 50 mM KCl, 2.0 mM $MgCl_2$, 0.2 mM of each dNTP, 10 µg activated calf thymus DNA, and varying amounts of enzyme.

10X DisplaceAce Reaction Buffer: 0.2 M Tris-HCl (pH 8.5) and 50 mM $MgCl_2$.

Contaminating Activity Assays: DisplaceAce DNA Polymerase is free of detectable exo- and endonuclease and RNase activities.

Related Products: The following products are also available:

– dNTP Solutions

* patent pending

Triton is a registered trademark of Rohm & Haas, Philadelphia, Pennsylvania.

DisplaceAce is a trademark of EPICENTRE, Madison, Wisconsin.

Lit. #289
9/09

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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

K100818

B. Purpose for Submission:

To obtain substantial equivalence for the Illumigene *C. difficile* assay

C. Measurand:

C. difficile toxin A gene

D. Type of Test:

Loop mediated isothermal amplification

E. Applicant:

Meridian Bioscience Inc.

F. Proprietary and Established Names:

Illumigene *C. difficile* Assay

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.2660 – Microorganism differentiation and identification device

2. Classification:

   Class 1

3. Product code:

   OMN – *C. difficile* nucleic acids

4. Panel:

   83 - Microbiology

H. Intended Use:

1. Intended use:

   The illumigene *C. difficile* DNA amplification assay, performed on the *illumipro-10,* is a qualitative *in vitro* diagnostic test for the direct detection of toxigenic *C. difficile* in human stool specimens from patients suspected of having *Clostridium difficile*-associated disease (CDAD).

   The illumigene *C. difficile assay* utilizes loop-mediated isothermal DNA amplification (LAMP) technology to detect the pathogenicity locus (PaLoc) of toxigenic *Clostridium difficile.* The *Clostridium difficile* PaLoc is a gene segment present in all known toxigenic *C. difficile* strains. The *C. difficile* PaLoc codes for both the Toxin A gene (tcdA) and the Toxin B gene (tcdB), has conserved border regions, and is found at the same site on the *C. difficile* genome for all toxigenic strains. The illumigene *C. difficile* assay detects the PaLoc by targeting a partial DNA fragment on the Toxin A gene. The tcdA target region was selected as an intact region remaining in all known A+/B+ and A-/B+ toxinotypes.

   illumigene *C. difficile* is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

2. Indication(s) for use:

   The illumigene *C. difficile* DNA amplification assay, performed on the *illumipro-10,* is a qualitative *in vitro* diagnostic test for the direct detection of toxigenic *C. difficile* in human stool specimens from patients suspected of having *Clostridium difficile*-associated disease (CDAD).

   The illumigene *C. difficile* assay utilizes loop-mediated isothermal amplification (LAMP) technology to detect the pathogenicity locus (PaLoc) of toxigenic *Clostridium difficile.* The *Clostridium difficile* PaLoc is a gene segment present in all known toxigenic *C. difficile* strains. The *C. difficile* PaLoc codes for both the Toxin A gene (tcdA) and the Toxin B gene (tcdB), has conserved border regions, and is found at the same site on the *C. difficile* genome for all toxigenic strains. The illumigene *C. difficile* assay detects the PaLoc by targeting a partial DNA fragment on the Toxin A gene. The tcdA target region was selected as an intact region remaining in all known A+/B+ and A-/B+ toxinotypes.

   illumigene *C. difficile* is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

3. Special conditions for use statement:

   For professional use

4. Special instrument requirements:

   Illumipro -10 Automated Isothermal Amplification and Detection System

I. Device Description:

The ***illumi****gene* Molecular Diagnostic Test System is comprised of the ***illumi****gene C. difficile* DNA Amplification Test Kit, the ***illumi****gene C. difficile* External Control Kit and the ***illumi****pro-10* Automated Isothermal Amplification and Detection System. Additional specialized laboratory equipment is not required for execution of ***illumi****gene* Molecular Diagnostic Test System assays.

The ***illumi****gene C. difficile* DNA amplification assay utilizes loop-mediated isothermal amplification (LAMP) technology to detect the presence of toxigenic *C. difficile* in patients suspected of having *C. difficile* associated disease (CDAD). Each ***illumi****gene C. difficile* assay is completed using materials provided: ***illumi****gene* Sample Preparation Apparatus, ***illumi****gene* Reaction Buffer, ***illumi****gene C. difficile* Test Device, Sample Collection Brush, and ***illumi*** *gene* Extraction Tube. Samples are prepared using the Sample Collection Brush and the ***illumi****gene* Sample Collection Apparatus, target DNA is heat extracted in the Extraction Tube and DNA amplification occurs in the ***illumi****gene C. difficile* Test Device.

The ***illumi****pro-10* heats each ***illumi*** *gene C. difficile* Test Device containing prepared samples, facilitating amplification of target DNA. When toxigenic *C. difficile* is present in the patient sample, a cytotoxin specific sequence is amplified and magnesium pyrophosphate is formed. As the LAMP reaction progresses, magnesium pyrophosphate forms a precipitate in the reaction mixture. The optics system of the ***illumi****pro-10* detects the change in light transmission through the reaction mixture created by the precipitating Magnesium pyrophosphate. Sample results are reported as Positive or Negative based on the detected change in transmission.

The ***illumi****gene C. difficile* External Control Kit consists of a Positive Control Reagent and a Negative Control Reagent. External Control reagents are provided to aid the user in detection of reagent deterioration, adverse environmental or test conditions, or variance in operator performance that may lead to test errors. The ***illumi****gene C. difficile* External Control Kit is required for routine Quality Control.

Final Component Summary

illumi*gene C. difficile DNA* Amplification Assay

·***illumigene C. difficile* Sample Preparation Apparatus:** Sampling unit consisting of sample preparation chamber, dropper tip, cap and Sample Dilution Buffer (Phosphate Buffered Saline and formalin treated *Staphylococcus aureus* , with sodium azide (0.09%) as a preservative)
·***illumigene* Reaction Buffer:** Tris-buffered solution containing sodium azide (0.09%)as a preservative
·***illumigene C. difficile* Test Device:** Two separate chambers containing dry reagent lyospheres comprised of DNA polymerase, Deoxyribonucleoside Triphsophate (dNTPs), and either *C. difficile* specific primers (TEST Chamber) or *S. aureus* primers (CONTROL Chamber). The Control lyosphere contains quinoline yellow dye to differentiate it from the Test lyosphere
·**Sample Collection Brushes:** Tube cap fitted with stainless steel rod and nylon bristles
·***illumigene* Extraction Tubes:** 1.5 mL polypropylene microcentrifuge tubes with caps; RNase, DNase and pyrogen-free
illumigene C. difficile External Control Kit
·***illumigene* Positive Control:** Tris-buffered solution containing non-infectious Plasmid DNA (*S. aureus* and *C. difficile inserts)* with azide (0.09%) as a preservative
·***illumigene* Negative Control:** Tris-buffered solution containing non-infectious Plasmid DNA (*S. aureus insert)* with azide (0.09%) as a preservative

J. Substantial Equivalence Information:

1. Predicate device name:
   Cepheid Xpert C.difficile

2. Predicate 510(k) number:
   K091109

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Sample matrix	Uniformed unpreserved stool samples	Same
Assay type	DNA amplification	Same

Differences		
Item	Device	Predicate
Intended Use	Assay targets a conserved DNA fragment on the toxin A (tcdA) gene in the pathogenicity locus of toxigenic *C. difficile.*	Assay targets the toxin B (tcdB) gene
Instrument	Assay uses the Illumipro-10 instrument	Assay uses the Cepheid GeneXpert Dx System

Differences		
Item	Device	Predicate
Detection method	Assay uses loop mediated isothermal amplification (LAMP) technology and detects changes in turbidity by visible light transmission	Assay uses automated real time polymerase chain reaction (PCR) and detects fluorescence
Transport media	Sample in Cary Blair media is acceptable	Not for use with Cary Blair media
Extraction method	Manual	Self contained, automated

K. Standard/Guidance Document Referenced (if applicable):

User Protocol for Evaluation of Qualitative Test Performance (EP 12-A2)
User Verification of Performance for Precision and Trueness (IVD) (EP 15-A2)
Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff
Draft Guidance for Industry and FDA Staff: Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses
General Principles of Software Validation; Final Guidance for Industry and FDA Staff

L. Test Principle:

The ***illumigene*** *C. difficile* Assay is based on loop-mediated isothermal amplification technology (LAMP). Loop-mediated amplification is accomplished by the use of specially designed primers that provide specific and continuous isothermal DNA amplification. Magnesium-pyrophosphate is produced as a by-product of LAMP amplification. The magnesium-pyrophosphate forms a white precipitate in the reaction solution, giving the reaction solution a turbid appearance. The presence of turbidity signifies a positive reaction while the absence of turbidity represents a negative reaction.

The Toxigenic *C. difficile* Pathogen Locus (PaLoc) and *illumigene C. difficile* Primer Regions:

The ***illumi**gene C. difficile* assay contains primers that specifically amplify an ~204 base pair (bp) sequence within the 5' region of the toxin A (*tcd*A) gene that is part of the cytotoxin pathogen locus found in toxigenic *C. difficile*. This region is found in all cytotoxin positive (A+/B+ and A-/B+) strains characterized and is not present in cytotoxin negative strains (A-/B-).

The ***illumi**gene C. difficile* assay detects the presence of toxigenic *C. difficile* in stool samples from patients suspected of having *Clostridium difficile* associated disease in the following manner:

Patient stool sample is collected using the sample brush portion of the ***illumi**gene* Sample Collection Apparatus. The sample is added to the Sample Collection Apparatus containing Sample Dilution Buffer and formalin treated *Staphylococcus aureus*. *S. aureus* serves as an internal control for inhibition and system suitability.

The diluted sample is mixed, filtered through the Sample Collection Apparatus and dispensed drop-wise into an ***illumi** gene* Extraction Tube. The Extraction Tube is heated to facilitate DNA extraction of the sample and the internal control material.

Extracted DNA is added to an ***illumi**gene* Reaction Buffer tube, mixed and added to the ***illumi**gene C. difficile* Test Device. The ***illumi** gene* Test Device consists of two chambers, one for the sample (TEST) and one for the internal assay control (CONTROL). The TEST chamber contains a lyosphere comprised of DisplaceAce™ DNA polymerase, dNTPs, Bovine Serum Albumin, and ***illumi**gene C. difficile* primers. The CONTROL chamber contains a lyosphere comprised of DisplaceAce™ DNA polymerase, dNTPs, Bovine Serum Albumin, yellow dye and ***illumi**gene Staphylococcus aureus* internal control primers.

The Test Device is placed in the ***illumi**pro-10*™ for amplification and detection. Amplification occurs when the ***illumi**gene C. difficile* Test Device is incubated at 63 C. When toxigenic *C. difficile* is present in the patient sample, the cytotoxin specific sequence is amplified. Magnesium pyrophosphate, a by-product of DNA amplification, will reach saturation and precipitate producing a turbid solution in the TEST chamber of the Test Device. When sample preparation and the assay procedure have has been performed successfully and inhibition has not occurred, DNA from the internal control will amplify. Magnesium pyrophosphate will precipitate and form a turbid solution in the CONTROL chamber of the test device. Assay reactions take place in approximately 40 minutes.

Light transmission (650 ± 20 nm) through the TEST and CONTROL solutions is measured by the ***illumi**pro-10* at the on-set of the assay run and at completion. The ***illumi**pro-10* calculates the ratio between the initial absorbance reading and the final absorbance reading and compares the ratio to an established cut-off value. Valid test results will be reported for a change in absorbance above 90% in the CONTROL chamber. Positive test results will be reported for a change in absorbance above 90% in the TEST chamber and the CONTROL

chamber.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility studies were performed by three clinical sites using coded panels. The panels consisted of moderately positive (n=2), low positive (n=3), high negative (n=3) and negative (n=2) samples. The moderately positive and low positive samples were contrived from negative specimens spiked with toxinogenic *C. difficile* VPI 10463 to just above the LoD for the strain (weak positive) or below the limit of blank (high negative sample), as determined by replicate testing during manufacture of the samples. Negative samples were natural samples. Three lots of ***illumigene*** *C. difficile* and nine ***illumi*** *pro-10* instruments were used in reproducibility studies. Positive and Negative Controls were tested with each panel. Each clinical site tested two panels each day for five days. At least two operators each day at each facility performed the testing to demonstrate reproducibility. Reproducibility of the assay is 100% for moderate positive, low positive and negative samples. Reproducibility is 91% for high negative samples.

Positive samples were contrived from negative specimens. The moderately positive and low positive samples were contrived from negative specimens spiked with toxinogenic C. difficile VPI 10463 to just above the LoD for the strain (weak positive) or below the limit of blank (high negative sample), as determined by replicate testing during manufacture of the samples. Negative samples were natural samples. **Final concentrations of C. difficile in reproducibility panel samples were as follows:** Moderate Positive: 200 CFU/test (Positive) Low Positive: 64 CFU/test (Positive) High Negative: 0.5 CFU/test (Negative)

The sources of variability examined in the study included operators (minimum 2 at each site), laboratories (3 sites), runs (Panels tested twice per day), test date (panels tested for five days), and ***illumi*** pro-10 instruments (9 instruments).

Precision (within-run and within-laboratory) was calculated following CLSI EP 15-A2. 95% confidence intervals were calculated using the Wilson method.

Reproducibility of the assay is 100% for moderate positive, low positive and negative samples. Reproducibility is 91% for high negative samples. Sample type and replicate data is as follows: Percent Agreement Positive Samples: 60/60 Replicates or 100% Percent Agreement Low Positive: 90/90 Replicates or 100% Percent Agreement High Negative: 82/90 Replicates or 91% Percent Agreement Negative: 59/59 Replicates or 100% *(One negative sample produced an invalid result during testing. This value was not included in the calculations.)*

b. *Linearity/assay reportable range:*

N/A

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Internal control is provided in the Sample Preparation Apparatus and the Assay Device. The Sample Preparation Apparatus contains Sample Dilution Buffer with formalin treated *Staphylococcus aureus*. The CONTROL Chamber of the Assay Device contains a lyosphere with *S. aureus* primers. The internal control has the same reactants to that of the test chamber except for the primer composition and a yellow dye. Internal Control components are intended to monitor sample preparation, polymerase inhibition, system suitability and reagent integrity.

illumigene External Control Reagents will be sold separately as adjunct reagents to the ***illumigene*** *C. difficile* Assay. Each External Control kit contains a Negative Control reagent and a Positive Control reagent. External Controls aid the user in detection of reagent deterioration, adverse environmental or test conditions or variance in operator performance that can cause test errors. External Controls are required for routine Quality Control.

Positive Control: Tris-buffered solution containing non-infectious Plasmid DNA (S. aureus and C. difficile inserts) at 200.0 fg/µL with sodium azide (0.09%) as a preservative.

Negative Control: Tris-buffered solution containing non-infectious Plasmid DNA (*S. aureus insert)* at 200.0 fg/µL with sodium azide (0.09%) as a preservative.

d. *Detection limit:*

Sensitivity studies were designed to determine, within 95% confidence intervals, the analytical limit of detection (LoD) of *C. difficile* diluted in a human stool matrix. The LoD is the lowest number of colony-forming units (CFUs) per test aliquot that can be distinguished from Native samples with a high degree of probability.

Seven different strains representing five toxinotypes of *C. difficile* were evaluated. Each bacterial strain was spiked into negative stool and then diluted serially. Twenty replicates of each dilution were individually processed and tested to give a stated probability of 95% for the LoD dilution. The results obtained with each individual strain are given in Tables 2 – 5 on the following pages. The LoD point estimates and 95% upper and lower confidence intervals for each toxinotype are summarized in Table 1 below.

Table 1. 95% confidence intervals for *illumigene C. difficile* analytical LoD.

Strain ID	Toxinotype	Phenotype	LoD/Test	Lower Limit (95% CI)	Upper Limit (95% CI)
VPI 10463	0	A+/B+	4 CFU/test	83.9%	100%
2007431	III (NAP1)	A+/B+	32 CFU/test	83.9%	100%
BI8	III	A+/B+	64 CFU/test	76.4%	99.1%
2006240	V (NAP7)	A+/B+	32 CFU/test	83.9%	100%
CF1	VIII	A-/B+	64 CFU/test	83.9%	100%
2007858	IX/XXIII	A+/B+	32 CFU/test	83.9%	100%
8864	X	A-/B+	64 CFU/test	83.9%	100%

e. *Analytical specificity:*

Interference Studies:

Potentially interfering substances were added to a natural negative and a contrived positive sample at final concentrations of 5% v/v or greater. The contrived positive samples were prepared from a pool of donor stools that were confirmed negative by toxinogenic culture. The sample was inoculated with *C. difficile* VPI 10463 to just above the limit of detection (18 CFU/test) for this organism.

Potentially interfering substances were added at final concentrations of 5% V/V or greater. Dilution Controls for each sample were prepared by adding a phosphate-buffered saline solution in place of the potentially interfering substance. Each sample was tested in triplicate. The following substances, at the specified saturated solvent/diluents concentrations, were included in the study: Barium sulfate (5 mg/mL), fecal fat (equivalent to 2.65 mg stearic plus 1.3 mg palmitic acids per mL), hemoglobin (as methemoglobin) (3.2 mg/mL), IgA (5 mg/mL), Imodium AD® (0.00667 mg/mL), Kaopectate® (0.87 mg/mL), Metronidazole (12.5 mg/mL), mucin (3.33 mg/mL) Mylanta® (4.2 mg/mL), Pepto-Bismol® (0.87 mg/mL), Prilosec® (0.5 mg/mL), Tagamet® (0.5 mg/mL), TUMS® (0.5 mg/mL), Vancomycin (12.5 mg/mL), white blood cells (5%V/V), whole blood (5% V/V).

Crossreactivity Studies:

Potentially crossreactive or interfering microorganisms were added to a natural negative and a contrived positive sample at concentrations of 1.2×10^8/mL (bacteria and fungi) or at a minimum of $1 \times 10^{5.06}$ $TCID_{50}$/mL (viruses). The contrived positive sample was prepared from a pool of donor stools that were confirmed negative by toxinogenic culture. The sample was inoculated with toxinogenic *C. difficile* VPI 10463 to just above the limit of detection (18 CFU/test) for this strain.

Potentially cross-reactive microorganisms were added at concentrations of 1.2 x 10^8/mL (bacteria and fungi) or at a minimum of 1 x $10^{5.06}$ /mL $TCID_{50}$/mL (viruses). Dilution Controls for each sample were prepared by adding a phosphate-buffered saline solution in place of the potentially cross-reactive microorganisms. Each potential cross-reactive microorganism was tested in replicates of three. The following microorganisms were included in the study: *Aeromonas hydrophila, Bacteroides fragilis, Campylobacter coli, Campylobacter fetus, Campylobacter jejuni, Candida albicans, Citrobacter freundii, Clostridium sordellii, Clostridium perfringens, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli, Escherichia coli O157:H7, Escherichia fergusonii, Escherichia hermannii, Helicobacter pylori, Klebsiella pneumoniae, Lactococcus lactis, Listeria monocytogenes, Peptostreptococcus anaerobius, Plesiomonas shigelloides, Proteus vulgaris, Pseudomonas aeruginosa, Pseudomonas fluorescens, Salmonella* Groups B-E, *Serratia liquefaciens, Serratia marcescens, Shigella boydii, Shigella flexneri, Shigella sonnei, Staphylococcus aureus, Staphylococcus epidermidis, Vibrio parahaemolyticus, Yersinia enterocolitica,* Adenovirus Types 40 and 41, Coxsackievirus, Echovirus, Rotavirus.

Strain Reactivity Studies:

Aliquots from culture filtrates of each organism were first adjusted to MacFarland Standard 4 (approximately 1.2 X 10^9), then spiked into a natural negative stool matrix to a final concentration of (1) 64 CFU/test (the LoD at 95% confidence as determined in the LoD study, and (2) at 100 times the LoD (to represent heavily infected samples).

Strain reactivity studies were performed by testing *C. difficile* stock cultures from different sources at 64 CFU/test and 640 CFU/test with ***illumi**gene C. difficile*. Each sample was testing in triplicate. Strains and toxinotypes tested were as follows: **Type 0 Strains:** 10463, 2004111, 2004205, 2005070, 2005257, 2008029, 2008162, 2008341, 2008351, 2009066, 2009099, B1, G1, J7, K12, Y1; **Type III Strains:** 2004052, 2004118, 2007431, BI17, BI8; **Type V Strains:** 2005325, 2006240, 2008188, 2009018, 2009065, BK6; **Type VIII Strains:** 43598, 2008016, CF1; **Type X Strains:** 8864; **Type XII Strains:** 2007435; **Type IX/XXIII Strains:** 2007858; **Unknown Strains:** 2009132, 2009155, 2009277.

f. Assay cut-off:

The assay has a fixed cut-off based on the measured change in light transmission at the assay endpoint. There are no range values for the cut-off. The ***illumi**pro-10* measures the transmission of light through the Test Solution and the Control Solution at the start of the Assay Run and at the end point of the Assay Run, approximately 40 minutes for the ***illumi**gene C. difficile* assay. The ***illumi**pro-10* calculates the ratio of the Run End (Signal final or S_f) reads with the Run Start (Signal Initial or S_i) reads. Calculated S_f : S_i ratios less than 90% are reported as positive; Calculated S_f : S_i ratios greater than or equal to 90% are reported as negative. Fixed cut-off values

were based on well characterized clinical specimens.

2. Comparison studies:

   a. *Method comparison with predicate device:*

      Only discrepant samples were tested with the predicate device, Cepheid® Xpert® *C. difficile,* and TECHLAB® C. DIFF CHEK™ - 60.

      Of 5 false-negative samples, 2 were negative by an FDA-cleared molecular assay.

      Of 27 false-positive samples, 15 were positive by an FDA-cleared molecular assay

      Of the 12 remaining false-positive samples, 8 were positive by an FDA-cleared assay for C. difficile Common Antigen.

   b. *Matrix comparison:*

      N/A

3. Clinical studies:

   a. *Clinical Sensitivity:*

      Samples utilized in this study were stool specimens from patients suspected of having C. *difficile* associated disease. No restrictions with regard to age, gender or geographical location were included. All samples were left-over samples. The consistency of each sample was categorized as solid, semisolid, bloody, and watery with no solids or in transport medium. A total of 697 qualified patient samples were used in the study. One sample was obtained per patient. Two tests were performed with each sample (cytotoxic bacterial culture and illumigene C. difficile assay). Performance characteristics of the illumigene C. difficile assay were determined by comparison to cytotoxic bacterial culture. Four independent clinical test sites located in the Midwestern and Southern regions of the United States and the manufacturer evaluated a total of 697 qualified patient samples. Samples were collected from 274 (39.3%) males and 419 (60.1%) females. In the case of 4 (0.6%) of the patients, sex was not known. The age groups of patients range from 2 years of age to 96 years. No differences in test performance were observed based on patient age, sex, or geographical location.

      Overall sensitivity was determined to be 95.2% (95% CI: 89.2% - 97.9%); overall specificity was determined to be 95.3% (95% CI: 93.2% - 96.7%).

Overall performance data

Cytotoxic bacterial culture		*illumigene C. difficile*	
	Positive	**Negative**	**Total**
Positive	99	5	104
Negative	27	546	573
Total	126	551	677
			95% CI
Sensitivity	99/104	**95.2%**	89.2 - 97.9%
Specificity	546/573	**95.3%**	93.2 - 96.7%
Correlation	645/677	**95.3%**	93.4 - 96.6%

b. Clinical specificity:

See 3(a) above

c. Other clinical supportive data (when a. and b. are not applicable):

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Samples used in this study were left-over samples for which a physician had ordered *C. difficile* testing. Observed *C. difficile* prevalence rate was approximately 15%.

N. Instrument Name:

The ***illumipro***-10

O. System Descriptions:

1. Modes of Operation:
The ***illumipro-10*** is a menu driven laboratory instrument with two independent sample processing blocks: Block A and Block B. Each ***illumipro-10*** Block is capable of batch processing up to five closed ***illumigene*** test devices.
The ***illumipro***-10 operates in four basic modes: ASSAY, RESULTS, SERVICE, and SYSTEM. Assay Selection and Sample Amplification occur in the ASSAY mode; Test Results are managed in the RESULTS mode; Basic instrument set-up is performed in the SYSTEM mode; and Optical performance verification is completed in the SERVICE

mode.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____X____ or No _____

3. Specimen Identification:

   Samples are identified by position. Default Sample Identification is based on Block and Well position (e.g. Block A, Well 1). The user may input Sample Identification information using the keypad, the barcode scanner or the optional external keyboard.

4. Specimen Sampling and Handling:

   Specimen Sampling and Handling is performed external to the ***illumi** pro-10*. Prepared Samples in closed ***illumi**gene* Test Devices are placed in the ***illumi**pro-10* for amplification and detection. The ***illumi**pro-10* has no direct contact with samples. Closed ***illumi**gene* Test Devices are discarded at the end of the assay to reduce the likelihood of contamination of the ***illumi**pro-10* or the workspace.

5. Calibration:

   The ***illumi**pro-10* was designed to be a self-monitoring instrument. Calibration by the end user is not required.

6. Quality Control:

   Quality Control requirements for the ***illumi**pro-10* are limited to verification of optical performance and routine surface cleaning/decontamination. Optics system verification is performed by the user at installation and at 30 day intervals thereafter. Optics Verification Standards consist of ten red acrylic pieces molded and polished to replicate the dimensions of each ***illumi**gene* Test Device chamber. The verification standards act like a high pass optical filter with the pass wavelength of 650 nm extending into the infrared range. Light transmission through the verification standard is used to confirm proper performance of the optics system. Failed optics verification testing for an instrument block will disable the block until the error is resolved. The ***illumi**pro-10* completes a Power-On Self Test (POST) at each power-on. POST testing confirms that the Hardware and Software elements of the system are performing as expected. The ***illumi**pro-10* reports an error if POST failures are obtained; the instrument is disabled until the error is resolved.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

N/A

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

1. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.