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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	Declaration of Gregory F. Heath.pdf(4011095 bytes) Exhibit 4 [ILLUM-0165].pdf(258641 bytes) Exhibit 11 [ILLUM-0224-225].pdf(566957 bytes) Exhibit 12 [ILLUM-1577-1579].pdf(353788 bytes) Exhibit 14 [ILLUM-0608-609].pdf(533413 bytes) Exhibit 15 [ILLUM-0660].pdf(116813 bytes) Exhibit 16 [ILLUM-0932-933].pdf(217936 bytes) Exhibit 36 [ILLUM-1146-1149].pdf(384541 bytes) Exhibit 39 [ILLUM-1862-1864].pdf(373945 bytes) Exhibit 55 [ILLUM-0295-297].pdf(1402761 bytes) Exhibit 101 [ILLUM-0598-600].pdf(356062 bytes) Exhibit 102 [ILLUM-0601-603].pdf(375813 bytes) Exhibit 103 [ILLUM-0604-605].pdf(287756 bytes) Exhibit 104 [ILLUM-3479-3599].pdf(2241897 bytes) Exhibit 105A.pdf(3085049 bytes) Exhibit 105B.pdf(3661268 bytes) Exhibit 105C - [ILLUM-0657-661, 0016-64, 0165-186, 0199-205].pdf(1237954 bytes) Exhibit 106 [ILLUM-0955-958].pdf(946205 bytes) Exhibit 107 [ILLUM-0635-656].pdf(4467272 bytes) Exhibit 108 [ILLUM-0969-972].pdf(725731 bytes) Exhibit 109 [ILLUM-0633-634].pdf(329217 bytes) Exhibit 110 [ILLUM-0598-609, 224-25, 611-14, 466-79, 488-91, 537-43, 300-7].pdf(4431688 bytes) Exhibit 111 [ILLUM-1070-1071].pdf(63690 bytes) Exhibit 112 [ILLUM-1075-1076].pdf(61845 bytes) Exhibit 113 [ILLUM-1072-1074].pdf(86475 bytes) Exhibit 114 [ILLUM-1077-1079].pdf(85123 bytes) Exhibit 115 [ILLUM-1809-1810].pdf(229383 bytes) Exhibit 116 [ILLUM-1067-1068].pdf(65337 bytes) Exhibit 117 [ILLUM-1080-1081].pdf(64499 bytes) Exhibit 118 [ILLUM-1069].pdf(43933 bytes) Exhibit 119 [ILLUM-1082].pdf(44986 bytes)

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

Illumina, Inc.,	)	Opposition No.: 91194218
Opposer,	)	
v.	)	
Meridian Bioscience, Inc.,	)	
Applicant.	)	

DECLARATION OF GREGORY F. HEATH

I, Gregory F. Heath, Ph.D., declare as follows:

1. I have personal knowledge of the matters set forth herein and if called upon to testify, I could and would competently testify thereto.

2. I am a Senior Vice President of Illumina, Inc. and, from March 2008 through December 2013, I have been the General Manager of Illumina's Diagnostics Business Unit. In my current role with the company, as Senior Vice President of In Vitro Diagnostic (IVD) Development I am responsible for developing In Vitro Diagnostic products. I am also familiar with Illumina's use of the marks ILLUMINA®, ILLUMINADX®, ILLUMINOTES™, and ILLUMICODE™.

3. I have a B.S. in psychology from Illinois State University, an M.A. in experimental psychology from Hollins College, a Ph.D. in experimental psychology from Virginia Commonwealth University, and I completed my post-doctoral work in behavioral pharmacology at Michigan State University. I have published more than 25 articles and abstracts in science and business. I have more than 25 years of experience in the diagnostics field, including launching the first FDA-approved array for diagnostic use while employed at Roche Molecular

Systems and the first FDA-approved next generation sequencing product while at Illumina.

4. I was previously employed at Roche Molecular Systems, where I 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 my last role at Roche Molecular Systems, I was responsible for new product development and global marketing activities for the infectious disease, blood screening, genetics, and oncology portfolios. I was also responsible for the PCR (polymerase chain reaction) licensing, industrial business, and business development programs.

5. From 2000 to 2003, I was head of the Business Development and Licensing for the Diagnostics Division of F. Hoffman La Roche in Basel, Switzerland. There I 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, I held numerous roles in marketing and strategic planning with Roche Diagnostics' U.S. affiliate.

6. 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 and RNA 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.

7. In April 2005, Illumina acquired VeraCode® technology through its acquisition of CyVera Corporation with the intention of using the technology in products for the molecular diagnostics market, which is part of the clinical diagnostic market. VeraCode® technology is an array-based technology that utilizes microscopic glass beads embedded with a digital

holographic element. VeraCode® beads are provided in a liquid suspension and are used in combination with an assay and reader to determine whether particular DNA sequences are present in a sample. For example, an assay, such as Illumina's GoldenGate® genotyping assay, is used to process a DNA sample to attach specific portions of the DNA to the VeraCode® beads. Illumina's BeadXpress® reader is then used to analyze the DNA samples attached to VeraCode® beads to determine whether specific, known DNA sequences are present in the sample DNA. Attached hereto as Exhibit 4 is a news article announcing Illumina's acquisition of CyVera. The VeraCode® technology formed the basis of Illumina's BeadXpress® diagnostic platform.

8. At the time I came to Illumina in 2008, Illumina was putting even more focus on the development of products and services for the molecular diagnostic market with the creation of a Diagnostics Business Unit. Attached hereto as Exhibit 101 is a true and correct copy of an Illumina press release dated January 4, 2008, announcing Illumina's corporate reorganization. In particular, the Diagnostics Business Unit was tasked with developing diagnostic content for the BeadXpress® system and, eventually, for Illumina's sequencing products. In March 2008, I was appointed to serve as the General Manager of Illumina's Diagnostics Business Unit. Attached hereto as Exhibit 102 is a true and correct copy of an Illumina press release dated March 17, 2008, announcing my appointment.

9. Since its formation in 2008, the Diagnostics Business Unit has become a major focus of Illumina. For example, in 2010, I hired Emily Winn-Deen as Vice President of Diagnostics Business Development. Attached hereto as Exhibit 103 is a press release announcing Ms. Winn-Deen's appointment at Illumina. Ms. Winn-Deen joined Illumina after working for more than 20 years in the life sciences and diagnostics fields. Ms. Winn-Deen has been responsible for overseeing a number of key development projects in diagnostics, including, for example, cancer diagnostics.

10. In 2011, Illumina partnered with Siemens Healthcare to develop an assay to

detect HIV. In fact, Illumina built a Biosafety Level 2 (BSL-2) lab for the Research and Development group at this time to be able to handle blood samples received through Illumina's work with Siemens. A BSL-2 lab is a special lab designed to contain biological agents in an enclosed facility. In the United States, the Centers for Disease Control and Prevention specify the required levels. A level 2 facility is required for work involving agents of moderate potential hazard and requires that laboratory personnel receive specific training in handling pathogenic agents and be directed by scientists with advanced training. Companies build these types of labs, and Illumina did build its lab, to be able to work with infectious diseases.

11. In 2011, Illumina appointed Dr. Daniel Grosu as Vice President and Chief Medical Officer to further build Illumina's diagnostic capabilities. Attached hereto as Exhibit 16 is a press release dated October 31, 2011, announcing Dr. Grosu's appointment. Prior to joining Illumina, Dr. Grosu worked in diagnostics development at Ortho-Clinical Diagnostics, Bayer Healthcare Pharmaceuticals, and Siemens Medical Solutions.

12. Since joining Illumina, Dr. Grosu has been instrumental in establishing a medical affairs team, which is responsible for engaging in peer-to-peer dialog with physicians about how to use sequencing and array technology in practice. Dr. Grosu has also been responsible for heading up and building a clinical development team, which has enabled Illumina to perform clinical trials with more expertise. For example, the clinical development team includes field managers who travel to clinical trial sites to assemble the locations and train the personnel who conduct Illumina's FDA clinical trials.

13. Beginning in 2006, Illumina had a formal development program to seek regulatory approval for its BeadXpress® system utilizing VeraCode® technology for in-vitro diagnostic use. In March 2009, Illumina shipped BeadXpress® devices to three clinical sites in the United States to begin the required clinical trials. As was the case with all of Illumina's BeadXpress® readers, those products were labeled with the ILLUMINA® mark. Attached hereto as Exhibit 104 is a true and correct copy of the Clinical Trial Report section of Illumina's

510(k) submission for the VeraCode® Genotyping Test for Factor V and Factor II.

14. In September 2009, Illumina formally submitted its BeadXpress® system and VeraCode® Genotyping Test to the FDA for 510(k) market clearance. On April 28, 2010, the FDA granted 510(k) market clearance for Illumina's BeadXpress® system for multiplex genetic analysis. According to the FDA's indications of use, the BeadXpress® system is an in-vitro diagnostic device intended for the simultaneous detection of multiple analytes in a DNA sample utilizing Illumina's VeraCode® holographic microbead technology. On April 28, 2010, the FDA also granted a separate 510(k) market clearance for Illumina's VeraCode® Genotyping Test for Factor V (Leiden) and Factor II (Prothrombin). These tests are used to identify Factor V and Factor II mutations, caused by an inherited blood clotting disorder known as thrombophilia, which increases the patient's risk for venous thrombosis. True and correct copies of press releases, articles, and presentations discussing Illumina's successful efforts to obtain regulatory approval for products designed for diagnostics are attached hereto as Exhibit 105. Attached hereto as Exhibit 36 are website printouts from the FDA 510(k) premarket notification database regarding Illumina's BeadXpress® system and VeraCode® Genotyping Test for Factor V and Factor II. Attached hereto as Exhibit 106 is a true and correct copy of a BeadXpress® System brochure.

15. Due to my aforementioned experience, I am very familiar with the time and costs involved in obtaining market clearance by the FDA for products used for human in-vitro diagnostic use. Prior to the submission of any product to the FDA for market approval, a company must complete extensive clinical trials, the results of which can take years to complete and compile into meaningful data. As a result, life sciences companies typically spend five years or more for internal development and clinical testing prior to submitting diagnostic products to the FDA. Depending upon the results of clinical trials and the satisfaction of other FDA requirements, FDA approval typically takes an additional nine months to two years before a product (with no known similar product that has already been cleared by the FDA) is cleared

for commercial market use.

16. In 2009, Illumina launched its Cancer Discovery Initiative to validate genes associated with ovarian cancer and gastric cancer using its sequencing platform. The goal of the project was to use sequencing to identify novel biomarkers to determine genes associated with these cancers. Cancer diagnostics could then be developed based on the identification of these biomarkers. For example, a patient's DNA sample could be sequenced and the results analyzed to determine whether that patient has any particular mutations associated with a particular type of cancer. This facilitates early disease detection and helps to predict a patient's likely response to therapy or relapse. Attached hereto as Exhibit 107 is a true and correct copy of a slide presentation Ms. Winn-Deen prepared in 2010 regarding Illumina's approach to cancer discovery and diagnostics development. In 2011, Illumina added colorectal cancer as a third cancer type to the ongoing project. Attached hereto as Exhibit 14 is a true and correct copy of a news article dated January 18, 2011, discussing Illumina's Cancer Discovery Initiative. Attached hereto as Exhibit 108 is a true and correct copy of an Illumina brochure dated March 25, 2011, titled "Cancer Genomics." Attached hereto as Exhibit 109 is a true and correct copy of an Illumina brochure dated March 25, 2011, titled "The Illumina® Cancer Discovery Initiative."

17. During the first half of 2009, Illumina completed its Clinical Services Laboratory and received CLIA certification. Illumina's achievement in obtaining CLIA certification for its diagnostic services lab was heavily promoted to its customers, the molecular diagnostics industry, and the general public. True and correct copies of press releases issued by Illumina, articles, advertisements, and brochures relating to Illumina's efforts in the diagnostics field are attached hereto as Exhibit 110.

18. "CLIA" refers to the Clinical Laboratory Improvement Amendments of 1988, which are federal regulatory standards for clinical laboratory testing. In the United States, any facility that performs laboratory testing on human-derived specimens for the purpose of providing information for diagnosis, prevention, or treatment of disease or impairment, or for

health assessments must be CLIA-certified. Because of the regulatory requirements that must be met, the CLIA certification process typically takes 3-6 months to complete. Indeed, Illumina began the project for its CLIA-certified diagnostics services lab in Q3 2008. Attached hereto as Exhibits 11 and 12 are news announcements dated November 18, 2008, and January 21, 2009, announcing Illumina's plan to open a CLIA-certified lab.

19. Illumina's diagnostic services lab has offered physician-ordered individual whole-genome sequencing services for diagnostic purposes. Illumina's whole-genome sequencing is an example of a laboratory developed test ("LDT"). A LDT is a type of in-vitro diagnostic test that is designed, manufactured, and used within a single lab. High-complexity CLIA-certified labs, such as Illumina's Clinical Services Lab, are allowed to develop LDTs and deliver results for these LDTs to physicians. For example, Illumina's whole-genome sequencing services are frequently used by pediatric geneticists to diagnose rare childhood diseases and by oncologists for cancer molecular profiling. A second LDT offered by Illumina's subsidiary, which brands its products and services with the ILLUMINA® mark, is non-invasive pre-natal testing through a CLIA-certified lab that Illumina acquired in 2013 through the acquisition of a company called Verinata Health. Illumina's non-invasive pre-natal testing is used by obstetricians and gynecologists to screen for aneuploidies, conditions resulting in one or more extra or missing chromosomes such as trisomy 21, which is commonly referred to as Down syndrome.

20. Illumina is continually developing the next generation of molecular tests, systems, and services that will facilitate earlier diagnosis, selection of appropriate therapies, and monitoring of disease progression. 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 recent years, Illumina has received FDA clearance on a number of its products, and has sought approval on a number of new products as well.

21. For example, at least as early as August 2011, Illumina announced its plan to

submit its MiSeq® platform to the FDA for 510(k) market clearance approval for diagnostic applications. This information has been disseminated to Illumina's customers, to the molecular diagnostics industry, and to the general public. Attached hereto as Exhibit 15 is a true and correct copy of an announcement dated August 3, 2011, announcing Illumina's intent to seek FDA approval for the MiSeq® platform.

22. The availability of Next-Generation Sequencing ("NGS") technology at a lower price, along with the more focused applications of the MiSeq®, has led many clinical customers to purchase this sequencer.

23. On December 20, 2012, Illumina submitted its MiSeqDx® platform for FDA approval. Attached hereto as Exhibit 111 is a true and correct copy of Illumina's 510(k) Premarket Notification Letter regarding its MiSeqDx® platform sent to the FDA on December 20, 2012. Attached hereto as Exhibit 112 is a true and correct copy of the letter Illumina received from the FDA confirming that on December 26, 2012, the FDA received Illumina's 510(k) Premarket Notification submission for its MiSeqDx® platform.

24. On December 21, 2012, Illumina submitted its MiSeqDx® Cystic Fibrosis System for FDA 510(k) review. Attached hereto as Exhibit 113 is a true and correct copy of Illumina's 510(k) Premarket Notification Letter regarding its MiSeqDx® Cystic Fibrosis System sent to the FDA on December 21, 2012. Attached hereto as Exhibit 114 is a true and correct copy of the email Illumina received from the FDA confirming that on December 26, 2012, the FDA received Illumina's 510(k) Premarket Notification submission for its MiSeqDx® Cystic Fibrosis System.

25. On November 19, 2013, Illumina received FDA clearance for its MiSeqDx® platform and MiSeqDx® Cystic Fibrosis System. Attached hereto as Exhibit 39 is a true and correct copy of an FDA News Release announcing its approval of the Illumina MiSeqDx® for use with Illumina's Cystic Fibrosis Assays and universal kit for open use. Attached hereto as Exhibit 115 is an Illumina press release dated November 19, 2013, announcing the FDA approval of Illumina's MiSeqDx® for use with its Cystic Fibrosis assays and universal kit for

open use. FDA clearance of the MiSeqDx® with universal kit for open use allowed Illumina to promote this kit to others—including clinical diagnostic labs—to develop their own diagnostic tests.

26. Illumina has sought FDA clearance for multiple other diagnostic products as well. For example, on February 21, 2013, Illumina submitted its InfiniumDx™ CytoSNP-12 Assay for FDA review. The InfiniumDx™ CytoSNP-12 was used with Illumina's BeadArray™ technology to diagnose chromosomal anomalies associated with developmental delay and mental retardation. BeadArray™ technology is an array-based technology, similar to BeadXpress®. The InfiniumDx™ CytoSNP-12 assay was used to process DNA samples and attach specific portions of the DNA to an array. The array would then be inserted into a Hiscan® reader, which would determine whether specific, known sequences were present in the sample. Attached hereto as Exhibit 116 is a true and correct copy of Illumina's 510(k) Premarket Notification Letter regarding its InfiniumDx™ CytoSNP-12 Assay sent to the FDA on February 21, 2013. Attached hereto as Exhibit 117 is a true and correct copy of the letter Illumina received from the FDA confirming that on February 22, 2013, the FDA received Illumina's 510(k) Premarket Notification submission for its InfiniumDx™ CytoSNP-12 Assay.

27. By March 2013, Illumina began discussions with the FDA to submit its Prenatal In-Vitro Diagnostic Assay to the FDA for premarket approval. Attached hereto as Exhibit 118 is a true and correct copy of Illumina's Pre-Submission Information Letter regarding its Prenatal IVD Assay sent to the FDA on March 15, 2013. Attached hereto as Exhibit 119 is a true and correct copy of the letter Illumina received from the FDA confirming that on March 18, 2013, the FDA received Illumina's Pre-Submission for its Prenatal IVD Assay.

28. 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 Roche, GE Diagnostics/Healthcare and Bayer. True and correct copies of examples of companies selling both research and diagnostics products are attached hereto as Exhibit 120.

Although the documents in this exhibit were printed in 2012, many of the companies began serving both markets much earlier. For example, Roche has been in both the research and diagnostics markets for many years. More specifically, Roche acquired a company called Boehringer Mannheim in the 1990's, which had both diagnostics and life sciences businesses for decades. In addition, Roche collaborated with a company called Affymetrix to develop the first FDA-cleared array. The AmpliChip® array, which was cleared when I was at Roche in 2005, tests for the presence of two genes known to play a major role in the metabolism of many prescription drugs. In late 2012, Roche even attempted to acquire Illumina. Roche was particularly interested in Illumina's NGS technology and its application to diagnostics.

29. Indeed, it is common for a company to produce and sell goods for research use only (RUO) in addition and prior to selling diagnostic products. Unless a company begins by licensing or purchasing an approved technology from another company who has already conducted years of research on said technology, it is a natural progression to start using a technology for research, developing and refining said technology, and then eventually putting said technology into diagnostic use.

30. 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 and at the same trade shows. True and correct copies of advertisements and trade show exhibitor lists are attached hereto as Exhibit 121.

31. For example, Illumina markets its products and services to hospitals, clinical reference labs, clinical diagnostic labs, physicians, genomic research centers, academic institutions, government laboratories, and clinical research organizations, as well as pharmaceutical, biotechnology, agrigenomics, and consumer genomics companies. Meridian similarly markets its products and technologies to hospitals, reference laboratories, physician offices, research centers, veterinary testing centers, diagnostics manufacturers, and biotechnology companies. Attached hereto as Exhibit 55 is a true and correct copy of a

MedCity News Q&A with Meridian CEO Jack Kraeutler dated February 1, 2010, discussing Meridian's expansion into molecular testing.

32. I am familiar with Illumina's customers and potential customers for molecular diagnostic tests, systems, and services, as well as how those customers order such products and services. The customers for our molecular diagnostic products and services typically include lab managers, molecular supervisors, purchasing department personnel, physicians (including infectious disease doctors and pathologists), medical geneticists, hospital administrators, genetic counselors, lab directors and lab technicians, but also include others interested in cancer, genetics, infectious diseases, and transplantations. Our molecular diagnostic tests, systems, and services can be ordered by our customers through all standard channels, including via direct telephone, via our web site, via email, at trade shows, through sales representatives, and internationally through distributors.

33. While Illumina does offer customized products and services, a number of its products, including its diagnostics products, are "off the shelf" goods and standard services with set purchase prices. For example, Illumina's array and sequencing instruments are off the shelf goods that can be purchased at set prices. Moreover, it is not necessary for the purchaser to have a pre-negotiated purchasing contract with Illumina to order many of its products including its diagnostic products. In fact, Illumina has an e-commerce site on its homepage, through which customers can order Illumina products. Illumina has operated this e-commerce site since 2004.

34. Illumina has used 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 122. More recently, Illumina has rebranded its products and now markets almost all of its products and services with the ILLUMINA® mark. However, Illumina's VeraCode® Universal Bead sets are still sold with the ILLUMINADX® mark.

35. I am familiar with Clinica, IVD Technology, GEN, and CAP Today, which are

publications cited in Illumina's declarations and notice of reliance.

36. Clinica is an online publisher that serves professionals in the clinical lab space such as lab directors, laboratory-based physicians, and lab technicians.

37. IVD Technology is an online publisher that serves professionals in the clinical lab space such as lab directors, laboratory-based physicians, and lab technicians, as well industry professionals such as original equipment manufacturers and developers of in vitro diagnostic products.

38. GEN is an online and print publisher that serves medical directors, laboratory directors, and industry professionals.

39. CAP Today is an online and print publisher that primarily serves laboratory professionals including lab directors and lab technicians.

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration resulting therefrom, declares that all statements made of his/her own knowledge are true; and all statements made on information and belief are believed to be true.

Executed this 7th day of November, 2014 at San Diego, California

Gregory F. Heath, Ph.D.

19285756

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing OPPOSER'S DECLARATION OF GREGORY F. HEATH upon Applicant's counsel by depositing one copy thereof in the United States Mail, first-class postage prepaid, on November 7, 2014, addressed as follows:

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Sarah Beno Couvillion

Exhibit 4

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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Exhibit 11

Amplify Single Cell DNA Samples, WGA
GenomePlex® Whole Genome Amplification
SIGMA-ALDRICH
SIGMA Life Science Where bio begins

Matt Dublin on
New algorithms

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 may play a larger role in its diagnostics offering in the future.

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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."

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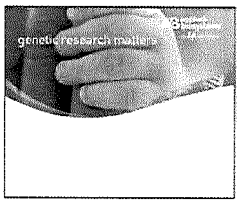
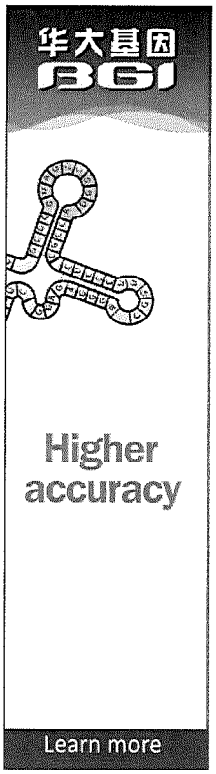




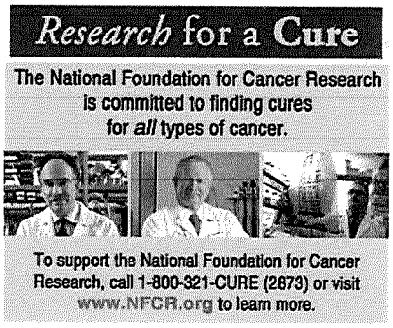
Tech Guide Archives

Real-Time PCR Technical Guide, Volume One

'Functional Complotype' and Susceptibility to Alternative Pathway-Driven Disease
Heurich, Martinez-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.

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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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Illumina Unveils Strategy to Enter Molecular Diagnostics Market

January 21, 2009

Illumina Unveils Strategy to Enter Molecular Diagnostics Market

By Turna Ray

Illumina plans to enter the molecular diagnostics space by forging partnerships with customers, opening a new CLIA lab, and launching a research project to study cancer genomes, CEO Jay Flatley said during a recent presentation to investors.

Speaking at the JPMorgan Healthcare Conference in San Francisco last week, Flatley said the company will invest to improve existing sequencing technologies and develop new ones to enable it to play in the molecular diagnostics space, which he estimates to be worth $3 billion.

"We are really excited about what's happening in the sequencing market," Flatley said during his presentation. "We think over the next few years, it's going to be the most exciting segment in life sciences tools, so we continue to make major investments in this space."

As part of what Flatley called Illumina's "platform partnering" program, the company plans to work with customers to develop diagnostic applications using its existing BeadXpress genotyping platform and the sequencing technology it acquired last summer when it bought Avantome.

With the BeadXpress platform, Illumina has already begun partnerships to develop genotyping assays for blood typing, pharmacogenomics, and prenatal testing, Flatley said. Illumina hopes to garner clearance from the US Food and Drug Administration for the BeadXpress platform in the second half of the year.

Illumina has yet to commercialize the Avantome technology. Flatley did not update investors on the types of sequencing-based diagnostic tests Illumina plans to develop with the Avantome platform, or the partners Illumina is working with on this effort.

Additionally, Illumina plans to open its own CLIA-certified diagnostic laboratory, which will allow the company to introduce tests and testing services while waiting for the US Food and Drug Administration to clear test kits being developed under its partnering program.

He said the CLIA lab will also enable Illumina to offer services based on proprietary content from

its licensing and discovery programs, and to offer sequencing services for "traditional [genetic] targets" such as carrier testing for Rett syndrome; drug-resistance testing for HIV and Mycobacterium; mutation detection in the genes P53, KRAS, BRAF, EGFR; and HLA testing.

The company plans to apply for CLIA-certification during the first half of this year and hopes to start generating revenue from diagnostic services in the second half of 2009. An Illumina spokeswoman told *PGx Reporter* sister publication *In Sequence* this week that the company's primary interest for the CLIA lab is to provide sequencing services on its Genome Analyzer.

The last piece of Illumina's plan to enter the diagnostics space involves an internal discovery-research project to study ovarian and gastric cancer. To that end, the company plans this year to sequence approximately 50 cancer genomes and their controls, and to conduct whole-trascriptome and methylation-profiling analyses of these samples, Flatley said.

After validating the results in a larger number of samples, Illumina plans to implement diagnostic tests using these results on its array platform. Specifically, for ovarian cancer, Illumina aims to "identify very early markers for diagnosis" and to "begin to look at the genetics of therapy resistance, in particular resistance to platinum therapy," according to Flatley.

He said Illumina can embark on a project of this scale because "we can sequence so rapidly, and at such great cost points."

The decreasing cost of sequencing technologies has particularly impacted the nascent consumer genomics industry. Both 23andMe and Navigenics have said they plan to offer their customers whole-genome sequencing as the costs of this technology decrease.

Flatley told the JPMorgan conference that the molecular diagnostics market will grow from $3 billion to $5 billion by 2011, while the sequencing market will grow from $1.1 billion to $1.5 billion during that period. Illumina is betting that its sequencing know-how will enable it to win a slice of the broader molecular diagnostics space.

In this regard, Flatley said Illumina plans to launch several new products in the near term, including a sequencing add-on module, called Harmonia. The module works in concert with Illumina's iScan genotyping platform, set for launch in the second half of this year, and will be marketed to the company's genotyping customers who want to try sequencing technology.

Last week, as reported in *In Sequence*, Illumina announced it had made an $18 million investment into UK-based startup Oxford Nanopore Technologies. Oxford's nanopore sequencing technology "holds tremendous promise to be one of the first technologies to reach the sub-$1,000 genome and become the cheapest and fastest way to sequence DNA," Flatley said during his presentation (see *In Sequence* 1/13/2009)

— *Julia Karow, editor of* In Sequence, *contributed to this article.*

Related Stories

- Cincinnati Children's, Claritas Partner on Pediatric Genomics
  November 12, 2013 / GenomeWeb Daily News
- Empire Genomics Clinical Lab Gets CLIA Certification, New York Approval
  November 12, 2013 / GenomeWeb Daily News

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- Sequenom Undeterred by Patent Invalidation, Reimbursement Issues, as Sales of MaterniT21 Climb
  November 11, 2013 / Clinical Sequencing News
- Foundation Medicine's Revenues Double as it Readies Hematological Cancer Panel
  November 8, 2013 / Clinical Sequencing News
- Former Sequenom CEO Harry Stylli Seeks $1.6M in Damages from Firm
  November 8, 2013 / GenomeWeb Daily News

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Exhibit 14

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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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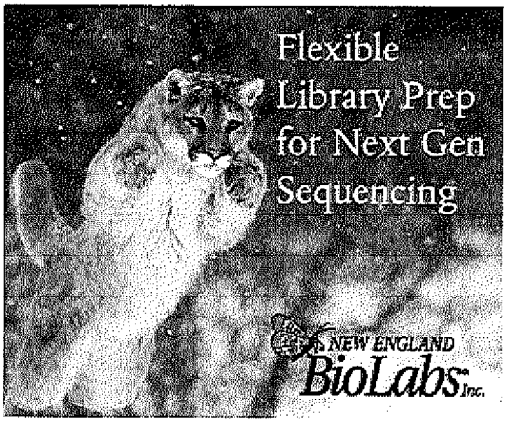

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People on the Move

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

Science	Business	Funding	Genome Technology Magazine
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.	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.	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.	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.

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No. The anything da getting out
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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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Related Stories

- IOM Workshop Discusses Interim Strategies to Handle Unresolved Challenges of Clinical Sequencing
  July 27, 2011 / Clinical Sequencing News
- Sequenom Signs Supply Deal for T21 Test with Illumina; Firms to Collaborate on Regulatory Approval
  July 12, 2011 / Clinical Sequencing News
- Illumina to Apply Rare-Cell Capture to Ovarian Cancer Program; Expects Clinical Apps for MiSeq
  May 4, 2011 / Clinical Sequencing News
- Illumina Starts Shipping 600 Gb HiSeq Reagent Kits; Takes First Orders for MiSeq
  May 3, 2011 / In Sequence
- Following Diagnostic Sequencing Success, MCW Creates Comprehensive Framework to Guide Future Cases
  March 29, 2011 / Clinical Sequencing News

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Exhibit 16

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

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molecular medicine and ultimately transforming healthcare.

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CFR Title 21[14]|Radiation-Emitting Products[15]|X-Ray Assembler[16]|Medsun Reports[17]|CLIA[18]|TPLC[19]

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Device Classification Name	Instrumentation For Clinical Multiplex Test Systems[20]
510(K) Number	K093128
Device Name	ILLUMINA BEADXPRESS SYSTEM
Applicant	ILLUMINA, INC. 5200 Illumina Way San Diego, CA 92122
Contact	Donald R Ellis
Regulation Number	862.2570[21]
Classification Product Code	NSU[22]
Date Received	10/02/2009
Decision Date	04/28/2010
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Clinical Chemistry
Review Advisory Committee	Hematology
Statement	Statement[23]
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Clinical Trials	NCT00959504[25]
Reviewed By Third Party	No
Expedited Review	No
Combination Product	No

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Device Classification Name	Test, Factor V Leiden Mutations, Genomic Dna Pcr[20]
510(K) Number	K093129
Device Name	ILLUMINA VERNCODE GENOTYPING TEST FOR FACOR V AND FACTOR II
Applicant	ILLUMINA, INC. 9865 Towne Centre Drive San Diego, CA 92121 1975
Contact	Donald R Ellis
Regulation Number	864.7280[21]
Classification Product Code	NPQ[22]
Subsequent Product Code	NPR[23]
Date Received	10/02/2009
Decision Date	04/28/2010
Decision	Substantially Equivalent - CLIA Submission (CS)
Classification Advisory Committee	Hematology
Review Advisory Committee	Hematology
Statement	Statement[24]
FDA Review	Decision Summary[25]
Type	Traditional
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Expedited Review	No
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FDA NEWS RELEASE

For Immediate Release: Nov. 19, 2013
Media Inquiries: Susan Laine, 301-796-5349, susan.laine@fda.hhs.gov
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FDA allows marketing of four "next generation" gene sequencing devices
Two devices aid in screening and diagnosis of cystic fibrosis

Today the U.S. Food and Drug Administration allowed marketing of four diagnostic devices that can be used for high throughput gene sequencing, often referred to as "next generation sequencing" (NGS). These instruments, reagents, and test systems allow labs to sequence a patient's DNA (deoxyribonucleic acid).

The new technology also gives physicians the ability to take a broader look at their patients' genetic makeup and can help in diagnosing disease or identifying the cause of symptoms.

"NGS is changing the way we look at genomics," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in FDA's Center for Devices and Radiological Health. "Before NGS, sequencing genes associated with a particular disease was a long and costly process. Today, we have the capability to read and interpret large segments of DNA very quickly in a single test and this information-rich technology is becoming more accessible for use by physicians in the care of their patients."

Two of the newly cleared devices are used to detect DNA changes in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, which can result in cystic fibrosis (CF), an inherited chronic disease that affects the lungs, pancreas, liver, intestines, and other organs of those who inherit a faulty CFTR gene from both parents.

More than 10 million Americans are CF carriers and approximately 30,000 children and adults in the U.S. are affected with CF. Most children with CF are diagnosed by age 2 and the average life span for people with CF who live to adulthood is approximately 37 years.

The cleared devices include:

- The Illumina MiSeqDx Cystic Fibrosis 139-Variant Assay, which checks specific points in the patient's CFTR gene sequence to detect known variants in the gene. Information about which DNA changes are associated with symptoms of cystic fibrosis is found in the Clinical and Functional TRanslation of CFTR database (CFTR2).
- The Illumina MiSeqDx Cystic Fibrosis Clinical Sequencing Assay, which sequences a large portion of the CFTR gene to detect any difference in the CFTR gene compared to a reference CFTR gene.

Data submitted by Illumina for their cystic fibrosis tests included comparisons of the sequence results to Human Genome Build 19, a reference representation of the human genome. In addition, Illumina evaluated the performance of its instrument and reagent systems against a publically available quality-weighted human reference genome that was created through collaboration between the FDA and the National Institutes of Standards and Technology (NIST).

FDA authorized sequencing devices provide labs with quality and performance information

The FDA also granted de novo petitions for the Illumina MiSeqDx instrument platform and the Illumina Universal Kit reagents, two devices that make up the first FDA-regulated test system that allows laboratories to develop and validate sequencing of any part of a patient's genome. The Universal Kit reagents isolate and create copies of genes of interest obtained from patient blood samples, and the MiSeqDx platform analyzes the genes. The software compares the patient's genomic sequence to a reference sequence and reports back any differences between the patient and the reference.

"The FDA's review of the MiSeqDx and sequencer and Universal Kit reagents provides clinical laboratories with information about the expected performance of the device and the quality of the results," said Dr. Gutierrez. "This information was not previously available for next generation sequencers, and, with this platform, labs can develop tests for clinical use with greater confidence because they use FDA authorized devices."

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The FDA reviewed the Illumina MiSeqDx instrument platform and the Illumina Universal Kit reagents through its de novo classification process, a regulatory pathway for some novel low-to-moderate risk medical devices that are not substantially equivalent to an already legally marketed device.

For the de novo petitions, the FDA based its decision on the demonstrated performance of the MiSeqDx instrument and Universal Kit reagent systems across numerous genomic segments spanning 19 human chromosomes.

Illumina MiSeqDx instrument platform, Universal Kit reagents, MiSeqDx Cystic Fibrosis 139-Variant Assay, and MiSeqDx Cystic Fibrosis Clinical Sequencing Assay are manufactured by Illumina, Inc. in San Diego, Calif.

Relevant Web Links:

FDA: Medical Devices

NIH: What is Cystic Fibrosis?

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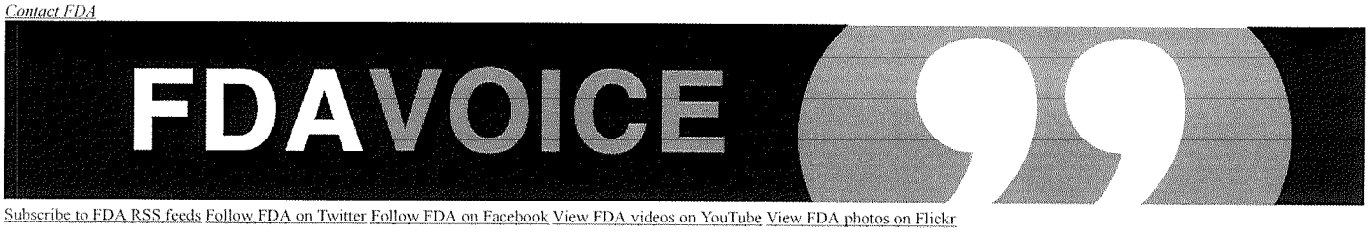

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Exhibit 55

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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.

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By Mary Vanac

MEDCITY NEWS

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 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,

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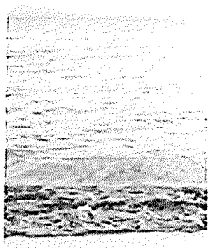

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you have to raise and lower the temperature of the sample several times to amplify it so that it can be tested. It usually requires large pieces of capital equipment to do PCR.

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 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.

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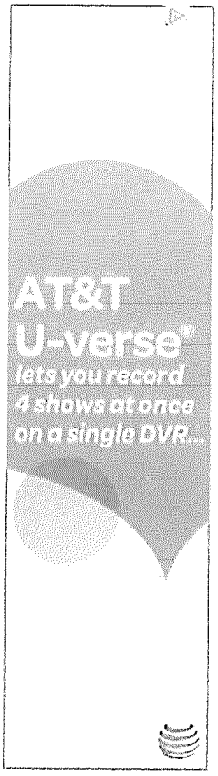

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And then there are a number of diagnostic opportunities, either carve-outs that are non-strategic for bigger businesses, or a number of smaller [firms], both public and private, that have been wandering for years and could use a good home.

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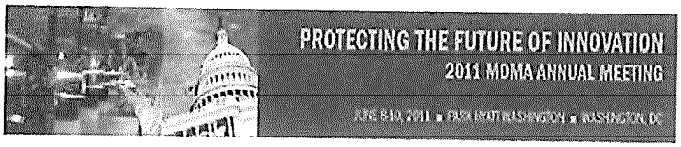

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Exhibit 101

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.

SOURCE: Illumina, Inc.

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Exhibit 102

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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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Exhibit 103

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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.

ILLUM-0604

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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Brokerage Partners

ILLUM-0605

Exhibit 104

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Exhibit 105A

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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Comments (0)

No Comments

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We prefer not to publish articles related tc OTCBB or Pink Sheet Securities. We do not accept articles containing offesive language, racial remarks, sex / pornography beyond the requirement of the story.
The sector scan is based on 15-30 minutes delayed data. The Pattern scan is based on EOD data.

ILLUM-0659

Drupal.behaviors.print = function(context) {window.print();window.close();}>

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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Related Stories

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- Sequenom Signs Supply Deal for T21 Test with Illumina; Firms to Collaborate on Regulatory Approval
  July 12, 2011 / Clinical Sequencing News
- Illumina to Apply Rare-Cell Capture to Ovarian Cancer Program; Expects Clinical Apps for MiSeq
  May 4, 2011 / Clinical Sequencing News
- Illumina Starts Shipping 600 Gb HiSeq Reagent Kits; Takes First Orders for MiSeq
  May 3, 2011 / In Sequence
- Following Diagnostic Sequencing Success, MCW Creates Comprehensive Framework to Guide Future Cases
  March 29, 2011 / Clinical Sequencing News

ILLUM-0660

BusinessWire
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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wgrabill@illumina.com

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ILLUM-0661

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making sense out of life

Introduction to Illumina's VeraCode Technology

PRESENTED BY:

David Barker
VP and CSO

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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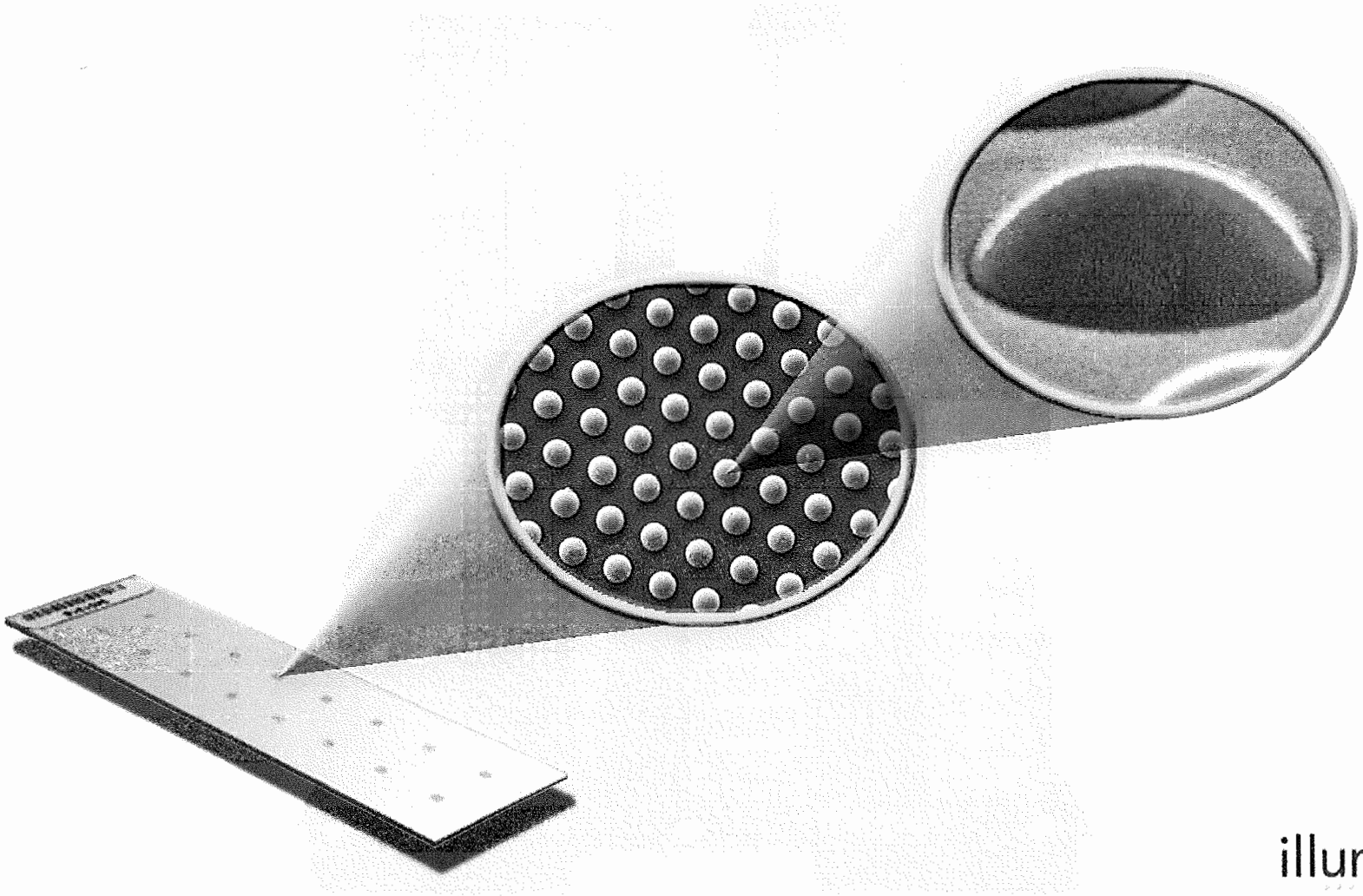
Illumina's Core BeadArray Technology



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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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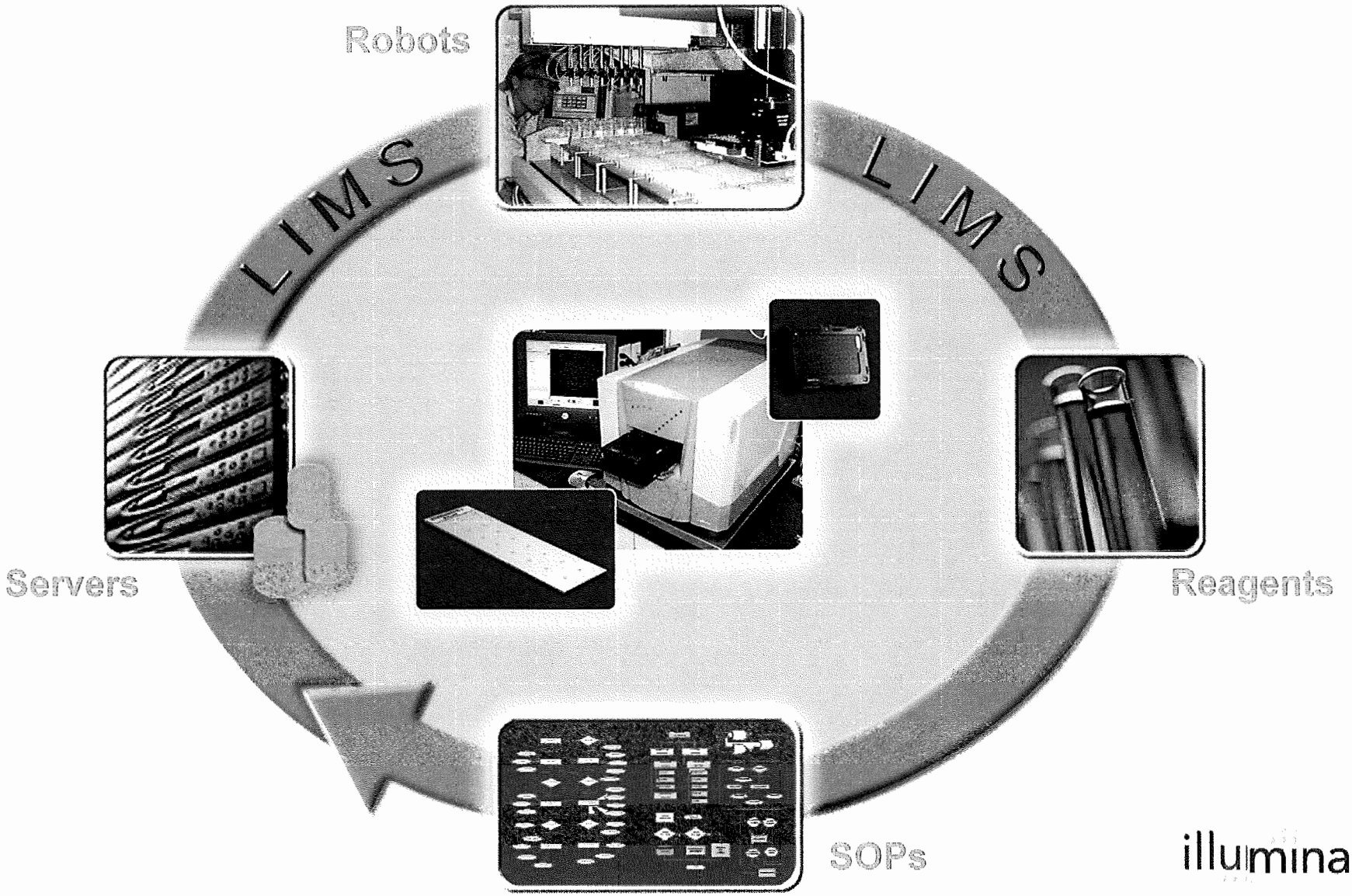
Illumina BeadLab – End-to-End, Turnkey Laboratory



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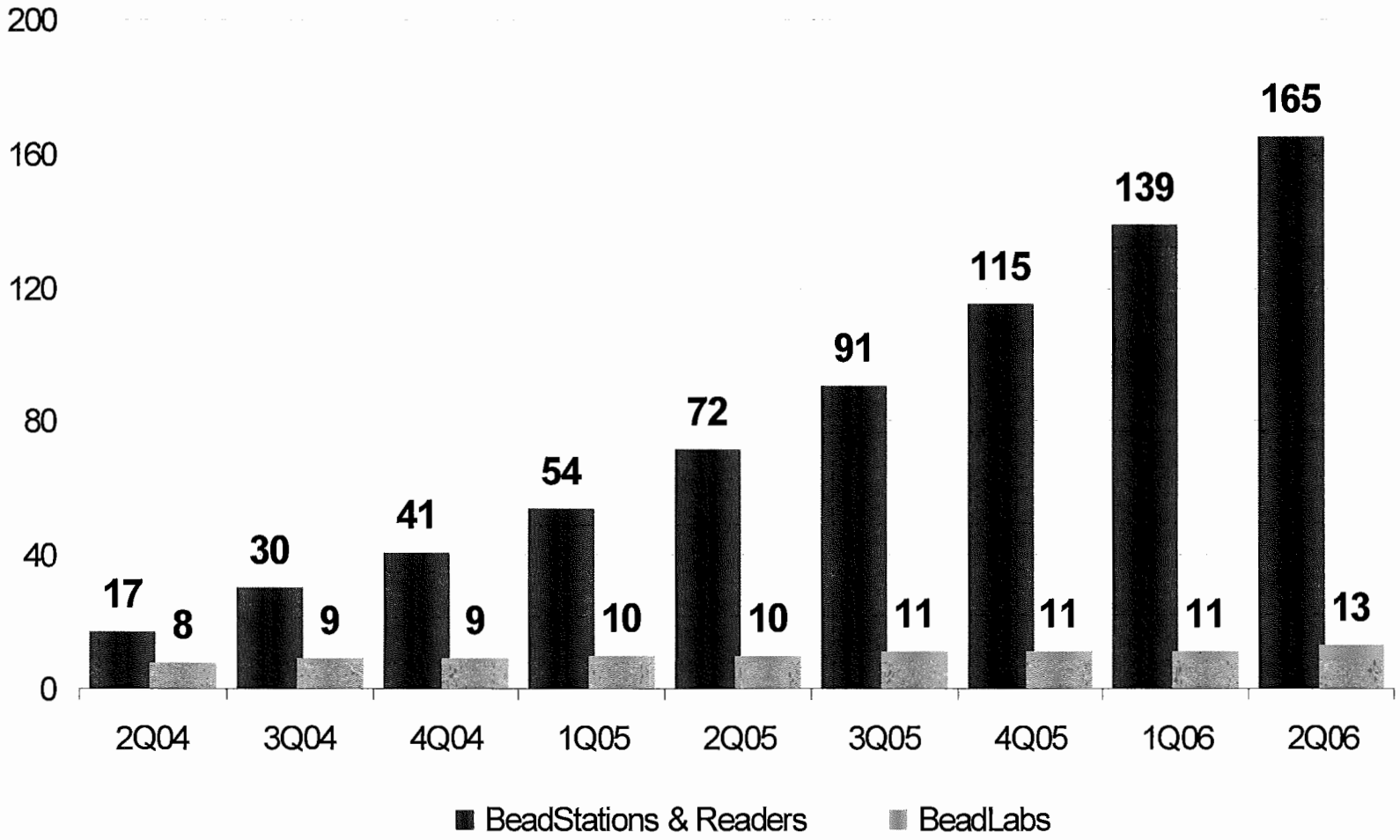
ILLUM-0020

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

ARRAY DENSITY

R&D/DISCOVERY

5K to 650K

- Basic biology of disorders, pathways, hormonal signaling
- Overall genetic functionality & regulatory network
- SNP/Haplotype Discovery/Mapping

FOCUSED ASSAYS (PHARMA & BIOTECH COS.)

500 to 5K

- Drug pathway validation
- Drug-drug interaction
- Identify specific genes of interest, e.g. drug pathways, etc.
- Focused SNPs/Haplotypes

100 to 500

- Drug efficacy
- Patient stratifications
- Clinical trials
- Disease staging & subtyping
- Clinical trial patient selection

BIOMARKER VALIDATION

DIAGNOSTICS

1 to 100

- POC Molecular diagnostics R&D
- Targeted treatment
- Personalized medicine
- Theranostics

CLINICAL SCREENING

MOLECULAR DIAGNOSTICS

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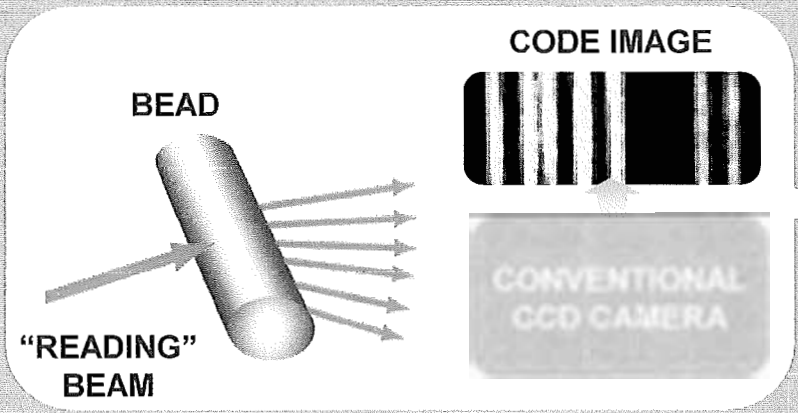
VeraCode Technology

CODE GENERATED BY CREATING EMBEDDED HOLOGRAPHIC DIFFRACTIVE ELEMENTS



BINARY CODE

101101010000101

DECIMAL CODE = 41133

ILLUM-0025

- Glass Surface of Beads Ideal for Bioassays
- High Density Codes Easily Imprinted (24 bit)
- Virtually Unlimited Multiplexing

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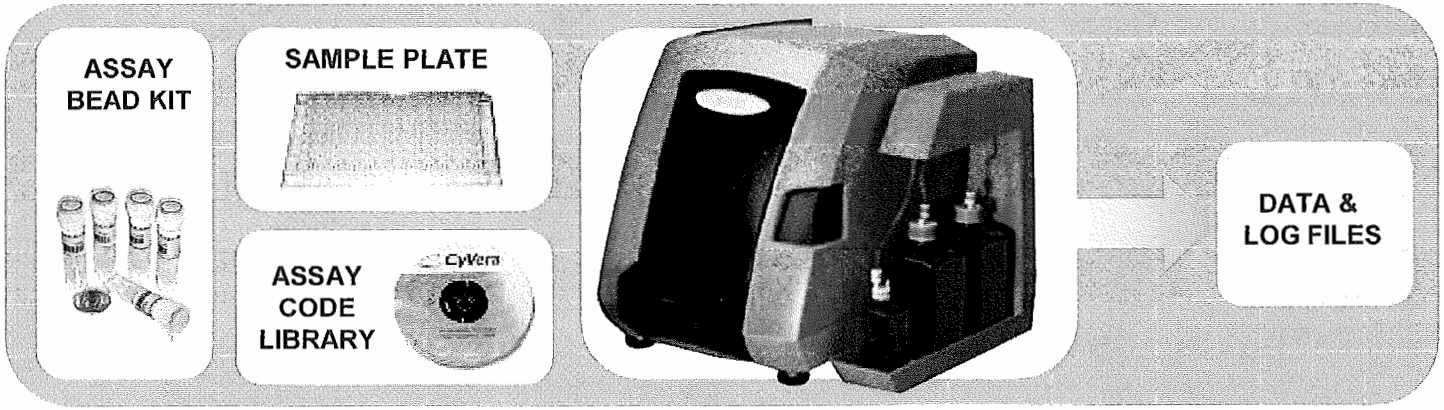
BeadXpress Reader



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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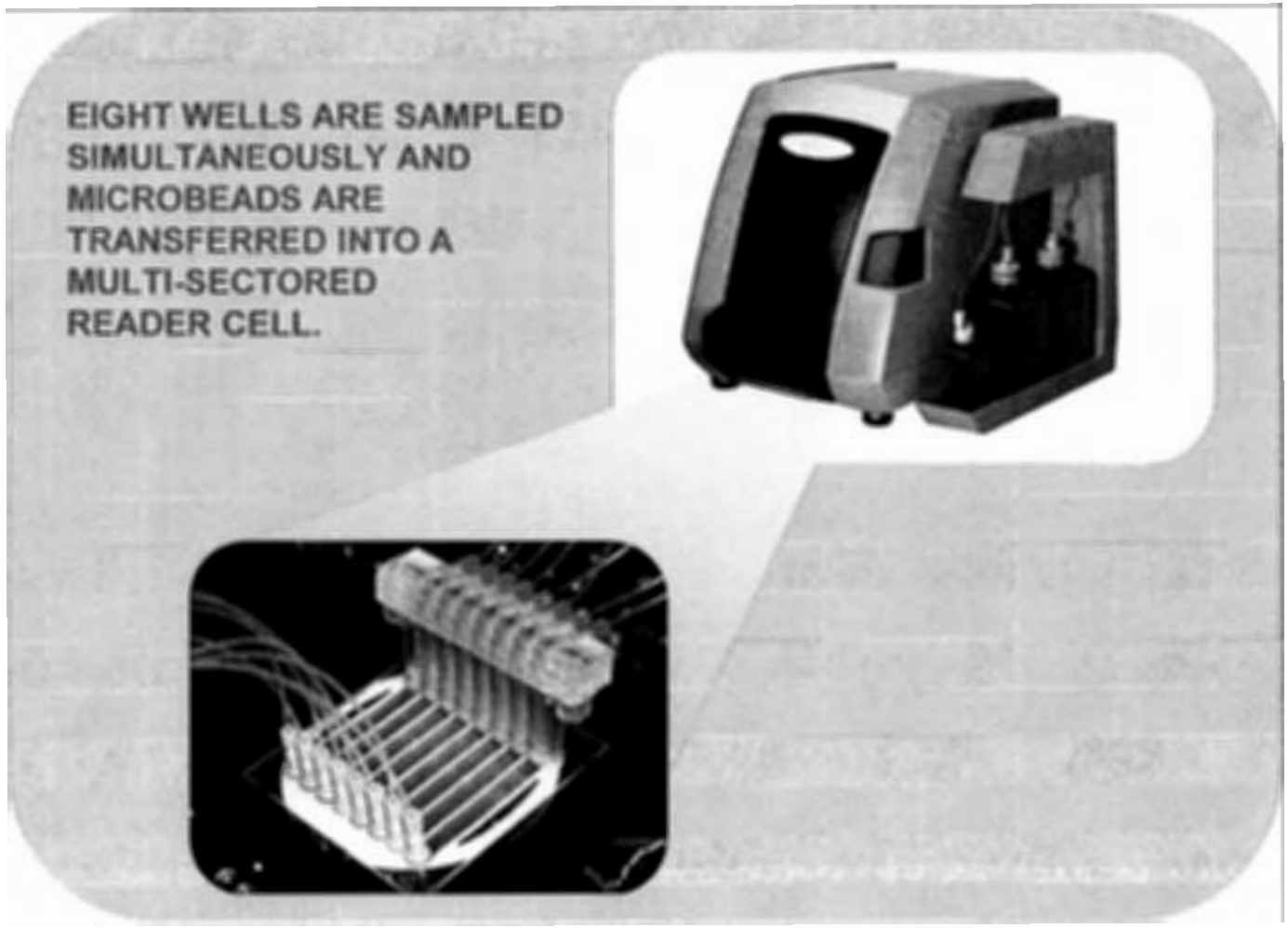
VeraCode Technology



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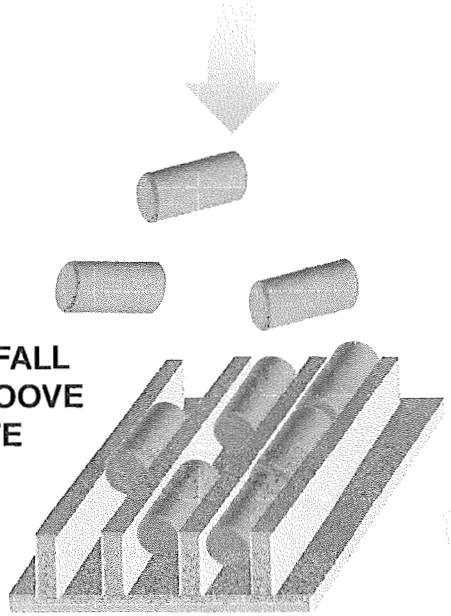
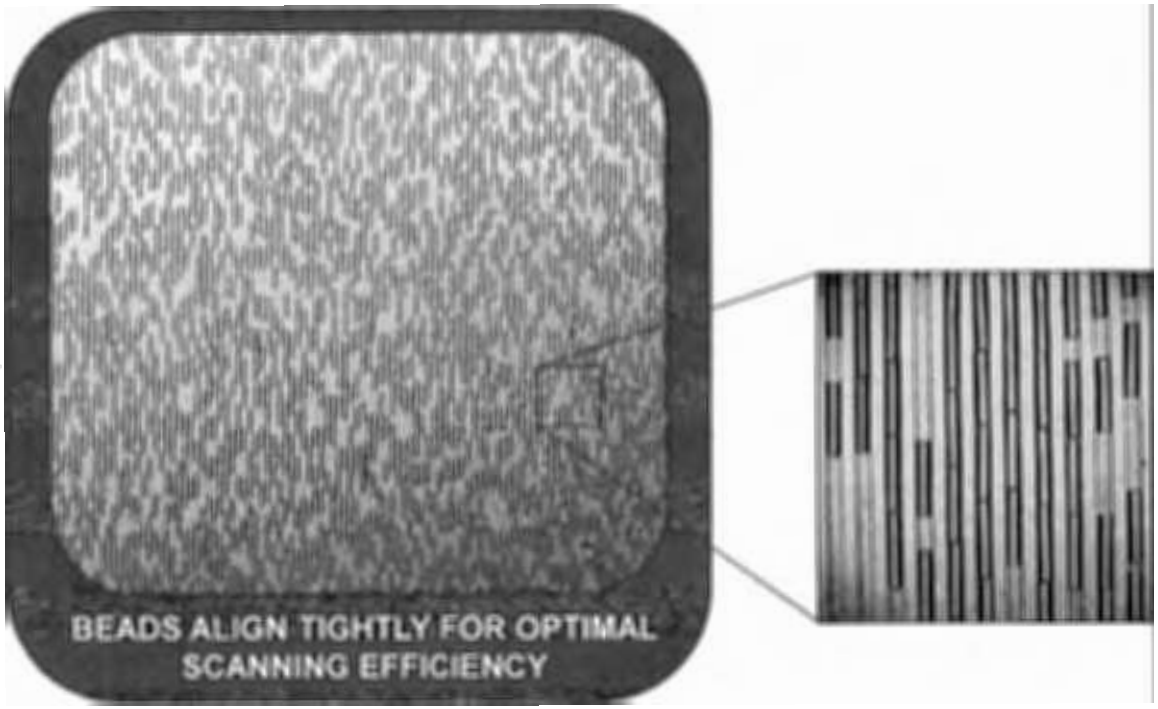
VeraCode Technology

CAPILLARY FORCE ATTRACTS BEADS INTO GROOVES



BEADS FALL INTO GROOVE PLATE



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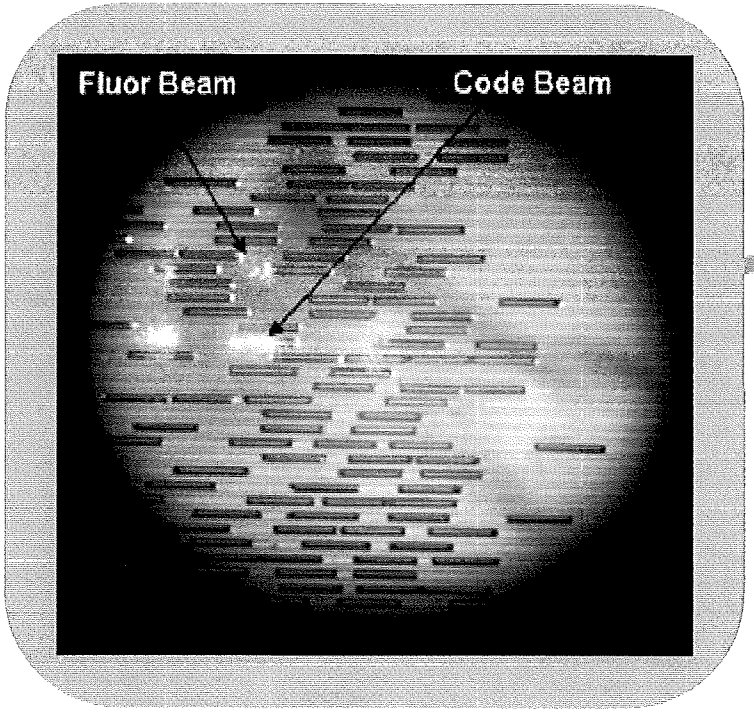
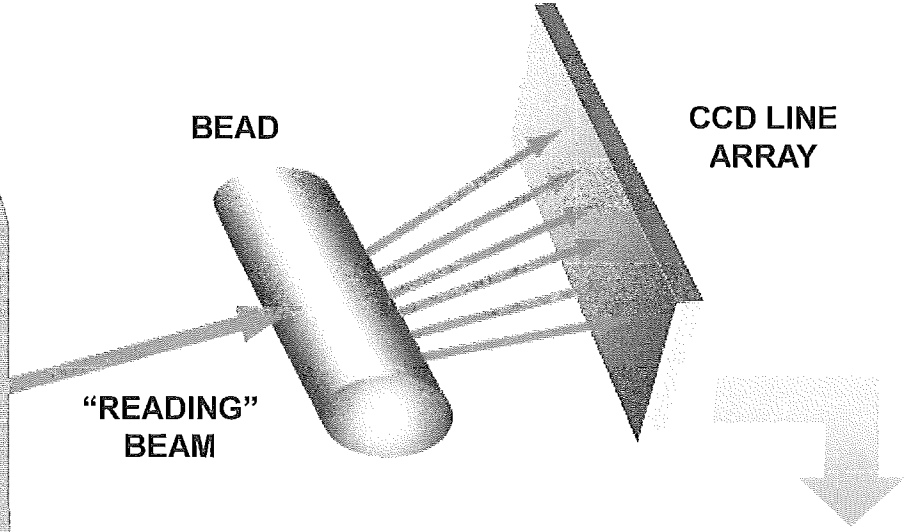
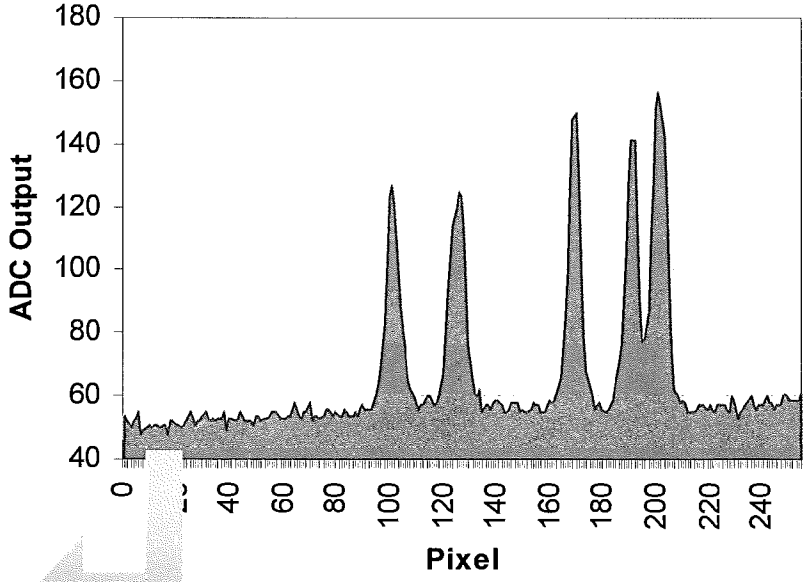
Code Detection







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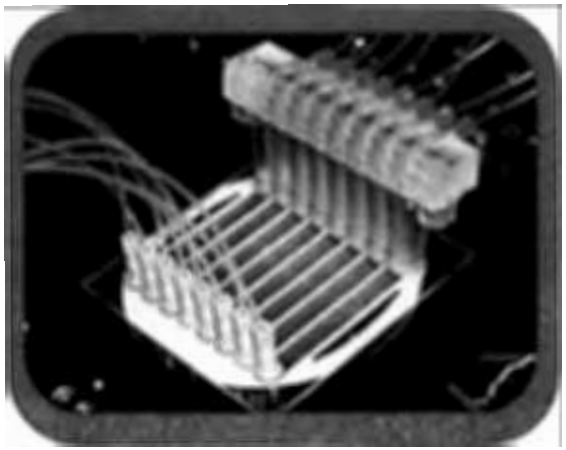
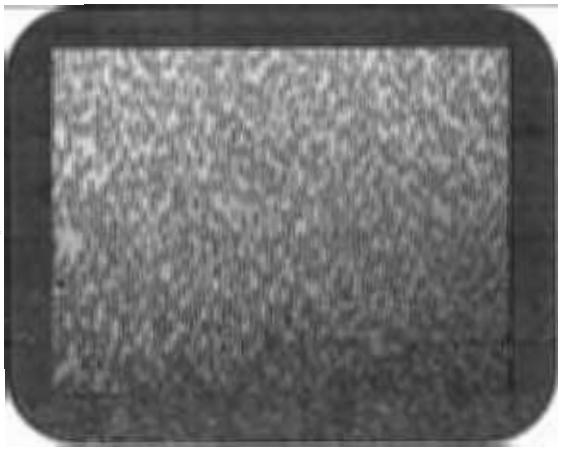
VeraCode Technology

FOLLOWING READOUT, THE BEADS ARE FLUSHED FROM THE READER CELL USING A SECOND ACTUATION PRESSURE CYCLE.





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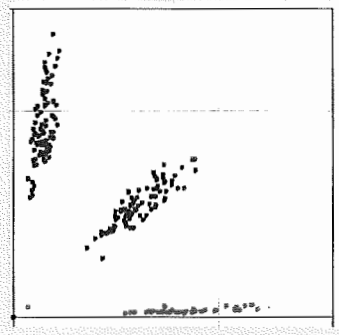
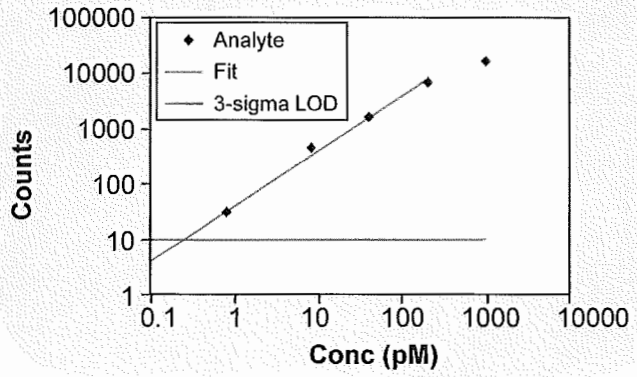
A Flexible Platform for Multiple Applications

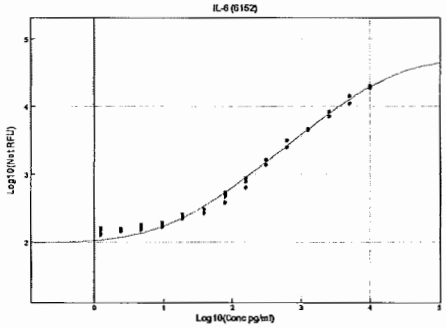
GENOTYPING



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

$COOH^-$
$COOH^-$
$COOH^-$
$COOH^-$
$COOH^-$
$COOH^-$
$COOH^-$
$COOH^-$
$COOH^-$
$COOH^-$
$COOH^-$
$COOH^-$

PROTEIN ATTACHMENT: TWO-STEP PROCESS

Covalently Bind — **EDC/Sulfo-NHS** — **Antibodies, Antigens, Peptides, Streptavidin**

- Fast
- Robust
- Inexpensive
- Stable

NUCLEIC ACID ATTACHMENT: ONE-STEP PROCESS

EDC/Sulfo-NHS plus NH^{2+}Oligo — **Nucleic Acids**

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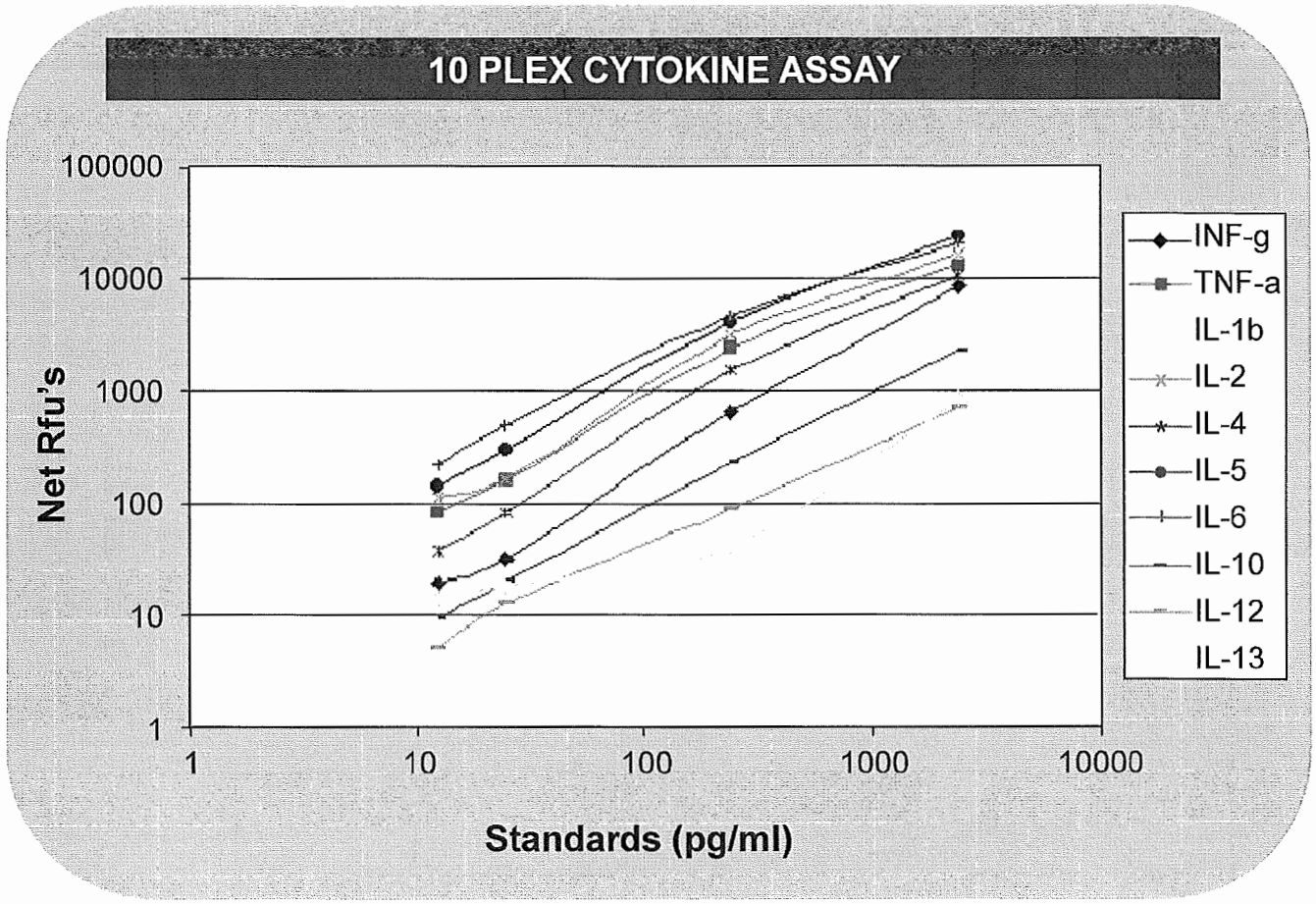
10-plex Cytokine Sensitivity Panel

- 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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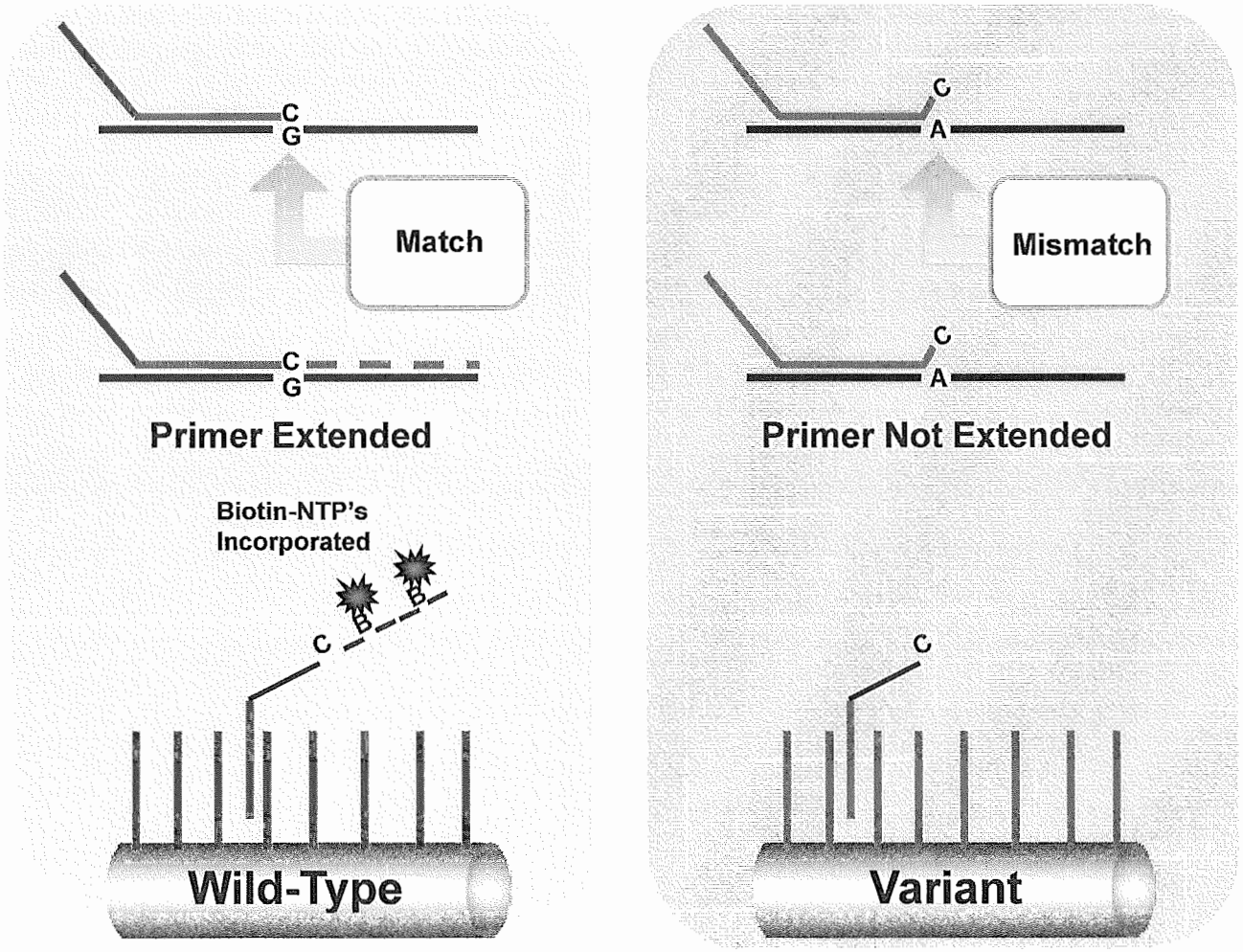
Multiplex Genotyping Example

ALLELE-SPECIFIC PRIMER EXTENSION (ASPE)



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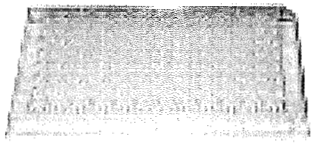
Products in Development

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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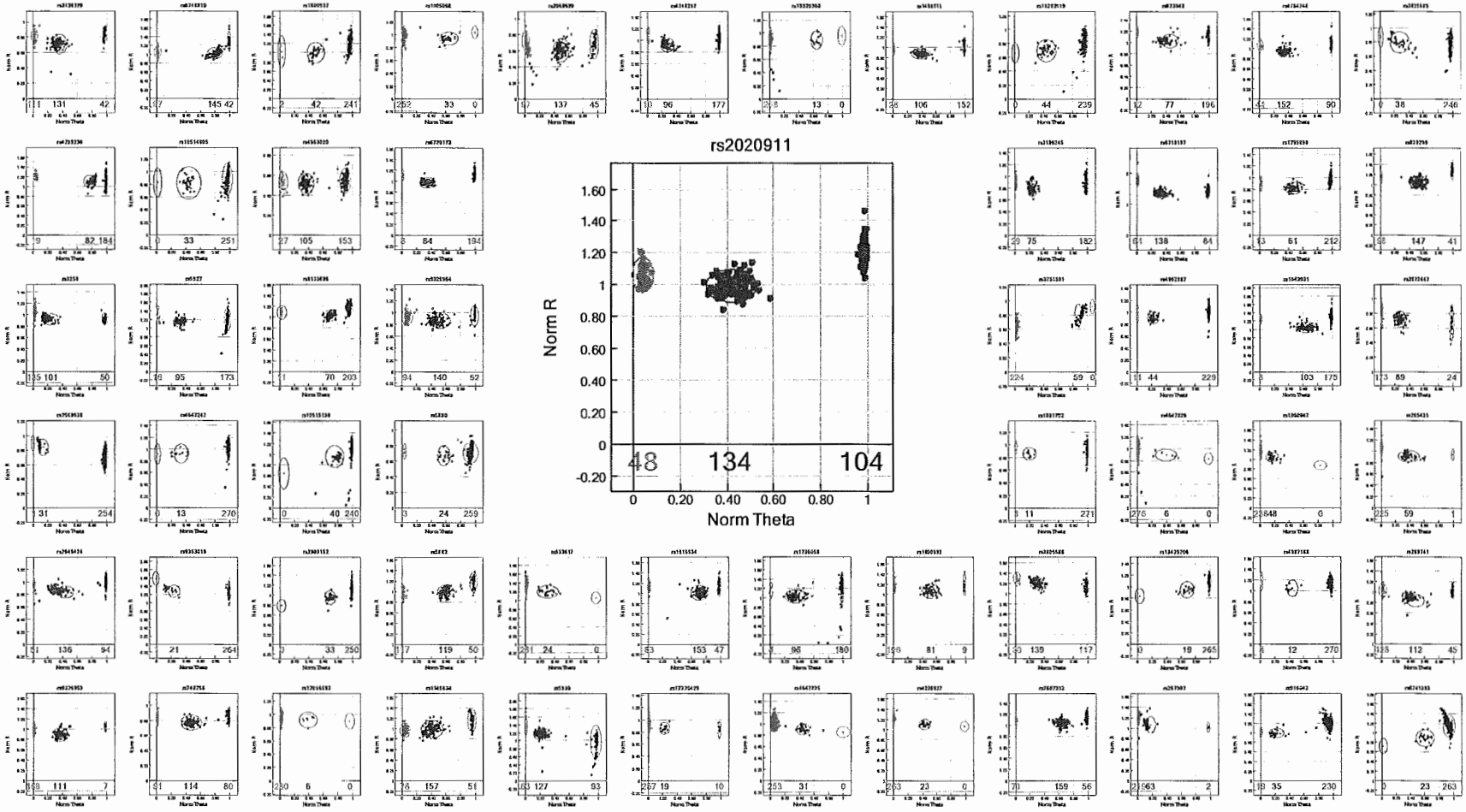
GoldenGate Assay Results



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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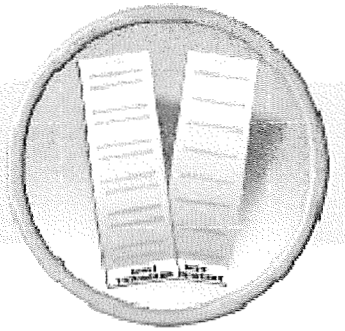
Technology / Platform Synergy

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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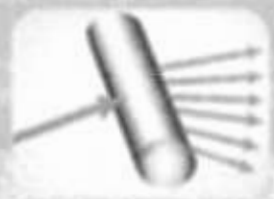
making sense out of life

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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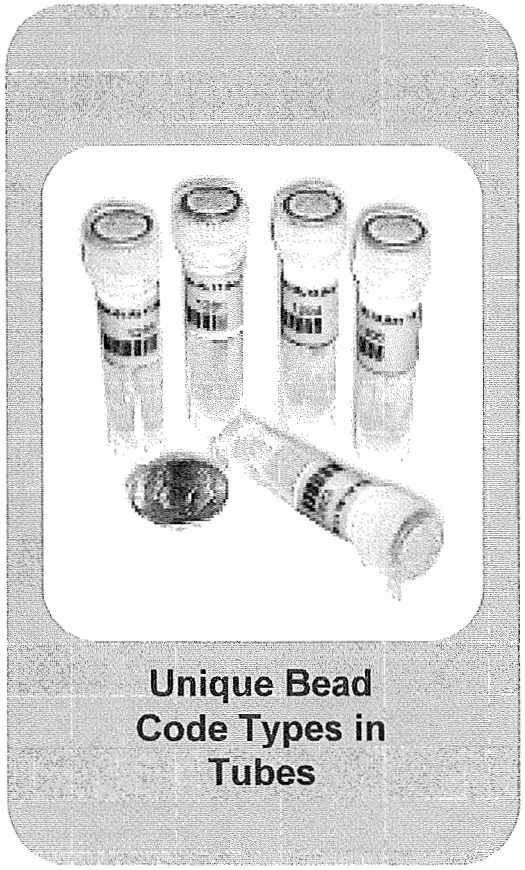
Exhibit 105B

VeraCode Carboxylated Beads

- Protein and Nucleic Acid Use
- Low Non-Specific Binding Characteristics
- Simple & Flexible Immobilization Chemistry
  - Proteins
  - Nucleic Acids
  - Controlled Density



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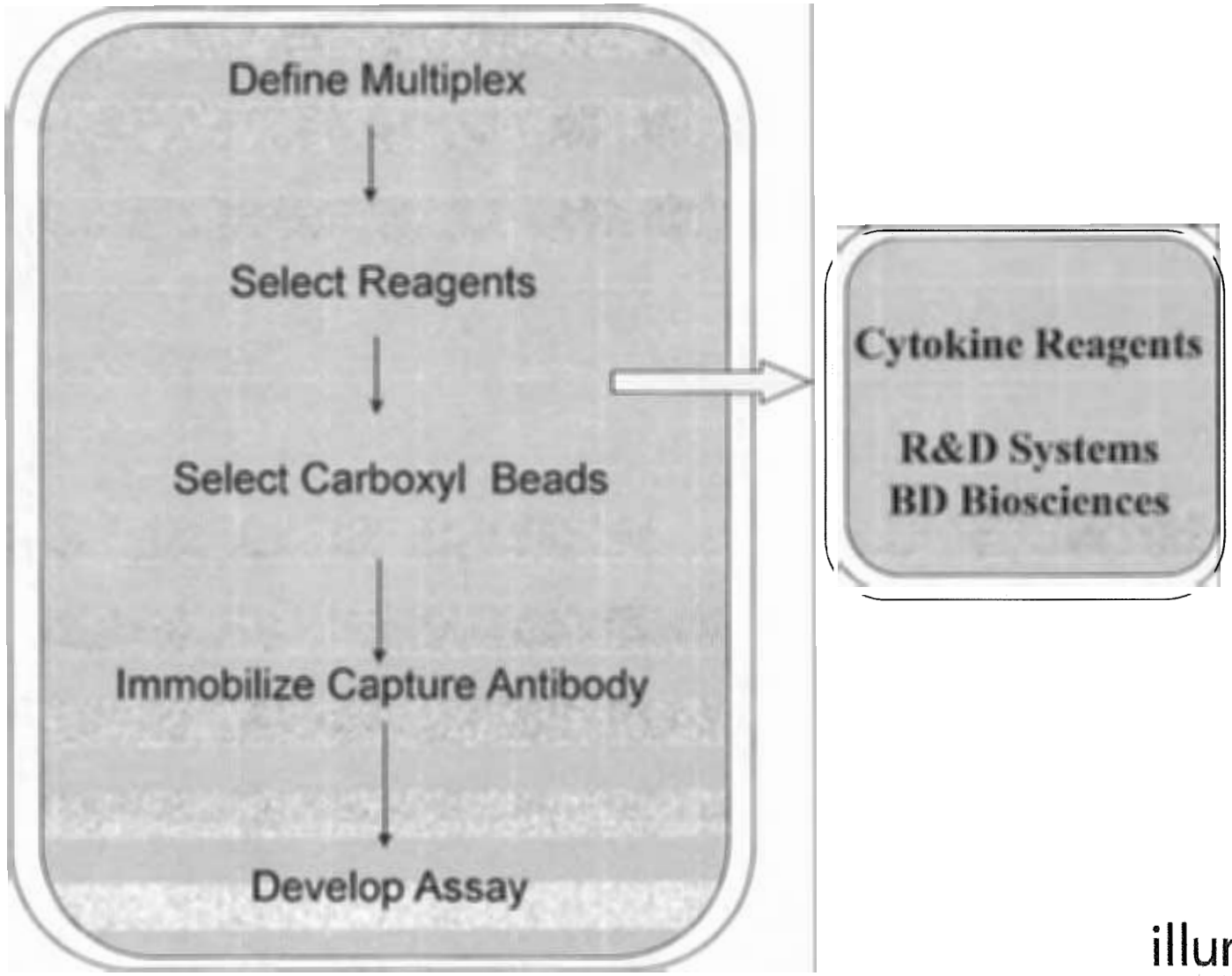
Carboxylate Beads: Assay Design For Proteins



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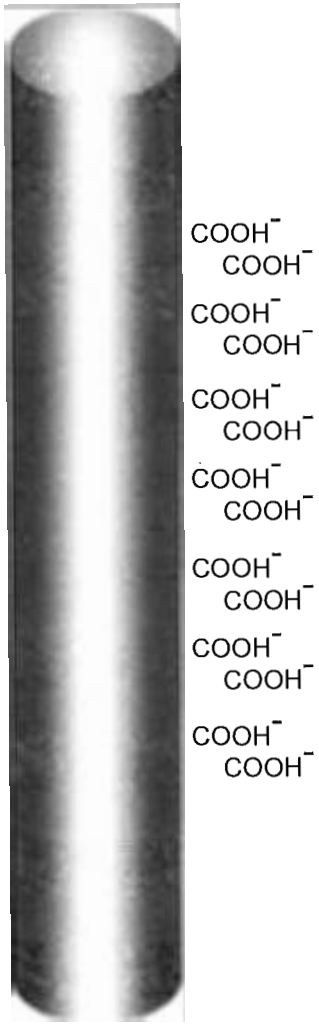
Carboxylate Beads: Chemistry of Attachment



PROTEIN ATTACHMENT: TWO-STEP PROCESS

EDC/Sulfo-NHS

Antibodies
Antigens
Peptides
Streptavidin

- Fast
- Robust
- Inexpensive
- Stable

NUCLEIC ACID ATTACHMENT: ONE-STEP PROCESS

EDC/Sulfo-NHS plus NH^{2+}Oligo

Nucleic Acids

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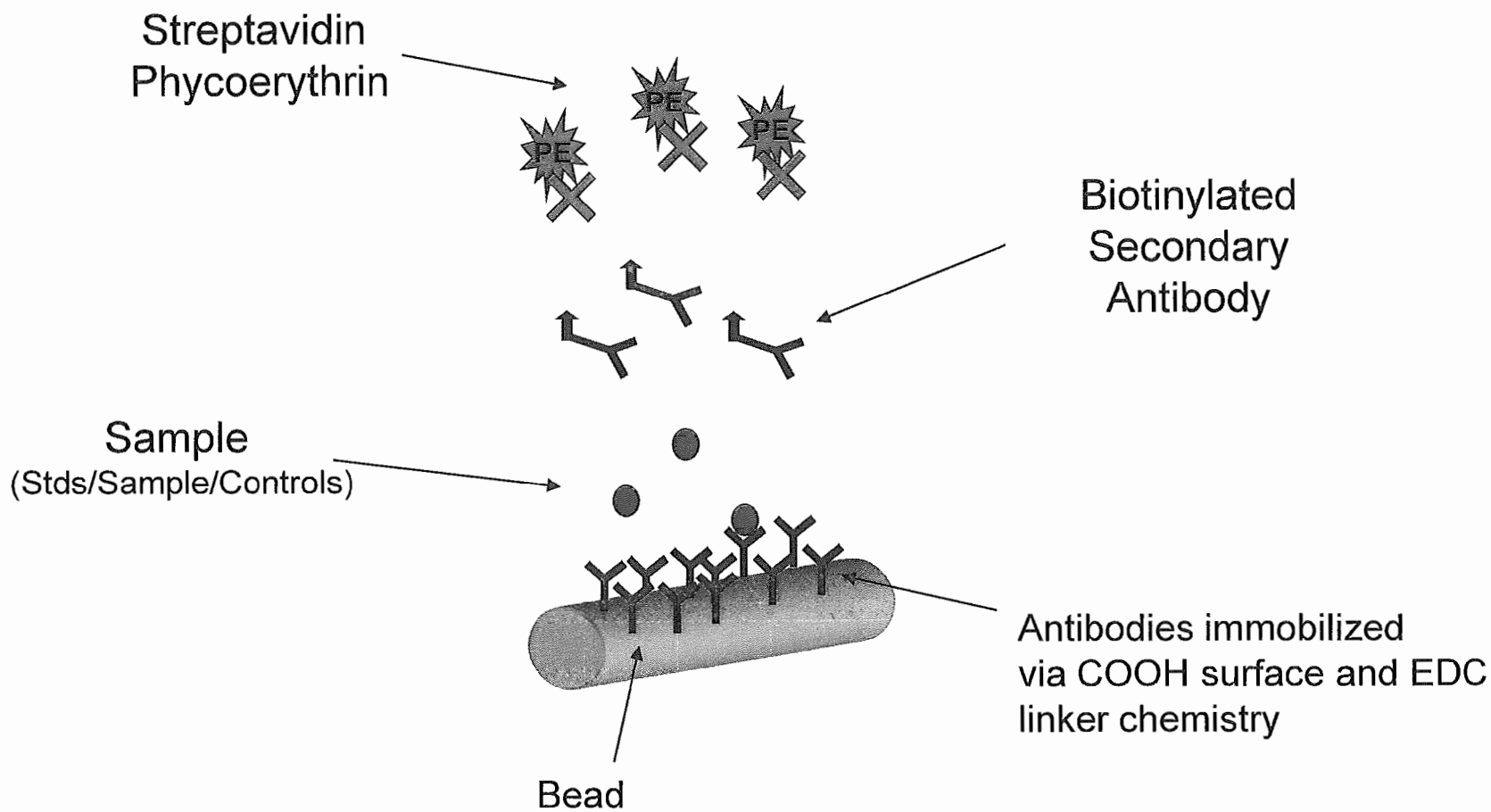
Multiplex Cytokine Assay Format



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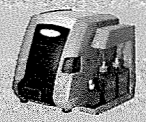
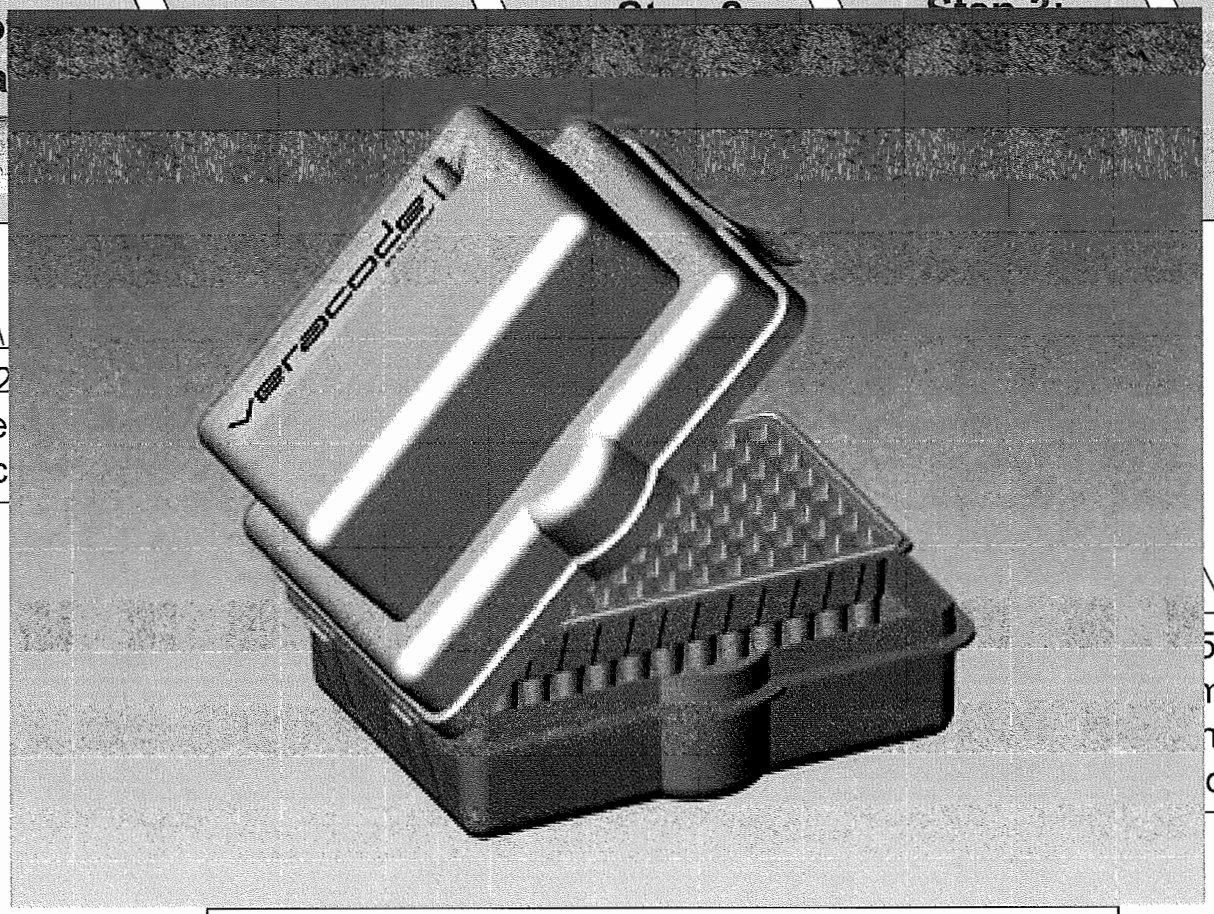
Multiplex Cytokine Assay Protocol

Prepare Micro Pla

Put plate in scanner



Kit beads to2 in 96 We Mic



50 ul Label
min at RT; Shaking
n 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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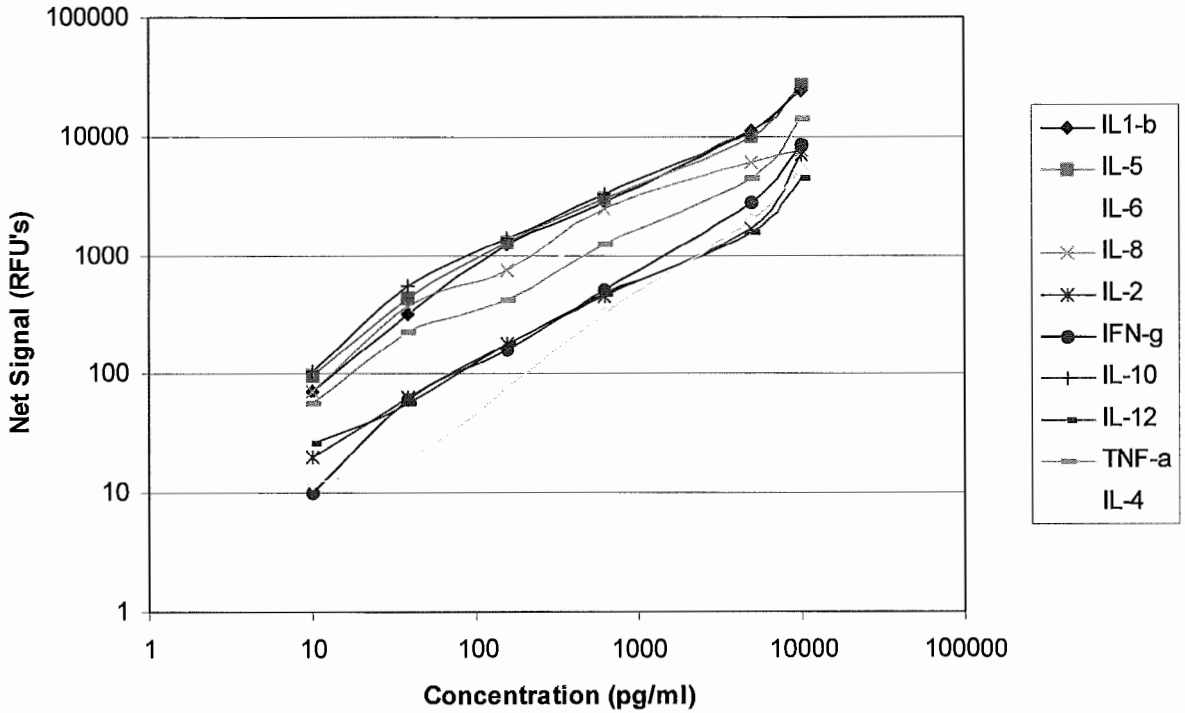
Sensitivity: 10-Plex Dose-Dependent Titration Curves



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

* 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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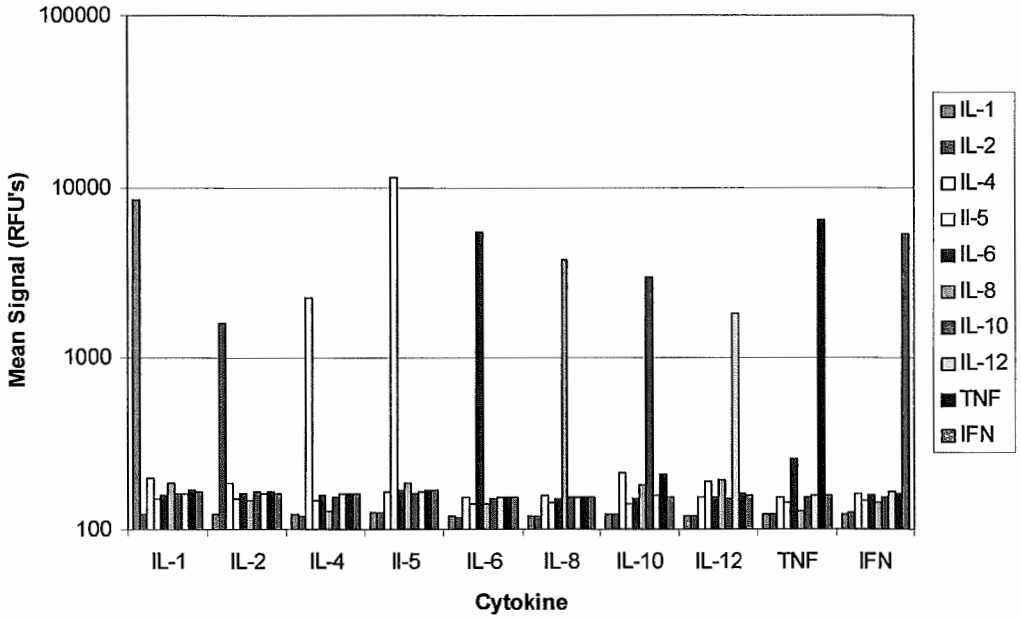
Multiplex Cytokine Assay Results

Specificity: Individual Standard @ 2500 pg/ml spike in Serum Diluent



Individual Standard @ 2500 pg/ml										
	IL-1	IL-2	IL-4	Il-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
Il-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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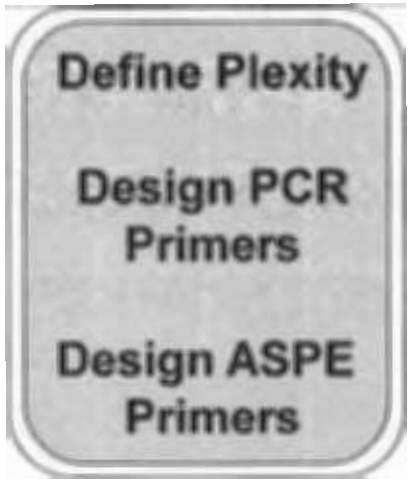
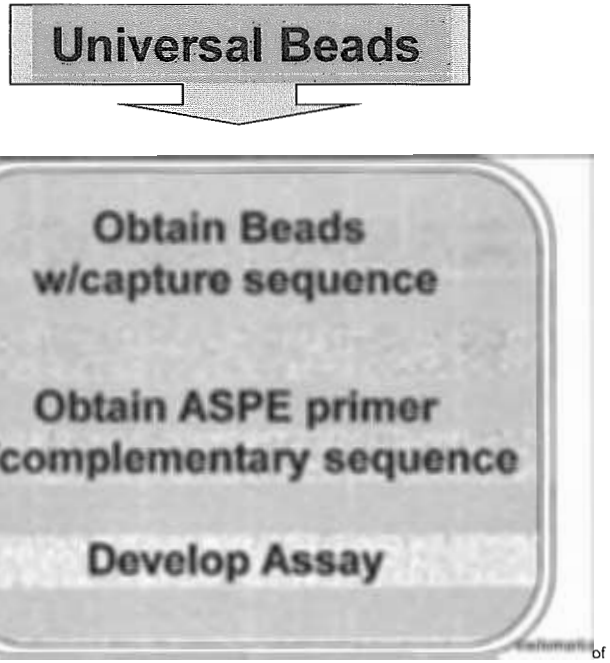
Assay Design For Genotyping (ASPE Chemistry)





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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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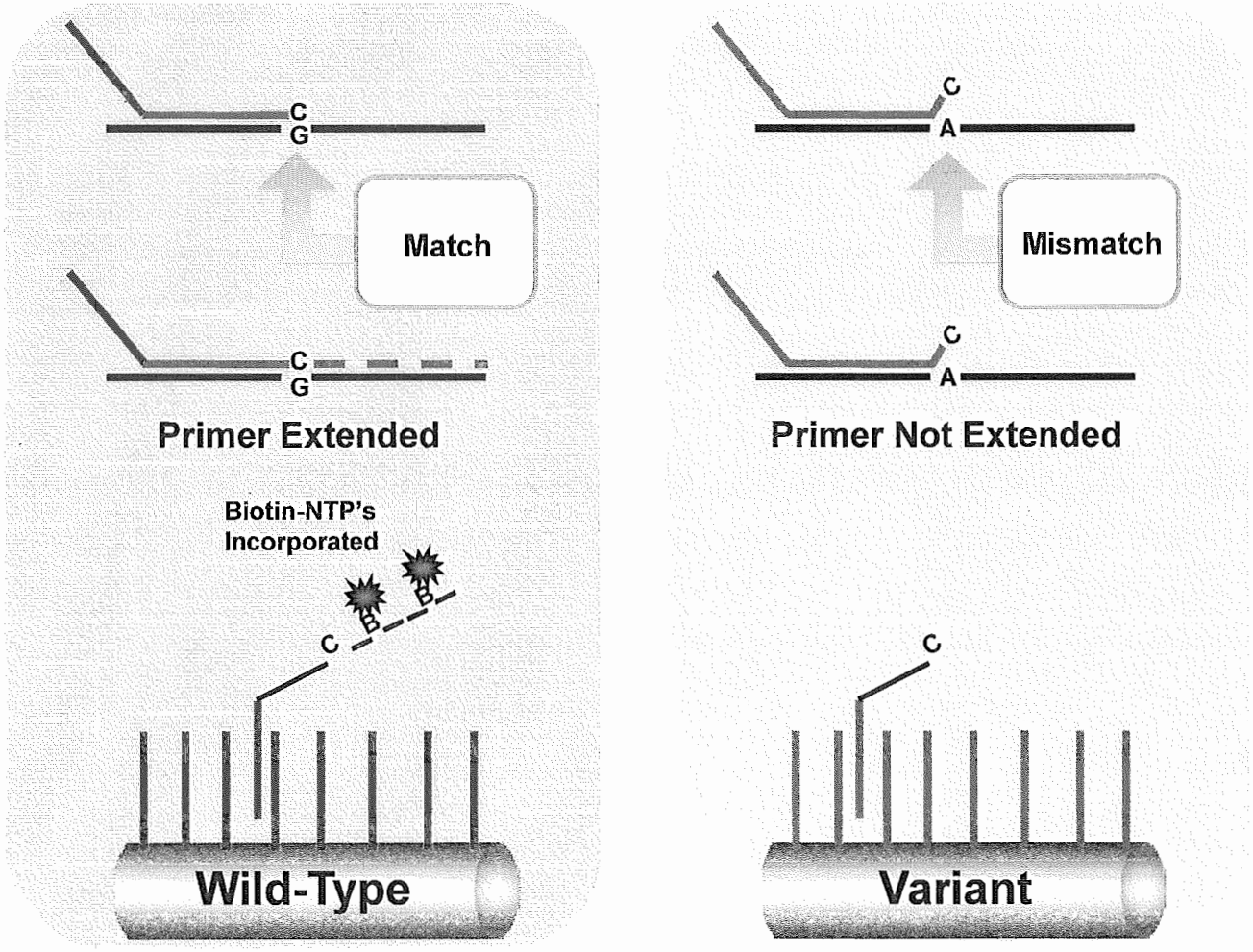
Multiplex Genotyping Example

ALLELE-SPECIFIC PRIMER EXTENSION (ASPE)



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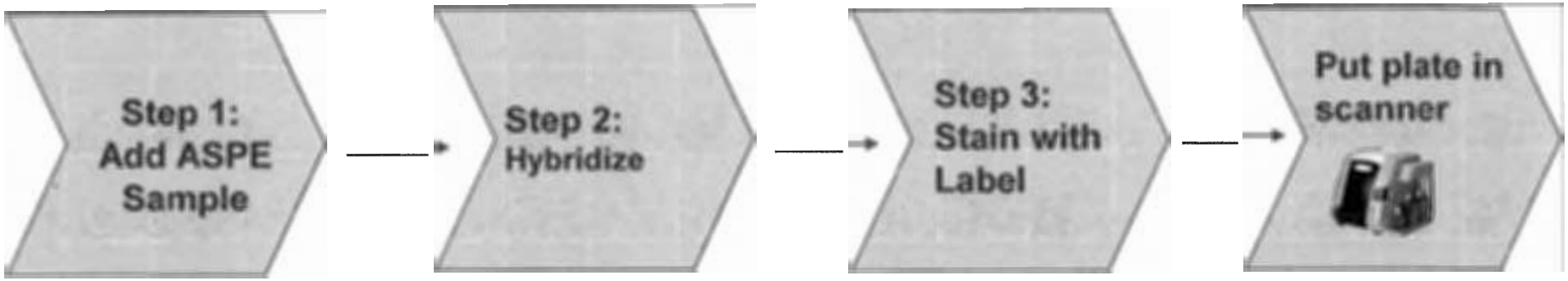
Multiplexing Genotyping Protocol

User defined Kitting Options

25 ul volume
25 ng gDNA

1:4 dilution
of PCR Products
In 20 ul

20-30 beads/well



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)	Genotype 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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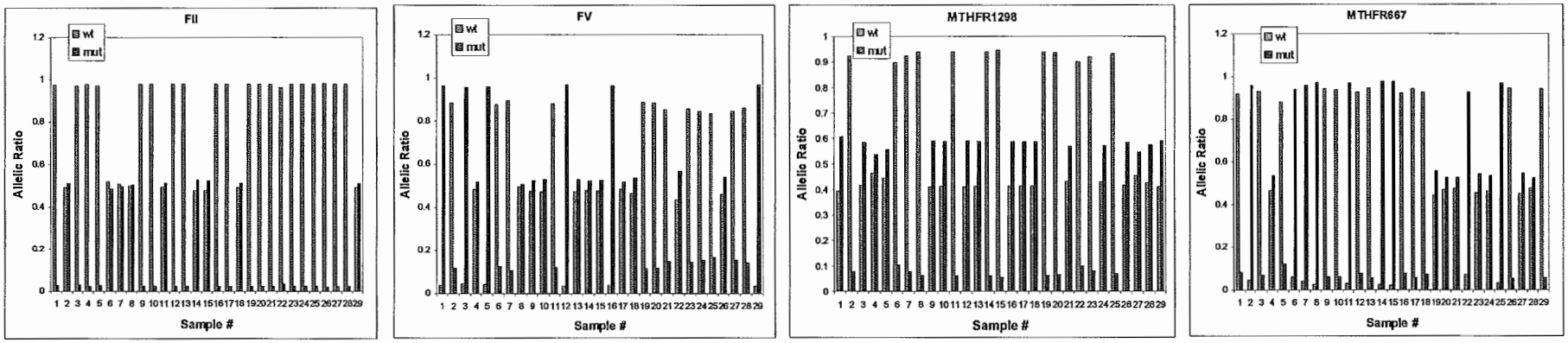
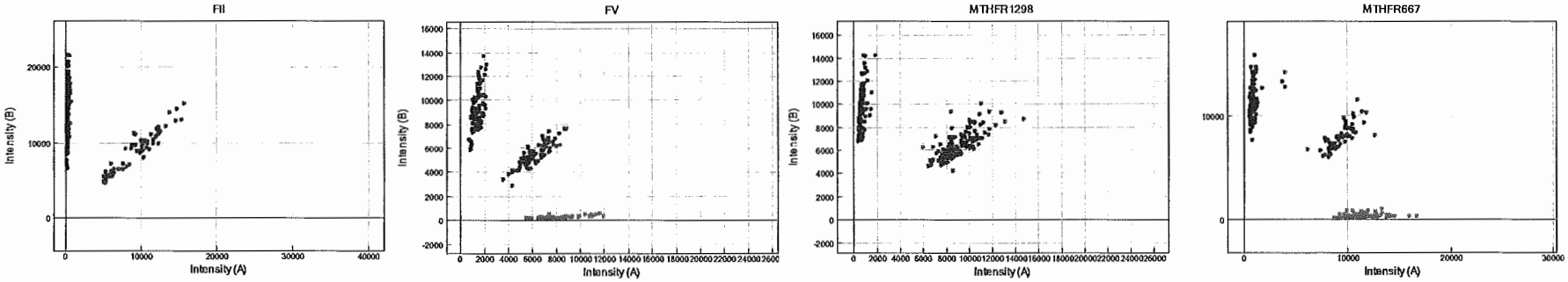
Low Plex ASPE Results – Thrombosis Panel





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

- 100% reproducibility
- 100% concordant genotypes

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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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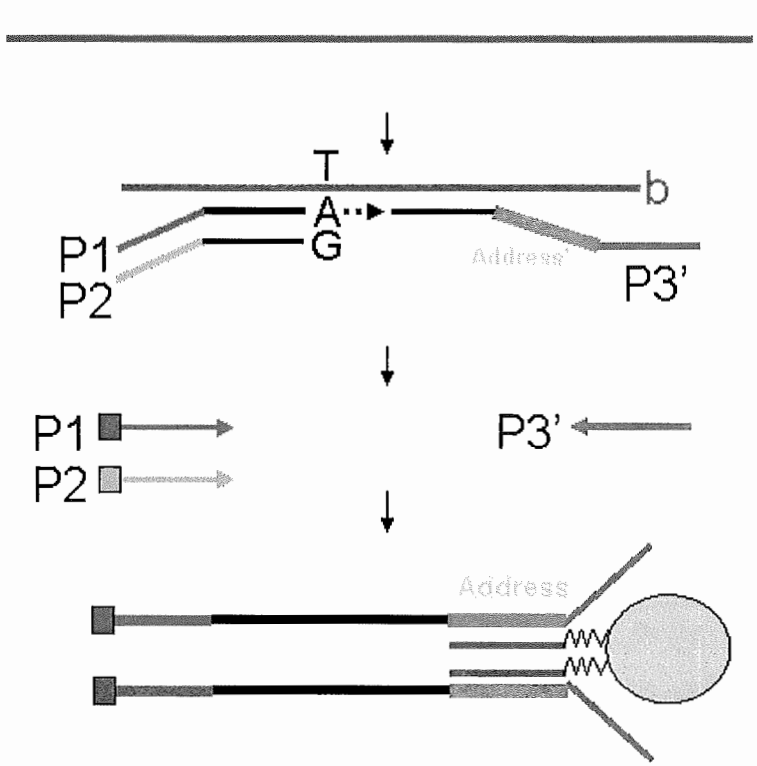
SNP Genotyping: GoldenGate™ Assay



genomic DNA

query oligo annealing, extension, and ligation

PCR with common primers

product capture by hybridization to array

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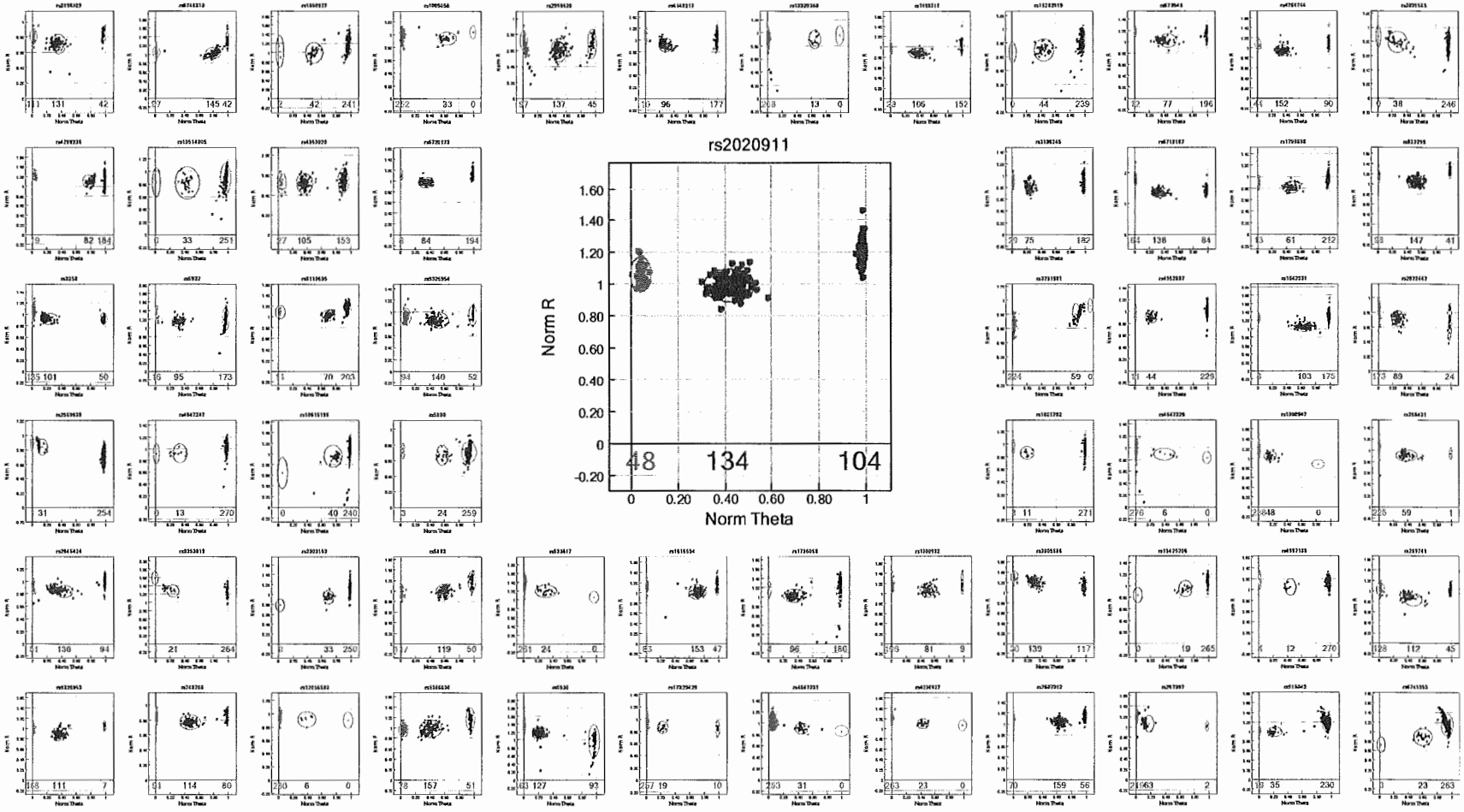
GoldenGate Assay Results



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

Illumina East	Dawn Gratalo Mary Trounstine Jane Tu Reader Team Bead Production Team
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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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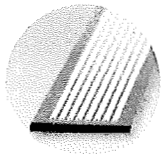

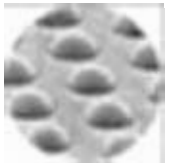

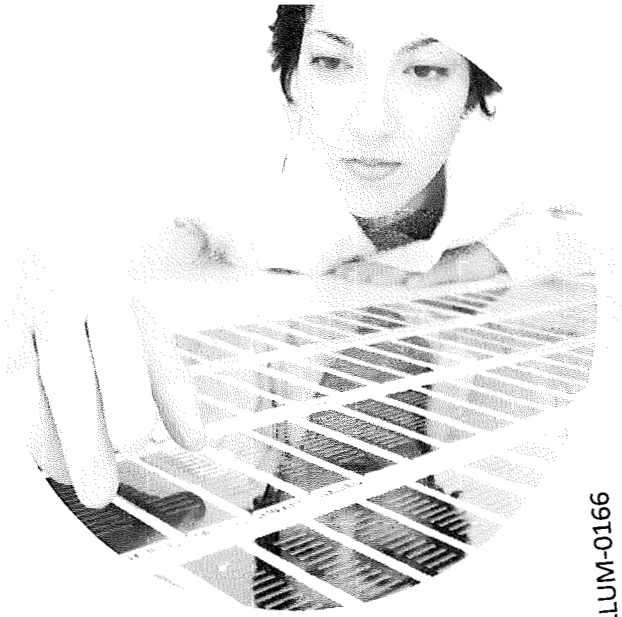

ILLUM-0166

VeraCode Technology – *From Research to Molecular Diagnostics*

Presented by:

Mickie Henshall,
Market Manager, Molecular Diagnostics

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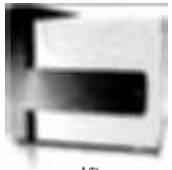
Illumina, Making Sense Out of Life, Sentrix, GoldenGate, DASL, Oligator, Infinium, BeadArray, Array of Arrays, BeadXpress, VeraCode, IntelliHyb, iSelect, CSPro, and Solexa are registered trademarks or trademarks of Illumina Inc.

Most Complete Genomics Assay Portfolio

APPLICATION	Sequence-Based Discovery	Whole-Genome	Targeted Analysis	Validation, Screening & Standard Tests
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) Custom; 96 to 1536 (GoldenGate) Standard	1 to 384-plex Custom
PRODUCT	Resequencing	Human1M-Duo	Infinium iSelect Genotyping Panels 6K-60K	Linkage-12	VeraCode GoldenGate 96- & 384-plex
	SNP & CNV Discovery	HumanHap650Y	GoldenGate Genotyping Panels 96-1536	CNV-12	DASL Expression
	De novo Sequencing	Human610-Quad	DASL Expression Panels 384-1536	MHC GG	Methylation
	Tag Expression	Exon610-Duo	GoldenGate Methylation Panels 384-1536	African American Admixture GG	Carboxyl - Protein
	Transcript Profiling	HumanCNV370-Duo		CanineSNP20	Universal Capture
	ChIP Sequencing	Human 6/Ref-8 Gex		BovineSNP50	
	MeDIP Sequencing	Mouse 6/Ref-8 Gex		Micro RNA	
	BiSulfite CpG	Rat Ref-12 Gex		Methylation Cancer Panel I	
		Genome-wide Methylation27			

2008 Release

illumina®

ILLUM-0167

Illumina's Solution for Diverse Applications

VeraCode® Technology

- Cylindrical glass microbeads
- 240 µm length x 28 µm diameter

ILLUM0168

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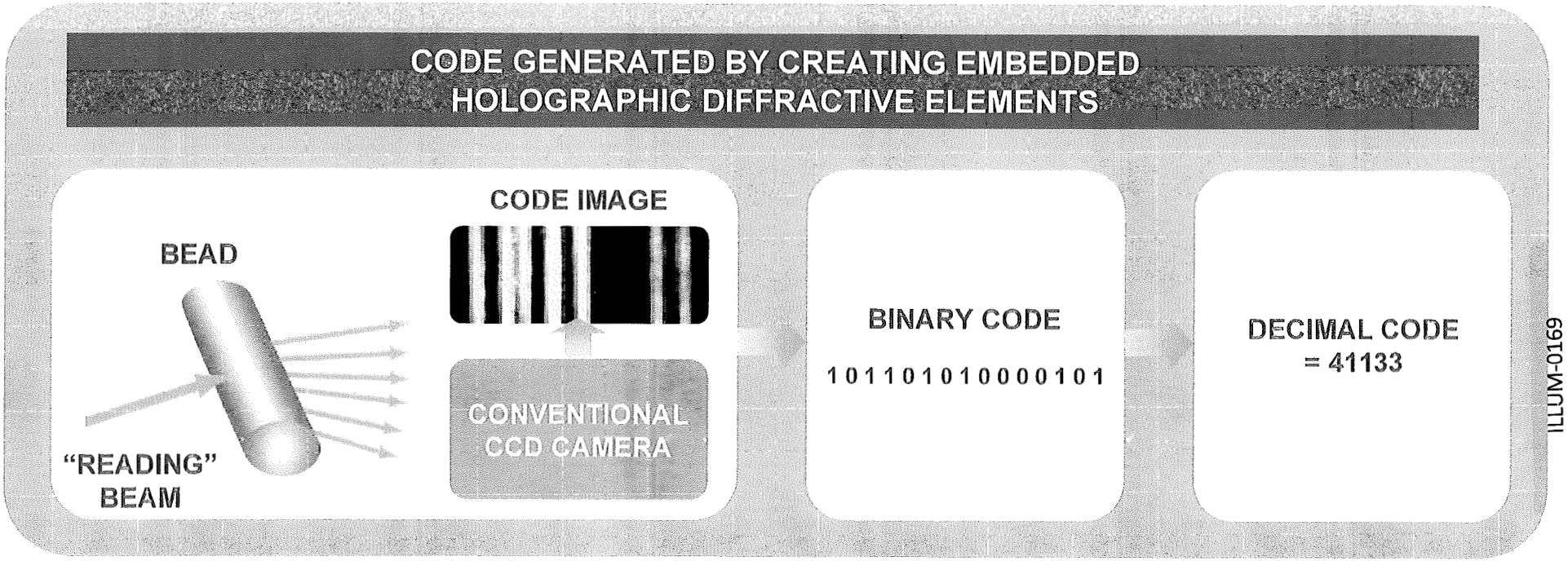
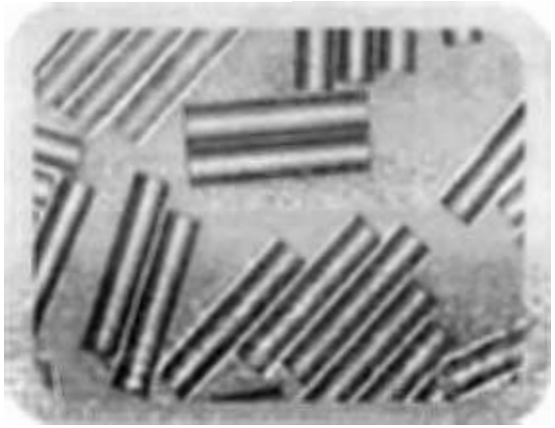
VeraCode Technology



ILLUM-0169



- 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

illumina®

Carboxyl Beads: Chemistry of Attachment

$COOH^-$
$COOH^-$
$COOH^-$
$COOH^-$
$COOH^-$
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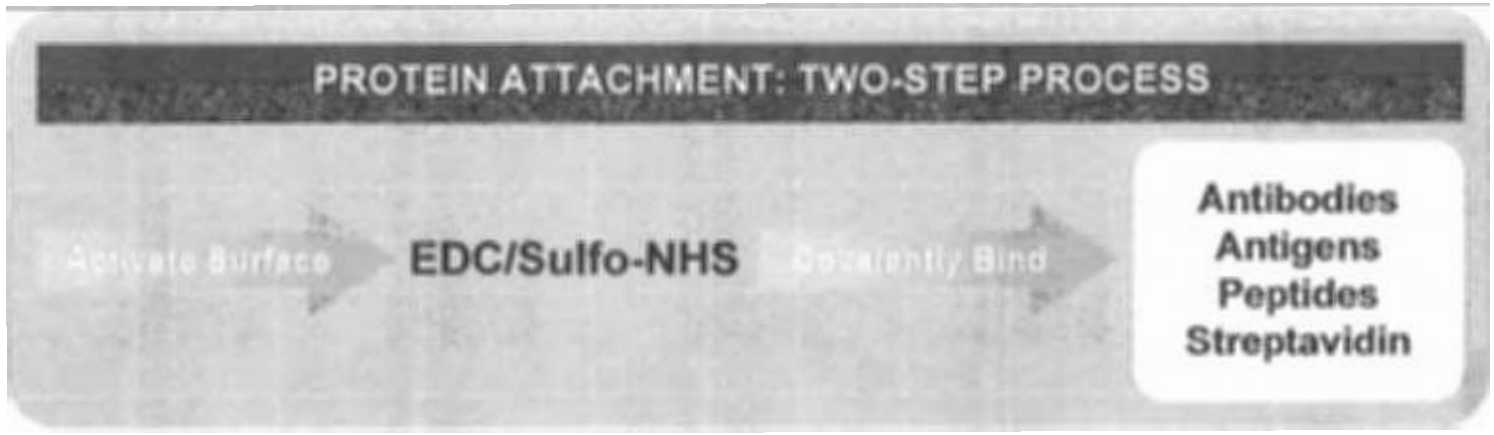

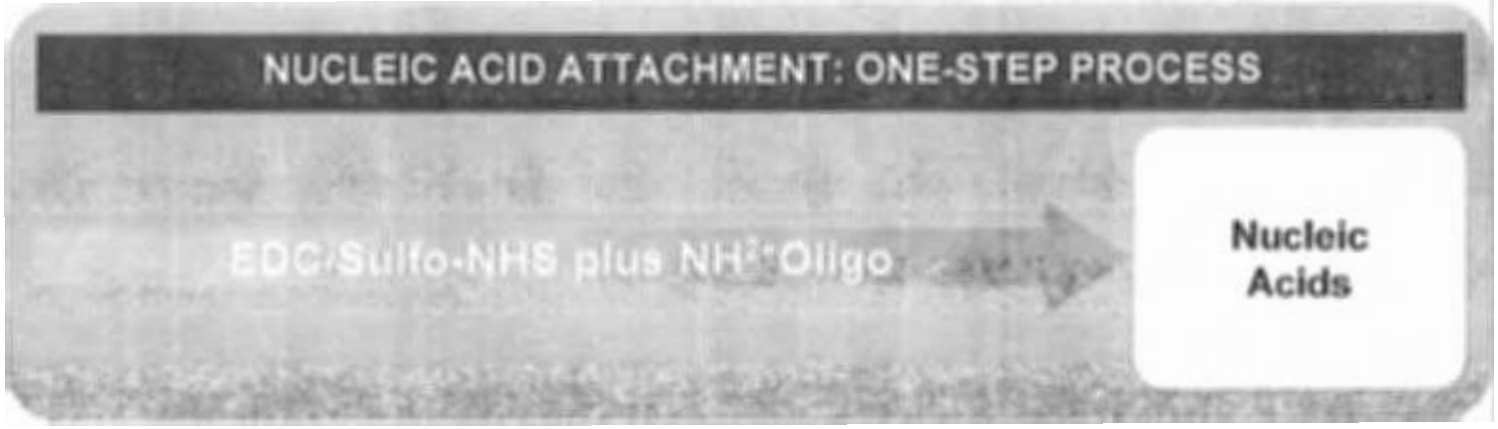

ILLUM-0170

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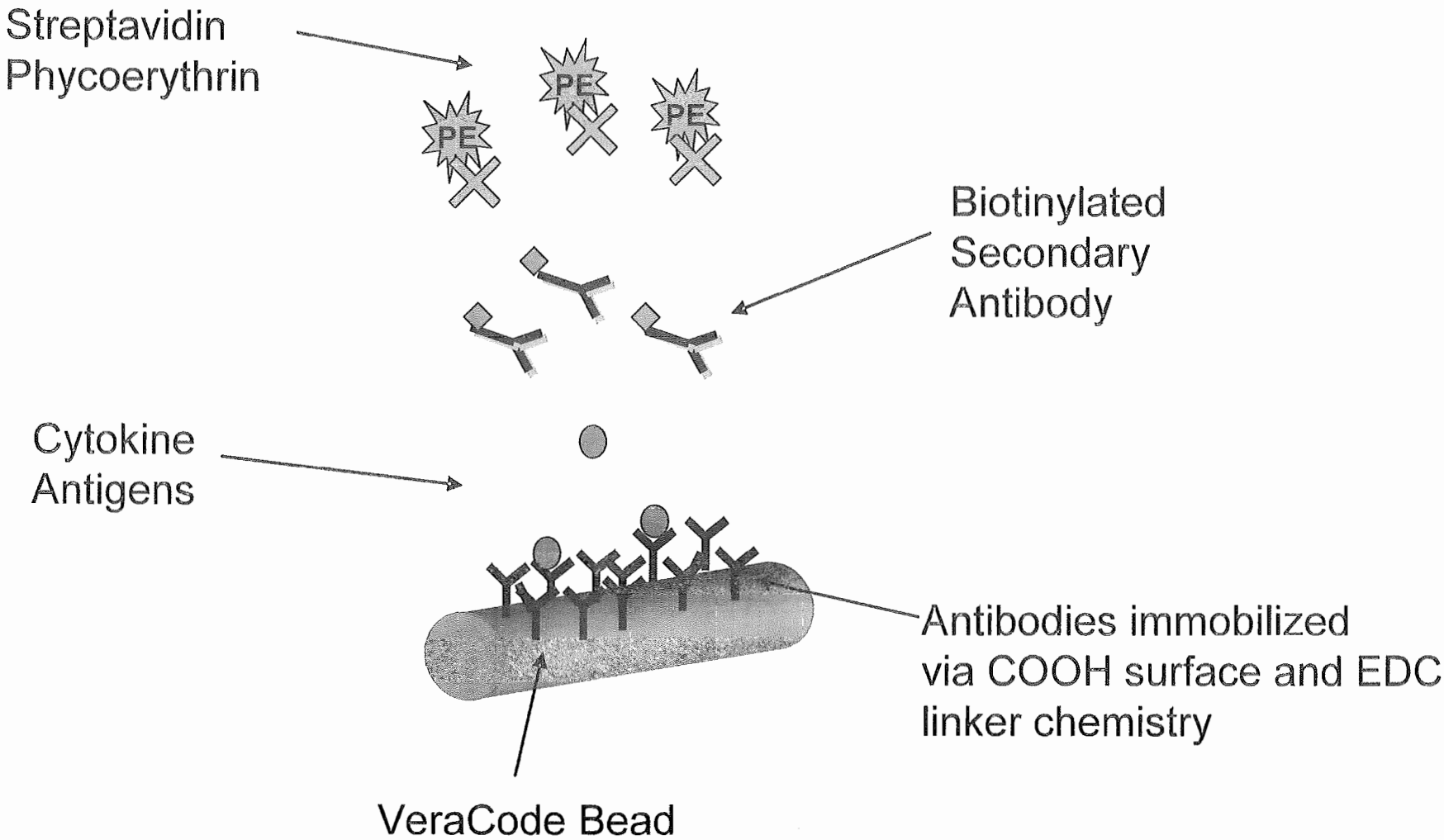
Cytokine Sandwich Assay



ILLUM-0171

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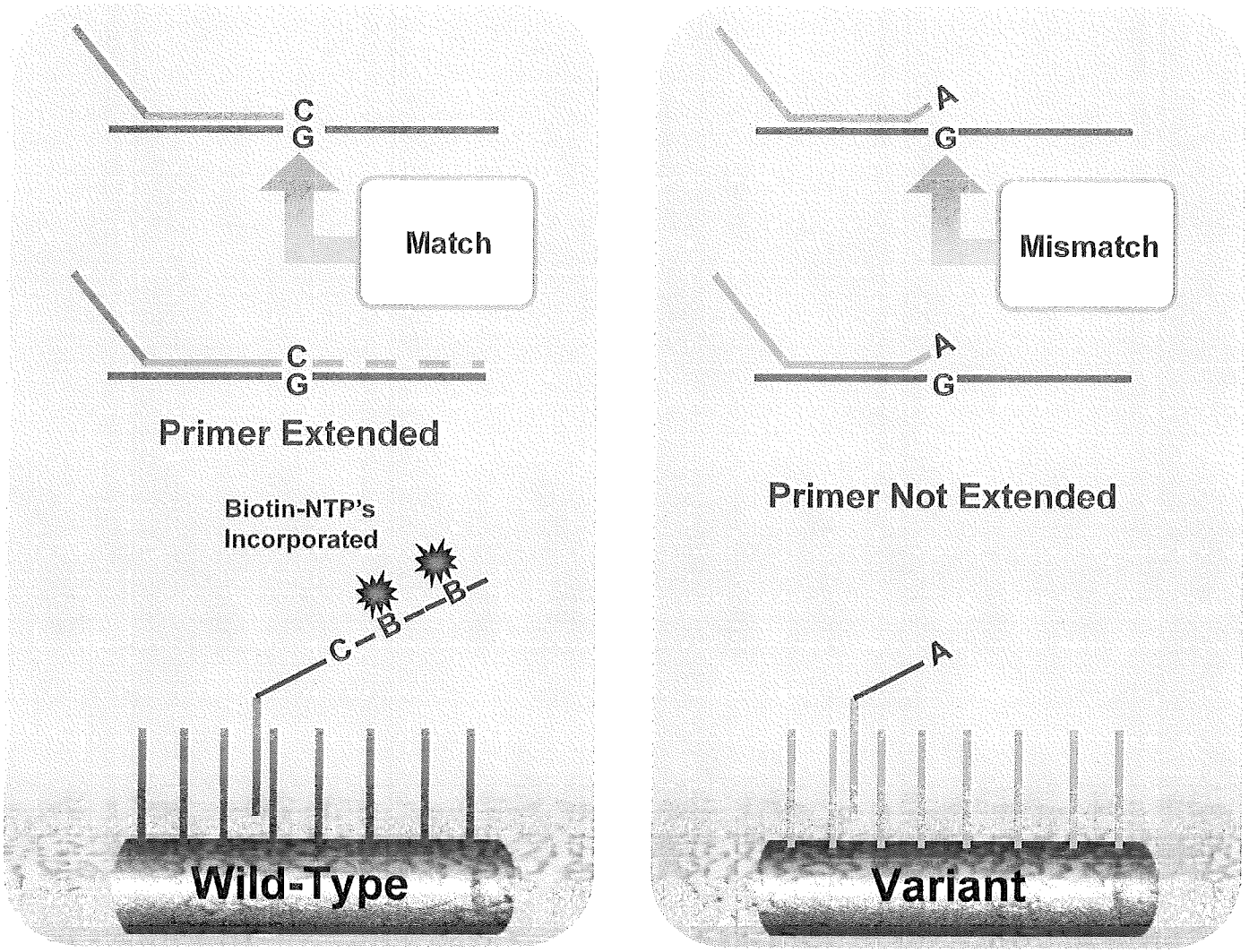
Universal Oligo Capture Beads



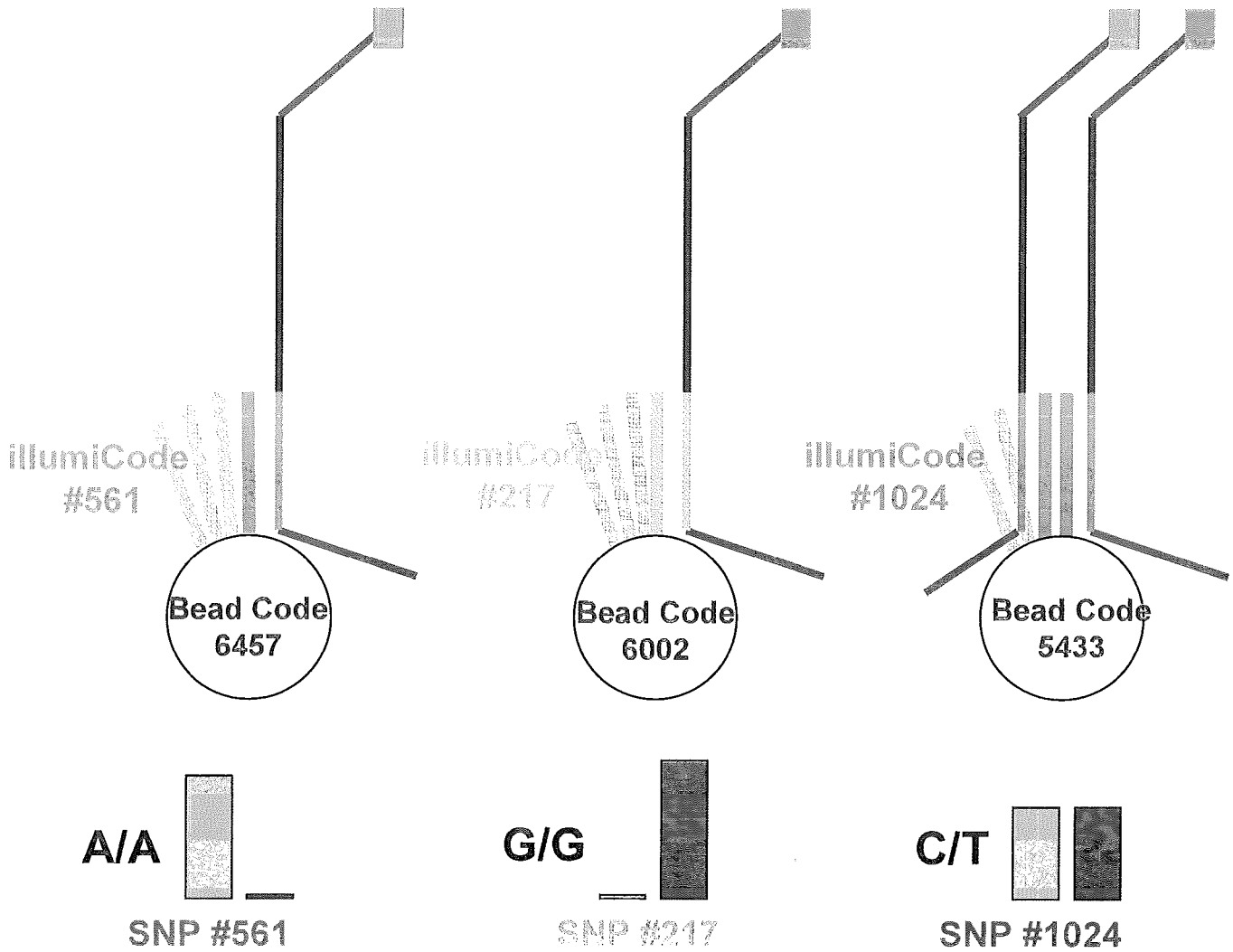
Allele Specific Primer Extension Assays

ILLUM-0172

illumina

GoldenGate Assay – two color detection

- Hybridization to VeraCode Beads – one SNP per bead type



ILLUM-0173

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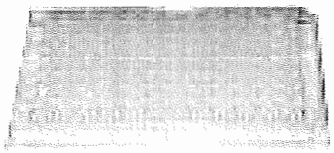
Easily adaptable to changing content requirements

VeraCode Beads Pre-plated into standard product

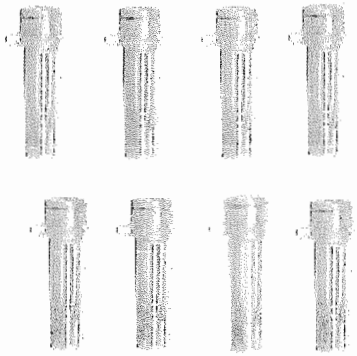


Beads Pooled in 96-well Plates

(96 & 384-plex/well)

+

Individual Tubes of VeraCode Beads



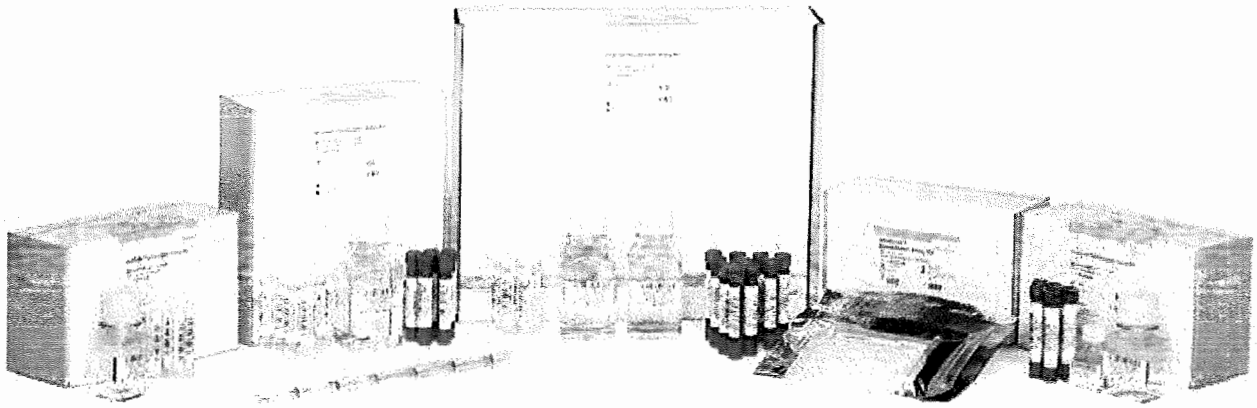
Customized panels created by pooling different tubes of beads

ILLUM-0174

illumina®

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



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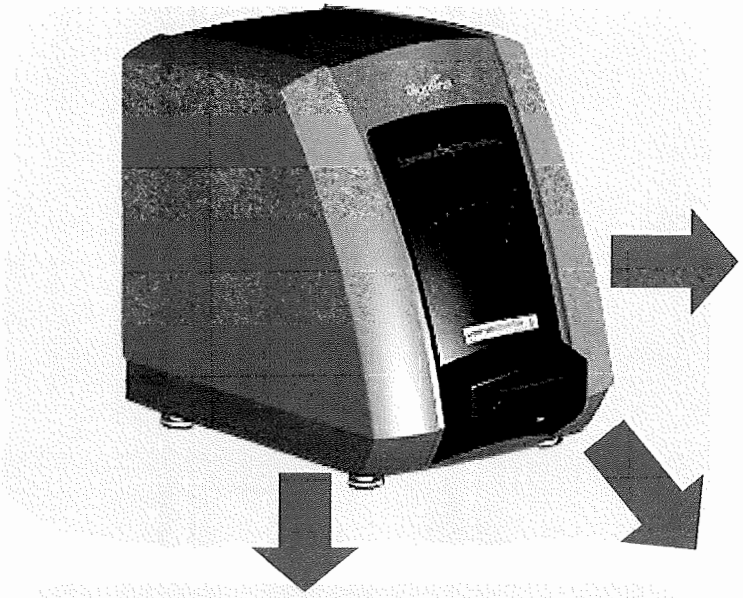
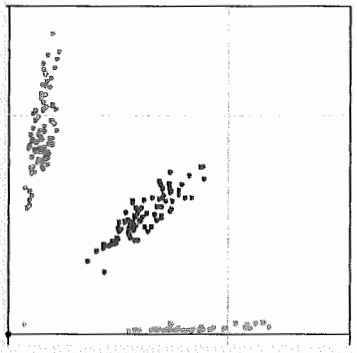
ILLUM-0175

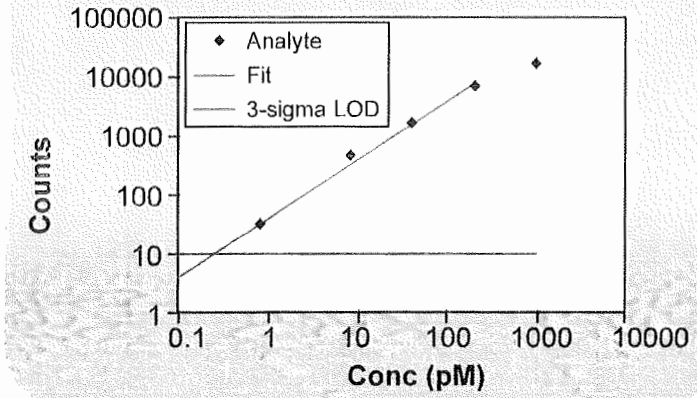
Analyzer for Multiple Applications



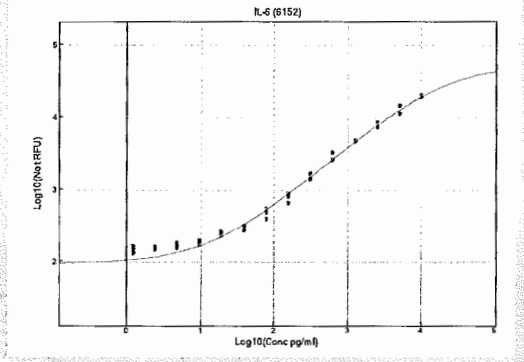
GENOTYPING



GENE REGULATION



PROTEIN EXPRESSION



ILLUM-0176

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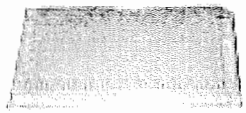
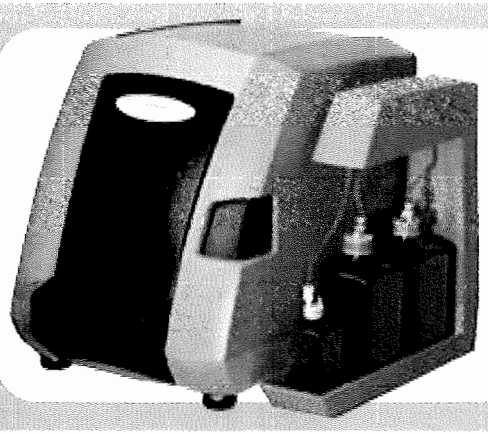
BeadXpress™ Reader

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

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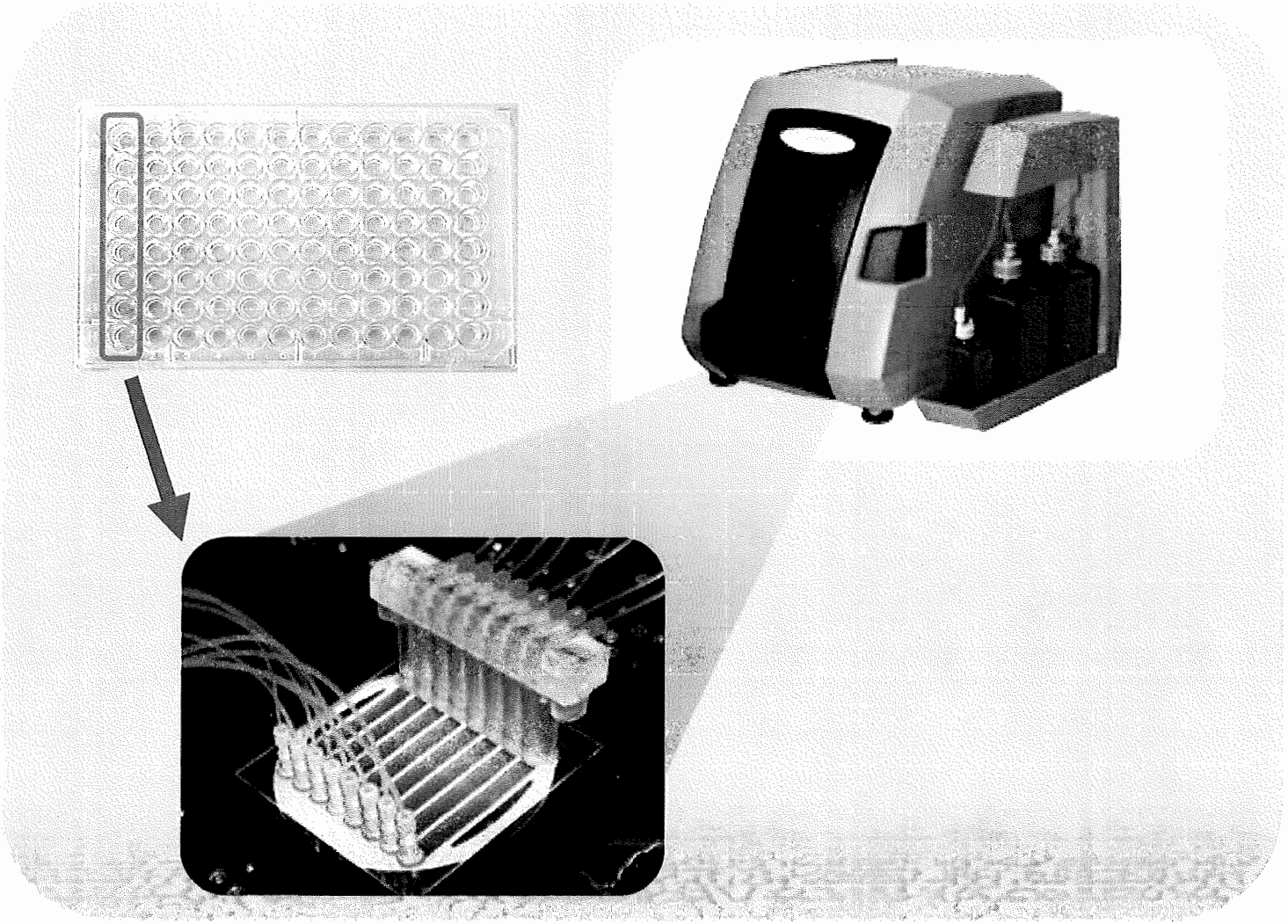
BeadXpress Reader



ILLUM-0178

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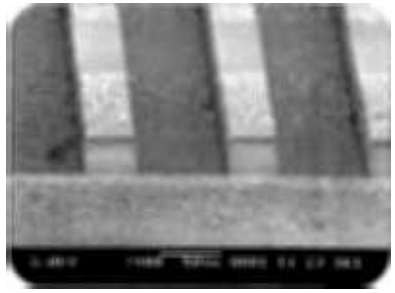
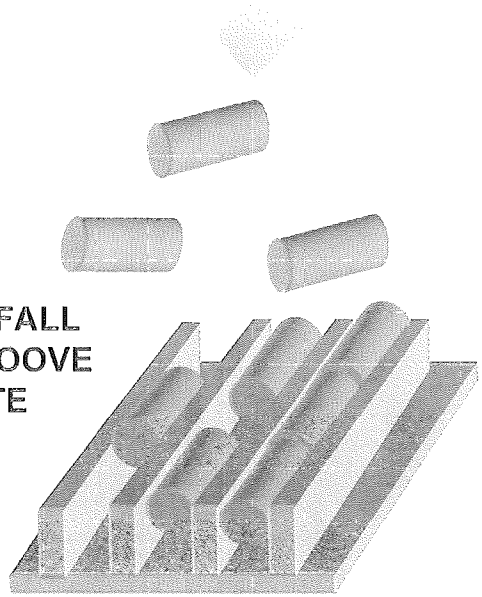
VeraCode Technology

CAPILLARY FORCE ATTRACTS BEADS INTO GROOVES

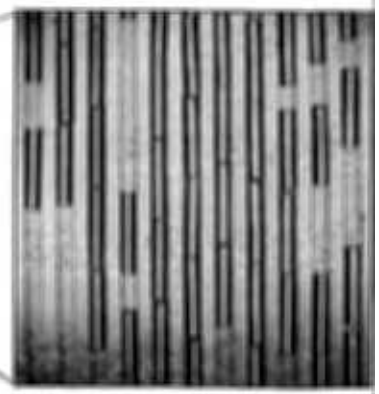


GROOVE PLATE CROSS-SECTION



BEADS FALL INTO GROOVE PLATE

BEADS ALIGN TIGHTLY FOR OPTIMAL SCANNING EFFICIENCY



ILLUM-0179

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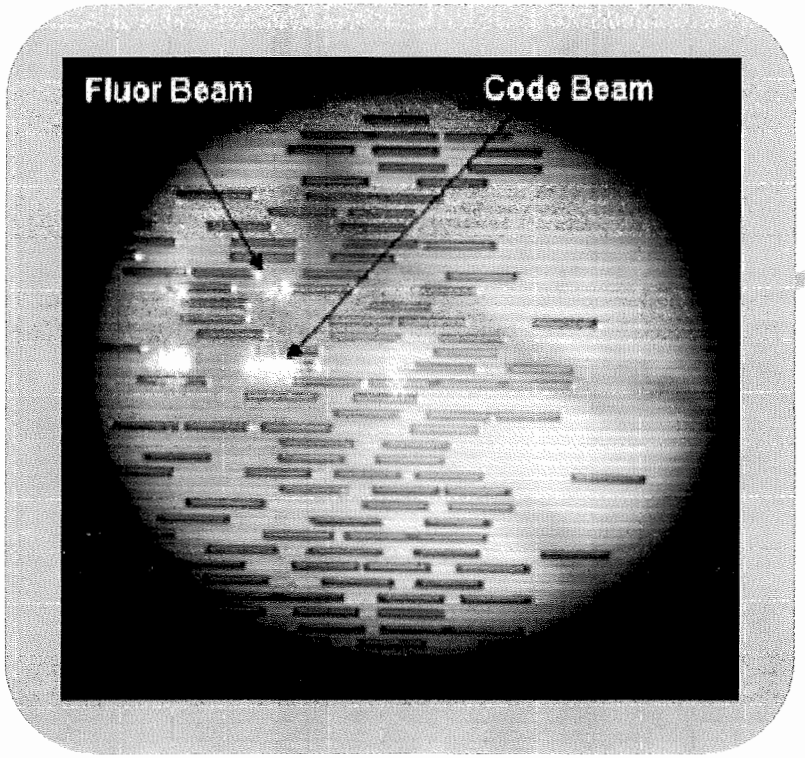
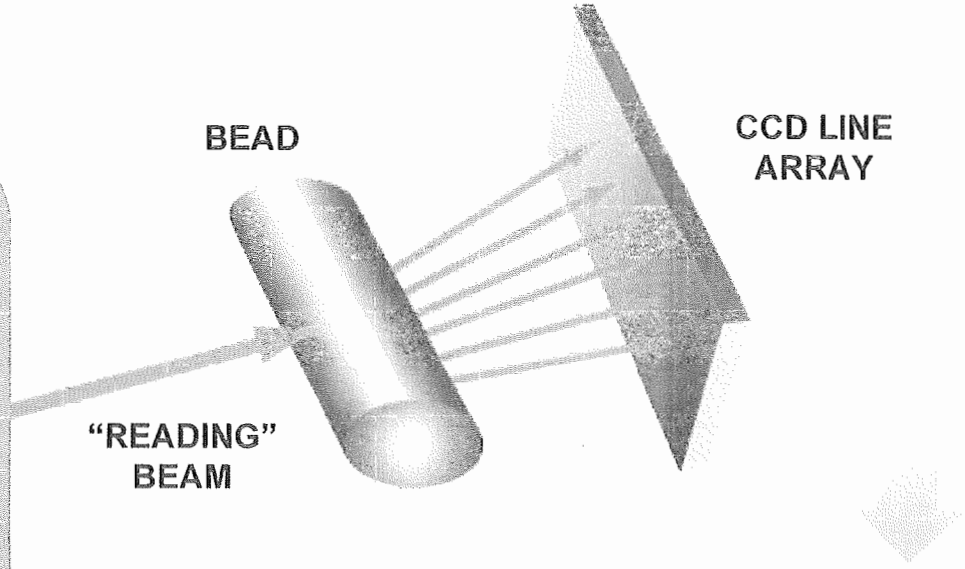
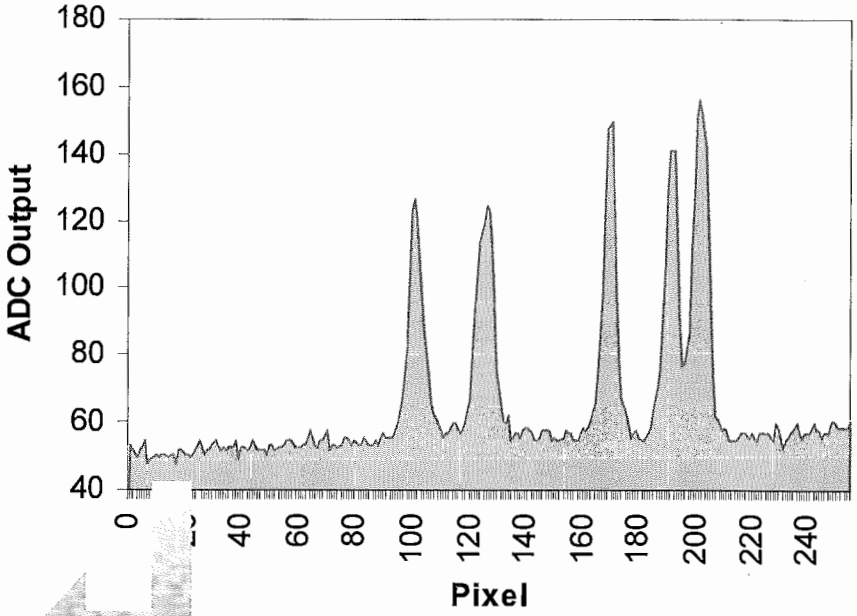
Code Detection







ILLUM-0180

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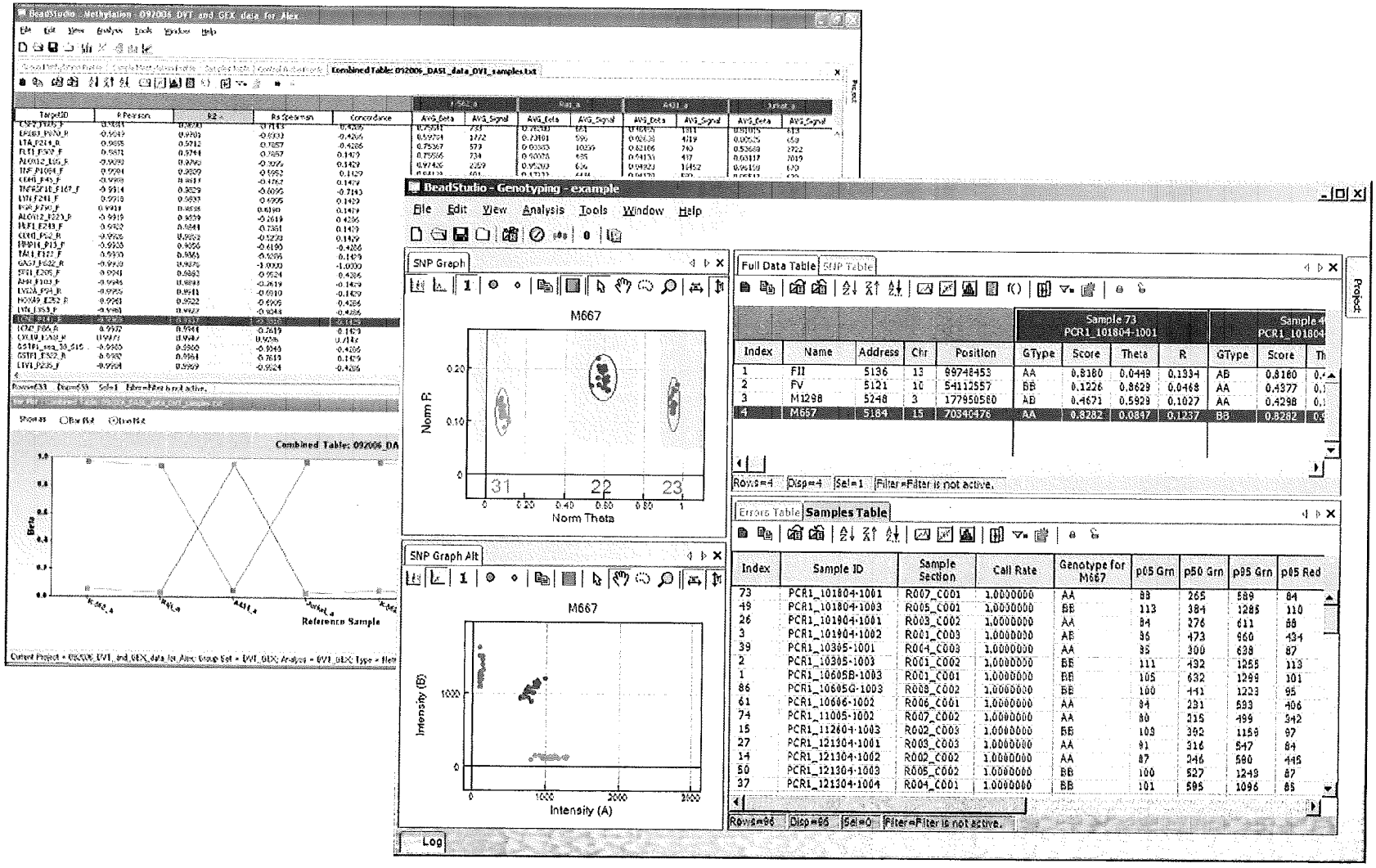
Exhibit 105C

Data Analysis Streamlined with BeadStudio



ILLUM-0181

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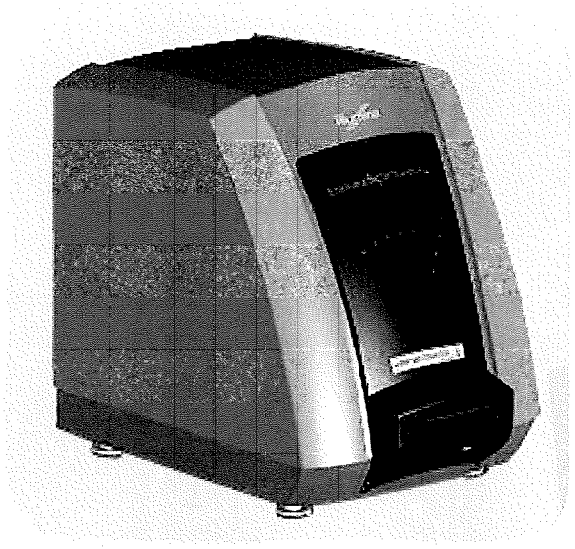
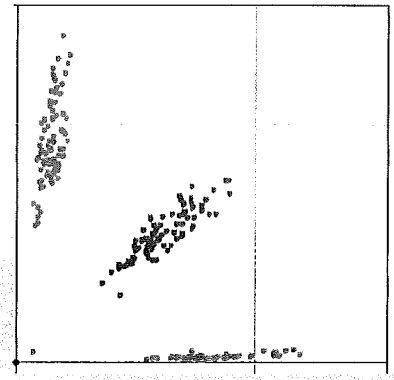
What's Next for BeadXpress

- 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®

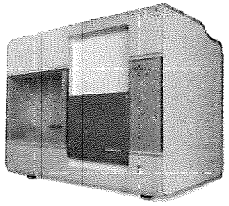
From Discovery to Molecular Diagnostics

Discovery | Focused Research & Validation | Molecular Dx

$>10^9$ | 10^8 | 10^7 | 10^6 | 10^5 | 10^4 | 10^3 | 10^2 | 10 | 1

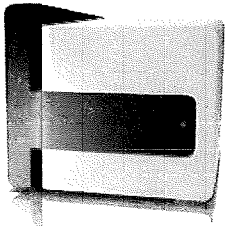
Whole Genome

Single Marker



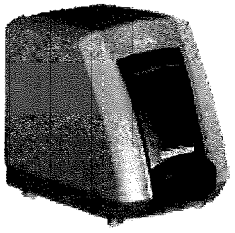
- WG Resequencing
- WG Gene Expression
- Micro RNA Discovery & Profiling
- WG ChIP-Seq
- Candidate-Region resequencing
- Whole Chromosome sequencing

Genome Analyzer



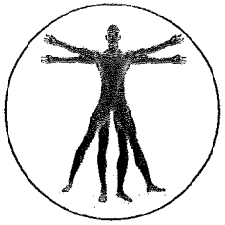
- Gene Expression
- WG Genotyping
- WG CNV
- Biomarker Discovery
- HT Biomarker/lead validation
- Custom genotyping
- Focused expression
- DASL for FFPE

iScan



- Low/mid density GT/GEX
- Protein applications
- Biomarker screening
- Biomarker panels

BeadXpress



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ILLUM-0183

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

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Print Page Close Window

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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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 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.

ILLUM-0200

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For more information about the VeraCode ADME Core Panel, please visit http://www.illumina.com/VeraCodeADME.

ILLUM-0202

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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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Exhibit 106

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.

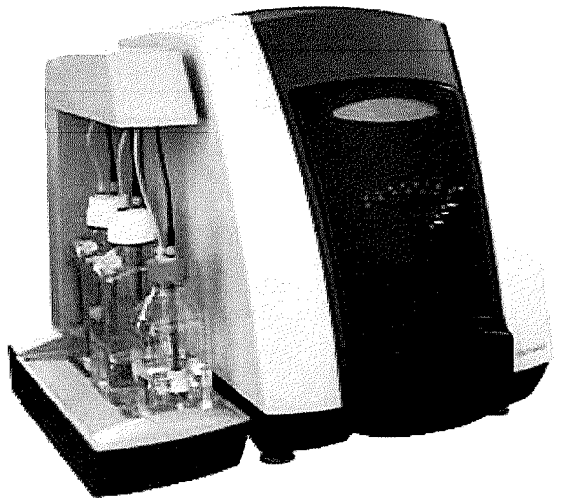
In addition to providing outstanding data quality for a broad spectrum of bioassays, the dual-laser BeadXpress Reader enhances the versatility of VeraCode technology by supporting robust single-color detection assays as well as two-color assays.

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.

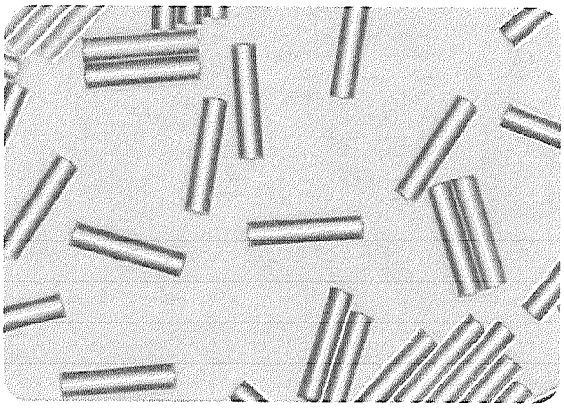
Complete System

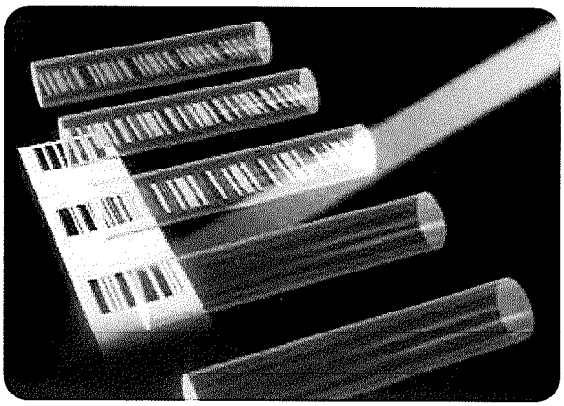
Included in the purchase of a BeadXpress Reader are:

- **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

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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

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ILLUM-0958

Exhibit 107

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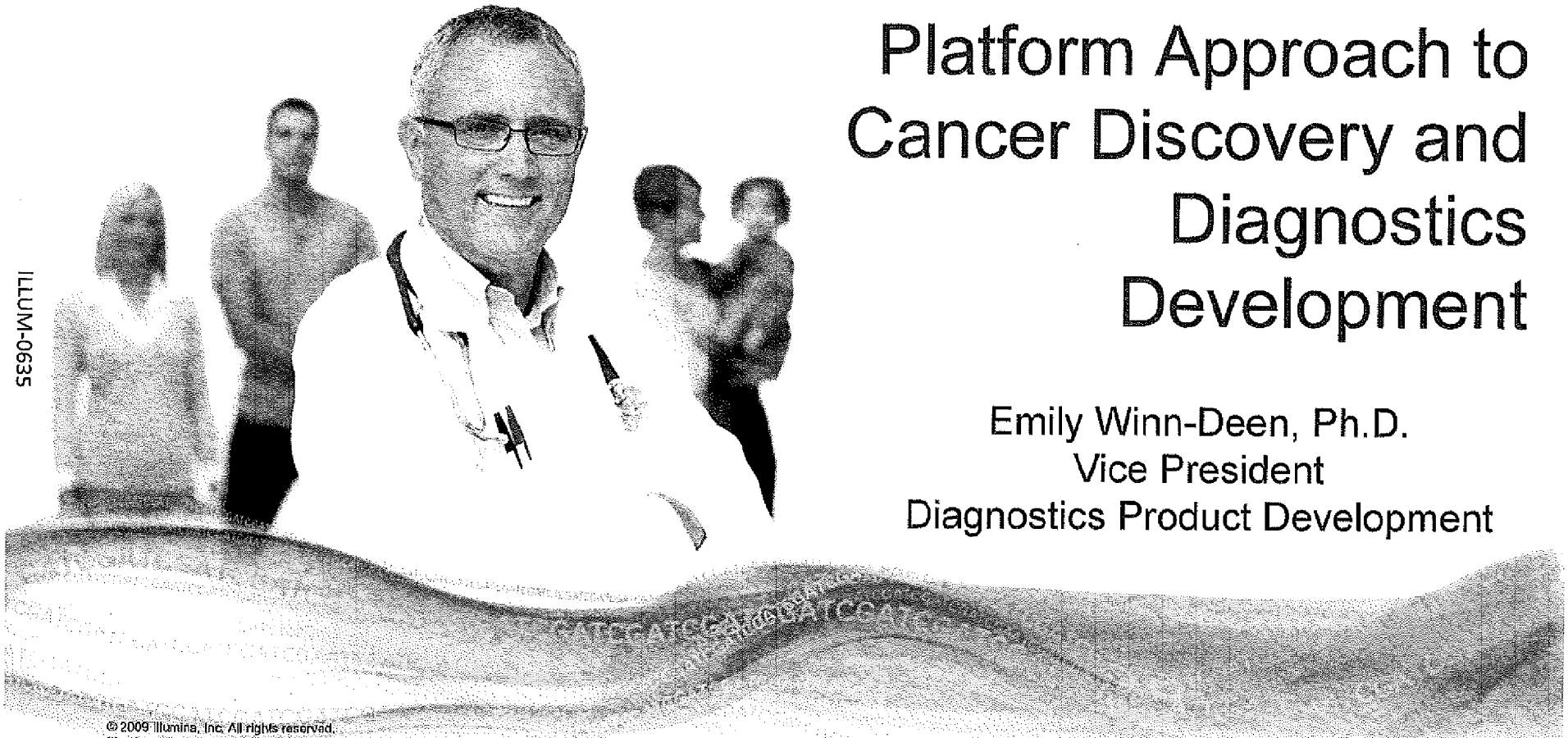

Platform Approach to Cancer Discovery and Diagnostics Development

Emily Winn-Deen, Ph.D.
Vice President
Diagnostics Product Development

ILLUM-0635

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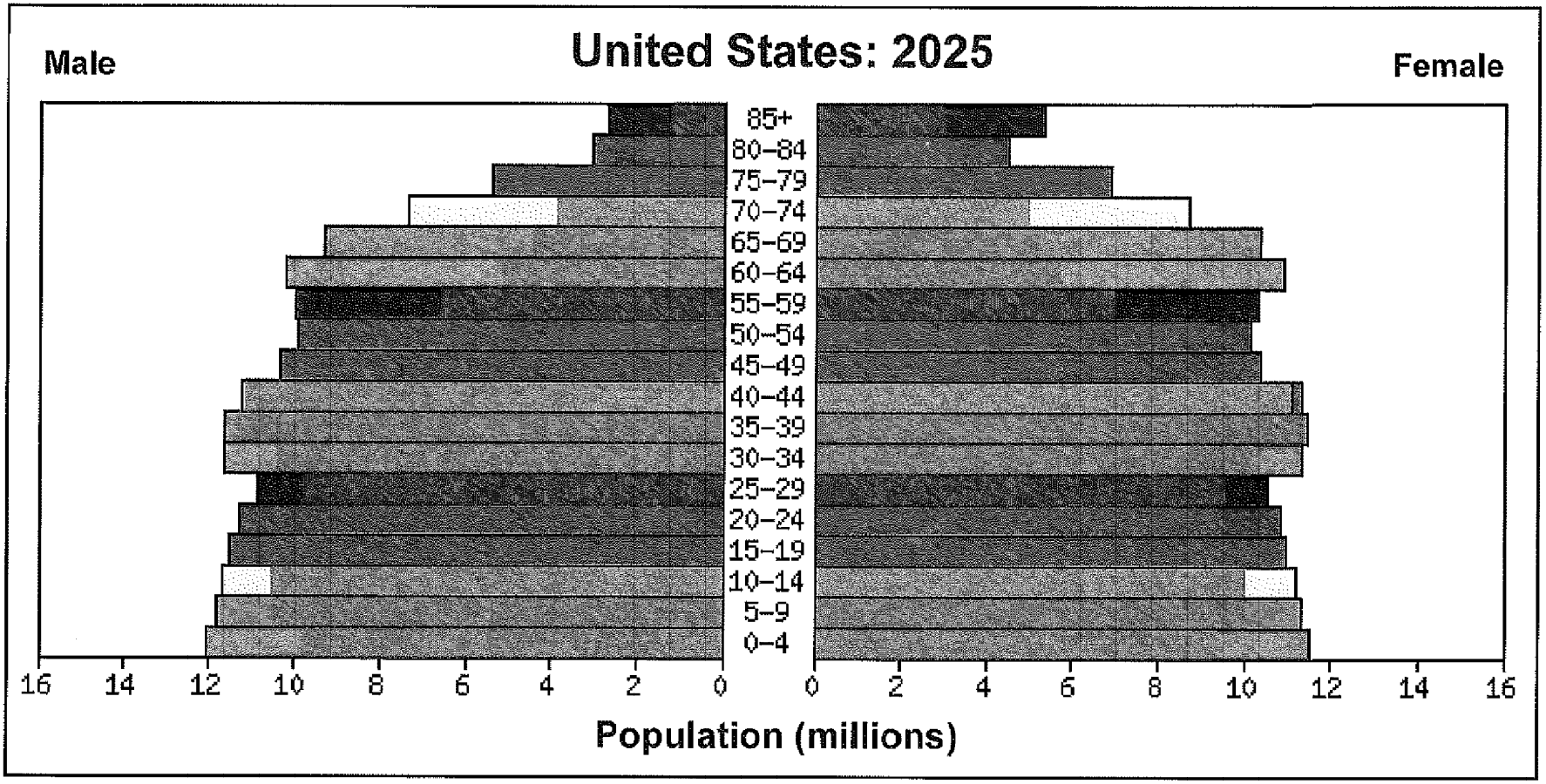
Why Focus on Cancer?
The Population is Aging



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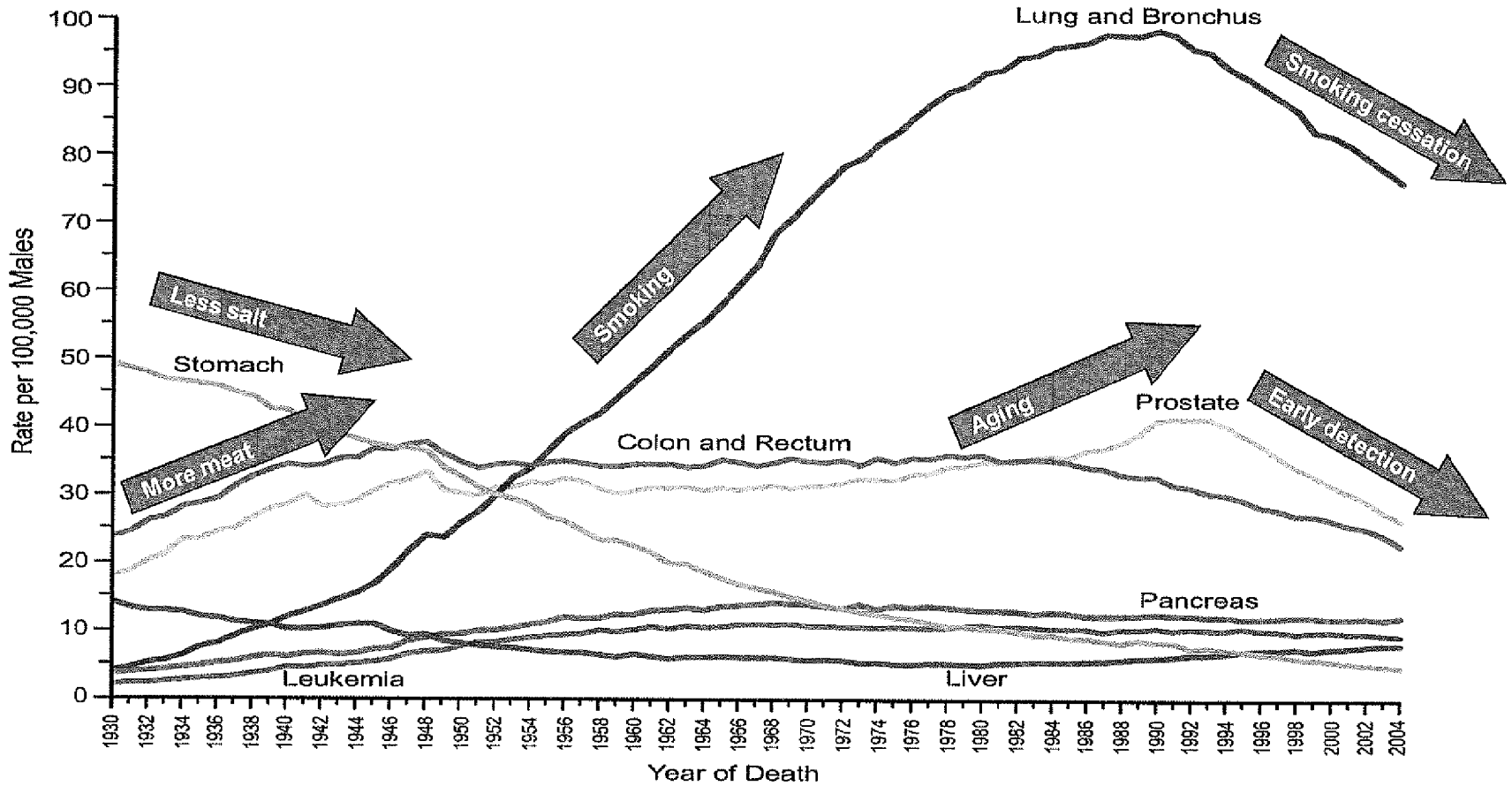
Cancer Continues to be a Major Health Issue

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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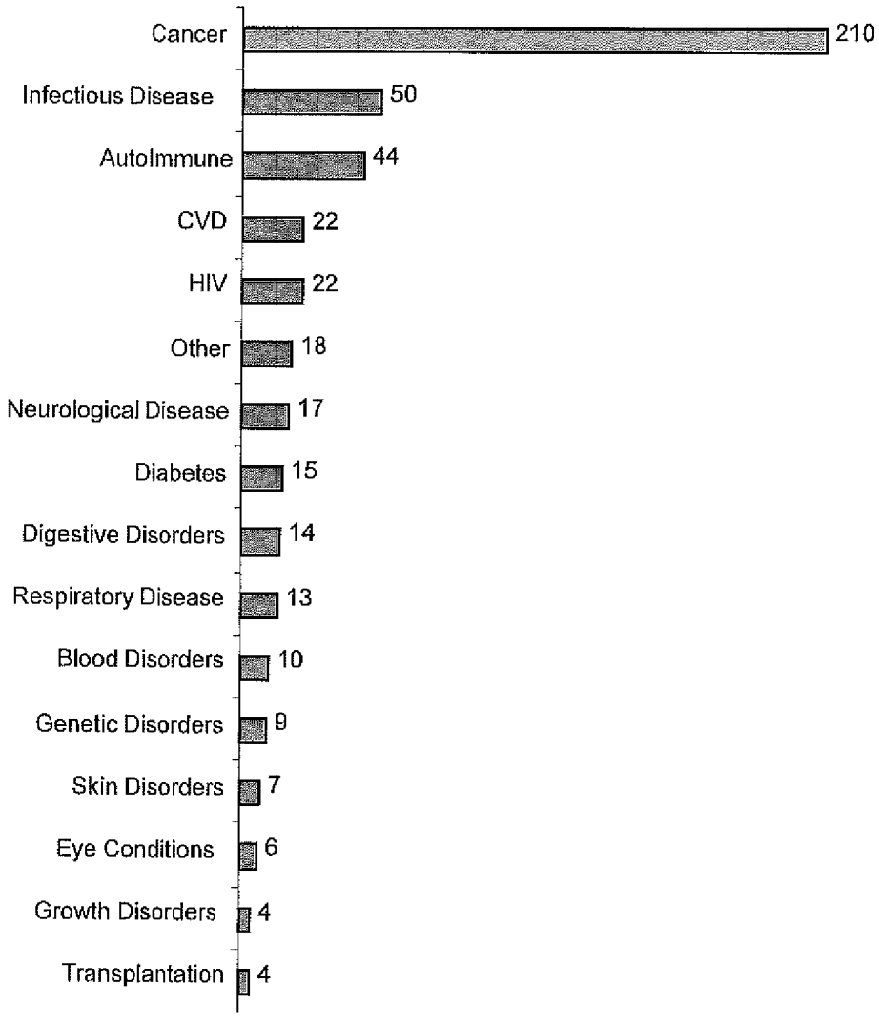
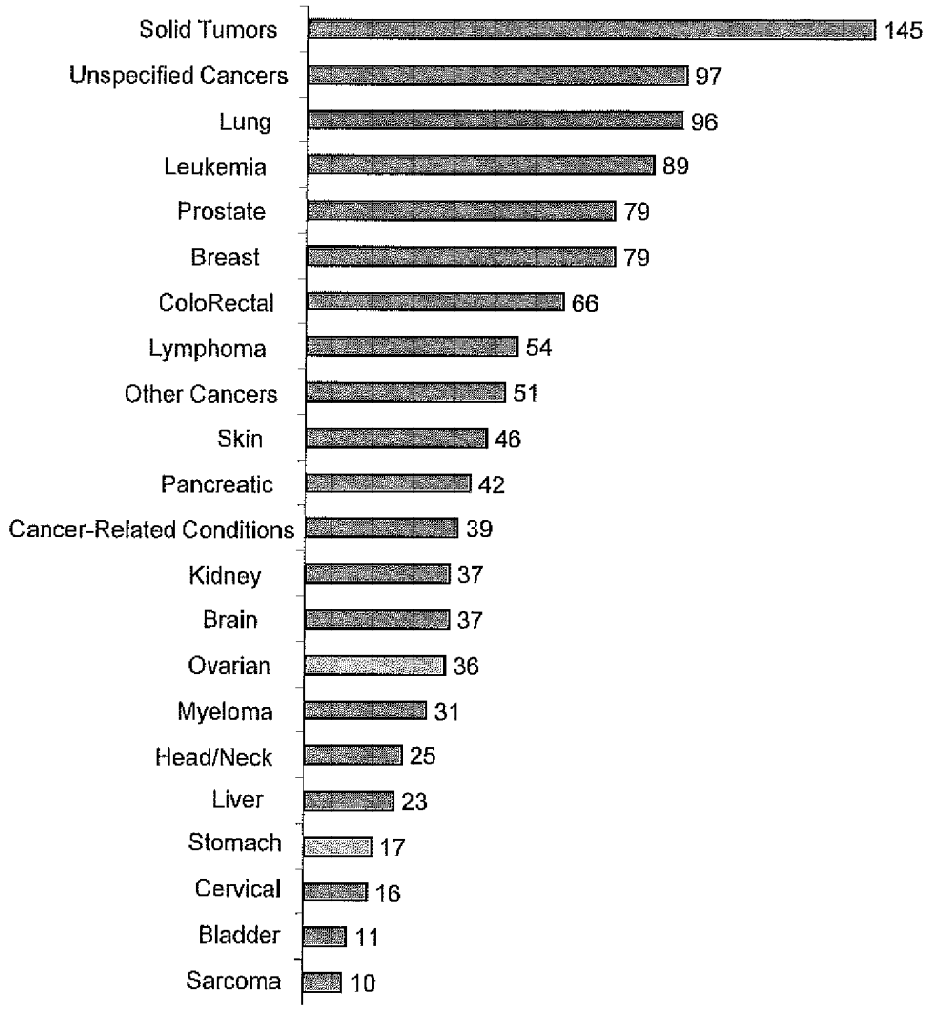
ILLUM-0637

Cancer Therapies Dominate the Biotech Pharma Pipeline



Solid Tumors Lead Cancer Therapies



Source: PhRMA: 2006 Medicines in Development Biotechnology

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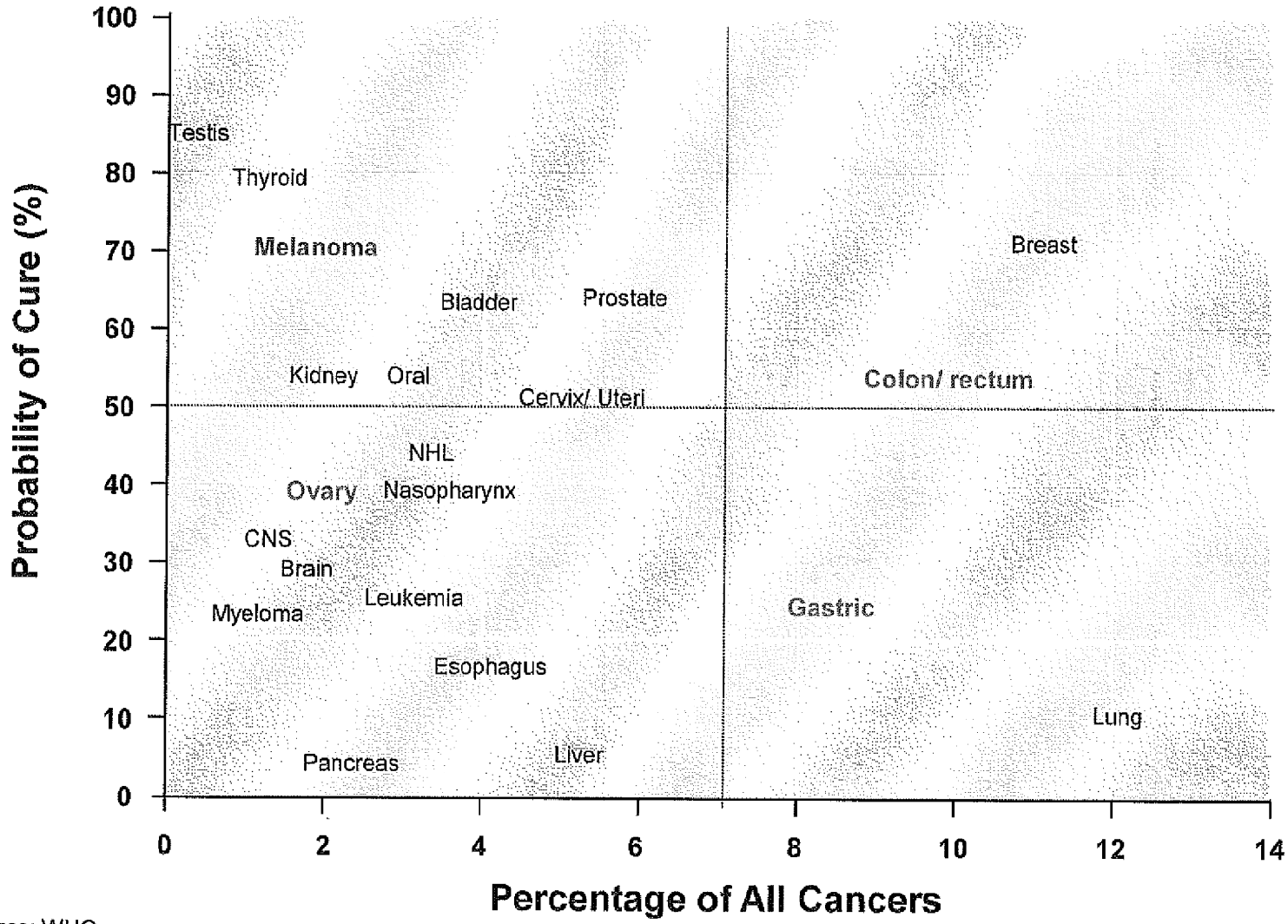
Oncology Discovery

Initial Targets



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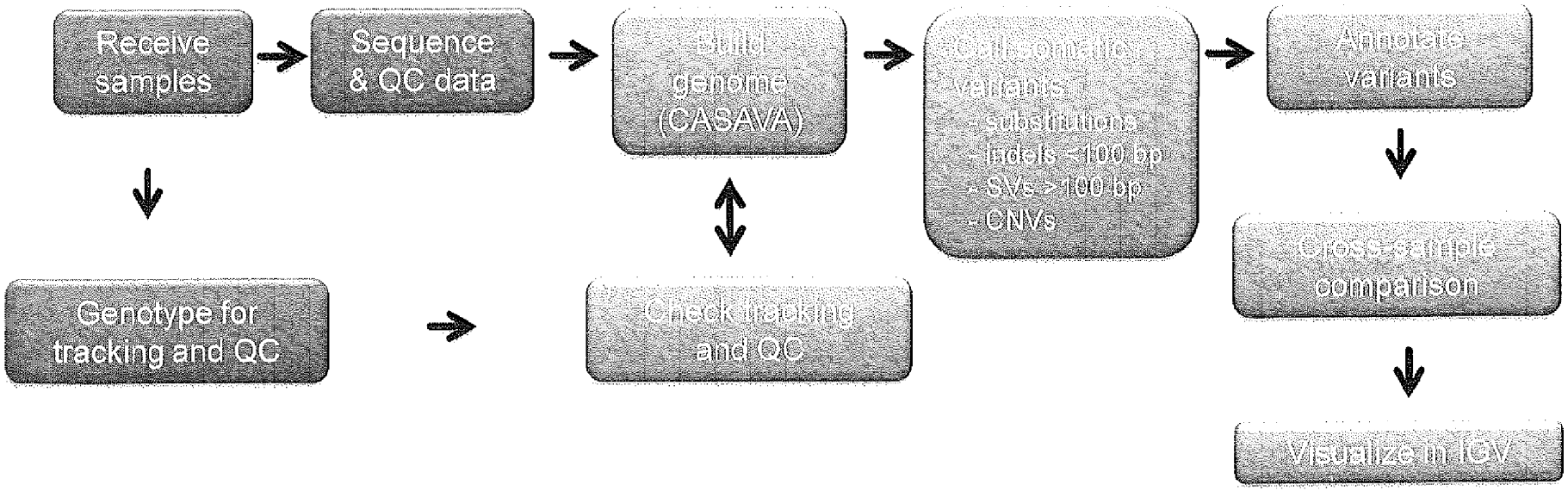
Cancer Sequencing Workflow



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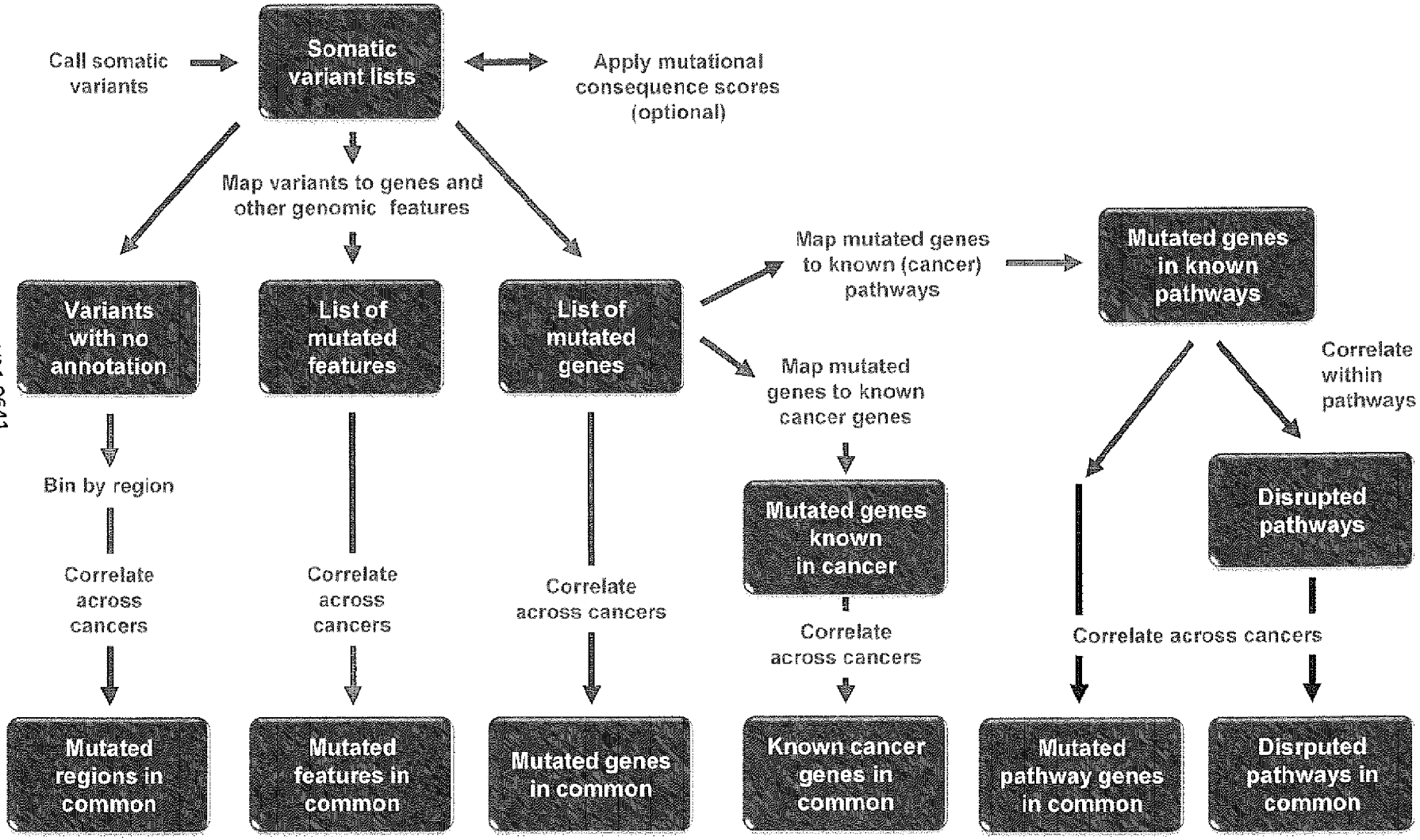
Oncology Discovery

Cancer Specific Analyses



ILLUM-0641

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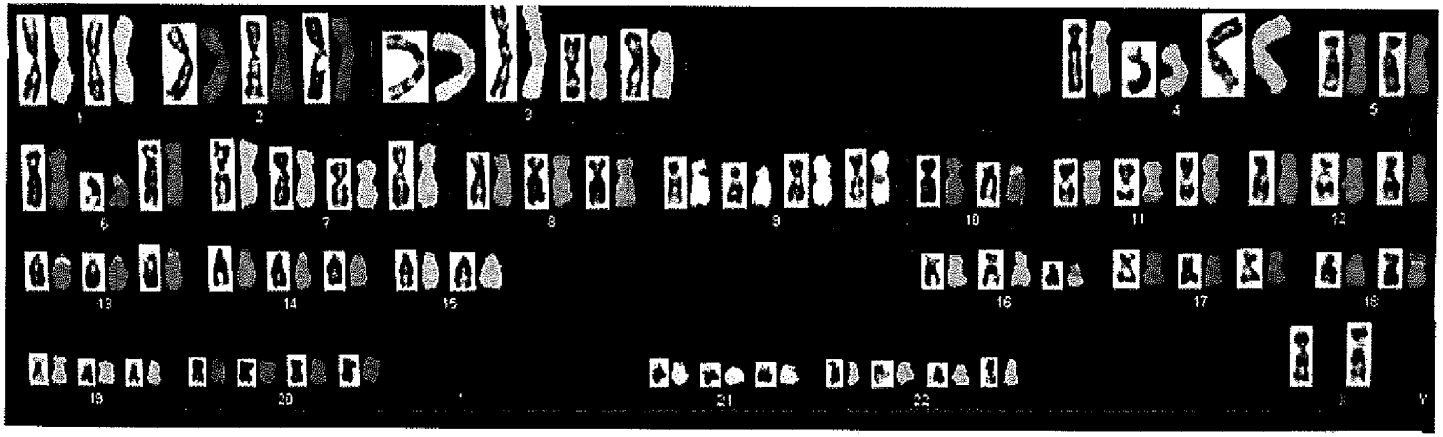
Melanoma: COLO-829

- 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



Karyotype courtesy of Paul Edwards, University of Cambridge

ILLUM-0642

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

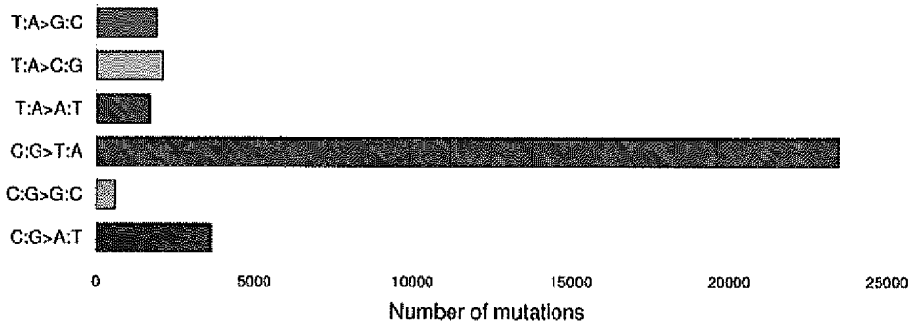
Somatic Substitutions in COLO-829

- **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

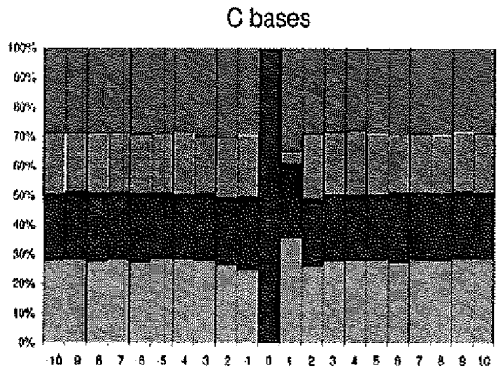
ILLUM-0644

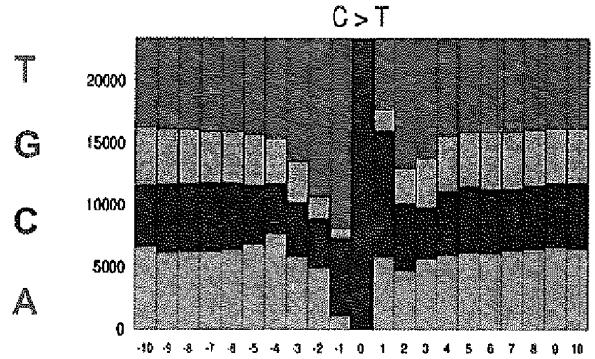
Somatic Mutational Signature of UV Exposure

- 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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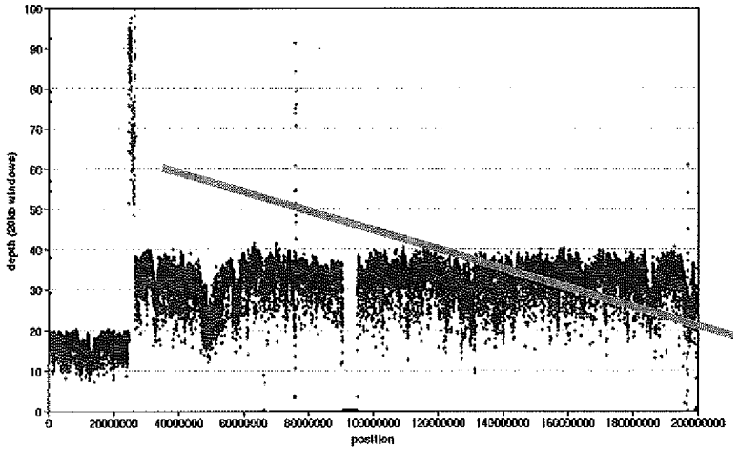
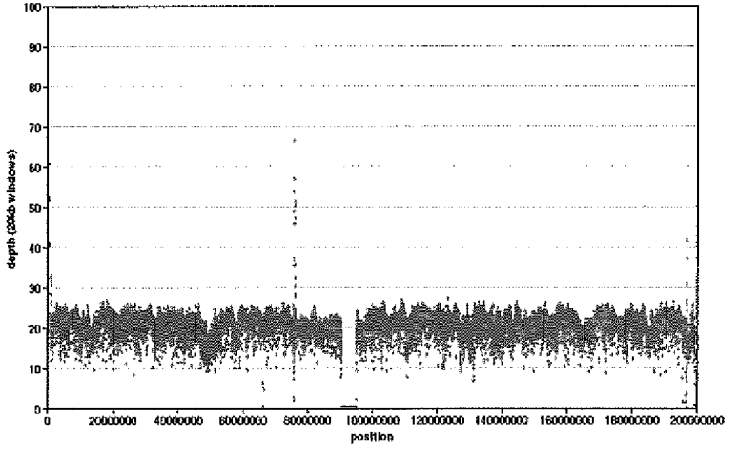
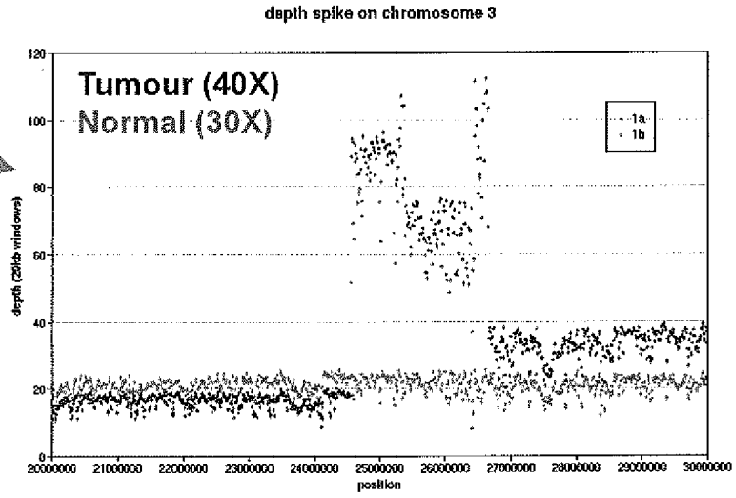
Complex CNV in tumour on chromosome 3

Tumor



Normal





4 genes in this region:
RARB, TOP2B, NGL1,KS

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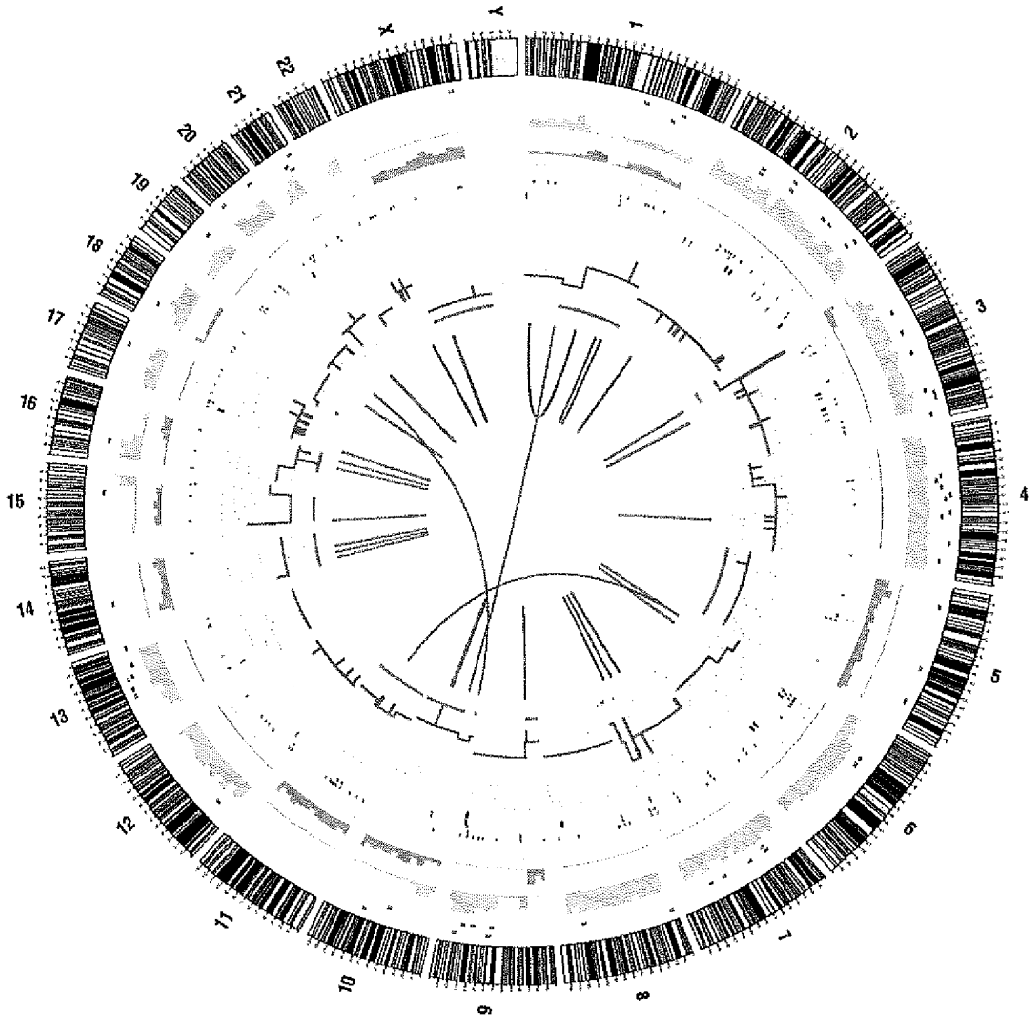
Catalogue of COLO-829 Somatic Variants



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

ILLUM-0647

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Oncology Discovery

Ovarian Cancer

Deadly

- 204,449 New cases annually; 124,860 deaths

Incurable

- Less than 40% are cured

Difficult Dx

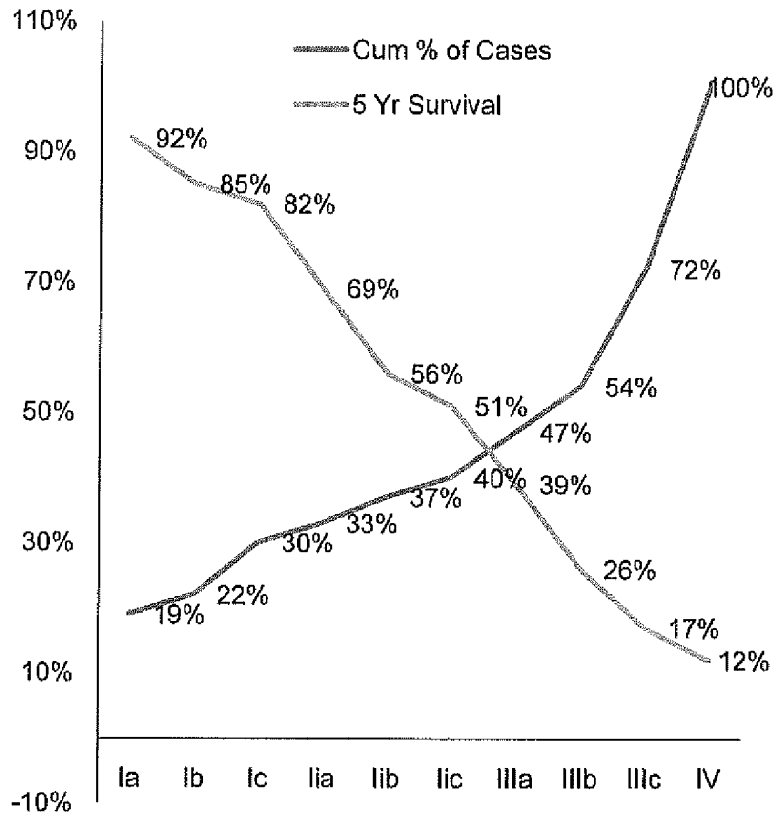
- Patients present with a suspicious/palpable mass

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



ILLUM-0648

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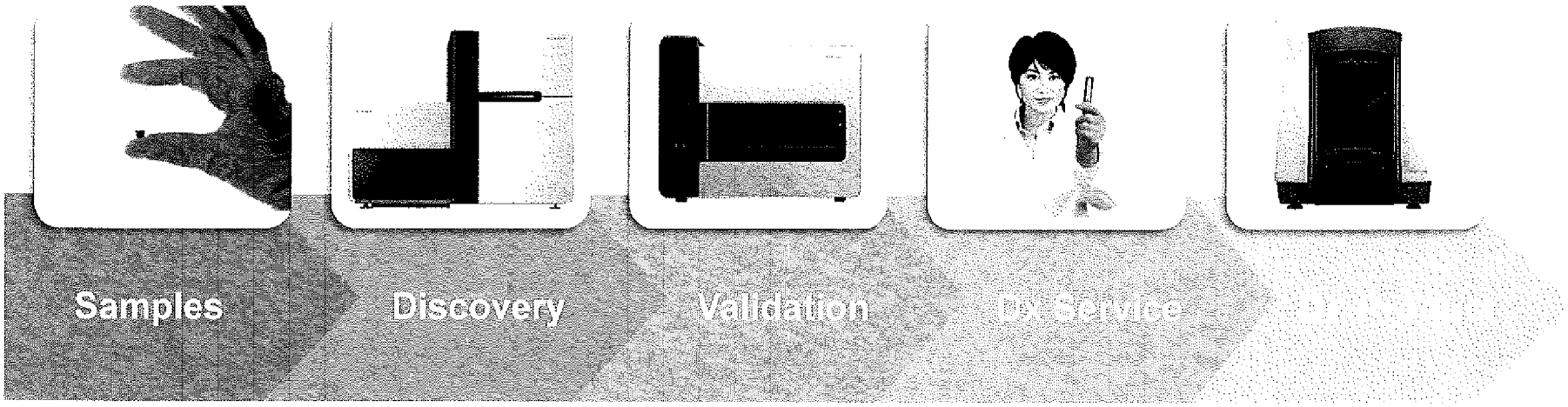
Ovarian Cancer Discovery

- 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



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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ILLUM-0650

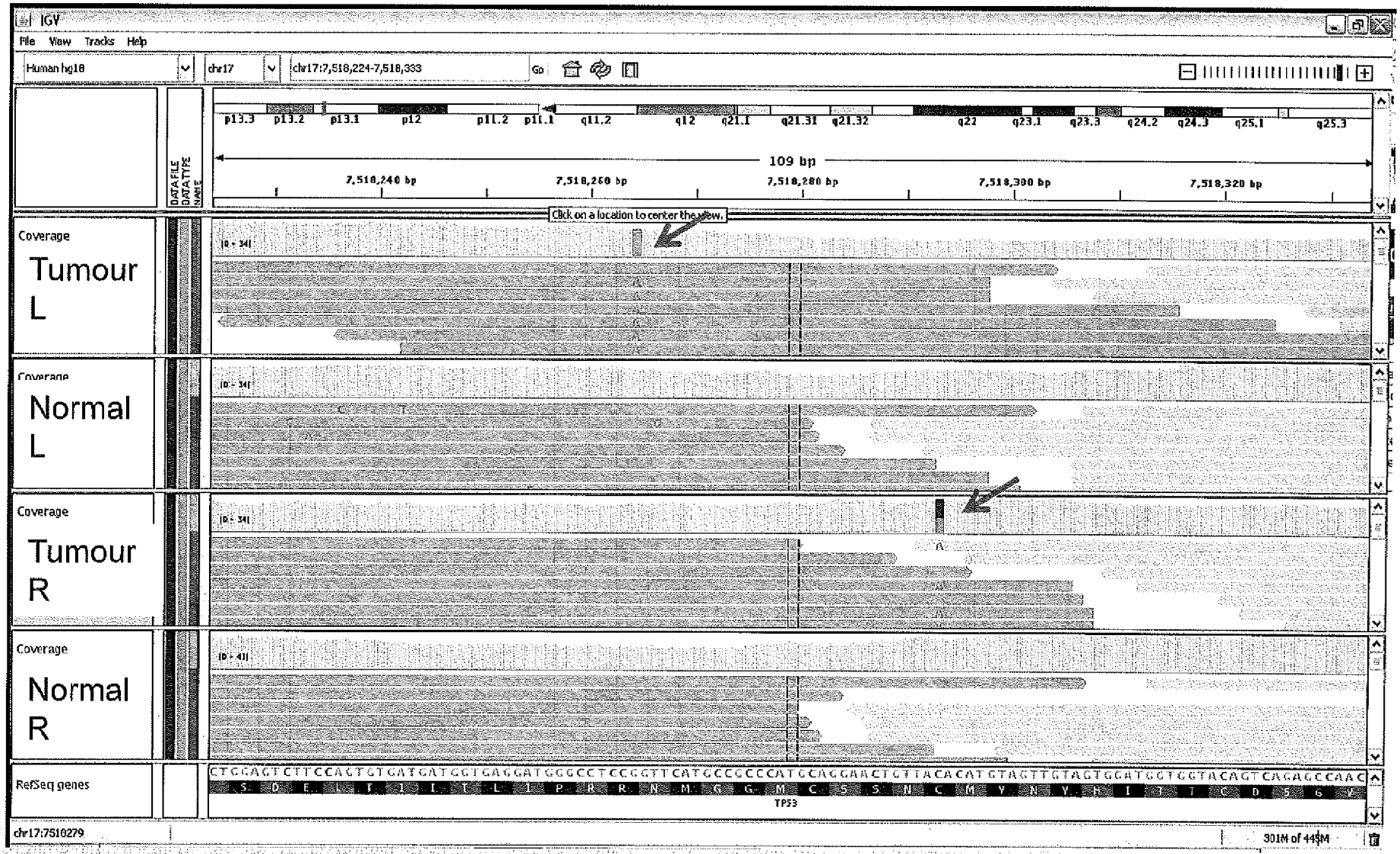
Cancer Genome Summary Statistics

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*



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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

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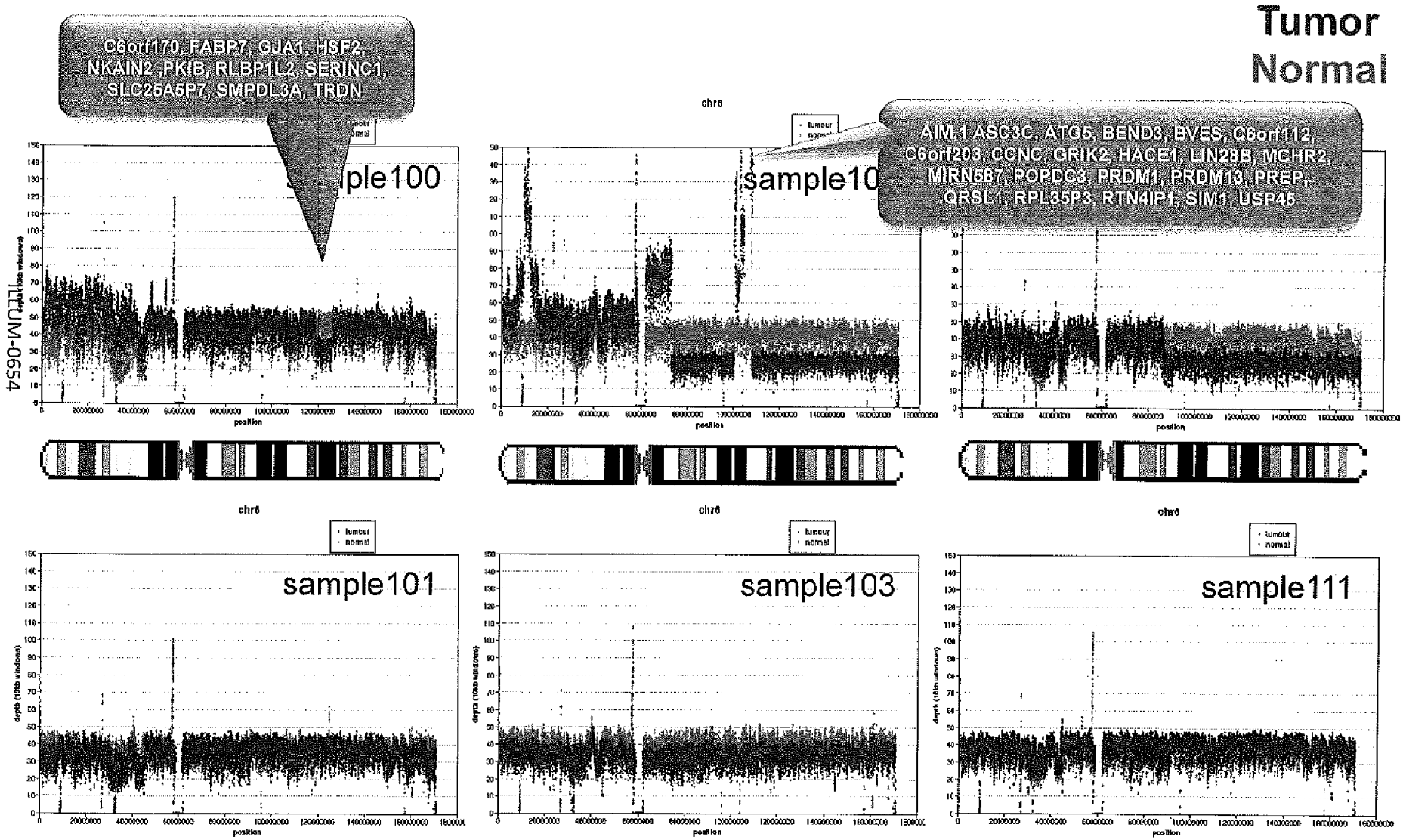

ILLUM-0654

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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…

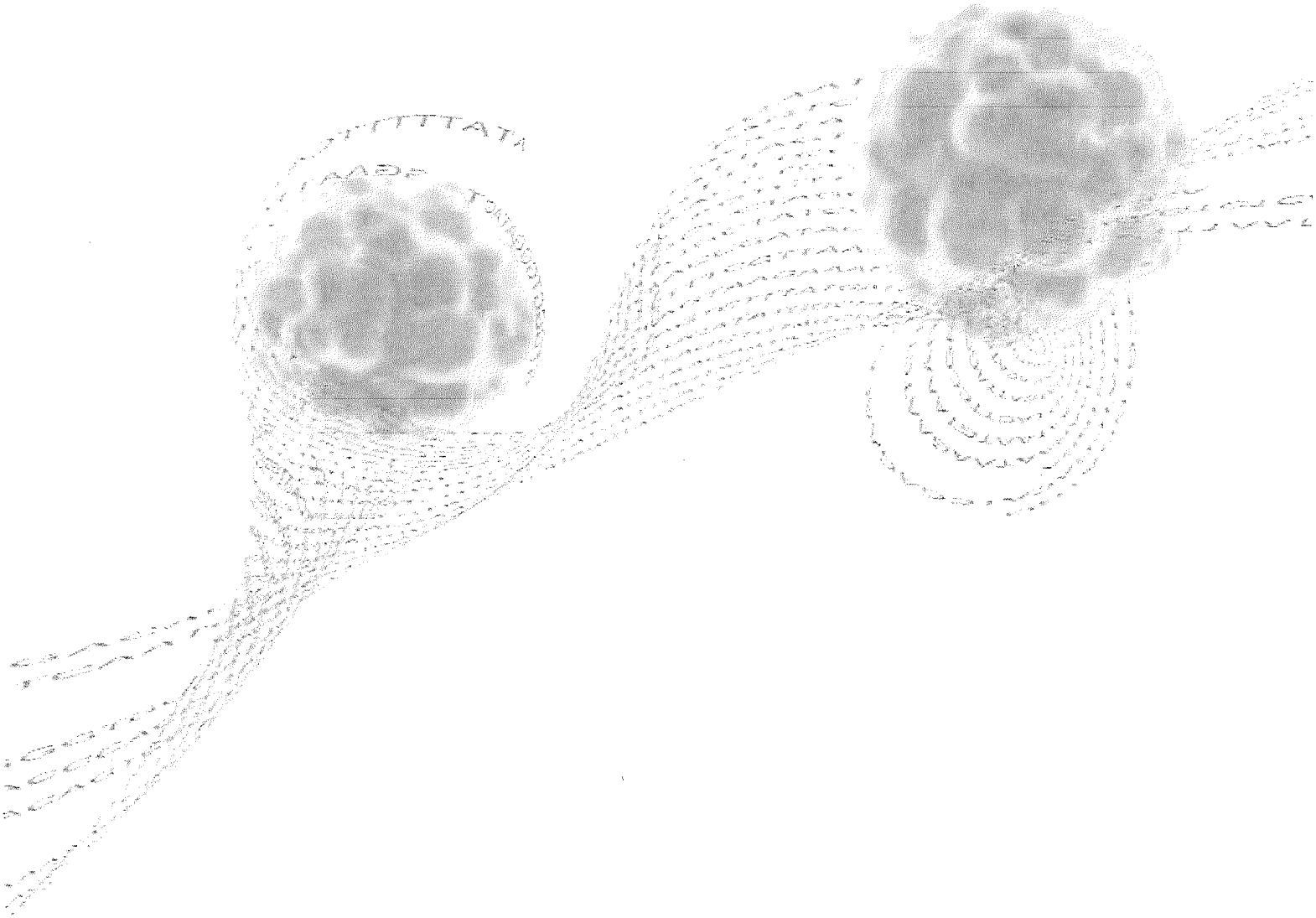
…and the Illumina teams…

ILLUM-0656

Exhibit 108

Cancer Genomics

Transforming our understanding of cancer

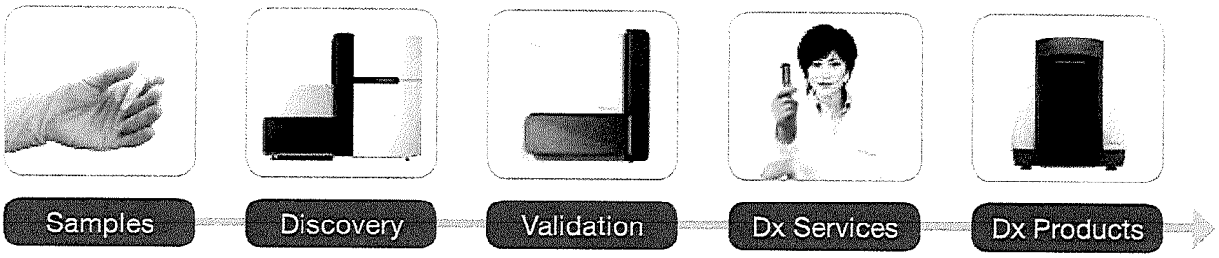


illumina®

ILLUM-0969

Accelerating translational medicine.

Technology enhances understanding. Drives discovery.

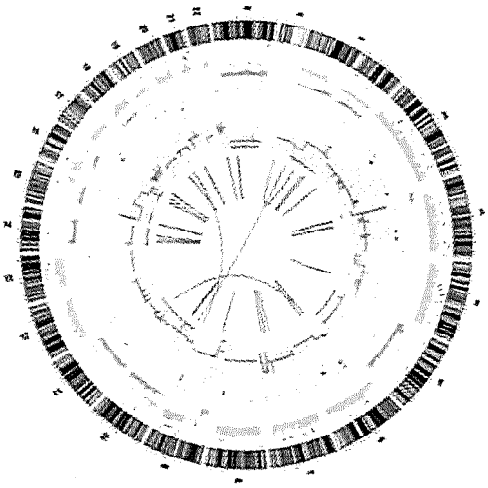


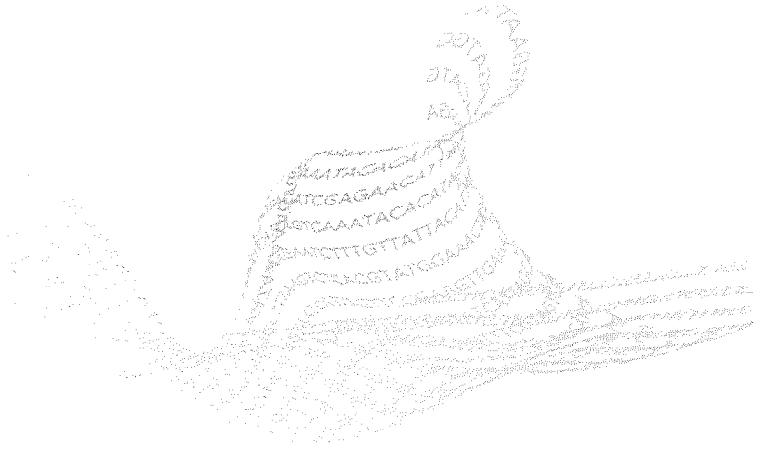
Illumina's cancer discovery initiative.

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.





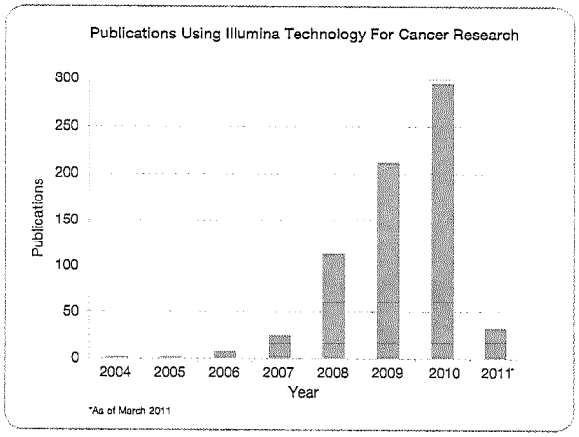
When taking a genome-wide approach to cancer, researchers can use a circus plot to visualize the extensive rearrangements and variations that are common to cancer. This plot shows variations found in a melanoma cell line, marking each chromosome on the outside ring, then showing validated indels, density 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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Pub No. 070-2010-012 Current as of 25 March 201

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Exhibit 109

The Illumina® Cancer Discovery Initiative

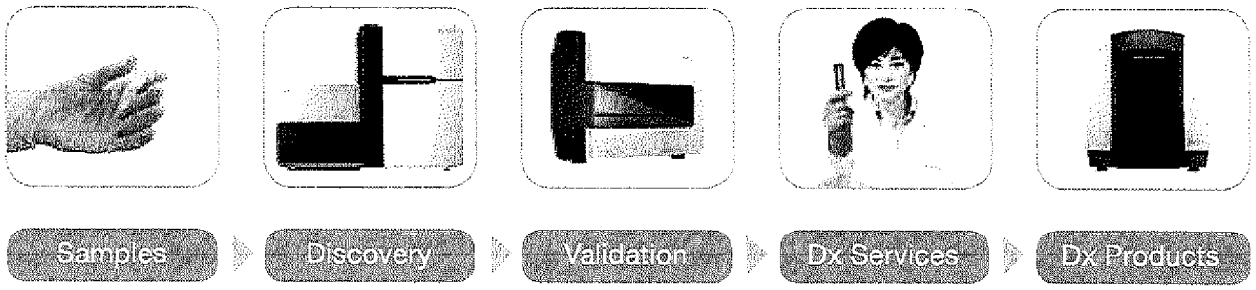
Cancer is one of the leading causes of death worldwide. Increasing health care costs and the escalating prevalence of disease among aging populations have spurred the need for innovative diagnostic approaches. As with many complex diseases, the variation of genetic associations poses a challenge for 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

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

ILLUM-0634

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Exhibit 110

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.

SOURCE: Illumina, Inc.

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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.

"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 Illumina's ability (i) to integrate effectively our recent acquisition of Solexa, Inc., (ii) 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, (iii) to manufacture robust microarrays and Oligator(R) oligonucleotides, (iv) to integrate and scale our VeraCode technology, 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 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.

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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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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.

Complete NGS Target Enrichment in Less Than a Day
Agilent Technologies

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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OGT Debuts Cyto CGH and SNP Array for Hematological Cancers; Plans More Oncology Chips
March 6, 2012 / BioArray News

Cleveland Clinic to Evaluate IntegraGen's Autism SNP Panel in 600-Patient Prospective Study
March 6, 2012 / BioArray News

As Marketing Push Drives Q4 Revenue Spike, CombiMatrix Plans Expanded Test Menu, Sales Force
March 6, 2012 / BioArray News

In this issue of BioArray News

1000 Genomes Project Could Fuel 'New Round of Chip Development,' Experts Say

1000 Genomes Project Could Fuel 'New Round of Chip Development,' Experts Say

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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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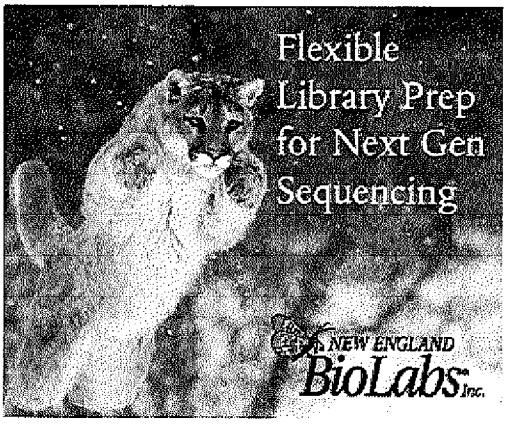

Video Spotlight

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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

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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

Science	Business	Funding	Genome Technology Magazine
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.	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.	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.	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.

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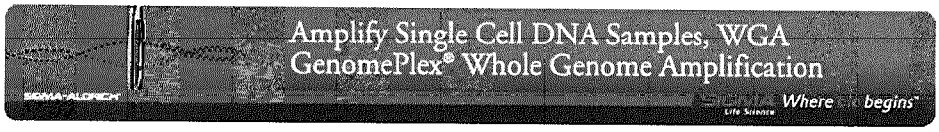

Matt Dublin on New algorithms

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Wednesday, May 11, 2011

Home » News » BioArray News

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 may play a larger role in its diagnostics offering in the future.

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May 10, 2011 / BioArray News

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FDA Clears Affymetrix Gene Expression Reagents for IVD Use
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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 Panomics Customers 'Surprised,' 'Concerned' About Affy's Impending Buy

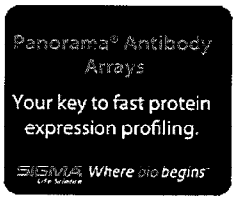
Microarray-Related NIH Grants in Fiscal Year 2008, Sep. 16 — Nov. 3, Part II of II

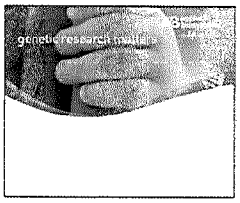
Young Investigator Profile

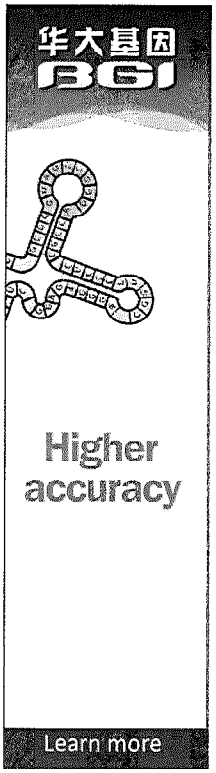
Blog

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

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'Functional Complotype' and Susceptibility to Alternative Pathway-Driven Disease
Heurich, Martinez-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

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- 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.

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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.

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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.

ILLUM-0614

VERIFIABLE DATA

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

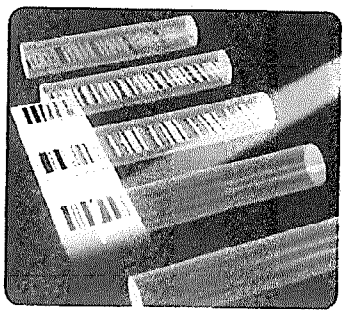
VeraCode's breakthough technology is based on the use of cylindrical glass microbeads that:

- 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

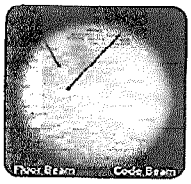
Making the code

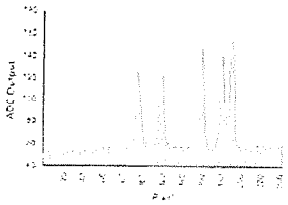
The VeraCode digital code uses a patented holographic inscribing and detection process:

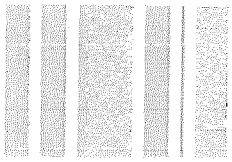
- The center of each bead supports a nanometer-scale, permanent change to index of refraction when exposed to ultraviolet light
- This index change forms a hologram that is imprinted via a local structural change of the glass matrix
- Successive writing of holograms into one microbead produces a specific 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

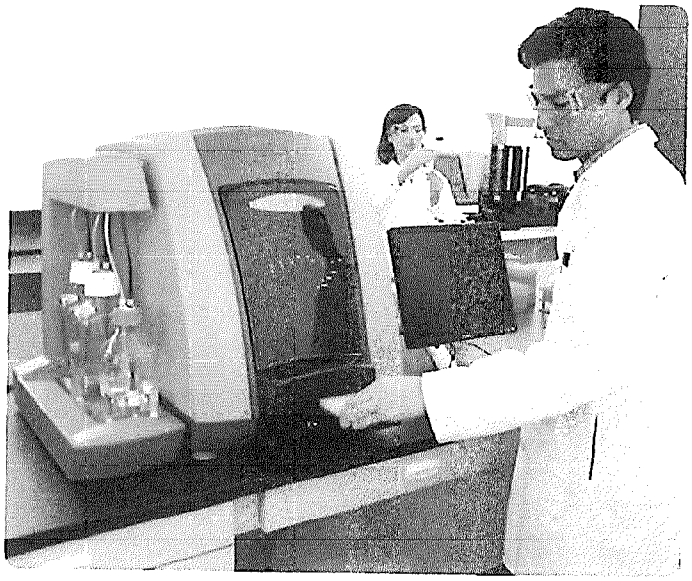
The holographic code image in each microbead diffracts an incident laser beam into multiple components. These components make up the optical "signature" of the bead code, which can be read using a CCD camera contained within the BeadXpress™ Reader.

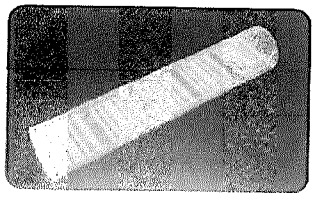
100% verifiability means true precision.

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:

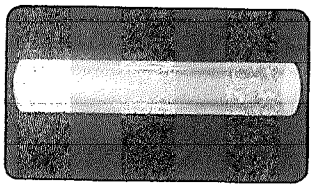
- Biomarker research and validation
- Pharmaceutical development
- Industrial testing
- Agriculture
- Clinical research
- Molecular diagnostic assay development





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.

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

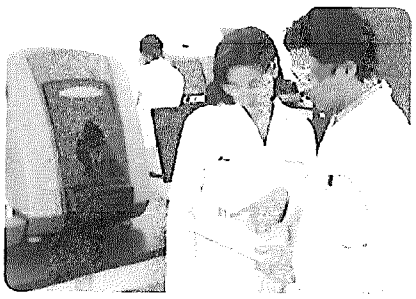
Whether you need a single-plex antibody detection assay or a 384-plex genotyping assay, VeraCode is the only technology to offer true multiplexing and assay versatility on one platform, providing researchers with a single powerful solution capable of meeting all of their assay needs.

- 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

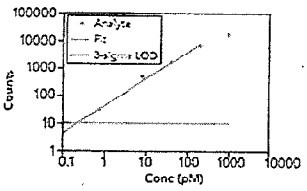
Unparalleled assay flexibility

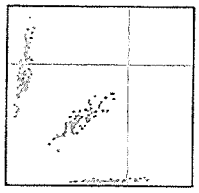
The glass surface of the VeraCode microbeads provides a single, flexible platform for the development of numerous types of solution-based bioassays with the power of microarrays. Existing applications for VeraCode include, but are not limited to:

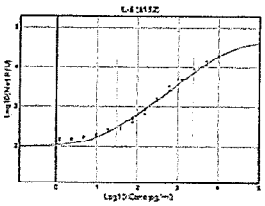
- Genotyping
- Gene expression
- Protein-based assays



Unmatched versatility in both multiplexing levels and assay applications







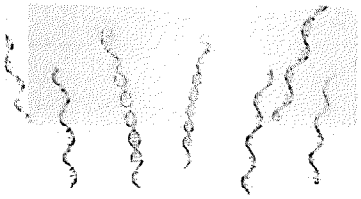
Perform multiple assay applications—such as SNP genotyping, gene expression, and protein-based assays—all on a single platform.

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:

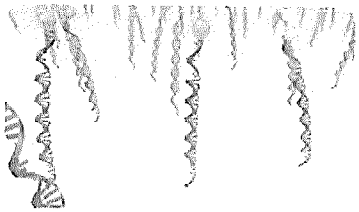
- Simultaneous genotyping of 96 to 384 SNPs for each sample in a 96-well microplate
- A high degree of multiplexing throughout successive extension and amplification steps
- Minimization of time, volume, and material requirements
- Call rates, reproducibility, and heritability rates >99.9%



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.

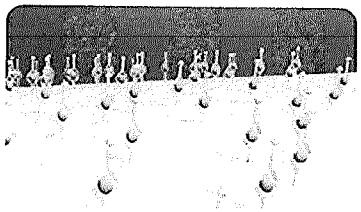
- Unique oligonucleotide bead types offer one-of-a-kind code identifiers
- High-density capture oligonucleotides immobilized on the microbeads provide a flexible and open platform for assay development
- Pre-screened capture sequences avoid cross-reactivity within genome

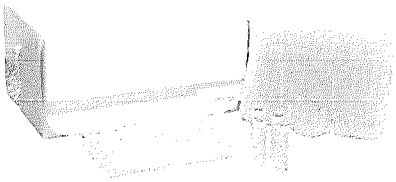


Carboxyl Beads

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.

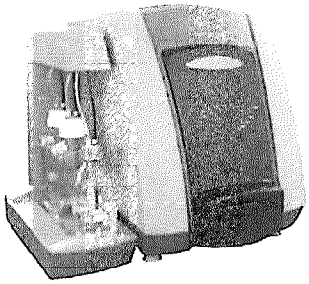
veracode BY ILLUMINA

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.

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

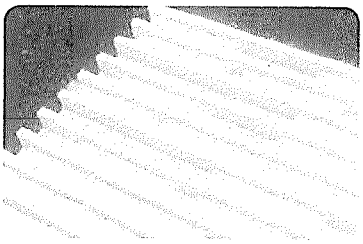
Powerful and friendly analysis software

Powerful VersaScan Software provides user-friendly customization of scanning protocols and is compatible with Illumina's proven BeadStudio Data Analysis Software.

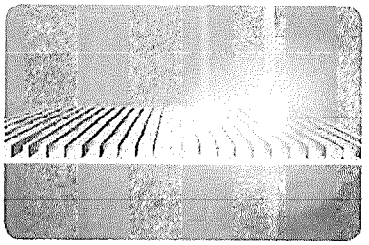
- Enables acquisition and viewing of intensity data, report generation, and data extraction for application-specific data analysis modules
- Generates *.csv and *.idat files for data export to Illumina BeadStudio or third-party data analysis programs

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.



beadxpress

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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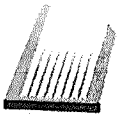
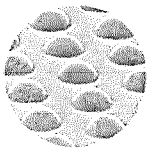
illumina

Tools for Cancer Genomics





illumina

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:

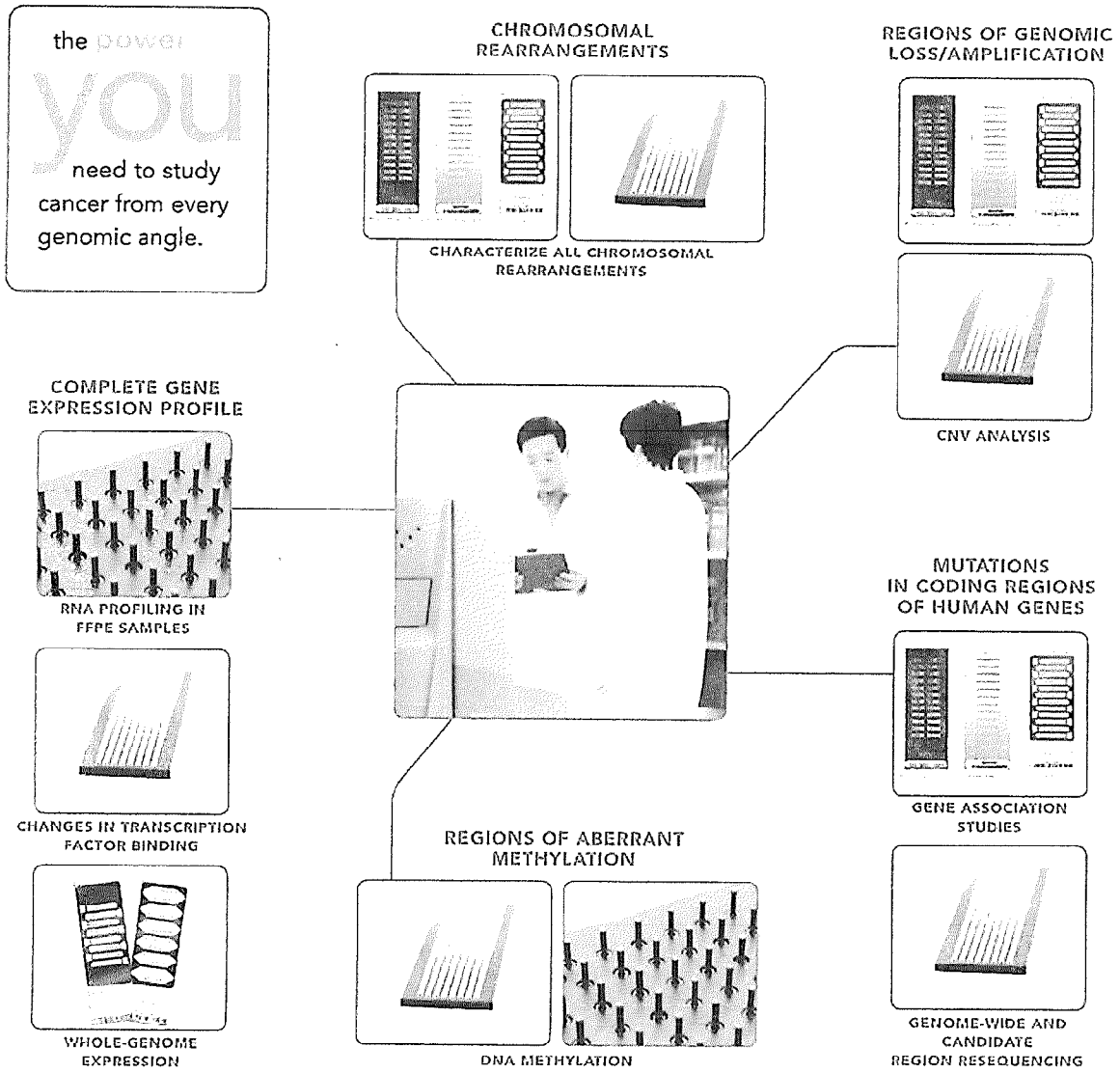
- Genomic loss and amplification – of specific regions in the genome, including those that contain cancer-associated genes
- Chromosomal rearrangements – that may impact key genes or pathways and impact tumorigenesis
- Epigenetic changes – such as aberrant DNA methylation, histone binding changes
- Genetic 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.

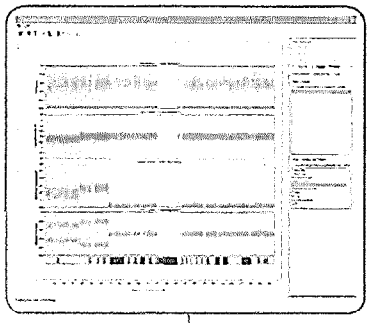
Illumina provides the technologies, tools and support to find the answers that will help to move your cancer research program forward. All of our technologies deliver high data quality, reproducibility, multi-sample formats and superior value. Whether you need RNA or DNA-based applications, genome-wide 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.

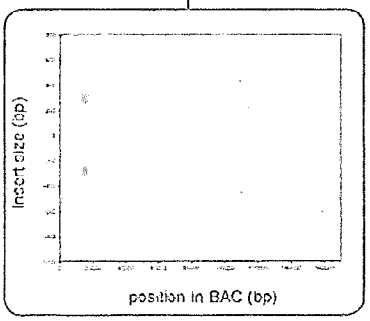


Genomic Loss and Amplification

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

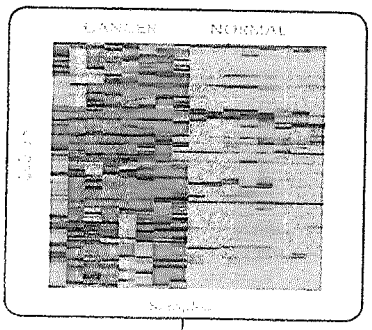


Chromosomal Rearrangements

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

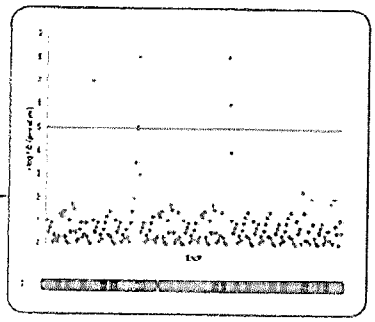


Characterize Epigenetic Changes

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

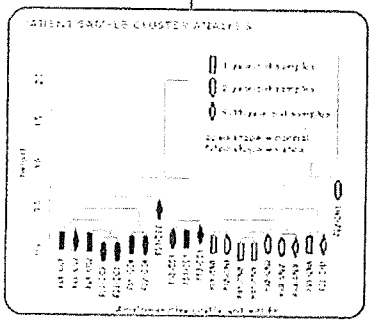


Study Genetic Changes in Genes

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		●	
Resequencencing		●	
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 ...

Explore Your Genome with Illumina

you can

discover more
validate seamlessly
screen quickly

Agriculture research powered by Illumina.

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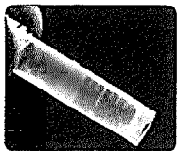

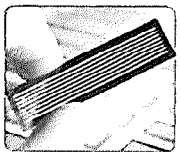

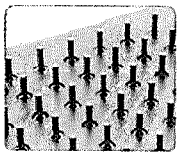

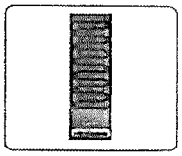

- Identify mutations in coding regions.
- Measure structural variation.
- Detect chromosomal rearrangements.

- Characterize epigenetic changes.
- Profile gene expression.

- Detect chromosomal rearrangements.
- Identify mutations in coding regions.
- Measure structural variation.

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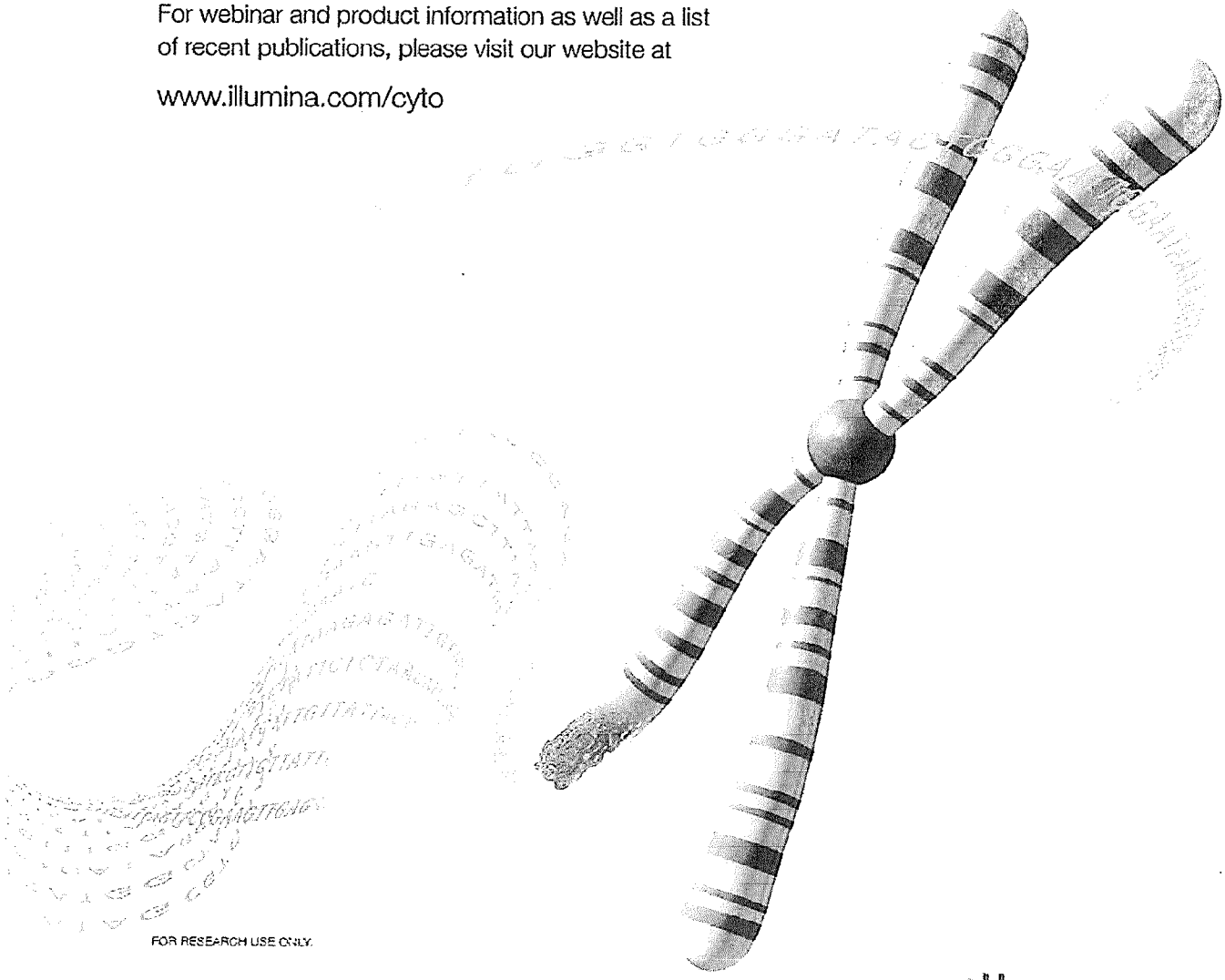

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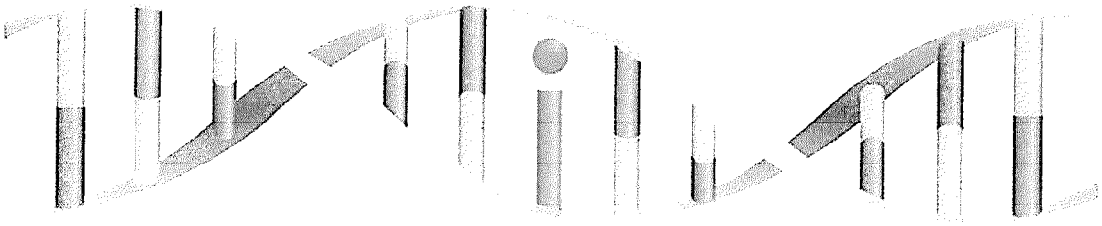

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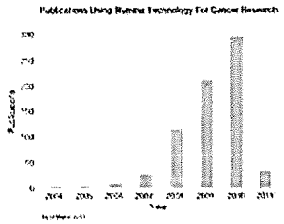


2008

- 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

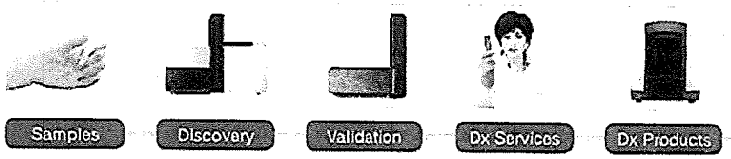
- Next-generation sequencing technology provides new insights into the mechanisms of cancer progression and a greater understanding of diagnosis and treatment options[5,6]
- Use of next-generation sequencing to inform a patient's treatment[7]

2011

- Discovery of causative gene mutations for a rare skin cancer condition[8]

Accelerating translational medicine

Technology enhances understanding. Drives discovery.

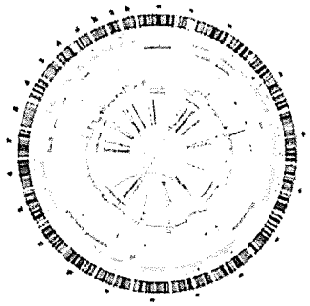


Illumina's cancer discovery initiative.

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 using a genome-wide approach to recover new variants can be a novel plot to visualize the relevant genomic variants and variants that are common to cancer. The plot shows variations found in a melanoma cell line, mapping 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.

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

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Comprehensive Cancer Assay 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	■		■		
Inversions, Deletions, and Translocations	■	+	+	+	•
Characterize Epigenetic Changes					
DNA Methylation Biomarker Panels		+	+	+	•
DNA Methylation Discovery	■		■		
ChIP-Sequencing (DNA-Protein Binding)	•		•		
Changes in Transcription Factor and Protein 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	+		+		

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Cancer Genomics

Transforming our understanding of cancer

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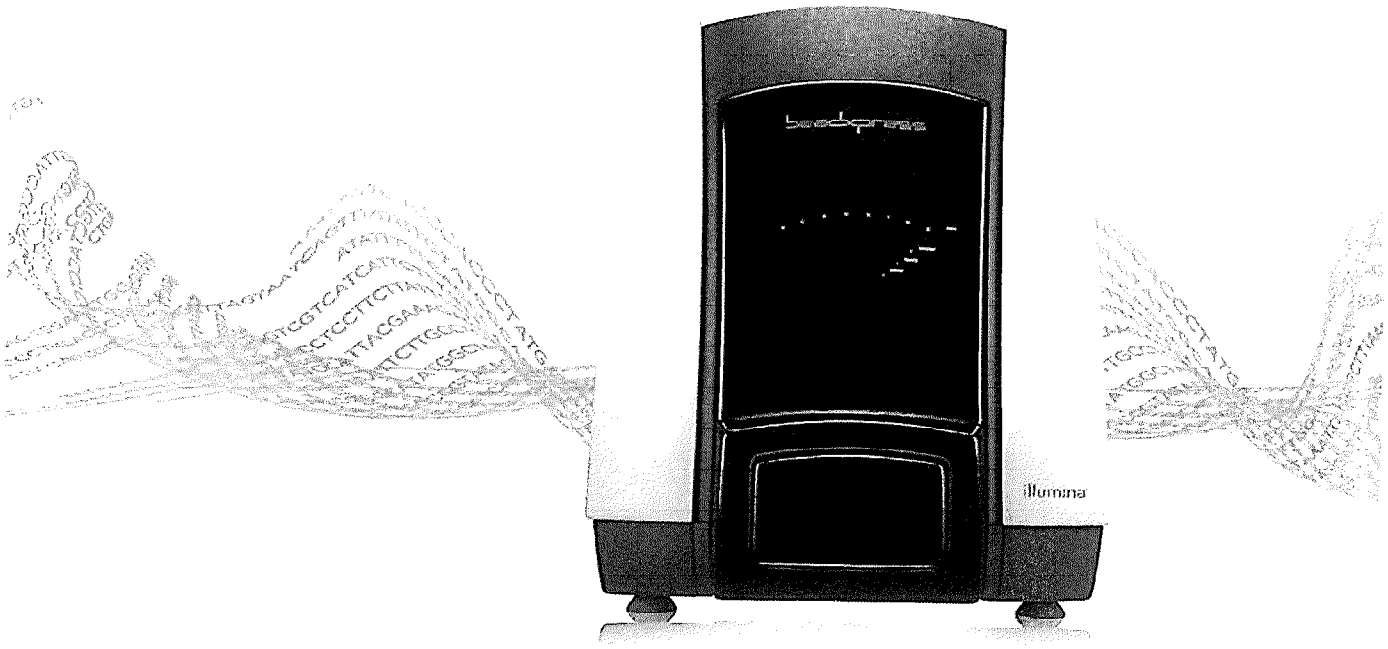

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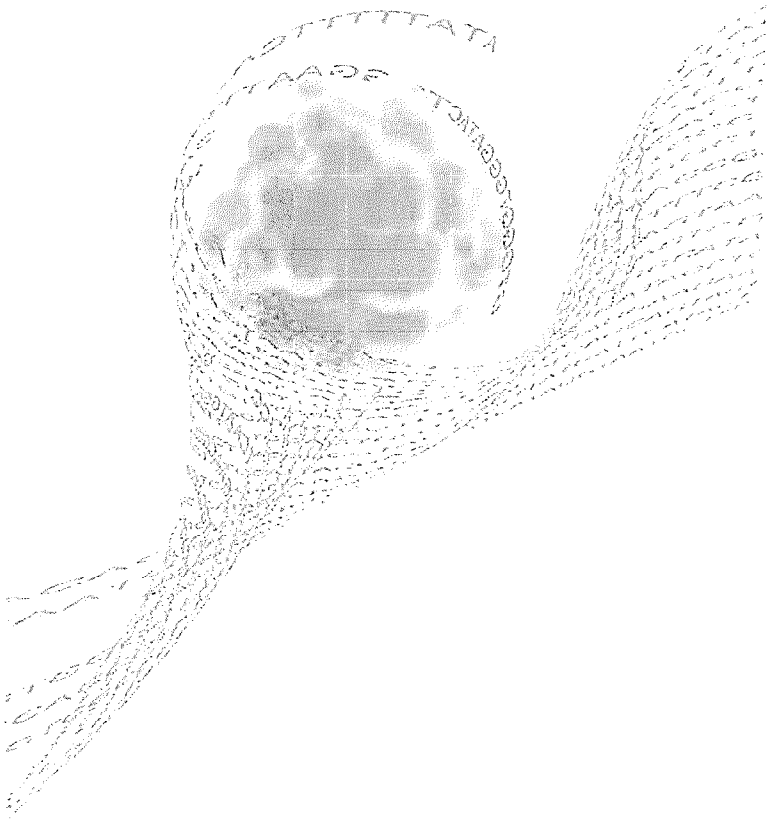

Illumina Diagnostics Asset Review- ADME

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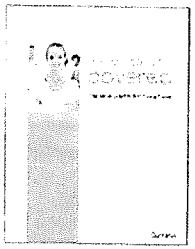

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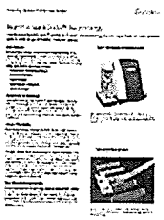

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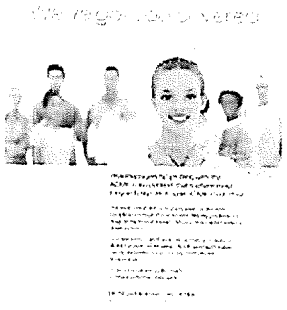

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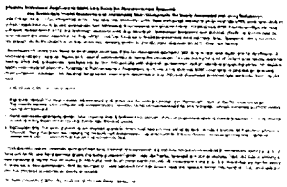

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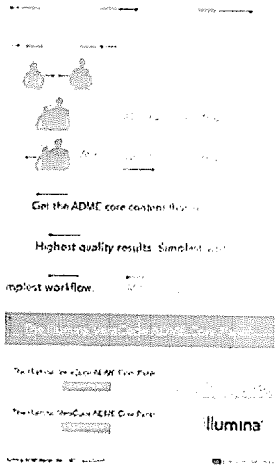
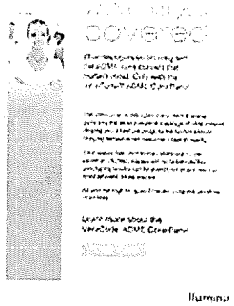
Web

Veracode ADME Web Banners



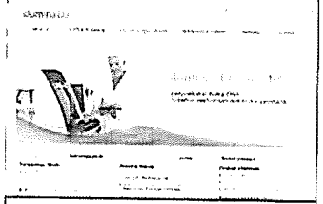
Direct Mail

E-mail Blast

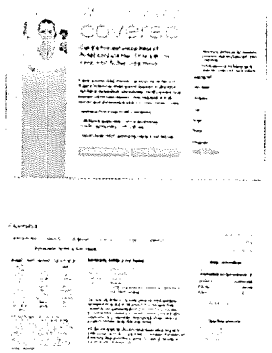


Web Page

Home Page



Landing Page



Tradeshows

None

ILLUM-0304

Illumina Diagnostics Asset Review- Cytogenetics

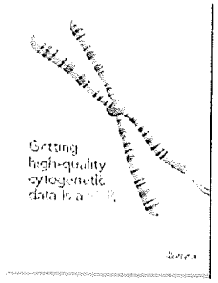
Sales Tools

Lead Generation Activities

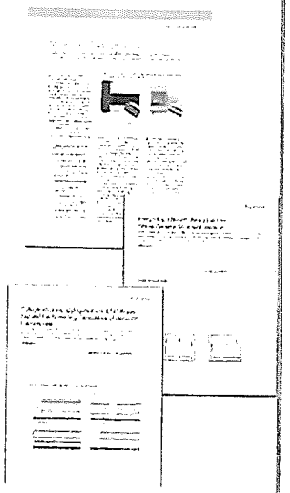
Sales Support

Sales Tools

Cytogenetics Brochure



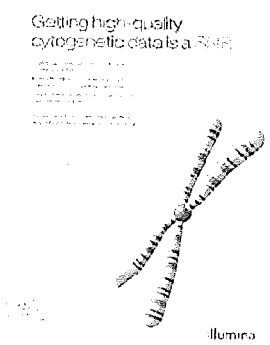
Cytogenetics Data Sheets



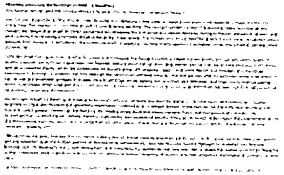
Advertising

Print

Cytogenetics Print Ad

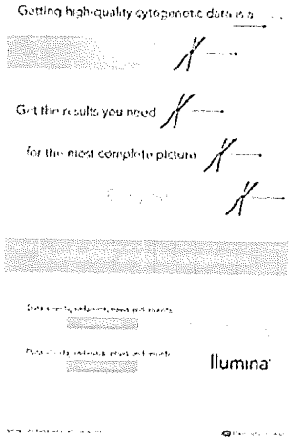


Press Releases



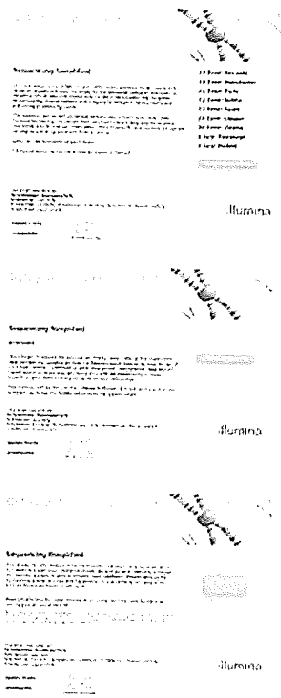
Web

Cytogenetics Web Banners



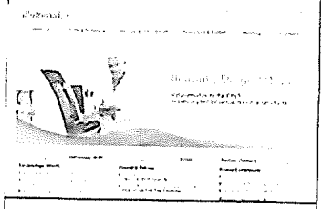
eMarketing

Seminar Series eMail Blasts

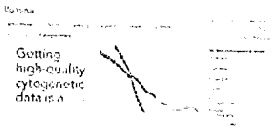


Web Page

Home Page



Landing Page



Tradeshows

None

ILLUM-0305

Illumina Diagnostics Asset Review- BeadXpress Reader and Veracode Technology

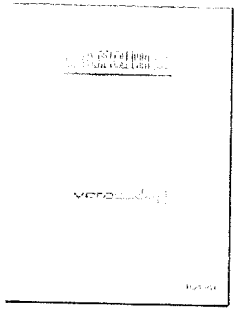
Sales Tools

Lead Generation Activities

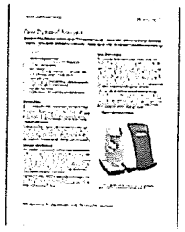
Sales Support

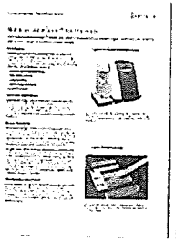
Sales Tools

Old Veracode Brochure



BeadXpress Reader and Veracode Data Sheets

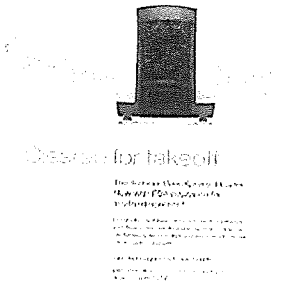




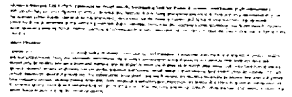
Advertising

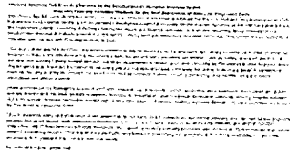
Print

BeadXpress Print Ad



Press Releases





eMarketing

Online

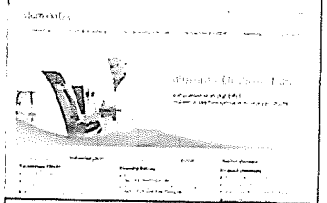
None

eMail Blasts

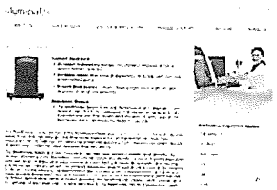
None

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

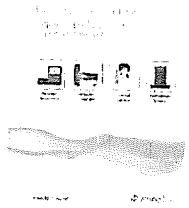
None

Press Releases

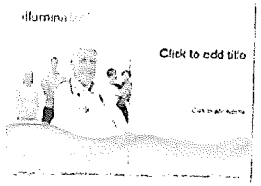
None

Printed Materials

DX Notebook

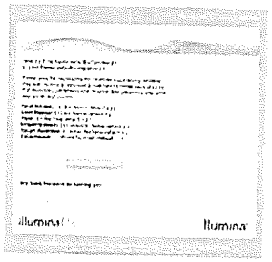


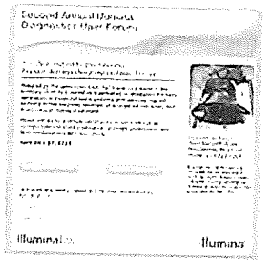
PPT Slide Deck

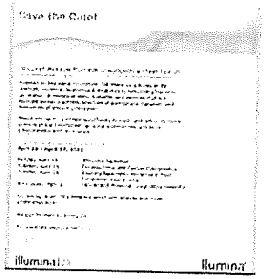


eMarketing

Marketo User Group eMail Blasts

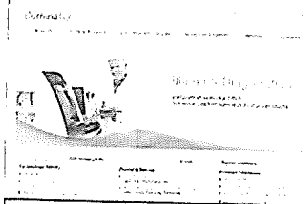






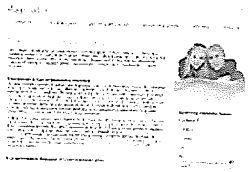
Web Page

Home Page

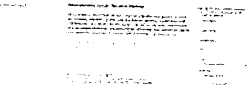


Landing Page

Illuminatix.com

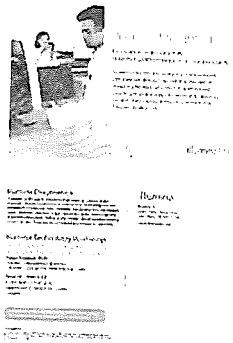


Illumina.com

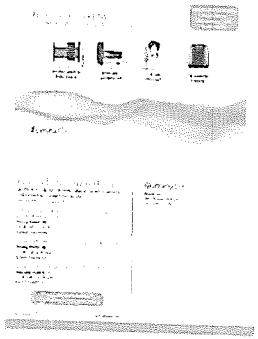


Tradeshows

ACMG 2011



ACMG 2010



ILLUM-0307

Exhibit 111

CONFIDENTIAL

[redacted]

TRADE SECRET/
COMMERCIALLY SENSITIVE

[redacted]

TRADE SECRET/
COMMERCIALLY SENSITIVE

Exhibit 112

CONFIDENTIAL

[redacted]

TRADE SECRET/
COMMERCIALLY SENSITIVE

[redacted]

TRADE SECRET/
COMMERCIALLY SENSITIVE

Exhibit 113

CONFIDENTIAL

[redacted]

TRADE SECRET/
COMMERCIALLY SENSITIVE

[redacted]

TRADE SECRET/
COMMERCIALLY SENSITIVE

TRADE SECRET/
COMMERCIALLY SENSITIVE

Exhibit 114

CONFIDENTIAL

TRADE SECRET/
COMMERCIALLY SENSITIVE

[redacted]

TRADE SECRET/
COMMERCIALLY SENSITIVE

[redacted]

Exhibit 115

illumina

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Illumina's MiSeqDxTM Receives FDA Premarket Clearance with Two Cystic Fibrosis Assays and Universal Kit for Open Use

Premarket Clearance is an Industry First for a Next-Generation Sequencing System

SAN DIEGO--(BUSINESS WIRE)--Nov. 19, 2013-- Illumina, Inc. (NASDAQ:ILMN) today announced that it received premarket clearance from the U.S. Food and Drug Administration (FDA) for the MiSeqDx system, the first high-throughput DNA sequencing analyzer to receive FDA clearance. Illumina also received FDA premarket clearance for the MiSeqDx Cystic Fibrosis 139-Variant Assay, MiSeqDx Cystic Fibrosis Clinical Sequencing Assay, and MiSeqDx Universal Kit.

The MiSeqDx benchtop sequencer offers users the ability to run diagnostic or research applications on a single, easy-to-use system. Designed and validated for the clinical market, the MiSeqDx with the portfolio of FDA-cleared *in vitro* diagnostic kits and assays leverage Illumina's sequencing by synthesis (SBS) chemistry for high confidence in results.

The MiSeqDx Cystic Fibrosis 139-Variant Assay is designed for simultaneous detection of 139 clinically relevant disease-causing mutations and variants within the cystic fibrosis transmembrane conductance regulator (*CFTR)* gene. The assay includes all cystic fibrosis-causing variants recommended for carrier screening purposes by the American College of Medical Genetics and Genomics (ACMG) and the American College of Obstetricians and Gynecologists (ACOG).

The MiSeqDx Cystic Fibrosis Clinical Sequencing Assay leverages Illumina's targeted resequencing chemistry to provide highly accurate sequencing data for the protein coding regions and intron/exon boundaries of the *CFTR* gene.

The MiSeqDx Universal Kit enables clinical laboratories to develop their own diagnostic tests. The kit includes library preparation reagents, sample index primers, and sequencing consumables needed for laboratories to develop amplicon assays on the *in vitro* diagnostic platform.

"Illumina is proud to be the first company to obtain FDA clearance for a high-throughput DNA sequencing analyzer and next-generation sequencing-based assays," said Greg Heath, Senior Vice President and General Manager of Illumina's Diagnostics business. "With the FDA clearance of the MiSeqDx, Illumina is providing clinicians and clinical laboratories with the tools needed to obtain comprehensive and reliable results from a DNA sequencing analyzer and enabling them to create and deploy NGS-based molecular diagnostic tests for cystic fibrosis and a wide-range of other applications."

The MiSeqDx, MiSeqDx Cystic Fibrosis 139-Variant Assay, MiSeqDx Cystic Fibrosis Clinical Sequencing Assay, and MiSeqDx Universal Kit are now available for immediate order with shipment before the end of 2013 in the United States and Europe. For more information, visit www.illumina.com/FirstNGSIVD.

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

ILLUM-1809

analysis research and its application, paving the way for molecular medicine and ultimately transforming healthcare.

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.

Source: Illumina, Inc.

Illumina, Inc.
Investors:
Rebecca Chambers
858-255-5243
rchambers@illumina.com
or
Media:
Jennifer Temple
858-882-6822
pr@illumina.com

Exhibit 116

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[redacted]

TRADE SECRET/
COMMERCIALLY SENSITIVE

Exhibit 117

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[redacted]

**TRADE SECRET/
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Exhibit 118

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COMMERCIALLY SENSITIVE

Exhibit 119

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