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

Proceeding	91194218
Party	Defendant Meridian Bioscience, Inc.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

ILLUMINA, INC.,)
))
OPPOSER,)
))
vs.) OPPOSITION NO:
) 91211615
MERIDIAN BIOSCIENCE, INC.,)
))
APPLICANT.)

Deposition of NAOMI O'GRADY, taken on behalf of the Applicant, Meridian Bioscience, Inc., at 12790 El Camino Real, San Diego, California, commencing at 7:48 a.m., on Thursday, December 4, 2014, before Tracy M. Fox, CSR Number 10449, Certified Shorthand Reporter in and for the State of California

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I N D E X

WITNESS:	EXAMINED BY:	PAGE:
NAOMI O'GRADY	MR. HANKINSON	6, 221
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E X H I B I T S

EXHIBIT NUMBER:	DESCRIPTION:	PAGE:
O'Grady Exhibit A	Article found on GenomeWeb entitled "Illumina's Pharma Deals Aim to Bring Universal MiSeqDx-based CDx through FDA Clearance" (3 pages)...	45
O'Grady Exhibit 302	Document entitled "VeraCode Technology - From Research to Molecular Diagnostics," Bates-stamped ILLUM-0166 through ILLUM-0184 (20 pages).....	152

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E X H I B I T S (Continued)

O'Grady Exhibit 303 Document entitled
"BeadXpress System and
VeraCode Technology Launch
Package," Bates-stamped
ILLUM-0544 through
ILLUM-0586 (44 pages).....52

O'Grady Exhibit 304 Document entitled
"Illumina Dx Diagnostics
Portfolio Management Plan"
July 20, 2009, Bates-stamped
ILLUM-3440 through
ILLUM-3473 (35 pages).....153

O'Grady Exhibit 315 Document entitled
"Gates Foundation
Pathogen Detection
Grant," Bates-stamped
ILLUM-3421 through
ILLUM-3439 (20 pages).....146

1 SAN DIEGO, CALIFORNIA, THURSDAY

2 DECEMBER 4, 2014

3 7:48 A.M.

4

5 NAOMI O'GRADY,

6 called as a witness and sworn in by

7 the deposition officer, was examined

8 and testified as follows:

9

10 DEPOSITION OFFICER: Would you raise your

11 right hand.

12 Do you solemnly state that the testimony

13 you are about to give in the following deposition

14 will be the truth, the whole truth, and nothing but

15 the truth?

16 THE WITNESS: Yes.

17 DEPOSITION OFFICER: Thank you.

18

19 EXAMINATION

20 BY MR. HANKINSON:

21 Q. Good morning.

22 A. Good morning.

1 Q. We were just introduced, but I'll say it
2 again.

3 I'm Tom Hankinson. I represent Meridian
4 in this case.

5 With me today is Mike Hurst, who also
6 represents Meridian.

7 Thank you for coming in.

8 Have you ever been deposed before?

9 A. No.

10 Q. I'll be asking questions. You'll be
11 giving the answers. We'll try not to talk over each
12 other so that the court reporter here can take down
13 the complete question and answer.

14 Is that okay?

15 A. Yes.

16 Q. If at any point you don't understand my
17 question or would like for it to be repeated, please
18 just ask.

19 Is that okay?

20 A. Yes.

21 Q. If you answer, I'll assume that you
22 understood it and heard it.

1 Is that fair?

2 A. Yes.

3 Q. These are just preliminaries.

4 If at any point you'd like to take a
5 break, just let us know. Okay?

6 A. Yes.

7 Q. You'll have to answer any question that's
8 already pending, and then we can take the break.

9 Do you understand?

10 A. Yes.

11 Q. And you're doing a great job already, but
12 try to answer with a "Yes" or a "No" instead of a
13 head nod or an "Uh-huh," because that can be
14 ambiguous in the transcript.

15 Is that fair?

16 A. Yes.

17 Q. Thank you.

18 I'd like to start by talking about your
19 background a little bit.

20 Would you please take me through your
21 education after high school.

22 A. I received a bachelor's degree in biology

1 with a specialty in cell and molecular biochemistry
2 at San Diego State University.

3 I also have a master's degree in business
4 with an emphasis in entrepreneurship, also from San
5 Diego State University.

6 Q. Is that your complete formal education
7 after high school?

8 A. I also have a certificate in design
9 control from the University of California San Diego.

10 Q. The bachelor's in biology, was that a
11 four-year program?

12 A. Yes.

13 Q. Your MBA, was that two years? Three
14 years?

15 A. I'm not sure what the formal duration was.

16 Q. Were you working at the time?

17 A. Yes.

18 Q. Where were you working then?

19 A. I was working at a biotech company called
20 Nanogen, and also at Illumina at the time I was
21 getting that degree.

22 Q. No wonder it's a blur.

1 And then how long was the program at the
2 University of California San Diego in design
3 control?

4 A. It was a several-week program.

5 Q. About when did you go through that
6 design-control program?

7 A. It was during my time at Nanogen.

8 DEPOSITION OFFICER: Can you spell that?

9 THE WITNESS: N-a-n-o-g-e-n.

10 DEPOSITION OFFICER: Thank you.

11 THE WITNESS: Prior to 2007.

12 ///

13 BY MR. HANKINSON:

14 Q. Do you use your biology background and
15 your specialty in cell and molecular biochemistry in
16 your work at Illumina?

17 A. Yes.

18 Q. And in what ways would you say that that
19 background applies to your current work at
20 Illumina?

21 A. The field of molecular diagnostics is
22 looking at DNA and RNA sequences, so the specialty

1 in cell and molecular biochemistry is very useful to
2 that understanding.

3 Q. Your current work deals with -- is it
4 marketing of oncology services?

5 A. Product marketing for oncology. My focus
6 is the molecular diagnostics market.

7 Q. And your understanding or definition of
8 "molecular diagnostics" -- just to make sure that I
9 got it right -- is it that that field deals with
10 looking at DNA and RNA sequences?

11 A. No, not necessarily.

12 There are other applications of molecular
13 diagnostics beyond just looking at sequences.

14 Q. So I'm sorry if I misunderstood you.

15 You were answering that you use your
16 biology background in your work at Illumina insofar
17 as that work deals with looking at DNA and RNA
18 sequences in the products and services that are
19 offered?

20 A. The -- I'm sorry?

21 Is there a question -- was that a
22 question?

1 Q. Did I have that right?

2 A. There are additional uses of -- there are
3 additional fields of molecular diagnostics beyond
4 DNA and RNA that I focused on in my time at
5 Illumina.

6 Q. Okay. And would you please give me an
7 exhaustive list of those?

8 A. We --

9 Q. And do you understand "exhaustive" meaning
10 all of them?

11 A. Yes.

12 Q. Not that it's going to make us tired,
13 although it might.

14 A. Yeah.

15 Q. Sorry for interrupting.

16 A. We have a -- a technology called the
17 BeadXpress on which there -- we offered beads that
18 were carboxylated that enable protein and
19 cytokine --

20 Q. That's c-y-t-o- --

21 A. C-y-t-o-k-i-n-e.

22 -- assays.

1 So, in addition, we also detect
2 methylation.

3 Q. That's m-e-t-h-y-l-a-t-i-o-n; right?

4 A. Yeah.

5 Q. Oh, is that complete?

6 A. I'm thinking.

7 Yes, that's complete.

8 Q. And would you please tell me any other
9 aspects of molecular diagnostics that are not
10 looking at DNA and RNA sequences that Illumina
11 engages in its products and services?

12 Because I was asking about your work, and
13 now I'm broadening it out to the company.

14 MR. HORNE: You mean ever or now or --

15 BY MR. HANKINSON:

16 Q. I'd like to hear both, so let's start with
17 at the current time.

18 A. The carboxylated beads that I described
19 are enabling of protein detection, which has
20 application in molecular diagnostics.

21 Q. And how is that different from the one
22 that you listed for your own work?

1 A. It's the same.

2 Q. Okay. Are there any in addition to what
3 we've discussed already?

4 A. Not that I'm aware of.

5 Q. And in your work currently in oncology,
6 but previously more generally, would you expect to
7 be aware of the products and services offered by
8 Illumina?

9 A. I can't say that I would be aware of all
10 products and services offered by Illumina.

11 Q. What about within the field of molecular
12 diagnostics?

13 A. It's possible that there were others that
14 I was not aware of.

15 Q. Setting aside sort of a weird situation in
16 which -- like just in the realm of possibility
17 anything can happen, do you have any reason to
18 believe that you're unaware of a molecular
19 diagnostics product or service that Illumina
20 currently markets or sells?

21 A. Not markets or sells.

22 Q. You might not be aware of R&D that's going

1 on but isn't yet to market; is that what you're
2 saying?

3 A. Yes.

4 Q. And now let's ask the same question for
5 the past.

6 So any discontinued or no longer sold or
7 marketed products or services of Illumina within the
8 field of molecular diagnostics, would you please
9 list any of those that you're aware of.

10 A. The BeadXpress Factor V and II IVD is
11 discontinued.

12 Q. So that's "Factor," Roman Numeral "V," and
13 "Factor," Roman Numeral "II, IVD"?

14 Do I have that right?

15 A. It's probably not the official name of the
16 product, but in -- in general that's what it was
17 detecting.

18 Q. What was the product?

19 A. Are you asking me for the name?

20 Q. Yes.

21 A. I -- I'm not sure of the exact brand
22 name.

1 Q. The BeadXpress Reader was the machine that
2 was used in providing that?

3 A. Yes.

4 Q. Was the factor -- well, could you just
5 explain a little bit more about how that Factor V
6 and Factor II detection worked?

7 What was Illumina offering?

8 A. Sure.

9 It was a DNA genotyping assay for variants
10 associated with Factor V and II Leiden that was
11 detected on the BeadXpress Reader.

12 Q. Is your answer complete?

13 A. Are you -- are you looking for more --

14 Q. No, I just want to make --

15 A. -- specific molecular --

16 Q. I just -- before I ask my next question, I
17 didn't know if you were done speaking or not.

18 A. I'm done speaking.

19 Q. Could you spell "Leiden"?

20 A. L-e-i-d-e-n.

21 Q. And "variants" is v-a-r-i-a-n-t-s?

22 A. Yes.

1 Q. "Genotyping," G-e-n-o-t-y-p-i-n-g?

2 A. Yes.

3 Q. That has to do with genetics, I'm
4 assuming?

5 A. It's inherited, yes.

6 Q. So genotyping is a field related to
7 inherited genes?

8 A. Yes.

9 Q. Who was using the BeadXpress machine when
10 it was used in detecting Factor V or Factor II at
11 the time that that service was offered?

12 A. Molecular Diagnostics Laboratories.

13 Q. The laboratory would purchase a BeadXpress
14 Reader?

15 Do I have that right?

16 A. Yes.

17 Q. Was that the first IVD product that
18 Illumina -- let me ask that a different way.

19 Was that the first use of an Illumina
20 product in the field of IVD?

21 MR. HORNE: Vague.

22 THE WITNESS: The -- no.

1 BY MR. HANKINSON:

2 Q. How many came before that?

3 A. Many. There were many products registered
4 with the FDA as a Class I exempt device prior to
5 Factor V and II.

6 Q. We were listing the products or services
7 sold or marketed by Illumina in the past that are
8 not currently offered in the field of molecular
9 diagnostics, and we just discussed the BeadXpress
10 Reader --

11 A. Uh-huh.

12 Q. -- as it pertains to Factor V and II and
13 IVD.

14 A. Uh-huh.

15 Q. Are there any others?

16 A. Yes.

17 Q. Could you go on?

18 A. The -- I'm unclear on exactly which
19 products are discontinued versus still available.

20 Q. How about all the ones we haven't talked
21 about already.

22 A. Whether or not they're discontinued?

1 Q. Yes. I think if you knew about them, you
2 would have -- and they were not discontinued, you
3 would have already listed them.

4 If you remember more, add to that answer.

5 Does that make sense?

6 A. I think -- I think -- no, it doesn't make
7 sense.

8 I'm sorry.

9 Q. Okay.

10 A. Previously I was describing fields of use
11 of the technology, and I didn't list exhaustively
12 all of Illumina's products.

13 And now you're asking me to list specific
14 products. I -- I understand that you're asking me
15 to list specific products, and -- and that's why I'm
16 confused.

17 Q. So when we were discussing Illumina's
18 current products and services that are offered and
19 marketed or sold in the field of molecular
20 diagnostics --

21 A. Uh-huh.

22 Q. -- you were listing fields as opposed to

1 products?

2 A. Yes.

3 Q. And in each field that you listed, there
4 might be additional, like, product names?

5 A. Yes.

6 Q. But the fields that you discussed were for
7 the current marketing and sales of Illumina -- the
8 BeadXpress when used with carboxylated --

9 Did we spell that for you?

10 DEPOSITION OFFICER: Yes.

11 THE WITNESS: Okay.

12 BY MR. HANKINSON:

13 Q. -- beads and detecting methylation.

14 Are those all fields?

15 A. The fields of -- the -- the analytes that
16 can be detected with Illumina technology are DNA,
17 RNA, and protein.

18 There are methods of detection available
19 from Illumina with multiple instruments and products
20 in those areas.

21 DEPOSITION OFFICER: How do you spell

22 "analytes"?

1 THE WITNESS: A-n-a-l-y-t-e-s.

2 BY MR. HANKINSON:

3 Q. Pardon me for being simplistic.

4 There are machines that are sold --

5 A. Yes.

6 Q. -- to laboratories; right?

7 A. Yes.

8 Q. And I kind of view those as like platforms
9 to run certain things at the lab?

10 A. Yes.

11 Q. And then there's inputs to that process
12 that are also sold by Illumina?

13 A. That's right.

14 Q. Including beads?

15 A. Yes.

16 Q. And including oligo? What's that? Are
17 those in the beads?

18 What starts with oligo, o-l-i-g-o?

19 A. What starts with oligo?

20 Q. I'm blanking.

21 A. I don't understand your question.

22 I'm sorry.

1 Q. I'm trying to remember some of the inputs
2 to those platforms that are sold by Illumina.

3 I'm remembering like --

4 A. Sure.

5 Q. -- a word that starts with that.

6 A. That -- it's -- it's not -- it's not that
7 simple.

8 Q. Okay.

9 A. It's -- it's just not that simple.

10 There -- there are many different assay
11 methods that Illumina offers and consumables
12 associated with them that interface with our array
13 and sequencing platforms.

14 Q. When you say "array and sequencing
15 platforms," are those machines that are sold to
16 laboratories?

17 A. Yes.

18 Q. And one of those is the BeadXpress;
19 right?

20 A. Yes.

21 Q. Is there a BeadArray machine?

22 A. A BeadArray Reader.

1 Q. And what are the other ones, currently?

2 A. Genome analyzer, MiSeq and MiSeqDx,
3 NextSeq, HiSeq.

4 And there are various versions of the
5 HiSeq available.

6 Q. What was the cheapest one of those?

7 A. I'm sorry.

8 There's one more instrument that I can't
9 recall the name of that was a PCR machine. That was
10 the cheapest.

11 Q. How much did that cost?

12 A. I don't recall the exact price.

13 Q. It's discontinued now?

14 A. It's discontinued.

15 Q. Was it more than 10,000 dollars?

16 A. Yes.

17 Q. Can you give me a ballpark so I don't just
18 march up by tens?

19 A. I think it was in the realm of 30- to
20 50,000.

21 I don't remember the exact price, but it
22 was a low-priced instrument for PCR.

1 Q. And that's no longer offered?

2 A. That's not available anymore.

3 Q. What's the price range for a genome
4 analyzer?

5 A. I'm not sure. I -- I don't want to
6 speculate on that one. I -- I don't know the
7 prices.

8 I -- I do know them of the other
9 instruments.

10 Q. It is more than 30- to 50,000 dollars?

11 A. Yes.

12 Q. What about the MiSeq.

13 And that's M-y --

14 A. No. M-i.

15 Q. M-i?

16 A. S-e-q.

17 Q. With a capital "S"?

18 A. Yes.

19 Q. How much will that run me?

20 A. 98,000.

21 Q. And what about the MiSeqDx?

22 A. 125,000.

1 Q. NextSeq?

2 All of these "Seqs" are capital S-e-q.

3 DEPOSITION OFFICER: Thanks.

4 THE WITNESS: 250,000.

5 BY MR. HANKINSON:

6 Q. I'm almost afraid to ask about HiSeq.

7 A. Because there are so many versions, I'm
8 not certain.

9 Q. What's the cheapest HiSeq?

10 A. I'm not sure.

11 Q. Is it more than 250,000?

12 A. Yes.

13 Q. Is it less than a million?

14 A. Yes.

15 Q. Does it run the gamut between those two
16 numbers?

17 A. Yes.

18 MR. HANKINSON: Gamut is g-a-m-u-t.

19 Do people use that anymore?

20 DEPOSITION OFFICER: It's right here,
21 believe it or not (indicating). Yes, my dad uses
22 gamut all the time.

1 MR. HANKINSON: That's funny.

2 BY MR. HANKINSON:

3 Q. What's the difference between the MiSeq
4 and the MiSeqDx?

5 A. FDA approval. We have FDA approval on the
6 MiSeqDx.

7 Q. Otherwise it's the same?

8 A. Not completely.

9 Q. So what are the differences?

10 A. There's a version of chemistry that is
11 currently not supported on the MiSeqDx.

12 Q. Why not?

13 A. Because it came after FDA approval.

14 I'm sorry. That's not correct.

15 It came during development of the MiSeqDx
16 for clearance.

17 Q. "Clearance," is that another term for FDA
18 approval?

19 A. It's a different type of FDA submission.

20 Q. Is it when there's an FDA-approved product
21 and then it's cleared for another use or -- just --

22 A. No.

1 Q. -- correct me. I'm just --

2 A. Yes.

3 Q. -- trying to stab around and get at it.

4 A. A 510(k) submission, which is a type of
5 application to the FDA, is cleared; and a PMA is
6 approved.

7 It has to do with risk and safety and
8 effectiveness.

9 Q. Are all of Illumina's products cleared, or
10 are some of them approved in the field of
11 diagnostics?

12 A. We have some instruments that are cleared;
13 we have not yet submitted a PMA to the FDA.

14 Q. So the MiSeq platform existed prior to
15 some point in time when it was decided to try to
16 clear that, or something similar, through the FDA;
17 right?

18 A. No.

19 Q. Okay. Correct me.

20 A. When that instrument was conceived, our
21 intention was to solis- -- to go to the clinic with
22 the system and seek FDA clearance or approval with

1 multiple applications.

2 Q. And when was that?

3 A. Are you asking me when development
4 initiated?

5 Q. Yes.

6 A. I don't know.

7 Q. What's the first date on which you
8 remember learning of the MiSeq?

9 A. I -- I don't recall.

10 Q. What is a Class I exempt device?

11 A. It's a -- I am not an expert in
12 regulatory, but I can explain what it means to me.

13 Q. Please do so.

14 A. It's a low-risk device that the FDA grants
15 exemption to a certain ranking.

16 Q. Is your field right now marketing?

17 A. I am a product marketer, and I also have
18 responsibility for some development projects.

19 Q. Do you use your biology background with
20 your specialty in selling molecular biochemistry in
21 your role as a product marketer, or only in your
22 role as taking part in certain development

1 projects?

2 A. Both.

3 Q. In what ways does that apply to your role
4 as a product marketer?

5 A. Communicating to customers, developing
6 marketing literature, planning life cycle of
7 products.

8 Q. So this is a different kind of marketing
9 than I'm used to where somebody's in communications
10 and -- and they're kind of working with
11 advertisement agencies or coming up with like a --
12 how much they're going to spend and how they're
13 going to do it.

14 I mean, those people aren't really
15 scientifically trained to talk to the customers, I
16 guess, because the products are not always so
17 sophisticated?

18 MR. HORNE: I just that lacks foundation.

19 Is that a question?

20 THE WITNESS: Are you asking me a
21 question?

22 BY MR. HANKINSON:

1 Q. Yeah.

2 I mean, does that strike you as right?

3 MR. HORNE: Vague, lacks foundation.

4 THE WITNESS: I -- I don't -- I don't
5 understand.

6 BY MR. HANKINSON:

7 Q. I'm sorry. That's because it's vague and
8 it lacks foundation.

9 So when you are communicating to
10 customers, how are you applying your biology
11 background with your specialty in cell and molecular
12 biochemistry?

13 A. Customers in the field of molecular
14 diagnostics are testing for -- they're looking for
15 answers to questions that are answered by molecular
16 biology, so my education gives me credibility in
17 communicating with that customer.

18 Q. So they expect somebody who's marketing
19 the product to like know the science?

20 MR. HORNE: Lacks foundation.

21 THE WITNESS: I don't know what the
22 customer -- if -- if all customers expect that.

1 BY MR. HANKINSON:

2 Q. But you find that that gives you
3 credibility with them?

4 A. I -- I -- yes.

5 Q. So they all must be scientifically
6 trained, and they're in that field; right?

7 MR. HORNE: Lacks foundation, vague.

8 BY MR. HANKINSON:

9 Q. Is it true?

10 MR. HORNE: Compound.

11 THE WITNESS: You know, I don't understand
12 your question.

13 I'm sorry.

14 BY MR. HANKINSON:

15 Q. Yeah. I mean, so you're credible to them
16 because you have this background and can speak the
17 language.

18 Is that fair to say?

19 A. Our -- our customers are lab directors in
20 a molecular laboratory and ask questions about
21 technology.

22 Q. What kind of questions about the

1 technology do they ask?

2 A. How it can answer their molecular -- or
3 their clinical question.

4 Q. What other types of questions?

5 A. Does a person have disease? Will they
6 respond to a drug?

7 Q. I'm asking you what other types of
8 questions do the lab directors that you're talking
9 about ask about the product?

10 A. What's the throughput in terms of samples
11 per run?

12 What's the laboratory workflow?

13 How is reporting done?

14 They ask questions about how it will be
15 implemented into their laboratory.

16 Q. Now, Illumina offers training in those
17 aspects; right?

18 MR. HORNE: Vague.

19 THE WITNESS: Can you ask the question in
20 another way?

21 BY MR. HANKINSON:

22 Q. Illumina offers training in how an

1 Illumina platform will be implemented in a lab;
2 right?

3 MR. HORNE: Vague.

4 THE WITNESS: Can you ask it another way?

5 BY MR. HANKINSON:

6 Q. Does Illumina offer training?

7 A. Yes.

8 MR. HORNE: Vague.

9 I'm just saying I'm not -- I'm
10 objecting -- I don't know if you mean to the
11 customers or the employees.

12 That's why I'm objecting, so...

13 BY MR. HANKINSON:

14 Q. Does Illumina offer training to personnel
15 at laboratories that buys platforms?

16 A. Yes.

17 Q. Does part of the training of the personnel
18 at the laboratories that buy Illumina's platform
19 include implementation of the platform at their
20 laboratory?

21 A. Yes.

22 Q. Nevertheless, the lab directors who are

1 making the purchasing decisions ask you questions
2 prior to purchasing as well; is that correct?

3 A. Yes.

4 Q. And those questions are as detailed as how
5 the work flow in their laboratory will work when
6 they are implementing Illumina's platform; is that
7 right?

8 A. Are you -- are you asking me if that's
9 the --

10 Q. It gets down to that level of detail?

11 A. Yes.

12 Q. And when we talk about laboratory work
13 flow, it has to do with who at the lab will have to,
14 you know, prepare whatever's going to be the input
15 to the platform, how long that will take them, who
16 else might be involved, how long it will be in the
17 platform while it's performing whatever it does, how
18 people will be notified that it's done, who's going
19 to take it out, how long that's going to take them,
20 what kind of data is coming out of it, and how long
21 that takes.

22 These are the types of questions that

1 they're asking?

2 MR. HORNE: Compound.

3 THE WITNESS: You -- you did say a lot of
4 things there kind of quickly.

5 Can -- can you maybe ask me a different
6 question in a different way?

7 BY MR. HANKINSON:

8 Q. Sure.

9 We've established that the lab directors,
10 prior to purchasing Illumina's platforms, ask about
11 laboratory workflow?

12 A. Yes.

13 Q. And I'm trying to give examples of what
14 laboratory workflow is.

15 A. Sure.

16 Q. Would you want to provide them instead of
17 me stabbing at them?

18 A. Sure.

19 Well, usually a lab manager will be
20 thinking from sample to answer. So how -- how is
21 that workflow going to impact their laboratory space
22 and resources from sample to answer.

1 And then they ask questions in that
2 regard.

3 Q. Does "resources" include people?

4 A. Yes.

5 Q. And what else does resources include?

6 A. Equipment, consumables.

7 Q. Does Illumina sell consumables that are
8 used by its customers outside of their use with
9 Illumina's platforms?

10 A. I don't understand your question.

11 Q. Does Illumina sell any consumables that
12 are used for purposes in the customers' laboratories
13 other than their use with platforms that have been
14 sold by Illumina?

15 A. Yes.

16 Q. Could you tell me what those consumables
17 are and how they are used outside of platforms that
18 are sold by Illumina?

19 A. Illumina has a company we acquired called
20 Epicentre that provides consumables, like enzymes,
21 that are useful with Illumina platforms and for
22 other purposes.

1 Q. Is that it?

2 A. I'm -- I'm not able to provide an
3 exhaustive list of consumables that could be used
4 outside of our instruments.

5 Q. So prior to purchasing an Illumina
6 platform, the lab director is interested in the
7 space within the lab and the utilization of the
8 lab's resources.

9 We already discussed that; right?

10 A. Yes.

11 Q. And when we say that a resource includes
12 people, what are the people doing with the platform
13 that's, you know, taking up lab resources?

14 A. Executing the assay process.

15 Q. And the idea -- and being curious about
16 this if I'm a lab director -- is that the people who
17 are executing that process would have other things
18 to do.

19 You want to sort of get a sense of how
20 long it takes and when these things are going to be
21 occurring?

22 Do I have that right?

1 A. Yes.

2 Q. And then in terms of consumables, if I'm a
3 lab director who's considering purchasing a platform
4 from Illumina, I want to know in advance, "Well,
5 what are the consumables that I'm then going to have
6 to continue to purchase in the future in order to
7 get the value out of platform?"

8 Right?

9 A. I -- can you ask the question another way?

10 Q. The lab director is interested in
11 questions about the consumables as a, you know, lab
12 resource that's going to be used; right?

13 A. They're interested -- I'm -- I'm sorry. I
14 don't understand the question.

15 Q. So you said that lab directors ask
16 questions about how the platform's going to impact
17 the space and resources?

18 A. Yes.

19 Q. And you listed consumables as one of
20 resources?

21 A. Yes.

22 Q. And I'm trying to get at details about

1 that.

2 A. Uh-huh.

3 Q. And so when they're asking questions about
4 consumables --

5 A. Uh-huh.

6 Q. -- they're trying to plan for the future;
7 right?

8 A. Maybe.

9 Q. Okay. And when they're -- what else would
10 they be planning for?

11 MR. HORNE: Pardon me. Lacks
12 foundation.

13 THE WITNESS: I don't -- I'm -- I'm not --
14 I don't understand your question. I'm sorry.

15 BY MR. HANKINSON:

16 Q. Well, they're asking a question before
17 they purchase a very expensive machine; right?

18 A. I do not agree that our instruments are
19 very expensive.

20 Q. They're asking a question about
21 consumables before they purchase a machine that
22 costs between 50,000 dollars and a million dollars;

1 right?

2 A. I don't agree that the -- a customer would
3 have decided what instrument they want before they
4 are having a question about consumables and what the
5 price of the instrument is.

6 Q. You're marketing the platform. That's how
7 we started talking about this; right?

8 A. Yeah. Yes.

9 Q. And so when you say they would have
10 already chosen the platform before they're asking
11 these questions of a marketing person, I don't
12 understand your answer.

13 A. Our systems and consumables are capable of
14 answering many types of questions.

15 So the right combination of instrument and
16 consumables would be discussed with a marketing or
17 sales representative as part of that conversation.

18 Q. Are there marketing or sales
19 representatives assigned to particular labs and lab
20 directors?

21 A. Yes.

22 Q. So each lab has its own account manager,

1 in a sense?

2 What is the term?

3 A. I'm not certain of the exact term that we
4 use.

5 And it's not -- some -- some labs may have
6 more than one account manager.

7 Q. Do --

8 A. So --

9 Q. -- the labs know who the account manager
10 is?

11 A. Labs where we are selling products know
12 who their account manager is.

13 Q. And that's the person who governs the
14 relationship on behalf of Illumina with that lab
15 going forward; right?

16 A. I don't know what you mean by "governs."

17 Q. Is the main contact person for the lab?

18 A. The account manager is the main contact
19 person for the lab for sales.

20 Q. About how many labs are in the market?

21 A. What type of lab?

22 Q. About how many labs that are permitted to

1 perform diagnostic work are in the market?

2 MR. HORNE: Vague.

3 THE WITNESS: Can you describe what you
4 mean by "market"?

5 BY MR. HANKINSON:

6 Q. The pool of labs to which Illumina can
7 sell its products in the field of molecular
8 diagnostics.

9 A. In -- my -- my -- globally? Are you
10 asking globally?

11 I don't know the exact number globally.

12 Q. What about in the United States?

13 A. In -- in the United States there is a type
14 of a customer called a CLIA laboratory that is
15 permitted to run diagnostic tests, and I don't know
16 the exact number of these labs.

17 Q. The FDA is the body that's permitting them
18 to do so?

19 A. No.

20 Q. Who is permitting them to do so?

21 A. The -- the permission or the -- the
22 governing -- ah.

1 Laboratories are permitted to run tests
2 under the CLIA laboratory improvement amendments.
3 They're regulated by C.A.P. and CLIA.

4 C.A.P. is the College of American
5 Pathology.

6 Q. What is involved --

7 DEPOSITION OFFICER: Can you spell CLIA?

8 Sorry.

9 THE WITNESS: C-L-I-A. It's capital
10 C-L-I-A.

11 DEPOSITION OFFICER: Thank you.

12 BY MR. HANKINSON:

13 Q. What's involved in becoming a CLIA
14 certified lab?

15 A. A CLIA certified lab is allowed under CLIA
16 to develop their own diagnostic tests based on
17 components. They're responsible for validating that
18 test.

19 Q. How is permission acquired from C.A.P.?

20 A. C.A.P. audits laboratories.

21 Q. Is there an application procedure?

22 A. In some instances.

1 Q. Does Illumina have a CLIA certified lab?

2 A. Yes.

3 Q. Did it apply?

4 A. Yes.

5 Q. What was that procedure?

6 A. I'm not aware of the detailed procedure.

7 Q. After the acquisition of Epicentre, how
8 are the products that Epicentre sells branded?

9 A. I'm not sure.

10 Q. Who would know that?

11 A. I'm not sure.

12 Q. Would Karen Possemato know?

13 A. I -- I don't know for sure.

14 Q. Could I find that out by visiting the
15 website?

16 A. Are you asking me if you can find out who
17 would know --

18 Q. No.

19 A. -- on the website?

20 Q. How they're branded?

21 A. I don't know.

22 MR. HANKINSON: I'd like to mark something

1 as Exhibit A.

2 (Whereupon, O'Grady Exhibit Number
3 A was marked for identification by
4 the Deposition Officer and is
5 attached hereto.)

6 BY MR. HANKINSON:

7 Q. Ms. O'Grady, when you get it, would you
8 take a look at Exhibit A.

9 It's an article found on GenomeWeb with a
10 date of August 27, 2014. And the title is
11 "Illumina's Pharma Deals Aim to Bring Universal
12 MiSeqDx-based CDx through FDA Clearance."

13 (Document reviewed by the witness.)

14 BY MR. HANKINSON:

15 Q. Do you see that?

16 A. Yes.

17 Q. I'd like to call your attention to
18 paragraph 4, and specifically the last three
19 sentences beginning "A key difference..."

20 Are you with me?

21 A. Yes.

22 Q. And here there's a quote that's attributed

1 to you; is that right?

2 (Document reviewed by the witness.)

3 THE WITNESS: Yes.

4 MR. HORNE: Lacks foundation

5 BY MR. HANKINSON:

6 Q. I'll go ahead and read it, and then we can
7 talk about it.

8 "A key difference in using
9 the MiSeqDx for oncology purposes
10 is that it will need to be cleared
11 for use on formalin' -- it's
12 f-o-r-m-a-l-i-n, hyphen, 'fixed
13 paraffin,' p-a-r-a-f-f-i-n,
14 hyphen, 'embedded tissue,' O'Grady
15 said.

16 "Currently, it is cleared
17 only for targeted sequencing of
18 DNA from whole blood. It's use
19 also must be expanded to include
20 the detection of somatic,"
21 s-o-m-a-t-i-c, "rather than
22 germline," g-e-r-m-l-i-n-e,

1 "variants."

2 Did I read that correctly?

3 A. Yes.

4 Q. This quotation is discussing a use of
5 MiSeqDx for oncology purposes that's different from
6 the one that had been FDA cleared before?

7 Do I have that right?

8 MR. HORNE: Lacks foundation.

9 THE WITNESS: Can you restate that
10 question, please?

11 BY MR. HANKINSON:

12 Q. Sure.

13 There's a use on formalin-fixed
14 paraffin-embedded tissue that is needed to be
15 cleared, and there are prior uses of the MiSeqDx
16 that had already been cleared by the FDA; right?

17 A. Can you -- I -- I don't understand what --
18 what you're saying it's needed for.

19 Q. Well, you say it will be -- "it will need
20 to be cleared" in your quote.

21 A. Yes.

22 Q. And so I'm trying to use your words.

1 A. Okay. I'm -- I'm sorry. I still don't --

2 MR. HORNE: I'm going to object.

3 There's no quote here, so -- I don't see
4 quote marks on there, so I don't know if that is her
5 language or not.

6 That's my objection for lack of
7 foundation.

8 BY MR. HANKINSON:

9 Q. There's a use of the MiSeqDx that were
10 cleared already prior to the need to be cleared for
11 use on formalin-fixed paraffin-embedded tissue?

12 That's what I'm asking.

13 A. The -- the -- I -- that -- that's what
14 this quote says. That's what this article at
15 GenomeWeb says.

16 Q. And it's inaccurate, is that what you're
17 saying?

18 A. It's very specific to a particular use of
19 the technology.

20 Q. Would Illumina's customers for the MiSeqDx
21 be interested in details as specific as this when
22 they're purchasing and using Illumina's products?

1 A. I -- I don't know if our customers
2 would -- I -- I don't know.

3 Q. Wouldn't they have to be if they're
4 operating a CLIA certified lab?

5 MR. HORNE: Argumentative.

6 THE WITNESS: I don't -- I don't
7 understand the question.

8 BY MR. HANKINSON:

9 Q. Well, they're not going to use a product
10 for a purpose for which it hasn't been cleared;
11 right?

12 That would endanger --

13 A. That's not correct.

14 Q. Okay. Please correct me.

15 A. Molecular labs in a CLIA environment can
16 develop their own tests with components that are not
17 FDA cleared.

18 Q. Why would this particular use, then -- to
19 quote you -- "need to be cleared"?

20 A. To --

21 MR. HORNE: Just object; lacks
22 foundation.

1 THE WITNESS: To establish claims to
2 support a pharmaceutical drug application.

3 BY MR. HANKINSON:

4 Q. Another consumer of Illumina's products
5 are -- excuse me.

6 So are we talking about clinical trials?

7 A. Oh. Yes.

8 Q. And who's performing the clinical
9 trials?

10 A. A clinical trial would be performed at a
11 CRO, clinical research organization, or a hospital
12 laboratory governed by Illumina and/or a
13 pharmaceutical company for this particular
14 application discussed in this article.

15 Q. Who are the consumers for Illumina's own
16 CLIA certified lab?

17 A. That's a good question.

18 There are several consumers of Illumina's
19 CLIA certified lab. I don't -- one example would be
20 the Medical College of Wisconsin for rare pediatric
21 disease.

22 Q. It sounds like you're still answering.

1 A. That's one example.

2 Q. Is it only a handful of consumers or --

3 A. No.

4 Q. -- there's different types?

5 A. There's different types --

6 Q. Could you --

7 A. -- of consumers.

8 Q. -- list the types of consumers?

9 MR. HORNE: Lacks foundation.

10 THE WITNESS: I'm actually not sure of all
11 of the consumers, which is why I said it's a good
12 question. I -- I don't know all of them.

13 BY MR. HANKINSON:

14 Q. Could you list the ones you know, the
15 types?

16 A. I'm -- I'm -- I'm aware of the use of our
17 CLIA sequencing services for rare pediatric disease
18 for an offering that we call "Understand Your
19 Genome," and also to pharma.

20 Q. And what are the products and services
21 that the Illumina CLIA certified lab purchases?

22 A. I don't know what they purchase.

1 MR. HANKINSON: I'm going to use an
2 exhibit. The rest of my exhibits have a number
3 that's already been assigned to them --

4 THE WITNESS: Okay.

5 MR. HANKINSON: -- in the case, and I'd
6 like to use that same exhibit number to avoid
7 confusion.

8 THE WITNESS: Sure.

9 MR. HANKINSON: Does that work for you
10 guys?

11 MR. HORNE: Yeah. Why don't you just say
12 what's previously been marked?

13 MR. HANKINSON: Yeah.

14 MR. HORNE: Because they are all of record
15 with the board; right?

16 MR. HANKINSON: Uh-huh.

17 MR. HORNE: So let's just use that
18 number.

19 MR. HANKINSON: Yeah. So I'd like to mark
20 this as Deposition Exhibit 303 as well.

21 (Whereupon, O'Grady Exhibit Number
22 303 was marked for identification by

1 the Deposition Officer and is
2 attached hereto.)

3 DEPOSITION OFFICER: Okay.

4 MR. HORNE: I'm not here to run your
5 deposition. As far as I'm concerned, you can just
6 say, "I'll hand you what's previously been marked."

7 I don't know if you need to mark it again,
8 but I'll leave it to you.

9 DEPOSITION OFFICER: Here you go.

10 MR. HORNE: Thanks.

11 (Document reviewed by the witness.)

12 BY MR. HANKINSON:

13 Q. Exhibit 303 is a document that's
14 referenced in the declaration that you submitted in
15 this case; right?

16 A. Yes.

17 Q. What is Exhibit 303?

18 A. It's a document that we refer to as a
19 "Launch Package." It's a compilation of information
20 to help a salesperson communicate about our
21 products.

22 Q. Was this document used for training a

1 sales team on how to position BeadXpress technology
2 to prospective customers?

3 A. Yes.

4 Q. And the -- this launch package pertains to
5 BeadXpress system and VeraCode technology; right?

6 A. Yes.

7 Q. There's an acquisition of a company
8 called -- was it CyVera? C-y-, capital V, -e-r-a,

9 A. I'm not sure if the capital is there or
10 not, but it is CyVera, and it is spelled that way.

11 Q. And that occurred in roughly in 2007?

12 A. No, that --

13 Q. 2005?

14 A. Yes.

15 Q. And in 2007 the BeadXpress system and
16 VeraCode technology were being launched with this
17 launch package; right?

18 A. This launch package was developed in 2007.

19 Q. And when this was used to train the sales
20 team to position the BeadXpress technology to
21 prospective customers, the prospective customers
22 were laboratories; right?

1 A. Yes.

2 Q. And any other prospective that were not
3 laboratories?

4 A. Yes.

5 Q. And what were those?

6 A. We marketed the technology to prospective
7 diagnostic development partners.

8 Q. Other companies?

9 A. Other companies, yeah.

10 Q. Would the other companies purchase this
11 platform or just be licensed to use it through
12 Illumina?

13 A. Potentially, both.

14 Q. And who at the laboratories -- well, what
15 type of laboratories?

16 Are there multiple types?

17 A. Yes.

18 Q. And what types?

19 A. Molecular diagnostics laboratories,
20 academic laboratories, agriculture laboratories.

21 There are probably others that I can't
22 remember right now.

1 Q. Academic laboratories would be purchasing
2 the system and technology for research purposes;
3 right?

4 A. Yes.

5 Q. And in 2007 molecular diagnostic
6 laboratories who wanted to purchase and use the
7 BeadXpress system and VeraCode technology could use
8 it to develop their own lab-designed tests; right?

9 A. A lab-developed test.

10 Q. Lab-developed test -- or LDT?

11 A. Yes.

12 Q. And using the technology and system in an
13 LDT would be the only way at that time for a
14 molecular diagnostic lab to use it for diagnostic
15 purposes; correct?

16 A. Yes, in 2007.

17 Q. I have to remark that this launch packet
18 to train the sales reps is very long and detailed.

19 MR. HORNE: Argumentative.

20 MR. HANKINSON: What's that?

21 MR. HORNE: I said, "Argumentative."

22 MR. HANKINSON: I think we can all agree

1 on that.

2 BY MR. HANKINSON:

3 Q. The -- how big is the sales team that was
4 trained using this?

5 A. I don't remember.

6 Q. On the order of ten people or on the order
7 of 100 people?

8 A. I don't remember the size of the sales
9 force in 2007.

10 Q. Could it have been more than 100?

11 A. I'm not -- I'm not sure. It may be.

12 Q. And would you have been considered a part
13 of that or not?

14 A. Are you asking me if I was part of the
15 sales team?

16 Q. Yeah.

17 A. I was a product marketer.

18 Q. And should that mean to me that you were
19 not part of the sales team?

20 A. I was part of marketing; I was not part of
21 sales.

22 Q. Did the sales team have a required science

1 or technology background at the time?

2 A. I don't know.

3 Q. Was it preferred that they did?

4 A. I don't know.

5 Q. If information is contained in this launch
6 package which was used to train the sales team on
7 how to position the BeadXpress technology to
8 prospective customers, can we agree that it is
9 information that might interest or be asked about by
10 those prospective customers?

11 MR. HORNE: Lacks foundation.

12 THE WITNESS: I --

13 MR. HORNE: Vague.

14 Go ahead.

15 THE WITNESS: There's information in this
16 package that we would expect customers to ask. I
17 think there's a --

18 BY MR. HANKINSON:

19 Q. And that's why it's in --

20 A. -- "Frequently Asked Questions" section --

21 Q. Uh-huh.

22 A. -- intended to answer questions that a

1 customer may have.

2 Q. Uh-huh. And if it's in here, it's to
3 enable the sales team to interact successfully with
4 those potential customers; right?

5 That's the purpose of putting information
6 in this launch package?

7 A. Yes.

8 Q. The target market -- if you can turn to
9 page 4 under the heading "Target Market," sentence
10 two.

11 A. Uh-huh.

12 Q. The target market for the BeadXpress
13 Reader was a:

14 "...combined market serving
15 genotyping, gene expression, and
16 protein analysis..."

17 Right?

18 A. Yes.

19 Q. And that matches up with the three
20 analytes that you listed for me earlier; right?

21 A. Yes.

22 Q. DNA, RNA --

1 A. And protein.

2 Q. -- and protein.

3 And there's an issue in the market of sort
4 of different levels of multiplexing; right?

5 A. I don't understand.

6 Q. Well, multiplexing and the level to which
7 a system can multiplex seems to be a sales point,
8 and certain people need kind of a higher
9 multiplexing level and certain don't.

10 And then there's price differences between
11 the two?

12 Am I oversimplifying it?

13 A. The system was capable of a variety of
14 multiplexing levels, and there were applications
15 where that was relevant.

16 Q. And lower down under "Target Market,"
17 there's a bullet pointed list that has the preface:

18 "The target market and
19 customer base include."

20 A. Uh-huh.

21 Q. Right?

22 A. Uh-huh.

1 Q. And there's four types of customers
2 listed; right?

3 A. Yes.

4 Q. The first is:

5 "Researchers interested in
6 focused analysis of markers of
7 interest following a larger
8 microarray discovery project.

9 "These include existing
10 Illumina customers owning a
11 BeadArray Reader, in addition
12 to other competitive platforms."
13 That's the first bullet; right?

14 A. Yes.

15 Q. "Researchers" means people interested in
16 answering questions for the purpose of research, as
17 opposed to diagnostics; right?

18 A. Yes.

19 Q. And then the second bullet is:

20 "Researchers interested in
21 performing SNP genotyping analysis
22 of a broad range of multiplex

1 reactions, typically higher than a
2 3-plex reaction, and/or a high
3 volume of samples per project."

4 That's the second bullet; right?

5 A. Yes.

6 Q. And, again, it's researchers as opposed to
7 people using this for diagnostics; right?

8 A. Yes.

9 Q. Then the third type of customer in the
10 customer base for the BeadXpress system and VeraCode
11 technology in 2008 were:

12 "Researchers interested in
13 developing their own protein-based
14 multiplex assays and/or genotyping
15 assays."

16 Right?

17 A. Yes.

18 Q. And, again, those are researchers who are
19 answering research questions as opposed to clinical
20 diagnosticians answering a clinical diagnosis
21 question; correct?

22 A. Yes.

1 Q. And then the fourth part of the customer
2 base for the BeadXpress system and VeraCode
3 technology in 2008 consisted of:

4 "CLIA high complexity
5 certified laboratories interested
6 in developing laboratory-developed
7 tests using RUO products for
8 multiplex assays."

9 Right?

10 A. Yep. Yes, that's what it says.

11 Q. What is the meaning of "high complexity"
12 in the phrase "CLIA high complexity certified
13 laboratories"?

14 A. "High complexity" is a type of CLIA
15 certification, and molecular laboratories fall under
16 the high complexity category of CLIA.

17 Q. Did you say "molecular categories"?

18 A. I said, molecular diagnostics --

19 Q. Uh-huh.

20 A. -- falls under the CLIA high complexity
21 type of a CLIA lab. All molecular testing happens
22 in a high complexity laboratory.

1 Q. So it's all molecular testing falls under
2 the category of high complexity?

3 A. Yes.

4 Q. Are there like additional restrictions or
5 regulations to be a high complexity CLIA certified
6 lab?

7 A. The -- the main one that has to do with
8 molecular testing is the issue of contamination --
9 molecular contamination.

10 So having a pre- and a post-amplification,
11 the difference between a CLIA high complexity lab
12 and a moderate-complexity lab is very, very simple
13 assays that don't have that risk.

14 It could be run in a moderate complexity
15 environment, which is more like a -- a doctor's
16 office.

17 Q. So a middle level -- a middle
18 complexity -- is that what you said, "middle
19 complexity"?

20 A. I -- I'm most familiar with the high
21 complexity environment.

22 I know that there's also a CLIA waived,

1 which is like a doctor's office.

2 Q. So let me ask: A doctor's office would
3 not be a high complexity CLIA certified lab?

4 A. No.

5 Q. It would be an actual laboratory; right?

6 A. Yes.

7 Q. And when you say, "pre- and
8 post-amplification, potential molecular
9 contamination," are you talking about something that
10 would affect the results of a test, or contamination
11 like people could get sick?

12 A. The active detecting molecules frequently
13 requires amplification, making multiple copies of
14 DNA, and that process has a risk of contamination
15 from molecules around a lab.

16 So all molecular diagnostic labs are
17 required to do their testing in a CLIA high
18 complexity environment to control for risk
19 of a wrong result.

20 Q. Is it --

21 A. And that's what C.A.P. regulates.

22 Q. Is it equipment or procedures or both

1 that are required to protect against that
2 contamination?

3 A. The -- the laboratory process and
4 governance that a CLIA lab has to put in place
5 controls for it.

6 Q. It does sound highly complex.

7 A. That's why, yes.

8 Q. The use of "RUO" in the fourth bullet on
9 page 4, does that stand for "Research Use Only"?

10 A. Yes.

11 Q. So to the extent in 2008 that the target
12 market and customer base for the BeadXpress system
13 and VeraCode technology included laboratories for
14 diagnostic purposes, it would only be in the context
15 in which such a laboratory used a research-use-only
16 product to develop a laboratory-developed test;
17 correct?

18 A. I -- I'm sorry. I had a hard time
19 following what you just said. Could you please
20 repeat it?

21 Q. To the extent, in November 2008, that a
22 laboratory might be interested in purchasing the

1 BeadXpress system and VeraCode technology that this
2 launch package is about, it would be only to use
3 that product and technology, which was a
4 research-use-only product and technology at the
5 time, in developing a laboratory-developed test
6 which would then be used for diagnostic purposes --

7 MR. HORNE: Lacks foundation.

8 ///

9 BY MR. HANKINSON:

10 Q. -- right?

11 MR. HORNE: Sorry.

12 THE WITNESS: I -- I don't know.

13 BY MR. HANKINSON:

14 Q. "RUO" means research use only?

15 A. Yes.

16 Q. This is the fourth type of potential
17 customer in the customer base; right?

18 A. Yes.

19 Q. And the first three were research
20 applications as opposed to diagnostic applications;
21 right?

22 A. Yes.

1 Q. And the fourth one might have something to
2 do with diagnostic applications; right?

3 A. Yes.

4 Q. And that's the only part of the customer
5 base where it might have something to do with
6 diagnostic applications at that time --

7 MR. HORNE: Lacks foundation.

8 BY MR. HANKINSON:

9 Q. -- right?

10 MR. HORNE: Sorry.

11 ///

12 BY MR. HANKINSON:

13 Q. As expressed in this launch packet;
14 right?

15 A. No.

16 Q. Is there a customer not listed in the
17 launch package?

18 A. The four bullets that were listed here
19 represent the lowest hanging fruit for a sales
20 representative; are not an exhaustive list of
21 potential customers of the platform.

22 Q. What about -- does this include all the

1 laboratories that are included in the potential
2 customer base?

3 A. No.

4 Q. What other laboratories would there be?

5 A. I described previously agriculture testing
6 labs, diagnos- --

7 Q. Those would be --

8 Go ahead.

9 A. -- diagnostic development partnerships,
10 PhRMA.

11 There are other types of labs that were
12 customers of Illumina than the four listed on
13 this.

14 Q. Did you say "those were" or "there are"
15 other besides those three?

16 A. Those are examples of other customers.

17 Q. Are there any other examples of other
18 customers?

19 A. There was possibly other -- other
20 customers. Those are three examples I can come up
21 with.

22 Q. The only way for a laboratory in November

1 2008 to use the BeadXpress system and VeraCode
2 technology for a diagnostic purpose would be to
3 develop an LDT; is that accurate?

4 A. I don't know of another way.

5 Q. And --

6 A. I'm sorry. I'm going to strike that.

7 A customer could choose to solicit their
8 own FDA submission if they wanted to.

9 And outside of the United States, the
10 regulations are different.

11 Q. And that's complete -- your answer is
12 complete?

13 A. I'm not aware of another way.

14 Q. And that is true of any laboratories doing
15 agriculture testing, any laboratories at other
16 businesses that you might partner with for the
17 development of a diagnostic test, and for
18 pharmaceutical laboratories as well; correct?

19 They'd either have to do an LDT or seek
20 some sort of other FDA approval or clearance in
21 order to use the technology in a diagnostic
22 application?

1 A. In the United States, that is correct for
2 most types of diagnostic tests.

3 Q. And what are the types of diagnostic tests
4 that would be exceptions to that?

5 A. Well, one example would be preimplantation
6 genetic testing; it's not currently regulated.

7 They're -- they're examples of types of
8 tests that are not regulated.

9 Q. Any others?

10 A. Not that I'm aware of.

11 Q. When you say "preimplantation genetic
12 testing," you are talking about genetic testing of
13 a -- what are you -- what is the -- is it like in
14 utero?

15 A. Testing of embryos prior to
16 implantation.

17 Q. It's a little bit odd because it's sort of
18 chicanery whether that's diagnostics; right?

19 The reason that it's not regulated in the
20 way that diagnostics are is because it's not
21 considered diagnostics; right?

22 A. Depending.

1 MR. HORNE: Lacks foundation. It's
2 argumentative.

3 BY MR. HANKINSON:

4 Q. By the FDA?

5 A. I'm not aware of what the FDA thinks about
6 that.

7 Q. You don't have any reason to disagree with
8 that?

9 A. I'm -- I'm not aware of the FDA's current
10 thinking on that field.

11 Q. It's not currently regulated?

12 A. It is not currently regulated.

13 MR. HORNE: You need a little while longer
14 on this document?

15 We've been going an hour and a half. I
16 would suggest a break, but if you've got a few more
17 questions, we can hold off.

18 MR. HANKINSON: I might go on and on. You
19 want a break?

20 MR. HORNE: Yeah. Why don't we do that,
21 then?

22 DEPOSITION OFFICER: Off the record.

1 ///

2 (Whereupon, a recess was held
3 from 9:31 a.m. to 9:45 a.m.)

4 DEPOSITION OFFICER: Back on the record.

5 BY MR. HANKINSON:

6 Q. When a customer purchases a product or
7 service from Illumina's CLIA high complexity
8 certified laboratory -- first of all, is it a
9 product or a service or can it be either?

10 A. Our CLIA certified lab offers services.

11 Q. And not products?

12 A. And not products.

13 Q. When a customer requests a service from
14 that lab, what is the process?

15 A. An individual would require a doctor's
16 order and a consent. Their sample is sent to
17 Illumina; we test it and provide a report back to
18 their physician.

19 Q. What physical form or electronic form does
20 the report take?

21 A. I'm -- I'm not aware of that.

22 Q. You don't know if it's e-mailed or if it's

1 sent by --

2 A. I don't know.

3 Q. -- paper?

4 A. I don't know.

5 Q. Do you know what's in those reports?

6 A. No, I don't know exactly what's in the
7 report.

8 Q. Do you know what they look like?

9 A. No, I don't.

10 Q. Do you know how they're branded?

11 A. "Illumina." They're branded with
12 Illumina's name.

13 Q. In what sense?

14 A. All of our products and services are
15 branded with "Illumina."

16 Q. So you're taking the general proposition
17 that everything is branded with "Illumina," and then
18 you're concluding, even though you don't know what
19 the report looks like, that it is also branded
20 "Illumina"?

21 A. We have a policy that all of our labels
22 and materials are branded "Illumina."

1 Q. What about subsidiaries that are still --

2 A. I'm sorry.

3 I want to -- I just want to clarify
4 that.

5 It's a -- it's not a policy, it's a
6 guide.

7 Q. So it's a guide that they should be?

8 A. Our -- our -- our branding book says that
9 all things are labeled with "Illumina."

10 Q. The guide that you're referring to is not
11 referenced in your declaration, is it?

12 A. No.

13 Q. Do you have any knowledge of whether that
14 guide has been provided by Illumina to Meridian in
15 the process of discovery?

16 A. No, I don't know.

17 Q. Is that guide your basis for saying that
18 the report that comes out of the CLIA high
19 complexity certified lab run by Illumina is branded
20 with "Illumina"?

21 A. That would inform my assumption.

22 In addition to that, I have been at

1 presentations where we are speaking about our
2 services, and images of the report have been
3 presented that are branded "Illumina."

4 Q. So you have seen them?

5 A. I -- I have seen an image of a report. I
6 have not looked at the details of the -- the result.

7 When you asked me about what's in the
8 report, I'm assuming you mean what is the detail of
9 the result, and I -- I don't know the exact details
10 of that.

11 Q. So you're talking about like a slide deck?
12 It has a photo of a report?

13 A. Yes.

14 Q. And what, if anything, did you do to
15 confirm that that was an accurate image of an actual
16 report as opposed to something created for the slide
17 deck?

18 A. Nothing.

19 Q. When the individual -- excuse me.

20 When the sample is sent to the CLIA high
21 complexity certified lab run by Illumina, who sends
22 that sample?

1 A. I'm not sure.

2 Q. What entity does it come from?

3 A. It --

4 Q. The patient?

5 A. No.

6 Q. Does the patient send it?

7 A. No.

8 Q. Who sends it?

9 A. The -- the test order has to come from a
10 physician, and -- and someone needs to do a blood
11 draw. And whoever does that, I'm assuming sends the
12 sample.

13 Q. The test order that comes from the
14 physician is essentially -- I don't know --
15 "prescription" is not the right word, but the doctor
16 has to order that the test be done; right?

17 A. Our -- our CLIA service is only offered
18 when a physician orders the test.

19 Q. But the physician doesn't send the test
20 order to you? The blood's drawn by someone and then
21 that is sent to you along with the physician's order
22 that the test be done?

1 Do I have that accurately?

2 A. I -- I don't know.

3 Q. You're not sure?

4 A. I -- I don't know the exact details of how
5 the test order and the blood comes to Illumina.

6 Q. And that information, then, is not in your
7 declaration that was submitted in this case?

8 A. I -- I don't think so.

9 Q. You wouldn't have put something in your
10 declaration that you didn't think you knew?

11 A. Right. No, I wouldn't.

12 Q. So are you not sure whether the physician
13 makes the actual order for the service from
14 Illumina's CLIA certified lab, or whether it is a
15 laboratory that's separate from the physician that
16 does the blood draw?

17 You just don't know one way or the other?

18 A. I -- I know that a physician has to order
19 the test. I don't know if the physician or some
20 other blood-draw location takes the blood and sends
21 it to Illumina.

22 Q. So do you know who the customer of

1 Illumina's CLIA certified lab is -- or who --

2 A. I know --

3 Q. -- those customers are?

4 A. I know of some of the customers of a
5 Illumina's certified lab.

6 Q. And you said one is the Medical College of
7 Wisconsin for rare -- in relation to rare pediatric
8 disease; right?

9 A. Yes.

10 Q. And so when that customer wants to use the
11 service, who -- who's the individual that would
12 interact with Illumina to make that happen?

13 A. I don't know.

14 Q. Do you know what that person's position
15 is?

16 A. I'm -- I'm sorry?

17 Are you asking me about the Illumina
18 people, or are you asking me about Medical College
19 of Wisconsin?

20 Q. Medical College of Wisconsin.

21 A. Can you ask the question again?

22 Q. Sure.

1 When Medical College of Wisconsin wants to
2 get a service from Illumina's CLIA certified lab,
3 who at Medical College of Wisconsin makes that
4 happen?

5 A. I don't -- I don't know who there is
6 ordering the test.

7 Q. Do you know the position or positions of
8 the person or people who would be ordering the
9 test?

10 A. I do not.

11 Q. Do you know if the person or people who
12 are ordering the test are the customer of Illumina's
13 CLIA certified lab, or if someone else makes the
14 decision and the person who sends the order for the
15 test is just implementing that afterwards?

16 A. The test -- our -- our CLIA service is
17 implemented in our own laboratory.

18 Q. Right.

19 A. So the -- unlike a product, it -- it's a
20 service.

21 Q. Uh-huh.

22 A. A physician orders it and receives the

1 report. They're not implementing the test in their
2 own lab.

3 Q. Right.

4 A. It's a service.

5 Q. And Illumina doesn't do it randomly, they
6 do it by request; right?

7 A. Yes.

8 Q. So -- I mean, maybe I'm oversimplifying,
9 but somebody has to ask for it?

10 A. Yes.

11 Q. And you don't know who that person is.

12 And what I'm asking is: Do you know
13 whether whoever is sending the test is the person
14 who is making the decision to utilize Illumina's
15 service with its CLIA certified lab or not?

16 A. I don't know.

17 Q. What other examples of customers of
18 Illumina's CLIA certificate lab, other than Medical
19 College of Wisconsin, do you know?

20 A. I don't know of any other specific
21 customers.

22 Q. Are any of Illumina's products or services

1 used in a conventional physician's office as opposed
2 to a laboratory?

3 A. I -- I don't understand what you mean by a
4 "conventional physician's office."

5 Q. A doctor's office.

6 A. You're -- you're asking me if any of our
7 products are used in a conventional physician's
8 office?

9 Q. Yes.

10 A. I -- I don't know. I don't know.

11 Q. You don't consider the doctor's offices to
12 be part of the customer base of Illumina's
13 platforms, consumables, or services, do you?

14 A. Physicians order our CLIA high complexity
15 tests.

16 Q. Right.

17 But you don't know whether they ask for
18 them or whether they order that a test be done and
19 somebody else orders it from the CLIA high
20 complexity certified lab?

21 A. I --

22 Q. We were just going over that.

1 A. I don't know the process for how these
2 tests are ordered.

3 Q. Do you --

4 A. I'm not involved with that.

5 Q. Do you know whether a doctor requests
6 Illumina's lab as opposed to some other lab?

7 A. Do I? I -- I don't know.

8 Q. Because I've been ordered to get a blood
9 test, and then I have to go to like some third party
10 and they draw the blood.

11 A. Uh-huh.

12 Q. And -- and I guess what I'm hearing is,
13 you don't know whether like Quest, or whoever is
14 drawing the blood, is choosing to use Illumina's
15 CLIA certified lab or whether the doctor is choosing
16 to use Illumina's certified lab or whether it's
17 somebody, you know, higher up at Quest or the other
18 third party who like has a relationship with
19 Illumina's lab.

20 That's what I'm trying to ask.

21 A. Illumina offers a few services in a -- in
22 a CLIA lab. We offer non-invasive prenatal testing

1 and whole genome sequencing, and I'm not aware of
2 how those products are ordered and sold.

3 Q. So when I asked whether any products or
4 services were used -- excuse me.

5 When I asked you whether any products and
6 services of Illumina were used in a doctor's
7 office --

8 A. Uh-huh.

9 Q. -- you answered doctors order the tests
10 that are then sometimes done in CLIA's certified
11 lab.

12 Are there any physical products that would
13 go to a doctor's office -- to be purchased by a
14 doctor, not in a laboratory setting?

15 A. I'm not aware if as part of those
16 services, if a component is shipped to a physician
17 to -- to enable that test. I don't know.

18 Q. I thought a report went to the doctor?

19 A. If -- if -- I don't -- I do not know if
20 there's any component that goes to the physician to
21 enable a sample collection.

22 Q. So you don't know whether such a component

1 would be branded or not because you don't know even
2 if it exists; is that accurate?

3 A. I -- I'm -- I'm not involved directly with
4 their services business. I -- I don't have the
5 details of that.

6 Q. Could you turn to Exhibit 303 --

7 A. Uh-huh.

8 Q. -- and flip to page 5.

9 On page 5 there's a table of the top
10 competitors of the BeadXpress system and their
11 platforms; right?

12 (Document reviewed by the witness.)

13 THE WITNESS: Yes.

14 BY MR. HANKINSON:

15 Q. The most challenging competitor to
16 BeadXpress in late 2008 was Luminex; correct?

17 MR. HORNE: Vague.

18 THE WITNESS: I don't think I referred to
19 Luminex as the most challenging competitor.

20 BY MR. HANKINSON:

21 Q. Did you author Exhibit 303?

22 A. No, Mickie Henshall did.

1 Q. Did you have input into it?

2 A. At the time that it was updated in two
3 thousand -- in 2008, I assisted in that
4 modification.

5 Q. At that time were you aware of the entire
6 contents of the document or just parts that were
7 being modified?

8 A. I used this document many times.

9 Q. So you're aware of everything in it?

10 A. I -- yes, I read it many times.

11 Q. And when you assisted in the updating, if
12 there was anything in here that was inaccurate,
13 would you have brought that to the attention of
14 Ms. Henshall or someone else?

15 A. If I noticed something was wrong, I would
16 have fixed it.

17 Q. And would that have been part of your
18 duties?

19 A. I don't know -- yeah. I mean, I don't
20 know if it was my duty or not, but I would have done
21 it. I would have corrected an error.

22 Q. And who -- I assume Ms. Henshall signed

1 off on this document and took responsibility for its
2 final contents, because her name as on the cover of
3 it.

4 Do I have that correct?

5 A. She -- I -- I don't recall what the
6 sign-off process was when it was re-issued.

7 Q. There were multiple people who would have
8 reviewed this at Illumina and signed off on it prior
9 to it being considered complete?

10 A. I don't -- I don't recall the review
11 process prior to its distribution.

12 Q. But at least you and Ms. Henshall reviewed
13 it?

14 A. I don't recall the review process before
15 this was redistributed.

16 Q. If you look at page 5 --

17 A. Uh-huh.

18 Q. -- third sentence.

19 A. Yeah.

20 Q. (READING):

21 "While each competitor has
22 had success in the market, it is

1 Luminex that poses the most direct
2 challenge to BeadXpress,
3 especially in terms of the
4 multiplexing technology, a very
5 large install base" --

6 A. Uh-huh.

7 Q. (READING):

8 "-- and a formidable menu of
9 tests."

10 Did read that right?

11 A. Yes.

12 Q. So I had asked you whether it was the most
13 challenging competitor, but perhaps a better
14 question would be: Was Luminex the competitor that
15 most directly competed with the features -- that had
16 a product that most directly competed with the
17 features that BeadXpress was offering?

18 A. Yes, that's true.

19 Q. So it was the closest thing to BeadXpress
20 on the market at that time?

21 A. Yes, that's true.

22 Q. The table on page 5 has a column for

1 "Illumina BeadXpress," and right next to that, a
2 column for "Luminex"; right?

3 A. Yes.

4 Q. The instrument cost of the Illumina
5 BeadXpress at the time was 98,500 dollars; right?

6 A. Yes.

7 Q. And Luminex, there's a range listed of
8 20,000 to six hundred -- to 65,000 dollars for its
9 competing system?

10 A. That's -- that's what it says.

11 Q. The competing system was the Luminex 100
12 System, which was launched in 1999; right?

13 A. I do not recall when it was launched.

14 Q. I'll refer -- maybe it will refresh your
15 memory if you could check the fourth sentence of the
16 page, starting with "Since the commercial launch..."

17 A. Okay, yes. Thank you.

18 Q. And that refreshes your memory that the
19 Luminex 100 --

20 A. Yes.

21 Q. -- System was launched in 1999?

22 A. Yes.

1 Q. And the Luminex 100 System was, like
2 BeadXpress, used in genotyping, gene expression,
3 kinase selectivity, protein, and immunoassays?

4 A. Yes, it was --

5 Q. And Luminex --

6 A. -- capable of all those things.

7 Q. And Luminex, like Illumina, also reached
8 partnership agreements with other research and
9 diagnostic companies; right?

10 A. That's correct.

11 Q. Which is similar to the customer base of
12 the BeadXpress system and VeraCode technology that
13 we discussed earlier today; right?

14 A. I'm sorry? Can you ask that again?

15 Q. Yeah.

16 That's similar to the customer base that
17 we discussed earlier today for Illumina's BeadXpress
18 system and VeraCode technology?

19 A. Our customer base was -- we -- we had
20 similar customers. We also had additional customers
21 than -- than Luminex did.

22 Q. And like Illumina's customers, some of

1 Luminex's customers partnered to develop and market
2 their own branded assays to run on the Luminex
3 system; right?

4 A. It is correct that Luminex partnered with
5 other companies to offer their own tests.

6 Illumina did not offer tests that were
7 branded by other partners.

8 Your -- I think your question said Luminex
9 did that like Illumina. But Luminex did it.

10 I'm not agreeing that Illumina did that.

11 Q. Illumina had partnerships with other
12 companies to develop -- for those companies to
13 develop assays?

14 A. That's correct.

15 Q. When there's an LDT in 2008 developed by
16 using the BeadXpress in a customer's laboratory --

17 A. Uh-huh.

18 Q. -- what physical form does that LDT
19 take?

20 A. I don't -- I don't understand the -- the
21 question. That's kind of --

22 Q. An LDT is a thing; right?

1 A. It's a service.

2 Q. It's a service?

3 A. Yeah, a lab-developed test is a service.

4 Q. So there's not a physical product that
5 comes out of an LDT?

6 A. There are physical products that go into
7 the process in the lab that results in a -- in a
8 test offered by that lab.

9 A lab-developed test is a -- is a test
10 service where a lab purchases equipment and
11 consumables to offer that service in their lab.

12 Q. Uh-huh. And so when you say that unlike
13 Luminex, Illumina's -- excuse me.

14 So when one of Illumina's customers in
15 2008 developed an LDT, the output would be data?

16 A. A test report.

17 Q. A test report?

18 A. Yes.

19 Q. Would it be sent in some form to whoever
20 ordered the test?

21 A. To a physician, most likely.

22 Q. And that would be sent by the lab that is

1 Illumina's customer to the person who ordered the
2 test; right?

3 A. Yes.

4 Q. They wouldn't forward it to Illumina, and
5 then Illumina would forward it to the person --

6 A. Oh, no.

7 Q. -- who ordered the test?

8 That would be ridiculous; right?

9 MR. HORNE: Argumentative.

10 BY MR. HANKINSON:

11 Q. Well, it's just because you said, "Oh, no"
12 as if it would be calamitous.

13 A. We -- no, Illumina would not consume their
14 data prior to it being presented to whomever the
15 customer is of their lab service.

16 Q. And Illumina would not control the
17 contents of the report that went from the lab that
18 was Illumina's customer to the person who ordered
19 the results of the LDT?

20 A. They would not control that, no.

21 Q. Illumina would also not control any
22 branding associated with that report; correct?

1 A. No, they would not control that
2 branding.

3 Q. Are LDTs sometimes referred to as
4 "homebrews"?

5 A. Yes.

6 Q. Is there anything else that's included in
7 the term "homebrews"?

8 A. I'm -- I'm not aware of all of the uses of
9 that term.

10 Q. When you and Ms. Henshall used the term
11 "homebrews" in the launch packet, that is
12 Exhibit 33 --

13 A. Uh-huh.

14 Q. -- did you mean it to be synonymous with
15 LDTs?

16 A. Yes.

17 MR. HORNE: You mean Exhibit 303?

18 MR. HANKINSON: Excuse me.

19 303.

20 BY MR. HANKINSON:

21 Q. And your answer is the same?

22 A. Yes.

1 Q. In the "Pricing Restrictions" row of the
2 table on page 5 of Exhibit 303, under the columns
3 for "Illumina BeadXpress" and "Luminex," there is a
4 reference to "homebrew" in both columns, both for
5 Illumina BeadXpress and for Luminex; right?

6 (Document reviewed by the witness.)

7 THE WITNESS: Yes.

8 BY MR. HANKINSON:

9 Q. In the column for "Illumina BeadXpress" --
10 Did you get a spelling for "BeadXpress"?

11 DEPOSITION OFFICER: I did.

12 MR. HANKINSON: Okay.

13 DEPOSITION OFFICER: Thank you.

14 BY MR. HANKINSON:

15 Q. In the column for Illumina BeadXpress it
16 says:

17 "Customers developing
18 homebrews will need to optimize
19 reagents and workflow to
20 determine pricing (like Luminex)."

21 Did I read that correctly?

22 A. Yes.

1 Q. Can you explain in what way that was like
2 Luminex?

3 A. The -- both technologies had varying
4 multiplex capability, and so a single analyte assay
5 would cost a different amount than a multi-analyte
6 test or assay.

7 Q. If you were using a lower level of
8 multiplexing, then you wouldn't be maximizing the
9 capabilities of reducing the price of the test?

10 A. That's incorrect.

11 Q. Okay. Please correct me.

12 A. We offered beads in such a way that a
13 customer could run a single analyte test in a
14 cost-effective way.

15 Q. The cost per test would scale up and down
16 depending on multiplexing in the same way that it
17 would with Luminex's product?

18 Now do I have that correctly?

19 A. Yes, I -- yes, that's true.

20 Q. Then in the row that says "Number Apps
21 (GE, et cetera)," what does "Number Apps (GE, et
22 cetera)" mean?

1 A. It's talking about the number of
2 applications. I -- I don't recall what "GE" stood
3 for, but I'm going to assume it meant "gene
4 expression, et cetera."

5 Q. And --

6 A. The applications the system was capable
7 of.

8 Q. And in the column for "Illumina
9 BeadXpress," the applications that are listed are
10 "genotyping protein assays" and "gene expression";
11 right?

12 A. That's what it says, yes.

13 Q. And the same three applications, although
14 in a different order, are found in the column under
15 "Luminex"; right?

16 A. Yes, that's right.

17 Q. So in late 2008, Illumina BeadXpress and
18 Luminex, it says, 100 system were offered to an
19 overlapping pool of customers, each at a price
20 within the tens of thousands of dollars, each
21 sometimes used in developing homebrews or LDTs, and
22 each with the potential applications of genotyping

1 protein assays and gene expression.

2 Did I summarize that correctly?

3 A. Yes.

4 Q. If you could turn in Exhibit 303 -- excuse
5 me -- still on page 5 of Exhibit 303, "Sequenom" is
6 another competitor to Illumina BeadXpress that's
7 listed; right?

8 A. Yes.

9 Q. And that's S-e-q-u-e-n-o-m; right?

10 A. Yes.

11 Q. Is that still a competitor of Illumina?

12 A. Yes.

13 Q. Illumina offers the MiSeq product which
14 ends in S-e-q; correct?

15 A. Yes.

16 Q. And also the HiSeq product that ends in
17 S-e-q?

18 A. Yes.

19 Q. And at one point Illumina offered a
20 research-use-only assay called "GoldenGate"; is that
21 accurate?

22 A. Yes.

1 Q. And in 2008 Sequenom offered an iPLEX gold
2 assay; is that right?

3 A. Yes.

4 Q. Could you turn to page 14 of Exhibit 303.

5 Under "Ordering Information" there's a
6 reference to catalog numbers.

7 Do you see that?

8 A. Yes.

9 Q. Could you explain to me what the catalog
10 is that the catalog numbers are in?

11 A. Um --

12 Q. Or if that's a stupid question, just
13 explain why.

14 MR. HORNE: And I won't object
15 "argumentative."

16 THE WITNESS: It's a -- there's -- those
17 numbers are a way for us to refer to our -- our
18 products on the web and in different systems within
19 the organization.

20 BY MR. HANKINSON:

21 Q. Customers can use these catalog numbers to
22 order the products that they want; is that

1 accurate?

2 A. Yes.

3 Q. And they see them on the web sometimes, at
4 least?

5 A. Sometimes they're presented on the web.

6 Q. Can you order directly from the web?

7 A. Yes.

8 Q. Can you also order by calling your sales
9 rep?

10 A. Yes.

11 Q. Do you have any sense of what percentage
12 of the sales are made through the web as opposed to
13 through sales reps?

14 A. I don't know.

15 Q. Do you have any sense of whether
16 laboratory customers typically purchased through a
17 sale rep or through purchases on the web?

18 A. I'm -- I'm not aware of how -- what --
19 what frequency of orders are online versus to a
20 sales rep.

21 Q. Do laboratory customers typically have a
22 purchase-order system that they go through?

1 A. Yes.

2 Q. So when a lab customer purchases the
3 product from Illumina, the lab director is the
4 person who makes the final decision about whether to
5 order?

6 Is that accurate or not accurate?

7 A. I'm sorry? Can you ask that question
8 again?

9 Q. Yeah.

10 When a laboratory customer orders a
11 product from Illumina, does the lab director make
12 the final decision about whether to make that
13 purchase?

14 MR. HORNE: Vague, lacks foundation.

15 THE WITNESS: I don't know if all cases
16 it's the final decision. The lab director is a key
17 stakeholder in the decision-making process.

18 BY MR. HANKINSON:

19 Q. Who are the other key stakeholders in the
20 decision-making process?

21 A. A medical director, hospital
22 administration. There may be others.

1 Q. When it's the hospital administration, is
2 that a purchasing department?

3 A. I -- I was -- I was thinking higher up in
4 the organization, like president. And also -- I
5 mean, yes, purchasing agents are involved in the
6 process.

7 Q. So at times the president of the hospital
8 is involved in deciding whether to purchase a
9 product from Illumina?

10 A. I'm sorry?

11 Were you saying from Illumina or in
12 general?

13 Q. From Illumina.

14 A. Yes, in some cases that could be the case.

15 Q. Is the medical director usually somebody
16 who's placed within the laboratory or somebody who
17 is outside of the laboratory?

18 A. I'm not sure if they are necessary to
19 reporting into a laboratory organization, but that
20 would be a stakeholder that would provide feedback
21 on the medical need.

22 Q. Have we covered all of the stakeholders of

1 which you are aware in decisions among customers to
2 purchase Illumina's products?

3 A. I -- in that conversation I was really
4 thinking about a clinical use.

5 There might be other stakeholders in
6 different uses of the technology. Yeah, there --
7 there may be others --

8 Q. How --

9 A. -- based on different uses.

10 Q. How would that be?

11 A. Well, for -- for example, if we're talking
12 about agriculture, it's a different set of
13 stakeholders.

14 If we're talking about pharmaceutical
15 partnerships, it's a different set of stakeholders
16 that are deciding whether or not they want to use
17 that technology.

18 Q. As opposed to a clinical use?

19 A. A clinical use, yeah.

20 Q. And so you're saying the stakeholders at
21 places like that, agricultural and pharma
22 partnerships, would be different stakeholders

1 because you're not dealing with the same
2 stakeholders as in a clinical setting; is that
3 right?

4 A. Yes.

5 Q. The prices of Illumina's BeadXpress system
6 on page 14 -- actually, it's just one price for two
7 different catalog numbers.

8 There's a "List Price NA_EU" that's 98,500
9 dollars; right?

10 A. Yes.

11 Q. Is that North America and Europe?

12 A. Yes.

13 Q. Oh, my God. I got it right.

14 And then there's "List Price ROW" that's
15 118,200 dollars; right?

16 A. Yes.

17 Q. What is "List Price ROW"?

18 A. "Rest of World."

19 Q. And the price of the BeadXpress system --
20 is the BeadXpress system no longer offered?

21 A. The BeadXpress system is no longer
22 offered.

1 Q. It sounds like you wanted to say something
2 else.

3 A. Well, it -- it was like a double negative.
4 I didn't know how to -- whether to say "Yes" or "No"
5 to your question, so I'm restating that the
6 BeadXpress system is no longer offered.

7 Q. Thank you.

8 A. It -- it is, however, supported by the
9 organization. There are people still using it.

10 Q. When did it -- when did it -- when was it
11 discontinued?

12 A. I don't remember the exact date it was
13 discontinued.

14 Q. Was it after 2009?

15 A. I don't recall.

16 Q. In late 2008, at the bottom of page 14 --

17 A. Uh-huh.

18 Q. -- there is also a "BeadXpress Starter
19 Kit." The description actually goes on to page 15.

20 A. Uh-huh.

21 Q. And the starter kit has a North American
22 and European price of 3,237 dollars; right?

1 A. Yes.

2 Q. And then at the time, there was a
3 GoldenGate assay for research use only; right?

4 A. Yes.

5 Q. And the satellite kit for GoldenGate for
6 BeadXpress would cost a customer 18,940 dollars in
7 North America and Europe; right?

8 A. Yes.

9 Q. And the GoldenGate accessories kit, which
10 was optional, would cost an additional 94,683
11 dollars in North America and Europe in 2008;
12 right?

13 A. Yes.

14 Q. Different catalog codes apply to purchases
15 of training services; right?

16 A. Yes.

17 Q. And if we look, for example, on page 17
18 at the VeraCode GoldenGate training kit --

19 A. I'm sorry?

20 Q. Excuse me.

21 I should --

22 A. Where are you again?

1 Q. On page 17.

2 A. Okay.

3 Q. And let's actually look at -- well, let me
4 ask generally.

5 How often was training purchased alongside
6 of a BeadXpress platform?

7 A. The catalog number of the BeadXpress
8 platform included a one-day training. It was not
9 common for a customer to order additional training
10 because it was included in the instrument.

11 Q. So the training was not just recommended,
12 but included in the price of purchasing the
13 system?

14 A. That's right.

15 Q. The page -- at page 18 of Exhibit 303, we
16 get to solve the mystery of the word that I was
17 trying to remember earlier.

18 It's "oligonucleotide."

19 A. Okay.

20 Q. So on page 18 there begins a list of
21 catalog numbers for "VeraCode Universal Capture Bead
22 Set" where that's the description of the product for

1 many, many rows of this list of catalog numbers --

2 A. Yes.

3 Q. -- right?

4 A. Yes.

5 Q. And the only distinction in the

6 description of the product -- excuse me.

7 What's the column that I'm referring to?

8 The title of the product? The product name?

9 A. The VeraCode Universal Capture Beads.

10 Q. And is that the product name or the

11 product title?

12 A. That's the -- the product name.

13 Q. So the product name for the following --

14 one, two, three, four, five, six, seven, eight --

15 nine pages, each with five or six products per page.

16 The product name is the same for each row,

17 "VeraCode Universal Capture Bead Set," except that

18 there's a different number at the end.

19 A. Yes.

20 Q. And it's a four-digit number in each

21 case?

22 A. Yes.

1 Q. So there's at least three dozen different
2 VeraCode Universal Capture Bead Sets that are
3 differentiated in product name only by number --

4 A. Yeah.

5 Q. -- at the end; right?

6 A. Yes.

7 Q. And the next column over to the right, is
8 that like a product description?

9 A. Yes.

10 Q. And so for the several pages, and over
11 three dozen products that are titled "VeraCode
12 Universal Capture Bead Set," the product description
13 is also completely identical for each product except
14 for a series of letters in parentheses in the middle
15 of each description.

16 Do I have that right?

17 (Document reviewed by the witness.)

18 THE WITNESS: Yes.

19 BY MR. HANKINSON:

20 Q. And the series of letters in parentheses
21 on the fourth line of each description for the
22 VeraCode Universal Capture Bead Set sets out a

1 different combination of the letters T, C, G, and A;
2 right?

3 A. Yes.

4 Q. And those are -- tell me what the vocab
5 is. It has to do with DNA or RNA.

6 What are T, C, G, and A?

7 A. Those are bases of nucleic acid.

8 Q. And when you're sequencing DNA or RNA, it
9 is expressed in series of these letters, T, C, G,
10 and A; is that right?

11 A. I -- I just want to make sure there's not
12 confusion that this is a sequencing solution.

13 Q. Sorry. Please explain it to me.

14 A. This -- this series of letters is a code
15 that -- or a series -- it's an oligonucleotide
16 that's attached to the bead.

17 And we refer to this series of bases as
18 the unique Illumina code; it's the unique identifier
19 for that bead.

20 Q. And what are the different beads with the
21 different oligonucleotides used to do?

22 A. It's a capture sequence, so an assay

1 that's being developed to target some molecular
2 signature would be tagged with a complement of this
3 string of bases so that it could be captured and
4 detected on the BeadXpress.

5 Q. And there -- these are a series of many
6 dozens of preloaded oligonucleotides?

7 A. These oligos are attached to the beads
8 before being received by a customer.

9 Q. And "Illumina Code" appears nowhere -- the
10 words "Illumina Code" appears nowhere in the product
11 description; right?

12 A. It does not appear in the product
13 description.

14 Q. The series of the letters T, C, G, and A
15 within the parentheses of each product description,
16 are those of uniform length? They always have the
17 same number of letters?

18 A. I -- I don't know for certain if they are
19 exactly the same length.

20 I haven't counted them for every single
21 one, but the combination and order has a certain
22 melting temperature that's uniform.

1 I'm -- I'm sorry.

2 The bond that's created in that capture
3 has a -- a certain melting temperature, and that
4 combination of letters is -- is designed for that.

5 Q. And the series of letters, there's more
6 than 20 letters in each series; right?

7 (Document reviewed by the witness.)

8 THE WITNESS: Sure. Yes.

9 BY MR. HANKINSON:

10 Q. And so looking at the product description,
11 one can differentiate these products by checking the
12 series of 20 letters to see if that order of the
13 letters T, C, G, and A is the one that you want; is
14 that right?

15 A. No.

16 Q. Its the only difference in this table;
17 correct?

18 MR. HORNE: Lacks foundation.

19 THE WITNESS: This -- this table is
20 designed for a sales rep and for a field-application
21 scientist to help a customer.

22 The ordering information -- the last four

1 digits of the catalog number, being -5440, is the
2 identifier of the bead.

3 BY MR. HANKINSON:

4 Q. So once you figure out which one you want,
5 you can know the -- you can get the catalog number
6 and just refer to it by that?

7 Is that what you're saying?

8 A. Yes.

9 Q. And the sales rep and field-application
10 scientist would be available to assist a customer
11 in, you know, selecting which 20-letter sequence
12 oligonucleotide the customer needs?

13 A. The exact combination of -- of letters
14 isn't really important to the customer.

15 We -- what's important to the customer is
16 the 5440, for example. It's the first one on this
17 page.

18 And the association of that to this line
19 of letters is provided for service and sales as a
20 reference.

21 Q. In order to help them when they're dealing
22 with customers?

1 A. It -- it's more of a troubleshooting tool,
2 if -- if they needed that information, but --

3 Q. Because it's the --

4 A. -- it's not --

5 Q. Because it's the difference between
6 these --

7 A. Yeah. It's not a --

8 Q. -- products; right?

9 A. The -- it's useful for internal people to
10 have access to that code.

11 Q. Because it's the differentiator between
12 the products; right?

13 A. Because it's -- it -- it's used as part of
14 the detection mechanism of the -- it's a handle that
15 is used, so it's useful for them to know that.

16 Q. So the field reps -- excuse me.

17 The field-application scientists and the
18 sales reps have the education or training to make
19 use of this information about the oligonucleotide
20 when they need to; is that accurate?

21 A. There's -- there was software available to
22 the customer and to the sales rep that makes this

1 combination. They don't need to think about it.

2 Q. So there's a software that the customer
3 uses to select which catalog code --

4 A. Yes.

5 Q. -- they would choose, and that has to be
6 provided by Illumina to the customer?

7 A. Yes.

8 Q. And so when the customer wants to figure
9 out what product to order, they go into the Illumina
10 software and then figure it out there and then make
11 their order?

12 A. The software is useful in the design of
13 the assay that they're using these beads for.

14 Q. So before they ever make -- even make the
15 decision to purchase, they're actually using
16 software to design an assay?

17 A. No.

18 The decision to purchase is "I have a need
19 for a multiplex assay, and I'm going to use these
20 beads."

21 And the selection of the number of the
22 beads is associated with how many analytes they

1 wanted to test.

2 When they received them and are trained to
3 use them, there was software that managed this code
4 of sequences.

5 Q. Are there a --

6 A. They don't think about that in the
7 ordering process.

8 Q. Are there a ton of errors?

9 A. No, because they're software.

10 Q. So there's no errors?

11 A. I'm sorry?

12 MR. HORNE: Vague.

13 THE WITNESS: Um --

14 BY MR. HANKINSON:

15 Q. Do the customers make mistakes then have
16 to trade out the orders because they got the wrong
17 thing?

18 A. I've never experienced that happening.

19 Q. If you turn to the Frequently Asked
20 Questions --

21 A. Uh-huh.

22 Q. -- at the -- in Exhibit 303, they start at

1 page 32.

2 A. Uh-huh.

3 Q. These are questions that were frequently
4 asked by customers; right?

5 A. No.

6 The idea of a Frequently Asked Question
7 was a tool that marketing provides to sales
8 anticipating what -- what is the possible realm of
9 questions that you might get asked, and trying to
10 provide an answer.

11 It wasn't necessarily the other way
12 around.

13 Q. It was anticipating what questions would
14 be frequently asked?

15 A. Anticipating questions and providing an
16 answer.

17 Q. "Frequently asked" is just a meaningless
18 term here?

19 A. It's a --

20 Q. You weren't trying to anticipate --

21 A. It's kind of jargon, I guess is what I'm
22 trying to say.

1 Q. But you --

2 A. The term "Frequently Asked Questions" is
3 jargon.

4 Q. You weren't trying to anticipate every
5 single question; you were trying to anticipate
6 questions that would come up with a reasonable
7 degree of frequency?

8 A. The -- the frequency is kind of arbitrary.
9 It's "Here's some canned answers for you,
10 sales rep. I want to provide you answers that you
11 might get asked."

12 Q. By the customer?

13 A. By a customer.

14 Q. Can you turn to page 34.

15 A. Uh-huh.

16 Q. The question -- this is the last one on
17 page 34 is:

18 "What makes your product
19 better than Luminex? They seem to
20 be similar technologies."

21 Do you see that?

22 (Document reviewed by the witness.)

1 THE WITNESS: Yes, I do.

2 I'm sorry. I was reading it.

3 BY MR. HANKINSON:

4 Q. And that refers to the Illumina BeadXpress
5 and the Luminex product that we were comparing in
6 the table on page 5; right?

7 A. Yes.

8 Q. If you look at page 36 at the first
9 question, it's:

10 "Can the BeadXpress Reader be
11 used for diagnostic testing?"

12 Do you see that question?

13 A. Yes.

14 Q. The answer is:

15 "The BeadXpress Reader is
16 currently labeled as a "Research
17 use only" instrument, so it has
18 not been reviewed by the FDA.

19 "But we have had a lot of
20 interest expressed by CLIA high
21 complexity certified labs who are
22 interested in developing homebrew

1 assays with the technology."

2 Did I read it accurately?

3 A. Yes.

4 Q. So in the "Frequently Asked Questions"
5 section of the training materials given to sales
6 reps for the launch of the BeadXpress system and
7 VeraCode technology in late 2008, it was anticipated
8 that customers might ask whether the BeadXpress
9 Reader can be used for diagnostic testing; right?

10 That's why this is here?

11 A. Yes.

12 Q. And the answer given to the sales reps, as
13 you referred to as like the "canned answer," is
14 that:

15 "While it's research use
16 only, a CLIA high complexity
17 certified lab could make an
18 LDT."

19 And that would be the only thing the sales
20 rep would be told about diagnostic testing using the
21 BeadXpress Reader; right?

22 A. The answer that was provided was that a

1 CLIA high complexity lab that is interested in
2 homebrew assays might be interested in the
3 technology.

4 Q. There were no other customers listed in
5 response to the question about whether the
6 BeadXpress Reader could be used for diagnostic
7 testing in this launch package; right?

8 A. I'm sorry? Could you restate the
9 question?

10 Q. Yeah.

11 There's no other customers besides CLIA
12 high complexity certified labs that are listed in
13 the answer to this frequently asked question about
14 whether the BeadXpress Reader could be used for
15 diagnostic testing?

16 A. That's correct.

17 Q. Later on the same page, page 36 of
18 Exhibit 303, the second question up from the bottom,
19 within -- before the "Regulatory Terminology"
20 heading, it asks:

21 "Can the GoldenGate
22 genotyping assay be used for

1 diagnostic testing?"

2 Do you see that?

3 A. Yes.

4 Q. And there the answer is just:

5 "The GoldenGate genotyping

6 assay is a research-use-only

7 product. It has not been

8 reviewed by the FDA."

9 Did I read that correctly?

10 A. Yes.

11 Q. So there are no diagnostic testing

12 customers that could have made use of the GoldenGate

13 genotyping assay for those purposes at that time; is

14 that right?

15 MR. HORNE: Lacks foundation.

16 THE WITNESS: It -- no, it's not right.

17 BY MR. HANKINSON:

18 Q. The sales reps were told to respond that,

19 "The GoldenGate genotyping assay is a

20 research-use-only product"; right?

21 A. Yes.

22 Q. The next question down says:

1 "I work in a CLIA high
2 complexity lab and would like to
3 develop tests using the VeraCode
4 technology.

5 "Will Illumina help me
6 with designing and validating
7 a test?"

8 Did I read that right?

9 A. Yes.

10 Q. When this question asks about developing
11 tests using the VeraCode technology, is that
12 referring to LDTs or homebrews?

13 A. Yes.

14 Q. And the implication here is that the LDTs
15 or homebrews must be designed and validated, right,
16 by someone?

17 A. Yes.

18 Q. And the question is:

19 "Will Illumina help
20 with that?"

21 A. Yes.

22 Q. The answer is:

1 "No. Illumina can provide
2 technical support for working with
3 the VeraCode products and assist
4 with troubleshooting, but the CLIA
5 high complexity lab is responsible
6 for designing and validating their
7 own tests."

8 Did I read that right?

9 A. Yes.

10 Q. The technical support for working with the
11 VeraCode products and the troubleshooting, those are
12 not designing and validating the tests; right?

13 A. That is correct.

14 Q. Those are related to like customer
15 service, troubleshooting issues if the machine's not
16 working right; right?

17 A. That would certainly be covered, among
18 other things.

19 Q. But none of the things involved with
20 technical support and assisting with troubleshooting
21 would be the design and validation of the test?

22 A. We did not assist a customer in designing

1 their test or validating their test.

2 Q. And you weren't permitted to; right?

3 A. That's correct.

4 Q. And why not?

5 A. Because they were not FDA approved.

6 Q. "They were not"?

7 Is that what you said?

8 A. I said "they."

9 Q. And who --

10 A. Well --

11 Q. -- are you referring to by "they"?

12 A. I'm sorry.

13 I was referring to the beads.

14 The product was not FDA approved or

15 cleared.

16 Q. Can Illumina's IVD products be purchased

17 and used by doctors in an office as opposed to a

18 laboratory setting?

19 A. Can they?

20 Q. According to regulations.

21 A. No.

22 Q. Did you say "No"?

1 A. No. The answer's "No."

2 Q. So certainly they wouldn't be marketed to
3 doctors sitting in offices as opposed to
4 laboratories?

5 A. We would not do marketing to physicians
6 for purchase of the technology; however, we do have
7 marketing of our IVD tests to build awareness to an
8 ordering physician.

9 They're not -- they're not the direct
10 purchaser, but they're a -- a stakeholder in the
11 process.

12 Q. The stakeholders who are involved in
13 purchasing decisions for Illumina's products to be
14 used in connection with clinical diagnostics
15 include, as we had spoken about before, hospital
16 administrators, which might be the president or
17 someone very high up at the hospital, and it might
18 also include a purchasing agent or purchasing
19 department, the lab director, and the medical
20 director; right?

21 A. I'm sorry? Can you ask the question
22 again?

1 It was a -- a long question.

2 Q. It was. I'm just trying to get back to a
3 topic.

4 A. Okay.

5 Q. So the stakeholders --

6 A. Uh-huh.

7 Q. -- that are involved in the purchasing
8 decisions for Illumina's products for use in
9 relation to clinical diagnostics --

10 A. Uh-huh.

11 Q. -- include lab directors, medical
12 directors, and hospital administration; right?

13 A. All of those people could be involved.

14 Q. And the hospital administration can
15 include someone as high up as the president of the
16 hospital, and it can also include a purchasing agent
17 or purchasing department at the hospital; right?

18 A. Yes.

19 In the event we're working on a large,
20 committed, recurring revenue, oftentimes people high
21 up in the organization would be involved.

22 Like a recurring test order -- a

1 commitment to a recurring test order would be -- may
2 involve hospital administration.

3 Q. And if there's not a high volume of
4 recurring revenue, then when you say that the
5 hospital administration is involved as a
6 stakeholder, it probably refers more to a purchasing
7 agent?

8 A. That's right.

9 DEPOSITION OFFICER: Did you say
10 "occurring" or "recurring"?

11 THE WITNESS: Recurring.

12 MR. HANKINSON: Recurring.

13 DEPOSITION OFFICER: I was asking him.

14 Thank you.

15 THE WITNESS: I'm sorry.

16 DEPOSITION OFFICER: Not you, him. It was
17 what he said.

18 Thank you.

19 BY MR. HANKINSON:

20 Q. A lab director, in this context, would be
21 someone with at least a Ph.D; right?

22 A. It's usually either a Ph.D or a

1 pathologist.

2 Q. A pathologist being a medical degree?

3 A. Uh-huh. Yes.

4 Q. A medical director, would that person
5 normally have a medical degree?

6 A. Yes.

7 And that -- that's another example of a
8 stakeholder that would be involved if it's a
9 multi-year, high-volume commitment.

10 That's a -- usually not involved in the
11 first purchase, but if we're making a big deal with
12 a hospital for a multi-year commitment, then that
13 person's usually involved.

14 Q. Uh-huh. Excuse me.

15 Yes.

16 A purchasing agent within the hospital
17 would be someone whose job is to purchase products
18 and to see that process through for many, many
19 different products at the hospital.

20 Do I have that right?

21 A. I -- I don't know if they're responsible
22 for multiple products or not, but from my experience

1 a purchasing agent places orders.

2 Q. So it could be the case that there's a
3 person just responsible for one type of product
4 purchase at the hospital?

5 A. I -- I just didn't -- you said many, many
6 products. I -- I don't know what breadth of
7 products every purchasing agent purchases, so...

8 Q. Their job is to buy things for the
9 hospital?

10 A. Their job is to buy stuff, yeah.

11 Q. Does their job include either agreeing to
12 or negotiating the price of the products?

13 A. It could be.

14 Q. Does their job include making sure that
15 the hospital's purchase-order process is followed?

16 A. I don't know.

17 Q. What's your best understanding of what a
18 purchasing agent does for a hospital in connection
19 with products like Illumina's?

20 A. Placing purchase orders, ordering or
21 reordering product.

22 Q. Did you have any sort of non-compete

1 agreement when you left Nanogen?

2 A. I don't remember.

3 Q. Did Illumina ever inquire whether anything
4 would prevent you from working in the same industry
5 as Nanogen?

6 A. I don't remember.

7 Q. Do you think you would remember if it had
8 happened?

9 A. There was -- there was some sort of
10 process when I was hired, and I think that question
11 may have been asked, but I don't -- I don't remember
12 exactly. It was a long time ago.

13 Q. 2007?

14 A. Yeah.

15 Q. Do you remember who you're thinking of
16 that may have asked the question?

17 A. No.

18 Q. Just part of your on-boarding?

19 A. Yes. There's an on-boarding process at
20 Illumina.

21 Q. I don't mean to like focus on it too much,
22 but I'm just trying to figure out what the status

1 of "I think I remember that it might have been
2 asked" is.

3 I mean, there's something that's prompting
4 you not to just say, "No, it definitely wasn't
5 asked."

6 A. I just kind of -- I just kind of remember
7 it coming up. I -- I don't -- I don't remember
8 exactly what the conversation was around
9 non-compete.

10 There might have been something about
11 Illumina.

12 I -- I just -- it was never an issue. I
13 never had a non-compete conversation about
14 Nanogen.

15 Q. In your declaration submitted in this
16 case, at one point you discuss Illumina's attempt to
17 position the BeadXpress platform to the molecular
18 diagnostics market where Luminex Corp was a
19 competitor.

20 So Luminex was in the molecular
21 diagnostics field at the time?

22 A. Yes.

1 Q. And when Illumina wanted to position
2 BeadXpress in that platform, it would in a sense
3 become a competitor of Luminex by moving into that
4 field?

5 Do I have that right?

6 A. Illumina -- I -- I don't know that I agree
7 that the first intention to move into diagnostics
8 had to do with the BeadXpress.

9 Q. Okay.

10 A. The -- the vision of the company was
11 always to be a player in personalized medicine.

12 DEPOSITION OFFICER: "A player in...?"

13 THE WITNESS: "Personalized medicine."

14 DEPOSITION OFFICER: Thank you. I
15 couldn't hear the last word.

16 BY MR. HANKINSON:

17 Q. Prior to your time in 2007, you're saying
18 that that was the case?

19 A. I'm sorry? What's the question?

20 Q. Well, you said it had always been.

21 A. There was a --

22 Q. But you started in 2007, and the company

1 was founded in 1998, so I'm asking if you are
2 referring to the time before you came or just after.

3 A. We were -- we just were talking about our
4 vision statement as a company, and --

5 Q. Who was when?

6 A. My boss, John White, presented to my team
7 Illumina's vision statement and how it has modified
8 over the years. I mean --

9 Q. And when was that presentation?

10 A. This week.

11 Tracking over time, it showed that
12 Illumina was interested in personalized medicine.

13 Q. Do you understand that there were
14 corporation restructurings in 2008, 2011, and
15 2013?

16 A. Yes.

17 Q. And you're referring now to a presentation
18 that was given to you last week characterizing what
19 the company's vision had been in the past?

20 Is that what you're saying?

21 A. Yes.

22 Q. Did you take any steps to verify that the

1 characterization given in that presentation was true
2 as of the times that were being characterized?

3 A. No.

4 Q. So we jumped off there because you took
5 issue with whether my question was about a
6 particular time related to BeadXpress or the
7 company's vision.

8 A. Yeah.

9 Q. I'm going to quote from your declaration.
10 And -- I'm sorry. I didn't bring you a
11 copy.

12 A. Okay.

13 Q. But paragraph 5 says:

14 "By that time" -- the first
15 half of 2008 --

16 A. Okay.

17 Q. (READING):

18 -- "Illumina was positioning
19 the BeadXpress platform to the
20 molecular diagnostics market where
21 Luminex Corp was a competitor."

22 A. Yes.

1 Q. So you're with me there?

2 A. Yes.

3 Q. And so BeadXpress, at the first half of
4 2008, was already an existing product; right?

5 A. Yes.

6 Q. It had been sold prior to that time; it
7 wasn't like a new product that was about to
8 launch?

9 A. Yes.

10 Q. But it had been a research-use-only
11 product; right?

12 A. Yes.

13 Q. And it had been used in academic and other
14 research environments up to that time; right?

15 A. The -- it had been used in research and
16 academic environments and other environments as
17 well.

18 Q. And in the first half of 2008, an
19 environment that Illumina was positioning it for --

20 A. Uh-huh.

21 Q. -- forward going --

22 A. Yeah.

1 Q. -- was the molecular diagnostics market --

2 A. Yes.

3 Q. -- where Luminex Corp was a competitor; is
4 that right?

5 A. Yes.

6 Q. Luminex, at that time, had molecular
7 diagnostic tests for influenza; right?

8 A. Yes.

9 Q. And Luminex had a product named xMAP at
10 that time; right?

11 A. Yes.

12 Q. And Illumina was -- and there's -- here's
13 another quote from your declaration, paragraph 5:

14 A. Okay.

15 Q. (READING):

16 "Both Luminex's xMAP" --

17 MAP capitalized, "x" is little.

18 -- "and Illumina's BeadXpress

19 could be used to detect variants

20 in DNA in a multiplex fashion

21 leveraging beads."

22 So as BeadXpress was positioned to enter

1 the molecular diagnostics market, a product of
2 Luminex's that it would be competing with
3 potentially was xMAP.

4 Do I have that right?

5 A. Yes.

6 Q. But in order to do that, the BeadXpress
7 would have to be used in the context of an LDT
8 because Illumina did not have, and was not planning
9 to develop, an FDA cleared or approved assay; right?

10 MR. HORNE: Compound, lacks foundation.

11 THE WITNESS: I disagree that we did not
12 intend to develop assays to be FDA cleared or
13 approved.

14 BY MR. HANKINSON:

15 Q. But with respect to BeadXpress --

16 A. Uh-huh.

17 Q. -- that was not how BeadXpress was being
18 positioned to enter the molecular diagnostics market
19 at the time; right?

20 MR. HORNE: Vague.

21 THE WITNESS: Can you re-ask the question?

22 BY MR. HANKINSON:

1 Q. Yeah.

2 BeadXpress was a platform that could be
3 positioned to be used by CLIA high complexity
4 certified labs to create LDTs that then might test
5 for things like influenza, potentially; right?

6 A. Yes.

7 Q. That was the intent in late 2008?

8 A. That was an -- an intent.

9 Q. BeadXpress was never going to be an assay;
10 it was a platform on which assays could be run.

11 Right?

12 A. The BeadXpress was an instrument, and the
13 consumables sold were -- made up the assay. We --
14 we offered consumables.

15 Q. Well, the consumables being sold were not
16 assays?

17 A. We offered our GoldenGate assay and the --

18 Q. For research use only; right?

19 A. They're labeled as "For research use
20 only."

21 Q. Okay.

22 A. That's right.

1 Q. And the BeadXpress -- the other -- you
2 know, the consumables were not assays, right?

3 A. We offered our -- a methylation and a gene
4 expression assay.

5 Q. Again, for research use only at the
6 time?

7 A. Those were labeled "For research only."

8 MR. HORNE: Vague.

9 BY MR. HANKINSON:

10 Q. When you say that the consumables
11 could be, you know, made into assays, that's through
12 an LDT from a CLIA high complexity certified lab;
13 right?

14 That's what you're referring to?

15 A. The -- to me, an assay is the assay
16 process. That's why I'm confused with your
17 question.

18 When you said --

19 Q. So you would agree that a consumable
20 cannot be an assay, because one is a thing and
21 another is a process?

22 A. Sometimes I've used the word "consumable"

1 in a -- in a synonymous -- synonymous way with our
2 assays or our -- our products. So I would say some
3 are packaged assays and some are components, when I
4 say "consumable."

5 Q. And at the time, in the last half of 2008,
6 if Illumina had been marketing its consumables as an
7 assay for diagnostic purposes, it would have been in
8 trouble; right?

9 That was a no-no?

10 MR. HORNE: Vague.

11 THE WITNESS: Can you ask me that question
12 again?

13 BY MR. HANKINSON:

14 Q. Sure.

15 At the time, in the second half of 2008,
16 if Illumina had been marketing its consumables as
17 assays for diagnostic purposes, it would have been
18 in trouble?

19 MR. HORNE: Same objection.

20 THE WITNESS: I don't know the answer to
21 that question.

22 BY MR. HANKINSON:

1 Q. The FDA would not have approved of such a
2 marketing practice for Illumina's consumables in the
3 last half of 2008; correct?

4 MR. HORNE: Vague.

5 THE WITNESS: Um -- um --

6 BY MR. HANKINSON:

7 Q. Did you have an assay?

8 A. Uh-huh.

9 Q. Did Illumina have an assay in late 2008
10 that was cleared or approved by the FDA for
11 diagnostic use?

12 A. We had our -- our universal and carboxyl
13 beads that were registered with the FDA, and we
14 could market those for -- as components for
15 development of lab-developed tests.

16 And I --

17 Q. And your answer --

18 A. The date -- the date is not clear to me.

19 Q. Uh-huh. And they would only be components
20 of a lab-developed test, not a complete assay;
21 right?

22 A. Those are -- yeah, those are beads and

1 components that are part of an assay.

2 Q. And the assay would have been developed by
3 the lab; that's why it's called an "LDT,
4 lab-developed test"?

5 "Test" meaning assay; right?

6 A. I'm not sure that we're using the
7 terminology consistency -- "assay, component,
8 test" -- and that's why I'm struggling in answering
9 your question.

10 Can you -- can you try to ask it again?

11 Q. Yes, I can.

12 When I asked you whether --

13 A. Uh-huh.

14 Q. -- Illumina was approved or cleared by the
15 FDA to market assays --

16 A. Uh-huh.

17 Q. -- for diagnostics purposes, in my opinion
18 you didn't answer my question.

19 A. Okay.

20 Q. And I'll explain why, and maybe that will
21 explain why we're talking past each other.

22 A. Okay.

1 Q. Because your answer to that question was
2 "We were selling certain components" -- and I think
3 you listed carboxyl beads --

4 A. Uh-huh.

5 Q. -- and one other thing that could be used
6 in developing an LDT.

7 A. Right.

8 Q. Right? That was your answer?

9 A. Oh, okay.

10 Q. Okay. So do you understand how we're
11 communicating wrong?

12 A. So for terminology.

13 But the FDA will approve a test for
14 specific intended use. And an assay, to me, is more
15 of a -- a lab process that you're asking for
16 detecting DNA or something.

17 And that's why I'm having a hard time
18 answering your question.

19 Q. Oh.

20 A. It's because --

21 Q. Okay. Yeah.

22 A. -- of the use --

1 Q. Yeah. Yeah.

2 A. -- of the words --

3 Q. I'm sorry.

4 A. -- "assay" and "component" and "test."

5 Q. So at the time -- and I apologize.

6 So at the time in --

7 A. Uh-huh.

8 Q. -- 2008 Illumina would have been selling
9 research-use-only assays and components for assays
10 that might have been used by others in LDTs, but was
11 not selling tests, and that's why we're having --

12 A. Yes.

13 Q. -- a disconnect?

14 A. Yes, that's correct.

15 Q. In 2008 Illumina wasn't selling tests?

16 A. That's correct.

17 Q. So when we discuss Exhibit 315 -- I'm
18 sorry.

19 MR. HORNE: We've being going about an
20 hour and a half so...

21 MR. HANKINSON: I think this is a short
22 one.

1 MR. HORNE: All right.

2 (Whereupon, O'Grady Exhibit Number
3 315 was marked for identification by
4 the Deposition Officer and is
5 attached hereto.)

6 BY MR. HANKINSON:

7 Q. Take a look at what's been marked as
8 Exhibit 315.

9 A. Uh-huh.

10 Q. Does this pertain to a grant from the
11 Gates Foundation?

12 A. Yes.

13 Q. And the grant was made to the University
14 of Maryland, and Illumina was going to, in a sense,
15 partner with the University of Maryland on this
16 grant; right?

17 A. We were a -- we were contracted by the
18 University of Maryland to participate.

19 Q. And the University of Maryland was going
20 to use Illumina technology to sequence diarrheal
21 pathogens; right?

22 A. No, not correct.

1 It -- it was not a sequencing test.

2 Q. Okay. What does "Targeting signature
3 sequences" mean?

4 A. The -- the technology that was used for
5 this, the GoldenGate assay --

6 Q. Uh-huh.

7 A. -- would genotype or detect single bases
8 and not sequence a string of bases.

9 So this was using our genotyping
10 technology, not our sequencing technology.

11 It's a discrete change and not a series.

12 Q. And since this was GoldenGate, it was for
13 research use; right?

14 A. The -- the label on the product was "For
15 research use only."

16 Q. Uh-huh. And the purpose of the grant and
17 the work by the University of Maryland was
18 epidemiological; right?

19 A. Yes.

20 Q. Meaning sort of the tracking and tracing
21 of the spread of disease?

22 Do I have that correct?

1 A. Yes.

2 Q. So the test to detect certain -- did you
3 say "bases"?

4 A. Sure.

5 A nucleic acid base is the A's, T's, G's,
6 and C's.

7 Q. Uh-huh. And so the test, the
8 GoldenGate -- excuse me -- I shouldn't say "test."

9 The GoldenGate assay, which was
10 targeting -- when it's signature sequences, that's
11 where you're using the word "nucleic acid --
12 acid-based" -- something?

13 A. Yes.

14 Q. Okay. So the GoldenGate research-use-only
15 assay was targeting those bases from particular
16 pathogens to see which ones were occurring in which
17 people specifically in order to, then, sort of map
18 out the spread of disease?

19 Is that a fair statement?

20 A. The -- the assay was looking for -- the
21 assay targeted sequences that corresponded to the
22 infectious agents in the panel. There was 13 of

1 them.

2 So it was looking for those pathogens
3 in -- in humans.

4 Q. And those humans were not patients that
5 were being diagnosed and treated, were they?

6 A. I'm not aware if they were being diagnosed
7 or treated.

8 Q. Well, they weren't being diagnosed or
9 treated through the work of the University of
10 Maryland; right?

11 A. I don't know whether they were or not.

12 Q. The GoldenGate assay wasn't being used to
13 diagnose or treat anybody; right?

14 A. I don't know if the University of Maryland
15 used the GoldenGate assay to diagnose or treat
16 patients.

17 Q. You're not asserting that in your
18 declaration?

19 A. I'm sorry?

20 Q. You are not asserting that they were in
21 your declaration, are you?

22 A. I -- I don't think I did that, no.

1 Q. Because you don't know?

2 A. I don't know if they did that or not.

3 Q. The University Maryland was a research
4 institution; right?

5 MR. HORNE: Vague.

6 THE WITNESS: I -- I don't know.

7 ///

8 BY MR. HANKINSON:

9 Q. Exhibit 315 was non-public; correct?

10 A. It's -- that's correct.

11 Q. In fact, it's labeled "Trade
12 Secret/Commercially Sensitive" here.

13 A. The presen- -- this looks like it was
14 something that was added. They're -- I don't know
15 the right terminology.

16 Q. Yes, that's correct.

17 A. The presentation itself, and then this
18 part below it --

19 Q. Uh-huh.

20 A. -- that -- that part below it was
21 something that was added in the pdf.

22 Q. Do you disagree that it was either a trade

1 secret or commercially sensitive information?

2 A. No, I don't disagree.

3 Q. Okay.

4 A. I'm -- I'm just saying that the
5 presentation and -- and this (indicating) -- like,
6 we labeled -- I guess --

7 Q. But you agree --

8 A. -- the lawyers --

9 Q. -- with the label?

10 A. -- labeled that.

11 Q. Yeah.

12 A. I agree with it, yeah.

13 Q. You agree with the label?

14 A. Yeah.

15 MR. HANKINSON: We can take a break.

16 DEPOSITION OFFICER: Off the record.

17 (Whereupon, a recess was held

18 from 11:18 a.m. to 11:39 a.m.)

19 DEPOSITION OFFICER: Back on the record.

20 BY MR. HANKINSON:

21 Q. I'd like to hand you what we are marking
22 as Exhibit 302.

1 (Whereupon, O'Grady Exhibit Number
2 302 was marked for identification by
3 the Deposition Officer and is
4 attached hereto.)

5 DEPOSITION OFFICER: There you go.

6 THE WITNESS: Thank you.

7 (Document reviewed by the witness.)

8 BY MR. HANKINSON:

9 Q. Is this a presentation given by
10 Ms. Henshall in 2007?

11 A. Yes.

12 (Interruption in proceedings.)

13 ///

14 BY MR. HANKINSON:

15 Q. Could you just turn to the last page.

16 A. Is this what you want me to look at?

17 Q. Yeah.

18 A. Okay.

19 Q. Is this part of the presentation?

20 (Document reviewed by the witness.)

21 THE WITNESS: This -- I'm just looking
22 through the series of slides really quick.

1 This presentation was given many times in
2 different formats. It's like a standard story.

3 And it looks like in this instance it was
4 given before we had a speaker talking about the use
5 of the technology for different applications, so
6 this was like an introductory slide to that person's
7 story.

8 BY MR. HANKINSON:

9 Q. Was that person Leslie Lyons?

10 A. Yes.

11 Q. Is that a guy or a girl?

12 A. That's a woman.

13 Q. Was she affiliated with Illumina at the
14 time, or was she independently employed at the
15 Department of Population Health and Reproduction
16 School of Veterinary Medicine, University of
17 California Davis?

18 A. She was not affiliated with Illumina.

19 Q. I'd like to turn your attention to
20 Exhibit 304, which we will mark.

21 (Whereupon, O'Grady Exhibit Number
22 304 was marked for identification by

1 the Deposition Officer and is

2 attached hereto.)

3 THE WITNESS: Thank you.

4 DEPOSITION OFFICER: Uh-huh.

5 BY MR. HANKINSON:

6 Q. Is Exhibit 304 the "Diagnostics Portfolio
7 Management Plan" from July 20th, 2009?

8 A. Yes.

9 Q. Illumina first began making formal annual
10 portfolio plans to assess potential business
11 development options in 2009; right?

12 A. That's right.

13 Q. So this is the first document of its kind
14 for diagnostics portfolio management?

15 A. I'm -- I'm not aware if there were
16 informal plans prior to 2009, but this is the first
17 in this corporate planning process.

18 Q. Are all of the people who are listed on
19 the first page of the Diagnostics Portfolio
20 Management Plan co-authors?

21 A. They all were on that team that developed
22 the document.

1 Q. Did they all have sign-off on this
2 document?

3 A. There wasn't an official sign-off; it
4 was -- they were more authors.

5 (Interruption in proceedings.)

6 BY MR. HANKINSON:

7 Q. So they all had input into this
8 document?

9 A. They all had input, yeah.

10 Q. Did you have any input into this
11 document?

12 A. I assisted Mickie.

13 Q. Were you aware of the full contents of the
14 document before it was finalized?

15 A. I -- I'm trying to think. I'm not sure if
16 I -- I think so, yes.

17 Q. Would you have brought it to the attention
18 of the -- of Ms. Henshall or another author of this
19 document if you were aware of any inaccuracy in
20 it?

21 A. If I saw an error, I would have raised it,
22 yes.

1 Q. Who was the intended audience of this
2 document?

3 A. Senior management.

4 Q. Who would that include?

5 A. In 2009 I'm not certain who the -- I don't
6 remember the exact --

7 Q. By position.

8 A. -- makeup --

9 Q. By position.

10 A. -- but the -- the CEO.

11 Q. And others in senior management?

12 A. And others in senior management, yeah.

13 Q. This went all the way to the top of the
14 company?

15 A. Yes.

16 Q. So it was important to the authors' jobs
17 and departments that the information in this would
18 be completely accurate so that the senior management
19 could make decisions based on it; right?

20 A. Yes.

21 Q. When Illumina offers a new product, does
22 the decision whether or not to do so always go to

1 the board of Illumina?

2 A. No.

3 Q. When Illumina decides to begin developing
4 a new product or service, does that decision always
5 go to the board of Illumina?

6 A. No.

7 Q. Those are business decisions that can be
8 made by management; right?

9 A. Yes.

10 Q. Could you turn to page 3 of Exhibit 304.

11 I'd like to direct your attention to the
12 third sentence of the paragraph in the middle of the
13 page. It says:

14 "Without leveraging an
15 acquisition strategy, comparable
16 companies have typically shown of
17 span of eight to ten years before
18 establishing a successful business
19 in molecular diagnostics."

20 Did I read that right?

21 (Document reviewed by the witness.)

22 THE WITNESS: Yes.

1 BY MR. HANKINSON:

2 Q. This refers to essentially the lead time
3 of companies comparable to Illumina who wanted to
4 establish a molecular diagnostics business, from the
5 time that they wanted to be into it until the time
6 that they had a successful business in it.

7 Is that accurate?

8 A. Yes.

9 Q. And the implication is that by leveraging
10 an acquisition strategy, maybe that could go faster;
11 is that right?

12 A. Yes.

13 Q. And then if you go down to "Pipeline
14 Overview," the first sentence is:

15 "The diagnostic product
16 development pipeline can be
17 divided into three main sections:
18 (1), cancer biomarker discovery;
19 (2), molecular diagnostics panels;
20 and (3), clinical sequencing
21 service."

22 Is that accurate?

1 A. Yes.

2 Q. Is this a forward-looking statement about
3 development of future diagnostic products and
4 services?

5 A. Yes.

6 Q. Could you turn to page 7.

7 Looking under "Competitive Advantage" --
8 and this is the section related, "Molecular
9 Oncology."

10 A. Okay.

11 Q. Do you agree with that?

12 (Document reviewed by the witness.)

13 THE WITNESS: Yes.

14 BY MR. HANKINSON:

15 Q. And was oncology your role at the time?

16 A. Yes. I covered oncology as well as
17 genetics applications at that time.

18 Q. Under the section "Competitive Advantage,"
19 the first sentence states:

20 "With a discovery program
21 that is focused on comprehensive
22 genetic analysis, including whole

1 transcriptome and methylome

2 analysis" --

3 Those both end in "o-m-e."

4 "-- Illumina has a potential

5 to develop a highly specific

6 diagnostic test that addresses

7 the complexities inherent in

8 cancer."

9 Do you see that?

10 A. Yes.

11 Q. "Potential to develop" means that Illumina
12 did not have a test at that time; right?

13 A. That's correct.

14 Q. And that test, if and when it was
15 developed --

16 DEPOSITION OFFICER: I couldn't hear the
17 last few words you said.

18 BY MR. HANKINSON:

19 Q. -- would deal with human DNA; right?

20 A. Yes, that's correct.

21 Q. So when you called this a diagnostic
22 test -- excuse me. Let me ask a different question.

1 The last sentence in this paragraph reads:

2 "Relative to earlier cancer
3 diagnostics in the market,
4 Illumina shall have a rapid path
5 to commercialization through an
6 initial offering as a service by
7 the CLIA lab, which shall
8 facilitate data generation for
9 a likely PMA submission to the
10 FDA."

11 Do you see that?

12 A. Yes.

13 Q. So in July of 2009, the steps to develop a
14 diagnostic test that addresses the complexities
15 inherent in cancer would include first developing
16 and then offering a service by Illumina's CLIA lab,
17 which would then facilitate data generation;
18 meaning, lead to increased data in that field that
19 would then, after that, be used in a likely PMA
20 submission to the FDA.

21 Do I have that right, that those are sort
22 of steps to the commercialization of such a

1 potential product?

2 A. That -- that was the plan for this
3 discovery initiative.

4 Q. Can you turn to page 12.

5 And perhaps utilizing the prior couple of
6 pages, could you confirm that the key dependencies
7 on page 12 relate to the potential development of
8 products around a "herpes panel" or "viral
9 infections in transplant panel"?

10 A. I'm sorry. I was referring to the
11 previous pages when you said that.

12 Can you ask me the question again?

13 Q. Sure.

14 Do the key dependencies on page 12 have to
15 do with the potential development of what might be
16 called a "herpes panel" or "viral infections in
17 transplant panel"?

18 A. The --

19 Q. You might refer to page 10.

20 A. Okay.

21 (Document reviewed by the witness.)

22 THE WITNESS: The -- the forecast

1 projections that are defined on page 12 are
2 dependent -- the key dependencies are in reference
3 to the forecast projections on page 12.

4 BY MR. HANKINSON:

5 Q. And all of that relates to the herpes
6 panel; correct?

7 A. If I can review this for a second, please.

8 (Document reviewed by the witness.)

9 BY MR. HANKINSON:

10 Q. I should say "the development of a
11 potential herpes panel."

12 A. I'm not -- I'm not clear by looking at
13 this right now if that revenue is representative of
14 herpes or hospital-acquired infections -- and/or.

15 So I'm -- I'm not -- I'm not super sure.

16 Q. It looks to me like there are main
17 headings like "Cancer Biomarker Discovery Program,"
18 "Pharmacogenomics - ADME Core & CYP2C19," and
19 "Herpes Panel," each of which is followed by a
20 "Market Summary," a "Competitive Advantage," a
21 "Forecast," and "Key Dependencies" in this document.

22 A. Uh-huh.

1 Q. And then on page 10, it starts a "Herpes
2 Panel" or "Viral Infections in Transplant Panel"
3 section.

4 A. Okay.

5 Q. It is then followed a by a "Market
6 Summary," a "Competitive Advantage," a "Forecast,"
7 and "Key Dependencies."

8 Does that help to answer whether these
9 forecasts and key dependencies relate to a herpes
10 panel?

11 A. Yes, those refer to the herpes panel.

12 Q. And the herpes panel at the time was a
13 potential product development, not a current
14 product; right?

15 A. This was a plan for future products.

16 Q. One of the key dependencies on page 12 is
17 to:

18 "Complete EraGen/Illumina
19 agreement; enable development
20 with EraCode modified bases."

21 Do you see that?

22 A. Uh-huh.

1 Q. Was that agreement completed?

2 A. Yes.

3 Q. Subsequent to the agreement being put in
4 place, was EraGen purchased by Luminex?

5 A. Yes.

6 Q. And Luminex is a competitor of
7 Illumina's?

8 A. Yes.

9 Q. Was there any impact of the purchase of
10 EraGen by Luminex on the ability or intention of
11 Illumina to develop this product?

12 A. I'm not aware of what happened in the
13 relationship after the acquisition of Luminex.

14 Q. But the product hasn't been developed?

15 A. No, the product hasn't been developed.

16 Q. And, in fact, it says later on in this
17 bullet, "...the Dx platform team believes that
18 Illumina's infectious disease assays will need to be
19 reconsidered..." if EraGen's rapid assay chemistry
20 is not available to Illumina.

21 Do I have that right?

22 A. It says that the "FastGoldenGate assay"

1 would not be competitive.

2 Q. So the potential development of the herpes
3 panel might need to be reconsidered if EraGen's
4 technology was not available?

5 A. That's what it says.

6 Q. Do you have any reason to disagree with it
7 now?

8 A. No.

9 Q. It also says that a key dependency is:
10 "R&D developers experienced
11 in designing assays with viral
12 targets."

13 Did I read that right?

14 A. Yes.

15 Q. So in forecasting potential revenue from a
16 potentially developed herpes panel, one thing that
17 that project and those revenues would depend on was
18 hiring or acquiring R&D developers who were
19 experienced in making assays with viral targets such
20 as herpes?

21 A. That -- that's not exactly what it says.

22 It says that a dependency is:

1 "R&D developers experienced
2 in designing assays with viral
3 targets."

4 It doesn't talk about a hiring plan.

5 Q. Right.

6 I'm trying to picture a scenario in which
7 Illumina would have had R&D developers experienced
8 in designing assays with viral targets already, and
9 yet listed it on a key dependency list.

10 So doesn't that mean that they weren't in
11 place at that time?

12 A. It does not mean that they weren't in
13 place at that time.

14 Q. But they weren't, were they?

15 A. We had a team working on the application
16 of the GoldenGate assay for a infectious diarrhea
17 panel for the University of Maryland relationship.

18 There were R&D developers experienced in
19 viral targets.

20 The point of that bullet was to identify
21 that we needed specific resources applied to this
22 project, not just any R&D team.

1 Q. And that was not in place at the time?

2 MR. HORNE: Lacks foundation.

3 BY MR. HANKINSON:

4 Q. What you just described was not in place
5 already?

6 A. The -- the point of the document --

7 MR. HORNE: Vague.

8 THE WITNESS: -- is to ask for a new
9 project that we want to do, so we were saying we
10 want -- we want these resources in order to do that
11 project.

12 BY MR. HANKINSON:

13 Q. Could you turn to page 15.

14 The heading at the top is "iScanDx for
15 Cytogenetics"; right?

16 A. Yes.

17 Q. And does that begin a section related to a
18 potential cytogenetics diagnostic product?

19 A. Yes.

20 Q. I'd like you to turn to the next page
21 where the key dependencies for that cytogenetics
22 potential diagnostic product are listed.

1 Do you see that?

2 A. Yes.

3 Q. In the fourth bullet, it says:

4 "Document remediation to
5 bring the iScan instrument under
6 design control, or creation of a
7 new scanner under design control."

8 Did I read that right?

9 A. Yes.

10 Q. So in July 2009, there was such a thing as
11 an iScan instrument that already existed in the
12 world; right?

13 A. Yes.

14 Q. And was that a product that was being sold
15 at the time?

16 A. Yes.

17 Q. Was it a research-use-only product?

18 A. The instrument was labeled "For research
19 use only."

20 Q. It's interesting, whenever I ask if it was
21 research use only, you say "The instrument was
22 labeled for research only -- the instrument was

1 labeled for research use only."

2 Is there a distinction that you're trying
3 to make or is that just a verbal tick?

4 A. This were customers that were using the
5 instrument in a clinical laboratory setting. Our --
6 our label said "Research use only."

7 It does not mean that the instrument was
8 only used for research use.

9 Q. And those customers are previously
10 discussed CLIA high complexity certified
11 laboratories using it in LDTs; right?

12 A. That's right.

13 Q. So the iScan instrument, as of July 2009,
14 that was being sold was labeled "For research use
15 only" --

16 A. That's --

17 Q. -- right?

18 A. -- correct.

19 Q. What was the cause of needing document
20 remediation to bring it under design control?

21 A. To the -- this section is about asking to
22 build an IVD system -- to -- to build a system that

1 could be submitted to the FDA.

2 So there is documentation necessary about
3 the development of the iScan to facilitate that
4 submission.

5 Q. What type of submission would have been
6 made had these plans been followed?

7 A. The section refers to a 510(k)
8 submission.

9 Q. So to make a 510(k) submission for
10 clearance of the iScan instrument, there would need
11 to either be document remediation to bring it under
12 design control, or it would need to be -- a new
13 scanner would be needed to be designed under design
14 control?

15 Do I have that right?

16 A. Yes.

17 Q. So someone had designed the iScan
18 instrument without it being under design control
19 before July 2009; right?

20 DEPOSITION OFFICER: '-5 or '-9?

21 MR. HANKINSON: 2009.

22 DEPOSITION OFFICER: Thank you.

1 THE WITNESS: I'm not certain what level
2 of documentation was done prior to 2009.

3 BY MR. HANKINSON:

4 Q. But in --

5 A. The -- the assertion is that it was not
6 sufficient for an FDA submission.

7 Q. What company had designed the iScan
8 instrument prior to July 2009?

9 A. I -- I'm not -- I'm not aware if it wasn't
10 Illumina.

11 Q. I'm not suggesting it wasn't.

12 A. Oh, okay.

13 Q. Do you believe --

14 A. I assume --

15 Q. -- it was Illumina?

16 A. I assume it was Illumina.

17 Q. That's the best of your knowledge?

18 A. It's the best of my knowledge. It's
19 possible that there was some sort of subcontractor,
20 but I -- I assume it was Illumina.

21 Q. I see.

22 So it was either Illumina or by Illumina's

1 instruction with a subcontractor?

2 A. You know, I -- I wasn't involved with the
3 design of the iScan system. I don't want to
4 speculate how it was designed.

5 Q. Uh-huh. You are the person who referred
6 to Exhibit 304 in your declaration on behalf of
7 Illumina in this matter; right?

8 A. In regards to development of future
9 diagnostic applications in 2009?

10 Q. Yes.

11 A. Yes, I was involved in this.

12 The original development of the iScan
13 system was not something that I was involved with or
14 aware of.

15 Q. So the information upon which Illumina is
16 relying in this matter would be in this document or
17 your declaration; right?

18 A. That's right.

19 I'm sorry. I don't understand what that
20 meant. I just agreed with you.

21 I -- I don't -- I don't know whether or
22 not it's important. And Illumina is relying on my

1 knowledge of whether or not the instrument was --
2 when it was developed.

3 Q. Do you --

4 A. I don't know.

5 Q. -- have any reason to believe that it
6 wasn't Illumina?

7 A. I -- I -- I can imagine -- it's not
8 uncommon that device manufacturers will have
9 partnerships in their development. It's -- it's
10 possible that we partnered with someone to do that,
11 and that's why I'm not --

12 Q. Illumina is at least involved?

13 A. I -- yes, absolutely.

14 Q. Can you turn to page 18.

15 The heading in the middle of the page is
16 "Respiratory Viral Panel."

17 A. Yes.

18 Q. The second sentence says:

19 "To compete against the
20 Luminex RVP panel, and leverage
21 its 510(k) clearance, Illumina's
22 panel shall be comprised of a

1 14-plex (plus two internal
2 controls) assay targeting the
3 viruses and bacteria listed
4 below."

5 Right?

6 A. Yes.

7 Q. When it references leveraging its 510
8 clearance, is the "it" referring to Luminex's RVP
9 panel?

10 A. That's unclear.

11 Q. Well, Illumina didn't have an RVP panel at
12 the time; right? This was forward-looking to
13 developing one, potentially?

14 A. That's correct.

15 Q. And so Illumina certainly didn't have a
16 510(k) clearance for such a panel; right?

17 A. No, they did not.

18 Q. And so then Luminex is the only other
19 company mentioned in this paragraph; is that
20 correct?

21 A. Yes, that's correct.

22 Q. So do you think we can conclude, then,

1 that its 510 clearance refers to Luminex's 510
2 clearance for its RVP panel?

3 A. It just doesn't -- it doesn't make sense.
4 I -- I don't think that's what is meant
5 there.

6 I think -- I think it's trying to say that
7 the competitive advantage of a 510(k) instrument --
8 or device for respiratory viruses would be a 14-plex
9 assay, as compared to a Luminex assay which, I
10 assume, had fewer targets.

11 I think that's what that sentence is
12 trying to say.

13 Q. And this is another example where Illumina
14 would be developing a product to enter into a market
15 where Luminex was already marketing a product;
16 correct?

17 A. Yes.

18 Q. And after 2009, Illumina used the Illumina
19 Dx brand for its diagnostic products and services;
20 right?

21 A. The exact date is fuzzy to me, but yes, we
22 had an Illumina Dx brand that we used.

1 Q. Had this RVP panel been brought to
2 fruition, it would have been branded under Illumina
3 Dx; right?

4 MR. HORNE: Speculation, lacks
5 foundation.

6 THE WITNESS: I -- I don't know.

7 BY MR. HANKINSON:

8 Q. So counsel's objected that my question
9 about how this product -- whether this product would
10 have been branded under the Illumina Dx brand --

11 A. Uh-huh.

12 Q. -- had it come into fruition lacks
13 foundation --

14 A. Okay.

15 Q. -- and it's speculative.

16 A. Okay.

17 Q. So would it be speculation, as of July
18 2009, to say how Illumina would have branded an
19 RVP panel if it had come out, or was there a plan?

20 A. In 2009 the plan would have been to label
21 it "Illumina Dx."

22 Our branding strategy changed over time,

1 so it's speculation. It takes time to get a product
2 FDA cleared.

3 Q. It's speculation what would have happened
4 in the future. But at the time, it's not
5 speculation to say what the plan was?

6 A. There wasn't -- there wasn't a specific
7 branding plan with any of these products. Our
8 umbrella brand at that time was Illumina Dx.

9 Q. But you said you didn't know when Illumina
10 Dx began to be the brand.

11 A. Yeah, that's true.

12 If -- there wasn't a specific branding
13 strategy involved in this document.

14 Q. As of July 2009 --

15 A. Um --

16 Q. -- which is the date of this document?

17 A. In -- in this document we did not talk
18 about what the brand would be for the respiratory
19 viral panel.

20 Q. Okay. But I've been asking you what the
21 plan was at the time.

22 A. I don't know.

1 Q. You were working in part as a member of a
2 team to develop products for the molecular
3 diagnostic market in oncology; right?

4 A. Yes.

5 I'm sorry.

6 Q. No worries.

7 A. Yes. I nodded.

8 Q. Would you in that role have been aware of
9 the branding plans as they existed at that time?

10 A. Product marketing and brand were separate
11 organizations -- separate teams, so I don't know
12 what their opinion was at that time of our brand
13 planned for these products.

14 Q. Is Karen Possemato a member of the product
15 branding team?

16 A. Are you asking me if she is today?

17 Q. At any point in time.

18 A. Karen Possemato led our corporate
19 marketing organization, which included brand.

20 Q. And you were in a different silo, which
21 was product marketing?

22 A. I don't agree that it was a silo. I was

1 in a separate team that was product marketing.

2 Q. Sorry. I guess that's a midwestern term.

3 You're in a dynamic team with many touch
4 points like neurons.

5 A. I was in a cross-functional team that
6 interfaced with brand.

7 Q. That's wonderful.

8 A. That was product marketing.

9 Q. So it circled back.

10 You don't know what, if any, plan existed
11 as of July 2009 for the branding of any of the
12 products that are contemplated as future-developed
13 products in Exhibit 304?

14 A. We --

15 Q. I thought you just told me you don't?

16 A. This -- this prod- -- I'm -- I'm trying to
17 explain -- okay. No.

18 The answer to your question is "No."

19 Q. If you look at page 20, at the bottom
20 there's another reference to Luminex, this time in
21 the context of "respiratory viral"; is that right?

22 A. Yes.

1 Q. And the Luminex product there was xTAG; is
2 that right?

3 A. Yes.

4 Q. So had Illumina's RVP panel been
5 developed, it would have been in competition with
6 Luminex xTAG?

7 A. Yes.

8 Q. Could you turn to page 21.

9 Here we see the key dependencies for the
10 respiratory viral panel; right?

11 A. Yes.

12 Q. And then in the fourth bullet of those key
13 dependencies, it says:

14 "Performance meets or exceeds
15 performance demonstrated by
16 Luminex RVP as predicate device
17 for FDA submission."

18 Did I read that correctly?

19 A. Yes.

20 Q. So I think this might shed light on the
21 sentence we were discussing on page 18 that you said
22 didn't make sense. And let's examine that.

1 So the second sentence under "Respiratory
2 Viral Panel" on page 18 says:

3 "To compete against the
4 Luminex RVP panel and leverage
5 its 510(k) clearance, Illumina's
6 panel shall be comprised of a
7 14-plex (plus two internal
8 controls) assay targeting the
9 viruses and bacteria listed
10 below."

11 Right?

12 A. Yes.

13 Q. So when we see in the key dependencies on
14 page 21 that Illumina, at the time, was considering
15 relying on the Luminex RVP as a predicate device for
16 its FDA submission, then that makes sense, right,
17 that it would be leveraging the prior FDA 510(k)
18 clearance of the Luminex RVP panel; right?

19 A. It's assuming we would be allowed to use
20 that as a method of comparison to our own device.

21 Q. This plan is assuming that?

22 A. This plan is assuming that if we were to

1 develop our own test, that we could use the Luminex
2 RVP panel as a method of comparison.

3 Q. And to use a device as a predicate device
4 in a 510(k) clearance, it would have to be in the
5 same field doing the same function and at least as
6 safe and effective or more; right?

7 A. No.

8 Q. Well, what are the requirements for
9 listing a predicate device in an FDA submission?

10 A. It's the specific sensitivity and
11 specificity claims. It -- it's saying that we would
12 compare ourselves to those -- those claims.

13 Q. For doing the same thing?

14 A. For doing the same thing.

15 Q. And that expedites FDA clearance if you
16 can show that; right?

17 A. It doesn't necessarily expedite FDA
18 clearance.

19 Q. Is the reason for listing a predicate
20 device to try to expedite FDA clearance?

21 A. It's -- no.

22 Q. What is the reason to even try, then?

1 A. As part of a 510(k), the performance of
2 the test has to be compared to something, and
3 usually that's assaying or sequencing.

4 And in this case, they were assuming they
5 would be able to compare themselves to the Luminex
6 system instead of assaying or sequencing.

7 Q. So had an RVP panel been developed, it
8 would have done the same thing as Luminex RVP, and
9 the plan was that Illumina could show in a 510(k)
10 application that its sensitivity and -- what was the
11 other word?

12 A. Specificity.

13 Q. -- specificity were as good or better than
14 Luminex's RVP?

15 A. Yes.

16 Q. I'd like you to turn to page 22 where the
17 heading is "BeadXpress II."

18 Under the heading "Market Summary" in the
19 last sentence, it states:

20 "The clinical market is not
21 funded for capital equipment
22 purchases, so the instrument

1 systems are a function of reagent
2 rental contracts, rolled into the
3 overall price per test (or placed
4 at no charge in some instances)."

5 Is that correct?

6 A. Yes.

7 Q. The clinical market is the market in which
8 Illumina's contemplated potential diagnostic
9 products would be sold; right?

10 MR. HORNE: Vague.

11 THE WITNESS: Can you restate the
12 question?

13 BY MR. HANKINSON:

14 Q. Yes.

15 The clinical market, as used in the
16 sentence that is the last sentence under "Market
17 Summary" on page 22 of Exhibit 304, is the market
18 into which Illumina's contemplated potential
19 molecular diagnostics products would be sold?

20 MR. HORNE: One more objection.

21 Vague, lacks foundation.

22 BY MR. HANKINSON:

1 Q. Is that correct?

2 A. The -- the tests that were described in
3 this plan were intended to be sold in the clinical
4 market.

5 Q. No such test existed in July 2009;
6 correct?

7 A. It's possible that some of the items
8 described in this plan were available as -- were
9 available or under development.

10 It's not necessarily true that none of
11 them existed.

12 Q. None were being sold at the time;
13 correct?

14 A. I'm not -- I'm not sure.

15 Q. You don't know one way or the other?

16 A. I don't know -- I don't know one way or
17 the other.

18 Q. Before July 2009, had Illumina ever given
19 a platform to a clinic or a lab for free?

20 A. I don't know of specifics around
21 instrument giveaways.

22 Q. You just don't know one way or the --

1 A. I just --

2 Q. -- other?

3 A. -- don't know.

4 Q. Could you turn to page 23.

5 A. Sure.

6 Q. The heading that starts a little bit down
7 on the page is "Diagnostic Targeted Sequencing
8 (Prometheus II)"; right?

9 A. Yes.

10 Q. Does this relate to sequencing
11 technology?

12 A. Yes.

13 Q. Could you look at "Forecast Projections"
14 on page 24.

15 Are you with me?

16 A. Oh. I see, yes.

17 Q. There it states:

18 "Based on the development
19 times for a major system developed
20 under regulatory design control,
21 we do not anticipate
22 commercialization until 2013;

1 however, development will need
2 to be initiated and resourced
3 by Q2 2011."

4 Right?

5 A. Yes.

6 Q. In July of 2009, Illumina R&D was selling
7 a Prometheus product; is that correct -- pardon.

8 Illumina was selling a
9 research-use-only-labeled Avantome sequencing system
10 that was also known as "Prometheus"; is that
11 right?

12 A. No.

13 Q. It wasn't selling it?

14 A. No.

15 Q. Was it a product in development?

16 A. I'm not sure.

17 Q. Do you know anything about it?

18 A. A little.

19 Q. What do you know?

20 A. You know, I'm not -- I'm not sure about
21 the specifics about Avantome.

22 I -- I'm concerned that I'm confused about

1 a different technology. But I think it involved a
2 relationship with another organization. I'm not --
3 I'm not really sure.

4 Q. Thank you for clarifying. I appreciate
5 it.

6 Under "Forecast Projections," the
7 reference to "development times for a major system
8 developed under regulatory design control," was that
9 the same design control that we were discussing
10 earlier for FDA submissions?

11 A. Yes.

12 Q. And the idea here is that to develop the
13 Prometheus II diagnostic target sequencing, from the
14 beginning it would be intended to be developed under
15 regulatory design control so that when it was
16 designed and developed, that design control could be
17 used in support of an FDA submission; is that
18 right?

19 A. Yes.

20 Q. So for this one, where the design of the
21 product Prometheus II was being contemplated from
22 scratch, essentially, the plan was, under "Key

1 Dependencies," that the project be "resourced and
2 scoped to require regulatory design control" right
3 from the beginning; right?

4 A. You said a lot of stuff in that sentence.

5 Can you maybe start over so I can make
6 sure I'm understanding what I'm agreeing to?

7 Q. Sure.

8 For this one -- are you comfortable
9 reading stuff back?

10 DEPOSITION OFFICER: Sure. I'll do my
11 best.

12 MR. HANKINSON: Let's try that.

13 (THE RECORD WAS READ AS FOLLOWS:

14 Q. So for this one, where the
15 design of the product Prometheus
16 II was being contemplated from
17 scratch, essentially, the plan
18 was, under "Key Dependencies,"
19 that the project be "resourced
20 and scoped to require regulatory
21 design control" right from the
22 beginning; right?)

1 THE WITNESS: I -- I -- okay. Hold on.

2 (Document reviewed by the witness.)

3 THE WITNESS: Does -- did the question say

4 "Prometheus" or "Prometheus II"?

5 DEPOSITION OFFICER: "Prometheus II."

6 THE WITNESS: Yes. The answer is "Yes."

7 BY MR. HANKINSON:

8 Q. If you turn to page 26, there's a list of
9 CLIA labs certified to perform transplant testing;
10 correct?

11 A. Yes.

12 Q. If you look at the fourth one up from the
13 bottom, it's "Beth Israel Deaconess Medical Center."

14 Do you see that?

15 A. Yes.

16 Q. Do you know if that's in Boston?

17 A. I don't know.

18 Q. Could you turn to page 29 of
19 Exhibit 304.

20 Near the top of page 29, there's a major
21 heading that says "Development Costs."

22 Do you see that?

1 A. Yes.

2 Q. This is a heading that is general; right?
3 It's not specific to one of the particular potential
4 diagnostic products that we've been discussing under
5 the other headings?

6 A. Yes.

7 Q. And so this is the development cost
8 section that applies to the entirety of the
9 July 20th, 2009, Diagnostics Portfolio Management
10 Plan; right?

11 A. Yes.

12 Q. The full text under Development Costs is
13 in brackets, centered on the page, and it says:

14 "Still in process. Mike to provide
15 soon."

16 Do I have that right?

17 A. Yes.

18 Q. Who is "Mike"?

19 A. I'm not sure.

20 Q. The next major section is titled "Internal
21 Dependencies"; right?

22 A. Can I -- can I go back to your last

1 question you asked about Mike?

2 Q. No.

3 A. Okay.

4 Q. Yes, you may.

5 A. I was confused because there was more than
6 one Mike, but the author was Mike Poirier, finance
7 team member. That's who it was coming from.

8 Q. So the Mike mentioned on page 29 is an
9 author of the Diagnostic Portfolio Management Plan,
10 that is Exhibit 304, but at the time that it was
11 created, did not provide the development costs to
12 fill into this section?

13 A. That's right.

14 Q. So the next major heading is "Internal
15 Dependencies"; right?

16 A. Yes.

17 Q. And there's a chart that lists "Short-term
18 Needs," "Mid-term Needs," and "Long-term Needs," in
19 three different columns; right?

20 A. Yes.

21 Q. And on that page and the pages that
22 follow, there are rows listing the short-term,

1 mid-term, and long-term needs for: Instrumentation,
2 Automation, Assay/Technology, Manufacturing,
3 Software/Analysis, Regulatory -- excuse me --
4 Regulatory/Quality/Legal, Field Service & Support,
5 Sales Channel, Marketing, Other, and CLIA Services.

6 Right?

7 A. Yes.

8 Q. On page 30 in the row that pertains to the
9 short-term, mid-term and long-term needs for
10 Assay/Technology, in the column listing short-term
11 needs, the third bullet point reads:

12 "Less expensive, less
13 complex workflow."

14 Do you see that?

15 A. Yes.

16 Q. What is meant by "less expensive, less
17 complex workflow" here?

18 A. I'm not sure exactly which application
19 that's referring to.

20 Q. It might refer to one or more of the
21 potential diagnostic products referenced throughout
22 the plan, and you're not sure which one or more?

1 A. Yes.

2 Q. In the row pertaining to "Manufacturing,"
3 in the column pertaining to mid-term needs, in the
4 last bullet, it reads:

5 "QSR compliant manufacturing
6 for iScan and select BeadArray
7 and Avantome products for Dx."

8 Do you see that?

9 A. Yes.

10 Q. What is "QSR compliant"?

11 A. It's in reference to a manufacturing
12 process. "Quality System Regulations" is what it
13 stands for.

14 Q. What is the source of the Quality System
15 Regulations?

16 A. It's FDA.

17 Q. Does this relate to the design control
18 references in the dependencies that we spoke about
19 earlier within this document, Exhibit 304?

20 A. Yes, that is part of the Quality System
21 Regulations.

22 Q. So a mid-term need for Illumina to

1 realize the diagnostics plan that's set forth in
2 Exhibit 304 is to have QSR compliant manufacturing,
3 otherwise known as, you know, "bringing the product
4 development under design control" -- as it's
5 referenced elsewhere in the document -- for iScan
6 and select BeadArray and Avantome products?

7 Am I summarizing that correctly?

8 A. The design control part and the
9 manufacturing part are distinct; they both fall --
10 fall under QSR.

11 Q. Oh, interesting.

12 A. And they're both required.

13 Q. So in an FDA submission to get clearance
14 or approval for a diagnostic product, there's two
15 parts of QSR that would need to be addressed as to
16 the product that's being submitted, one being design
17 control and one being the manufacturing process?

18 A. Both -- yes, both of those are
19 requirements for a submission.

20 And design control covers manufacturing as
21 well as the upstream development of a product.

22 QSR and design control aren't synonyms, is

1 what --

2 Q. It's a rhombus --

3 A. -- trying to correct you on.

4 Q. It's a rhombus and a square.

5 So design control includes both
6 manufacturing and the development of the product,
7 whereas QSR compliant manufacturing would just be
8 what you referred to as upstream?

9 A. Another term that's been used is "GMP," or
10 Good Manufacturing Processes.

11 Q. And why do you bring that up?

12 A. Because the name has changed over time.

13 There's a manufacturing component and
14 there's the development component, and both of those
15 fall under QSR.

16 Q. So --

17 A. The terminology is a bit confusing.

18 Q. In July of 2009, to market an FDA cleared
19 or approved product that was iScan, BeadArray, or
20 certain -- certain BeadArray and Avantome products,
21 there was a need to change the manufacturing that
22 Illumina was doing to make it QSR compliant for the

1 FDA submission.

2 Is that accurate?

3 A. No.

4 Q. Okay. Please explain.

5 A. Well, we talked about the development of
6 an Avantome product from scratch, so there wasn't a
7 need to change manufacturing; it needed to be
8 developed following QSR.

9 Q. Oh. Interesting.

10 Okay. So that's Avantome.

11 A. The --

12 Q. Whereas iScan -- you were taking issue
13 because I said "change"?

14 A. Yeah.

15 Q. And iScan would be a change, whereas
16 Avantome would be starting from scratch?

17 A. Right.

18 Yes, Quality System Regulation compliant
19 manufacturing would be need to be developed for
20 iScan and BeadArray as well, or the -- or the
21 process modified.

22 I -- I don't know exactly how they would

1 go around making that change.

2 Q. On page 31 in the row related to
3 "Regulatory/Quality/Legal," and the column related
4 to short-term needs, the second bullet is:

5 "In-house regulatory expert."

6 Do you see that?

7 A. Uh-huh.

8 Q. As of July 2009, did Illumina have an
9 in-house regulatory expert, or was one needed, as
10 stated here?

11 A. I don't know when our internal regulatory
12 organization started. I -- I don't -- I'm not
13 sure.

14 Q. And it does not refresh your recollection
15 that this is referred to as a "short-term need"?

16 A. No.

17 Q. You just don't know one way or the
18 other?

19 A. I -- I don't know when our internal
20 regulatory organization was established.

21 Q. Did it happen after you began working at
22 Illumina in 2007?

1 A. Yes.

2 Q. Do you know if it happened in your first
3 year with the company in 2007?

4 A. I -- I don't remember. I don't remember
5 who had that responsibility.

6 Q. If Illumina had in-house as of July 20th,
7 2009, an in-house regulatory expert, would you
8 expect that that person, or someone from their
9 department, would be a team member in authoring the
10 "Diagnostics Portfolio Management Plan"?

11 A. Not necessarily. This is more about
12 business opportunity.

13 Q. There is a member of marketing, a member
14 of finance, a sustaining team member, a production
15 team member.

16 "Production" would be manufacturing; is
17 that right?

18 A. Uh-huh.

19 Q. A development team member. Would that be
20 like research and development?

21 A. It just -- it just says "development."

22 Q. Yes. And I'm asking you whether that

1 refers to research and development or some other
2 sort of development.

3 A. It's product development.

4 Q. Product development.

5 And then also Dx development team member;
6 right?

7 A. Our executive advisor, Greg Heath, came to
8 the company with substantial amount of IVD
9 experience and provided the guidance as to which
10 directions we should be going in the diagnostics
11 market.

12 Q. When did he begin his employment at
13 Illumina?

14 A. It was after I joined the company; I don't
15 remember exactly what year.

16 Q. And since Greg Heath, the executive
17 advisor, was providing input into which direction
18 Illumina should go with respect to diagnostics and
19 regulatory matters at the time, according to what
20 you just said, and he is an author on this plan, do
21 you think he would put "in-house regulatory expert"
22 as a short-term need if that had already been

1 fulfilled?

2 A. I -- I -- I don't know exactly what they
3 were asking for there.

4 Q. It says "in-house regulatory expert."

5 A. I -- I know that.

6 But I'm not sure if they're asking for
7 more resources for particular projects, or if there
8 was someone already in the company.

9 There -- there are people that this --
10 with this responsibility, and I don't remember when
11 they started and if it was before this was written.

12 That's why I'm not answering you directly,
13 because I don't remember.

14 Q. So you agree that you're not answering me
15 directly? Objection.

16 And I'm just going to keep on this a
17 little bit --

18 A. Okay.

19 Q. -- and we'll see if we get anywhere.

20 So I'm viewing authors.

21 A. Uh-huh.

22 Q. And you -- when I asked whether you would

1 expect a regulatory team member to be an author, if
2 one existed, you said -- you didn't say "Yes" or
3 "No," if I'm remembering correctly -- you said, this
4 is a like -- you said "finance" or like "business
5 plan."

6 And then I'm seeing people who are like
7 manufacturing, so it's certainly not just finance
8 and strategy people; it's people giving input about,
9 you know, what it's going to take.

10 This is why I'm asking the question. I'm
11 trying to explain it to you --

12 A. Uh-huh.

13 Q. -- so that we're communicating.

14 And so does that -- and so let me ask:
15 Given that this variety of people were involved in
16 authoring this plan, now being cognizant of that,
17 would you expect that if there was an in-house
18 regulatory expert or a team, that a member of that
19 team would be an author on this plan?

20 A. You said that manufacturing was on the
21 team, and --

22 Q. It says "production," and I'd asked you if

1 that meant manufacturing. I thought you had said
2 "Yes."

3 A. Okay. Okay. I don't disagree with that.
4 Can you ask me your question again?
5 You're asking me if -- if there was
6 someone on regulatory on the team?

7 Q. If a person was in place in-house who was
8 a regulatory expert, or a team of such people, would
9 you expect a member of that team to have been an
10 author on this?

11 A. Not necessarily.

12 Q. If you look at page 32, it carries over
13 from the prior page the row dedicated to
14 "Regulatory/Quality/Legal" needs.

15 In the second-to-last bullet --

16 A. Uh-huh.

17 Q. -- it states:

18 "Chief medical officer (for
19 Safety Board and Reimbursement
20 Program)."

21 A. Yes.

22 Q. What is the "Safety Board and

1 Reimbursement Program"?

2 A. I do not know what is meant by "Safety
3 Board."

4 "Reimbursement" is in regards to how
5 clinical laboratories get paid for diagnostic
6 tests.

7 Q. Did Illumina have, in July 2009, a chief
8 medical officer?

9 A. I am not aware of when our chief medical
10 officer started.

11 Q. Do you think that it's conceivable that
12 this bullet point saying chief medical officer --

13 A. Yeah.

14 Q. -- is a short-term need --

15 A. Yeah.

16 Q. -- that that would refer to just retaining
17 the current chief medical officer?

18 A. The -- at the time this was written, the
19 team was emerging, and exactly the series of events,
20 I'm not clear on.

21 Around this time frame we got a chief
22 medical officer. I don't know exactly when. He may

1 or may not have been here when -- at the time this
2 was finally published.

3 Q. At or near July 2009, Illumina hired a
4 chief medical officer?

5 A. We recognized the need and brought someone
6 into the organization. I don't know exactly when he
7 started.

8 Q. What was wrong with "hired"?

9 You -- are you saying that you --

10 A. It's just --

11 Q. -- recognized --

12 A. -- a process.

13 Q. -- the need in July 2009 and brought them
14 in later?

15 A. It's -- it's -- the creation of these
16 documents is a process.

17 Q. Is this the final one?

18 A. I believe so.

19 Q. And it's dated July 20th, 2009; right?

20 A. It is dated July 20, 2009.

21 Q. So at that time, at least the need for a
22 chief medical officer had been identified?

1 A. Yes.

2 Q. And that need was related to moving into
3 marketing of reimbursed diagnostic products;
4 right?

5 A. Yes.

6 Q. And then sometime at that time or after, a
7 chief medical officer was brought into the
8 organization?

9 A. Yes.

10 Q. If you look at the next bullet, there's
11 "Intensive Regulatory Training for Key Area
12 Managers."

13 Do you see that?

14 A. Yes.

15 Q. And that is a short-term need related to
16 the plan that is Exhibit 304; right?

17 A. Yes.

18 Q. At that time, had Illumina already given
19 intensive regulatory training to the key area
20 managers?

21 A. There were a few people at the company
22 with that experience.

1 Q. Had Illumina given --

2 DEPOSITION OFFICER: "Given..."? --

3 BY MR. HANKINSON:

4 Q. -- given them that experience or trained
5 them?

6 A. I don't know.

7 Q. In any event, their experience is not
8 what's being referred to by "intensive regulatory
9 training for key area managers"; correct?

10 A. Correct.

11 Q. That was something separate that was
12 needed in the short-term; right?

13 A. Yes.

14 Q. If you look in the next row, "Field
15 Service & Support," a mid-term need, in the middle
16 column at the second bullet was:

17 "Designated Dx field support

18 team for clinical customers (FAS,

19 FSE, and Tech support)."

20 Right?

21 A. Yes.

22 Q. What is "FAS"?

1 A. It's either "Field Application Specialist"
2 or "Scientist." I'm not -- I'm not sure on the "S".

3 Q. In any event, it's someone who is
4 scientifically trained?

5 A. It's a person that offers on-site support
6 and consulting to a customer.

7 Q. Are they scientifically trained?

8 A. Yes.

9 Q. And what is "FSE"?

10 A. A "Field Service Engineer."

11 Q. And what is that?

12 A. It's an individual that services
13 equipment.

14 Q. In July of 2009, did Illumina have an
15 existing field support team?

16 A. Yes.

17 Q. The need identified in the second bullet
18 that we were discussing is to designate a field
19 support team specifically for clinical customers; is
20 that right?

21 A. Yes.

22 Q. If we look in the next row, "Sales

1 Channel," the top bullet of the mid-term need is:

2 "Separate diagnostic sales
3 team focused on sales of
4 Illumina's diagnostic portfolio
5 exclusively."

6 Is that right?

7 A. Yes.

8 Q. In July 2009, did Illumina have a sales
9 team already?

10 A. Yes.

11 Q. And the mid-term need that was being
12 listed in this plan was to specifically devote a
13 sales team to the diagnostic field; right?

14 A. Yes.

15 I -- I would say maybe not "specifically
16 devote," but segregate. There were individuals that
17 were accountable for that market.

18 Q. And by "individuals that were accountable
19 for that market," are you referring to individuals
20 that sold products labeled "research use only" into
21 CLIA high complexity certified labs?

22 A. That, as well as our FDA registered

1 Universal Capture and Carboxyl Beads.

2 Q. Which were under a -- did you call it a
3 Level I?

4 A. Class I exemption.

5 Q. "Class I exemption," meaning they were
6 exempt from the FDA -- what are they exempt from?

7 A. It's a -- it's a level of safety and risk.
8 The -- the exact meaning of that is
9 something you'd have to get some regulatory expert
10 to comment on.

11 Q. And they're a --

12 A. I don't want to speculate.

13 Q. And they're a component, not a test?

14 A. They're a component.

15 Q. In the row related to "Marketing" lower
16 down on page 32 of Exhibit 304, the first bullet is:

17 "Development of Illumina
18 diagnostic branding and identity."

19 Is that correct?

20 A. Yes.

21 Q. So before, we were kind of trying to
22 figure out whether there was a plan in place at the

1 time that this document was finalized with respect
2 to branding of the products that were contemplated
3 to be developed in this plan.

4 Do you remember discussing that?

5 A. Yes.

6 Q. A short-term need identified in the plan
7 was to develop an Illumina diagnostic branding and
8 identity; is that correct?

9 A. That's what it says, yes.

10 Q. Do you have any reason to think that that
11 is inaccurate?

12 A. No.

13 Q. On the third bullet of the "Marketing"
14 row, it says:

15 "Focus sessions on laboratory
16 developed test applications."

17 Do you see that?

18 A. Yes.

19 Q. And that's identified as a short-term need
20 for marketing in the plan?

21 A. Yes.

22 Q. Some of the products that are in this

1 plan, if they had been developed, would be used
2 outside of laboratory developed test applications;
3 right?

4 A. Products where we said we would achieve
5 IVD clearance or approval would not be considered
6 lab-developed tests.

7 Q. And in the short-term, was it contemplated
8 in July 2009 that the focus of marketing would be on
9 the LDT applications, since that's what could happen
10 then?

11 A. This doesn't say "focus of marketing"; it
12 says "focus sessions."

13 Q. In the "Marketing" row?

14 A. In the "Marketing" row? I'm not sure what
15 that means by "sessions."

16 It -- it appears like a marketing tactic.
17 It does not say "focus marketing," though.

18 Q. Could you refer to the bottom of page 33
19 of Exhibit 304 --

20 A. Uh-huh.

21 Q. -- with the heading "Risks."

22 A. Yes.

1 Q. The fourth bullet is:

2 "Failure to discover
3 clinically relevant biomarkers."

4 Do you see that?

5 A. Yes.

6 Q. Illumina had planned to undertake research
7 and development to partnerships to develop
8 biomarkers in genetics for diagnostic purposes.

9 Is that accurate?

10 A. Can you restate that?

11 Q. I don't know.

12 You didn't have any biomarkers yet in
13 July 2009. You planned to get some?

14 A. The cancer discovery section was about
15 looking for biomarkers relevant to oncology.

16 And this bullet is about whether or not we
17 would find them in that discovery effort.

18 Q. Because you can devote resources to that
19 research and development and plan for a pipeline to
20 come, but there's a risk that you just don't
21 discover those biomarkers; right?

22 A. With that particular endeavor, there was a

1 risk that we might not find something.

2 Q. The sixth bullet says:

3 "Delays in QSR compliance."

4 Right?

5 A. Yes.

6 Q. That refers to the risk that either
7 changing the design or manufacturing of existing
8 products to be QSR compliant, or designing products
9 and manufacturing them in a QSR compliant manner
10 from scratch would take longer than anticipated.

11 Is that what that risk is about?

12 A. The -- the risk is about delays in
13 establishing QSR in the manufacturing pipeline for
14 the products listed in the document.

15 Q. Is there a reason that you wanted to
16 restate that instead of saying "Yes" or "No"?

17 A. You said "from scratch." I don't know.
18 I -- I didn't -- the way that you asked the question
19 when you said "developing it from scratch."

20 The -- the risk was about changing the
21 manufacturing process and how long it would take.

22 Q. I see.

1 Thank you.

2 And so the risk to the program and
3 achieving revenue forecast that's identified on 33,
4 that says "delays in QSR compliance," refers to the
5 time that it may take to make changes to existing
6 manufacturing techniques to bring them into QSR
7 compliance?

8 A. Yes.

9 Q. The next bullet point down says that:

10 "A risk to the program and
11 achieving the revenue forecast is
12 skepticism by customer on ability
13 for Illumina CLIA lab to support
14 true clinical testing."

15 Do you see that?

16 A. Yes.

17 Q. Why would a customer have been skeptical
18 in July of 2009 and going forward about Illumina's
19 CLIA labs ability to support true clinical
20 testing?

21 MR. HORNE: Lacks foundation.

22 THE WITNESS: In 2009 our CLIA service was

1 to do whole genome sequencing, and the clinical
2 utility of whole genome sequencing was in the
3 process of being established.

4 So by establishing that clinical utility,
5 we would address the -- the skepticism by
6 customers.

7 BY MR. HANKINSON:

8 Q. Some new work needed to be done to
9 convince customers that the CLIA lab sequencing
10 would be useful in true clinical testing?

11 A. The -- the clinical utility of the test
12 needed to be established.

13 Q. And the person who might not feel that the
14 utility had been established was the customer; is
15 that correct?

16 A. Yes.

17 And I would say the customer, in this
18 example, would be a physician.

19 Q. Any physician or a particular type or
20 field of physician?

21 A. Well, that's somewhat -- somewhat
22 circular.

1 The -- the intention of establishing
2 ourselves as a CLIA lab to do whole genome
3 sequencing is to help build the evidence of the
4 clinical utility of whole genome sequencing.

5 And that clinical utility would be
6 directed to a particular type of physician, so that
7 use was in development.

8 Q. It's an example of Illumina driving
9 adoption of a new technology as opposed to entering
10 a market where the use was already -- the utility
11 was already recognized by the customer?

12 A. That's correct.

13 MR. HANKINSON: Can we take like a couple
14 minute break, and then, probably, I'm done.

15 MR. HORNE: Absolutely.

16 Let's go off the record.

17 DEPOSITION OFFICER: Off the record.

18 (Whereupon, a recess was held
19 from 1:09 p.m. to 1:22 p.m.)

20 DEPOSITION OFFICER: Back on the record.

21 MR. HANKINSON: Ms. O'Grady, thank you
22 very much. I don't have any further questions at

1 this time.

2 I understand that counsel for your
3 company, Illumina, is going to ask one question, he
4 says -- although sometimes that's accurate -- in
5 what we call redirect.

6 I'm not aware at this time of the rules
7 governing whether he's allowed to do that, so we're
8 going to lodge an objection and reserve our rights
9 to any relief related to that later, but go ahead
10 and allow it to happen so that we've got the record
11 if it's appropriate and needed.

12 THE WITNESS: Okay.

13 MR. HORNE: And for the record, the
14 purpose of this redirect is to clarify testimony
15 given today, to the extent that makes any difference
16 going forward.

17

18 EXAMINATION

19 BY MR. HORNE:

20 Q. Ms. O'Grady, you were asked a question
21 earlier in your deposition about genotyping, and I
22 believe the question was whether genotyping relates

1 to inherited disease.

2 Do you remember that?

3 A. Yes.

4 Q. Is that all that genotyping relates to?

5 A. No.

6 Q. What else does genotyping relate to -- or
7 could genotyping relate to?

8 MR. HANKINSON: Objection; three
9 questions.

10 Go ahead.

11 THE WITNESS: Our genotyping products, or
12 the way we refer to genotyping, is discriminating
13 bases from each other to identify variants or answer
14 questions.

15 And that has application in inherited
16 disease; in oncology for somatic variant detection,
17 or discriminating variants in a tumor.

18 And it also is applicable to
19 distinguishing pathogens from each other in an
20 infectious disease environment.

21 BY MR. HORNE:

22 Q. Is that all?

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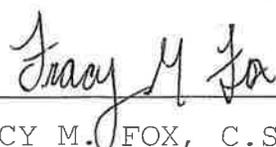
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6 Case: Illumina, Inc. v. Meridian Bioscience, Inc.

7 Date of deposition: December 4, 2014

8 Deponent: Naomi O'Grady

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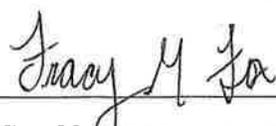
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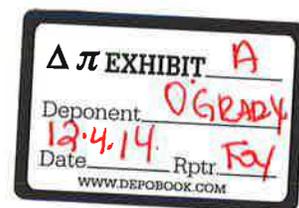
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Illumina's Pharma Deals Aim to Bring Universal MiSeqDx-based CDx through FDA Clearance

Aug 27, 2014 | [Monica Heger](#)

Premium

NEW YORK (GenomeWeb) – Illumina said this week that it is collaborating with pharmaceutical companies AstraZeneca, Janssen Biotech, and Sanofi to develop a next-generation sequencing-based panel to serve as a universal companion diagnostic.

The company told *Clinical Sequencing News* that it would leverage its US Food and Drug Administration-cleared MiSeqDx system to develop an oncology test kit that includes the NGS system, bioinformatics capabilities, and reagents necessary to target single nucleotide variants, indels, copy number variants, and gene fusions.

Earlier this year, Illumina [struck a deal with Amgen](#) to develop an NGS-based companion diagnostic test for its colorectal cancer drug Vectibix (panitumumab), which it also plans to bring through FDA approval. Illumina's Senior Product Manager of Oncology, Naomi O'Grady, told *CSN* that the recent pharma agreement will not impact the deal with Amgen. "The work we're doing with Amgen will be complementary to the claims we're trying to achieve on our system and with our technology to also support the work with our universal oncology test," she said.

Bringing the universal oncology panel through FDA clearance will not require substantial changes to the core sequencing technology, O'Grady said. Rather, the company aims to expand on MiSeqDx's indications for clinical use in oncology. The system [received FDA clearance](#) last year in conjunction with two cystic fibrosis assays as well as a universal assay. A key difference in using the MiSeqDx for oncology purposes is that it will need to be cleared for use on formalin-fixed paraffin-embedded tissue, O'Grady said. Currently, it is cleared only for targeted sequencing of DNA from whole blood. Its use also must be expanded to include the detection of somatic, rather than germline, variants.

In addition, O'Grady said that Illumina would be looking to develop targeted library prep methods and bioinformatics pipelines "tailored specifically for the variants requested by our pharma partners."

She declined to disclose how many genes would be included on the test, but noted that the pharmaceutical companies would drive its content. According to Illumina, there are an estimated 800 oncology drugs in development, many of which are designed to target specific mutations.

The test will be able to detect SNVs, indels, copy number changes, and gene fusions and will

1-A

include not only a DNA component, but also an RNA component, O'Grady said. The DNA and RNA assays will not be separate tests, but rather "parallel reactions" that are part of a complete kit.

Initially, the test will be developed for the pharmaceutical companies Illumina is working with to enable their drug registration trials, O'Grady said. And, as the companies achieve regulatory approval for the drug/CDx combination, Illumina will market the test to molecular pathology labs in the areas where that drug would be marketed, she said.

In order to bring the test through FDA clearance, Illumina will be working closely with its team at Myraqa, a regulatory and quality consulting firm that [it acquired last month](#).

Illumina also hopes to work with the FDA to implement a different process for bringing the multi-analyte test through approval. In the current companion diagnostic paradigm, "each diagnostic system is designed with the needs of a specific drug in mind," Mya Thomae, vice president of regulatory affairs at Illumina, told *CSN*. But because Illumina and its pharma partners are looking to develop one test for multiple biomarkers, "we'll be working with FDA to ideally find a pathway that allows us to take the system through just once and then provide follow-up submissions to update intended use statements or add new content as new markers are identified."

At the American Association for Cancer Research meeting in San Diego earlier this year, the FDA's Director of Personalized Medicine, Elizabeth Mansfield, said that the FDA is [open to such multi-analyte tests](#), but that for such a test to pass regulatory muster, there must be standards.

Illumina plans to address the issue of standards for clinical sequencing with its actionable genome consortium, a collaborative effort between the firm, major cancer centers, and other leaders in the oncology field to develop clinical sequencing standards. O'Grady said that Illumina would talk about its progress in this area soon.

She noted that the pharmaceutical collaboration will "create the ability to standardize testing in a decentralized way," and as such, clinical standards like the ones that will be defined by the actionable genome consortium will be necessary.

"Having a single test that's available in the regions where pharma is looking to offer drugs, really enables a unified test platform with standardized performance," she added.

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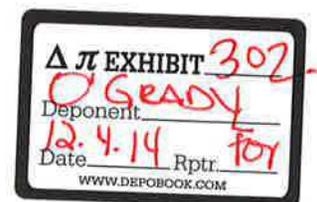
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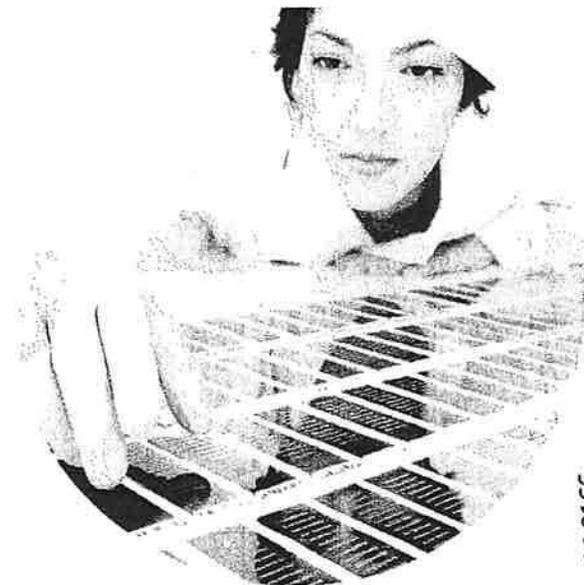
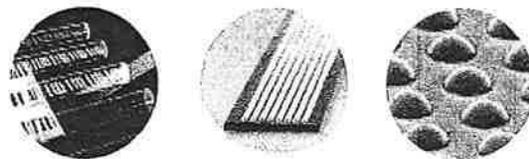
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Exhibit 302



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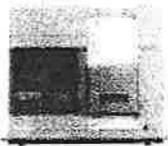
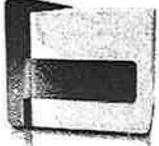
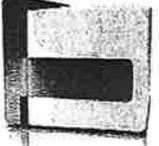
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VeraCode Technology – *From Research to Molecular Diagnostics*

Presented by:

Mickie Henshall,
Market Manager, Molecular Diagnostics

Most Complete Genomics Assay Portfolio

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TECHNOLOGY	Solexa Sequencing	BeadArray	BeadArray	VeraCode
PLATFORM	 Genome Analyzer	 iScan	 iScan	 BeadXpress
ASSAY	Sequencing by Synthesis	Infinium Assay Direct Hyb	Infinium Assay GoldenGate & DASL Assay	GoldenGate & DASL Assay
MARKER DENSITY	1base to >3GB	240K to 1M	6K to 60K (iSelect) 96 to 1536 (GoldenGate) Custom Standard	1 to 384-plex Custom
PRODUCT	Resequencing	HumanIM-Duo	Infinium iSelect Genotyping Panels 6K-60K	Linkage-12
	SNP & CNV Discovery	HumanHap650Y	GoldenGate Genotyping Panels 96-1536	CNV-12
	De novo Sequencing	Human610-Quad	DASL Expression Panels 384-1536	MHC CG
	Tag Expression	Exon510-Duo	GoldenGate Methylation Panels 384-1536	African American Admixture GG
	Transcript Profiling	HumanCNV370-Duo	CanineSNP20	Methylation
	ChIP Sequencing	Human 6/Ref-8 Gex	BovineSNP50	Carboxyl - Protein
	MeDIP Sequencing	Mouse 6/Ref-8 Gex	Micro RNA	Genome-wide Methylation
	BiSulfite CpG	Rat Ref-12 Gex	Methylation Cancer Panel I	
		Genome-wide Methylation27		

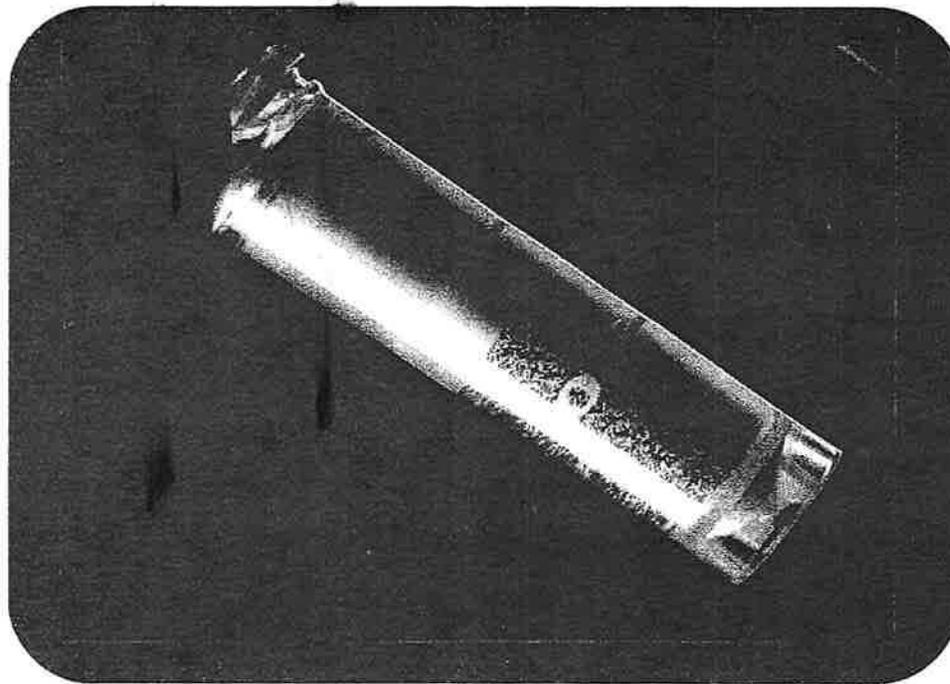
2008 Release

illumina®

ILLUM-0167

Illumina's Solution for Diverse Applications

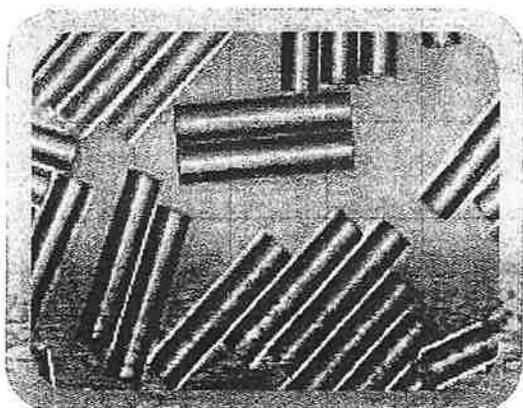
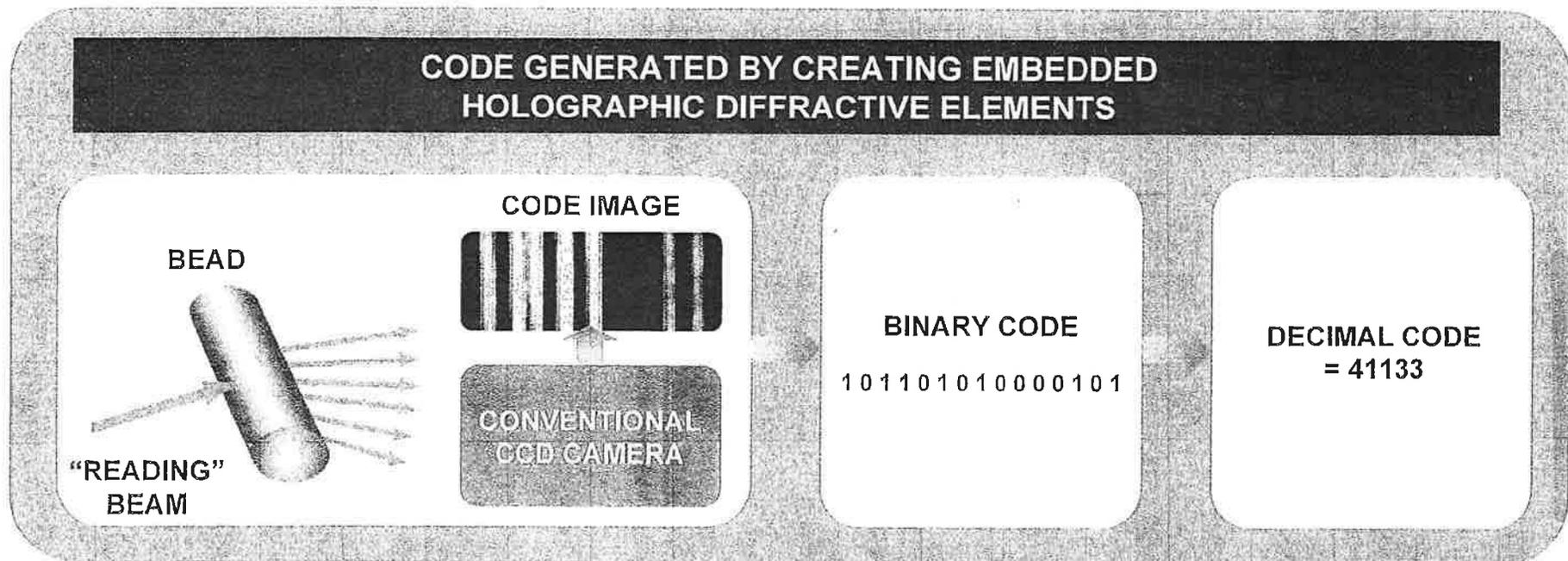
VeraCode® Technology



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

ILLUM0168

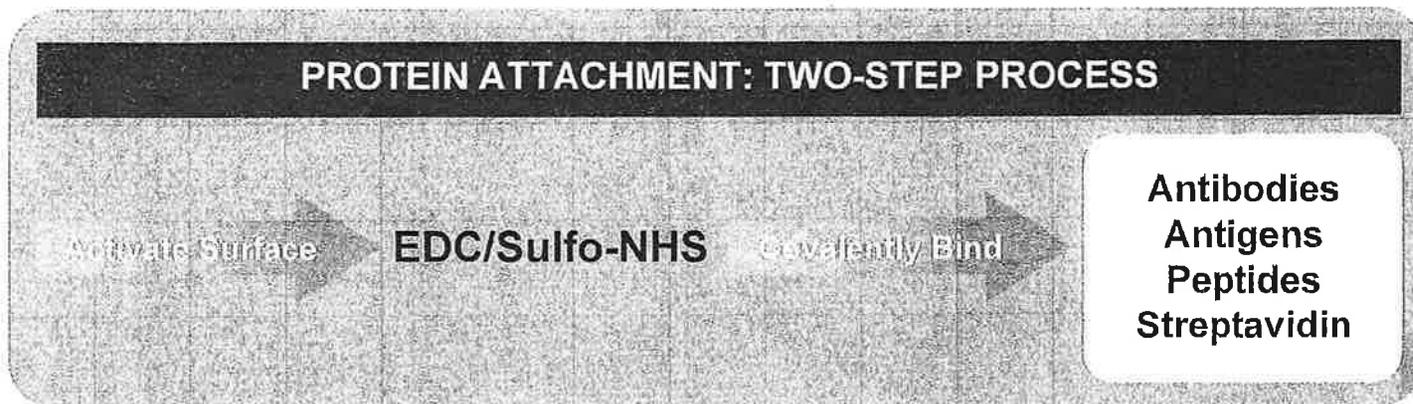
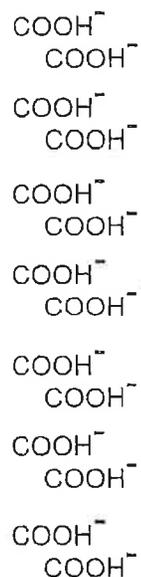
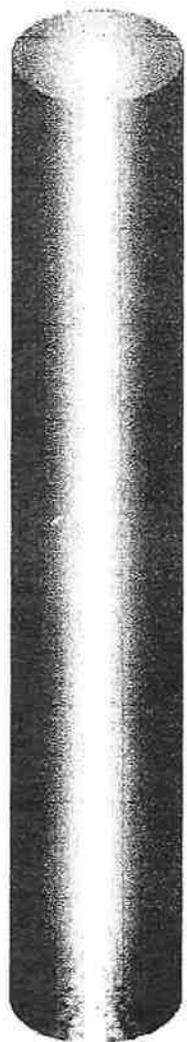
VeraCode Technology



- 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

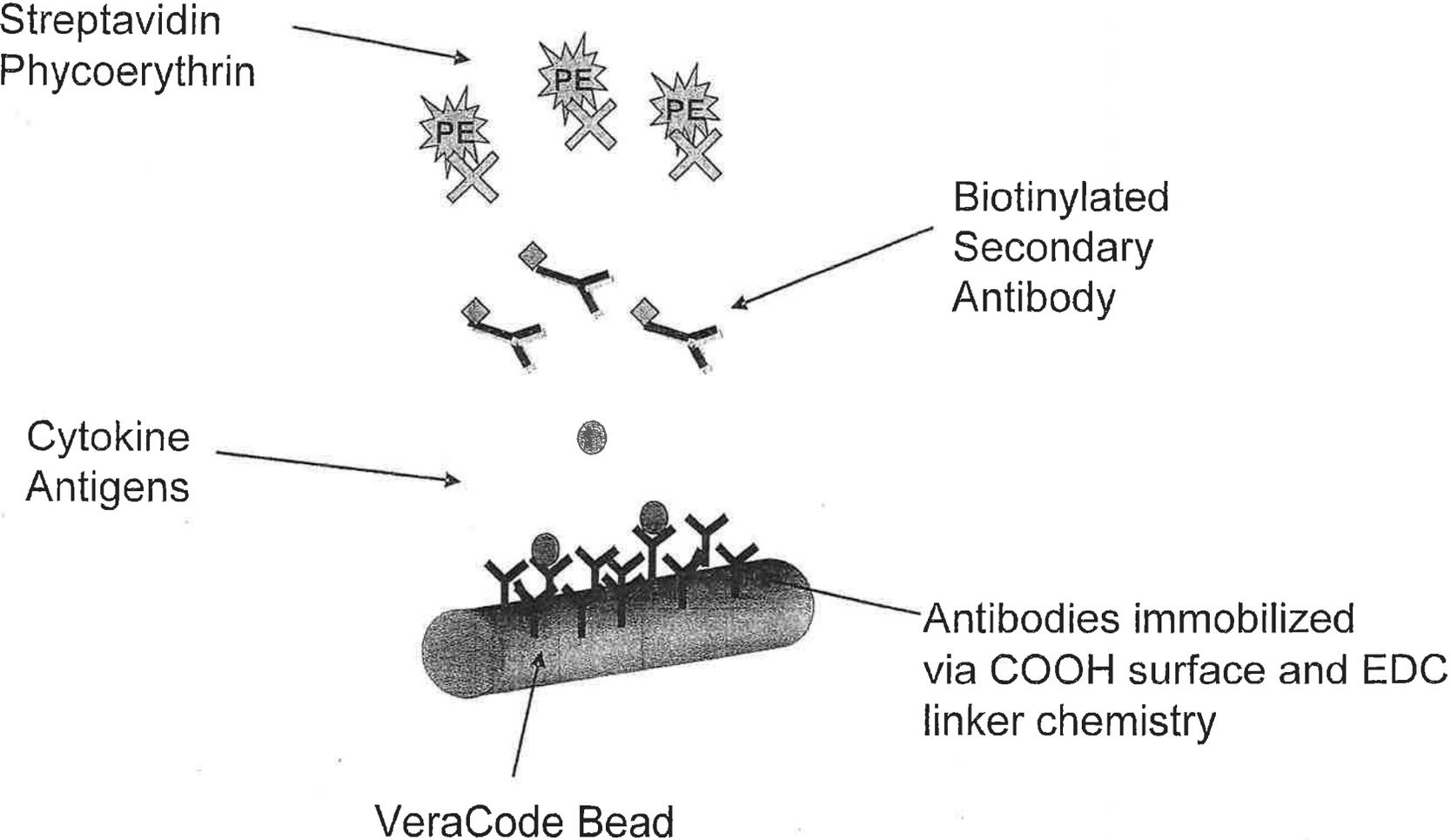
illumina®

Carboxyl Beads: Chemistry of Attachment



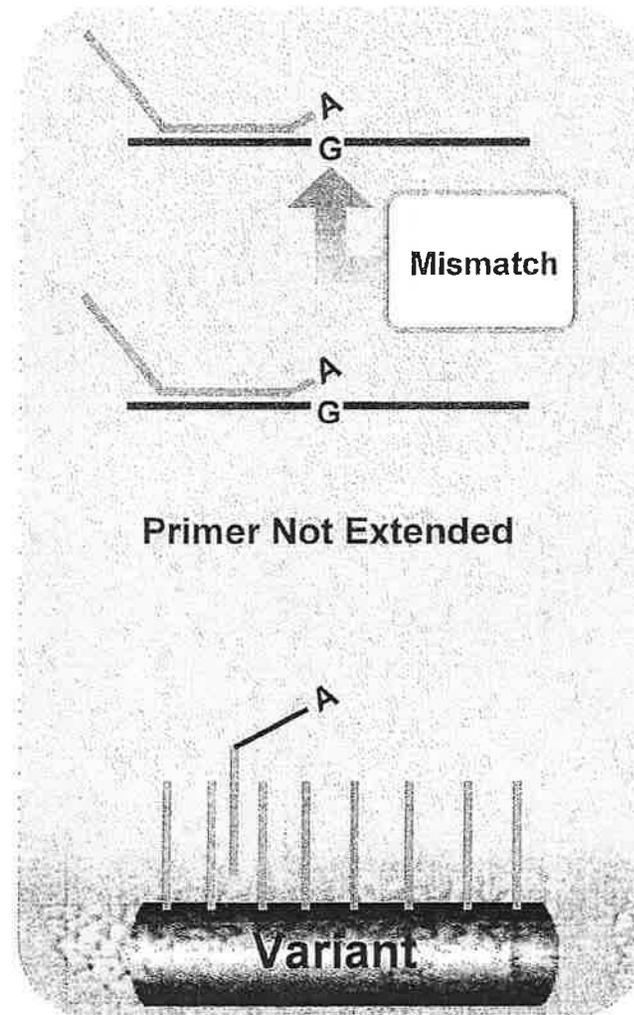
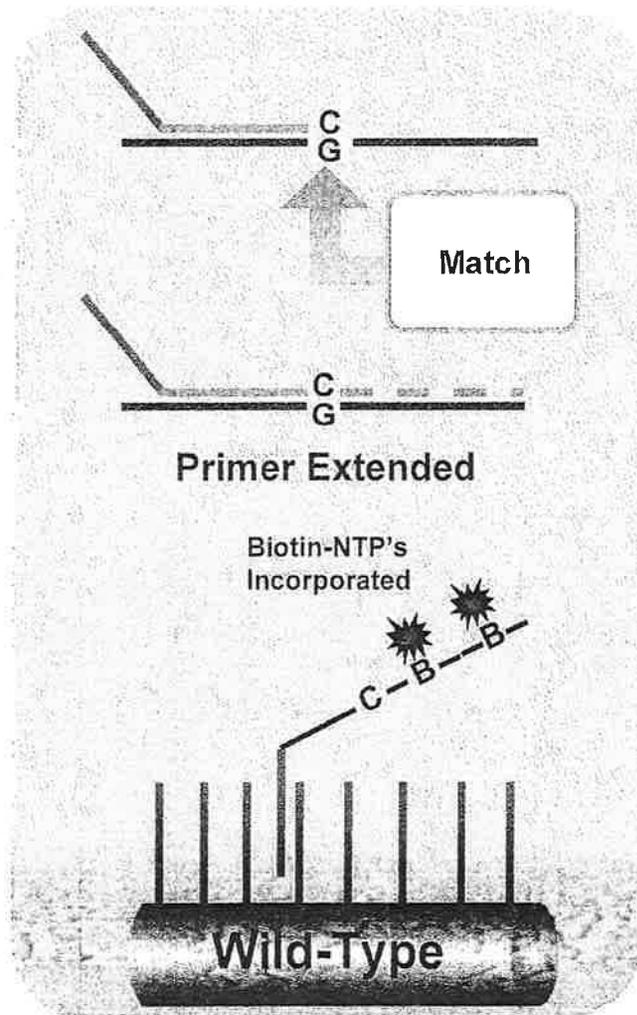
ILLUM-0170

Cytokine Sandwich Assay



ILLUM-0171

Universal Oligo Capture Beads

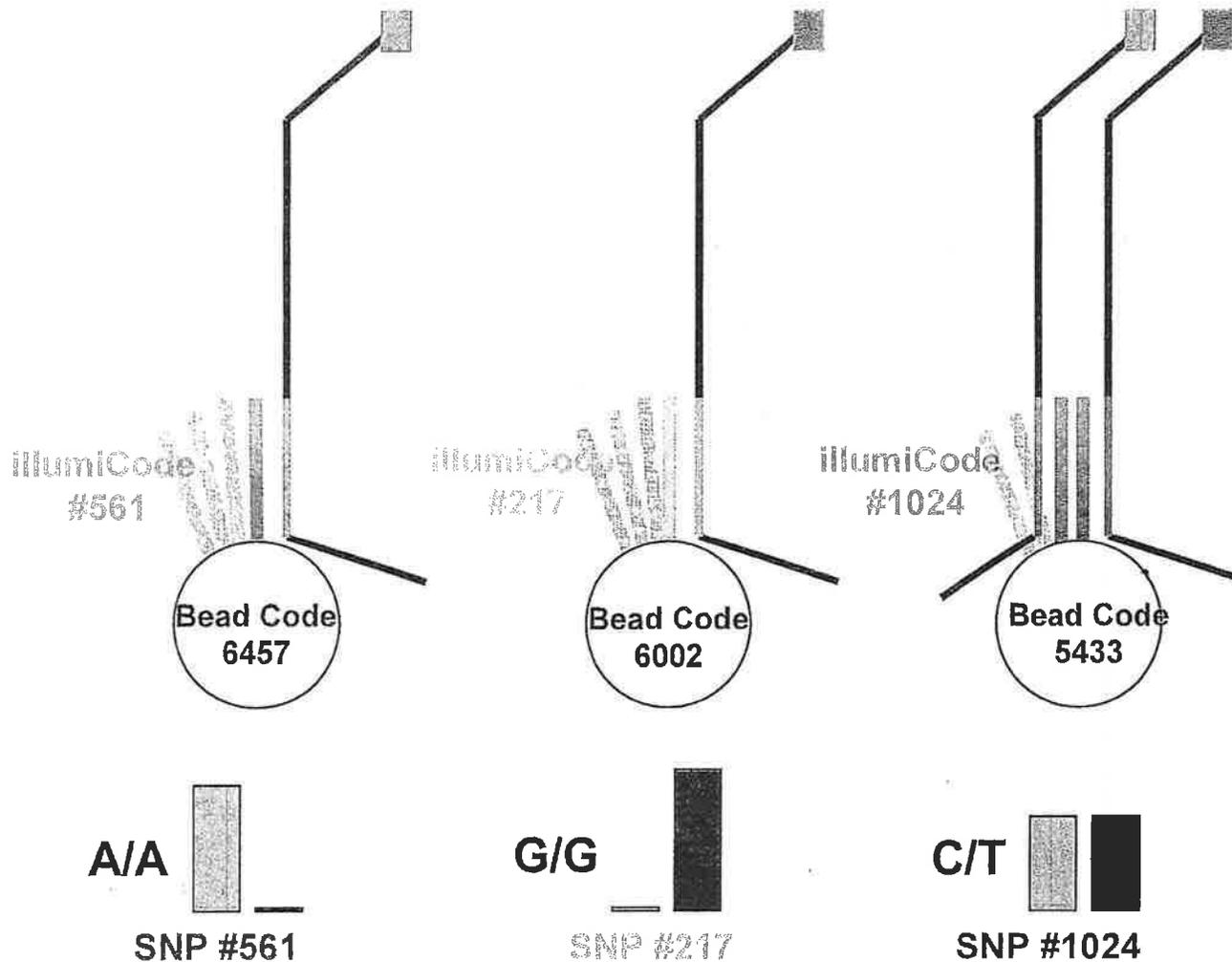


Allele Specific Primer Extension Assays

ILLUM-0172

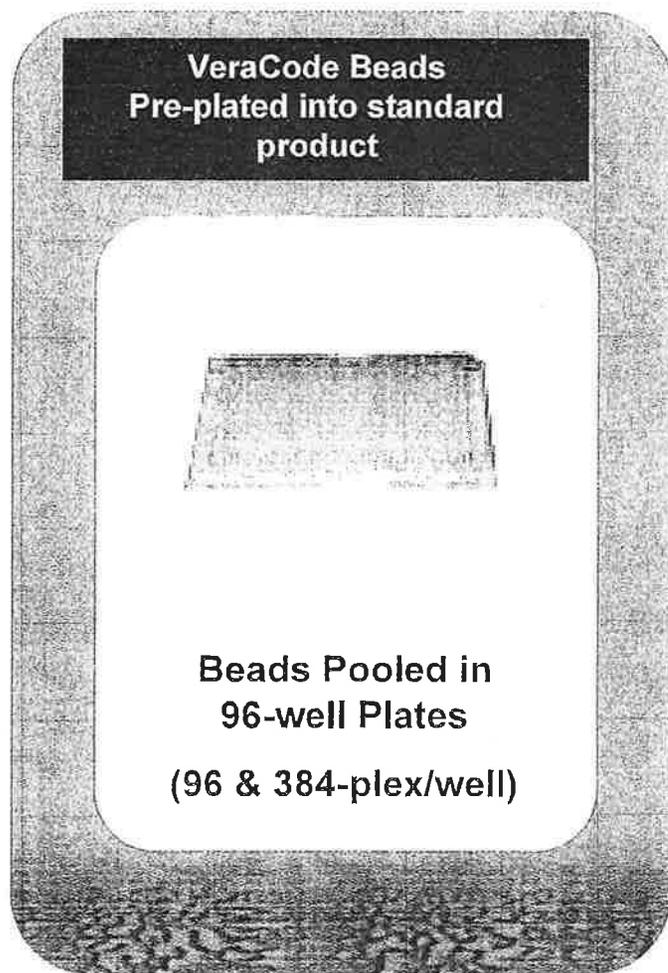
GoldenGate Assay – two color detection

- Hybridization to VeraCode Beads – one SNP per bead type

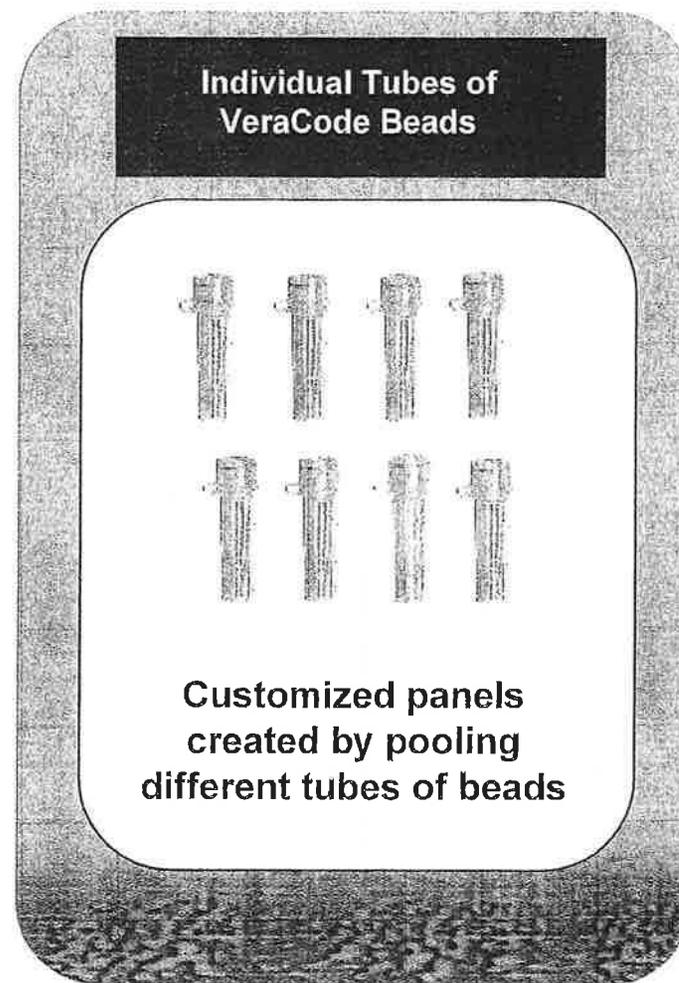


ILLUM-0173

Easily adaptable to changing content requirements



+

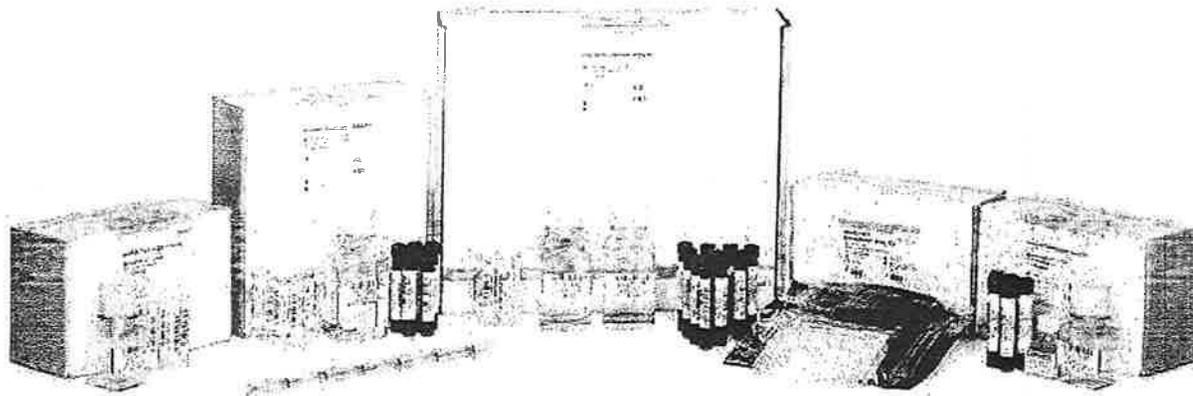


ILLUM-0174

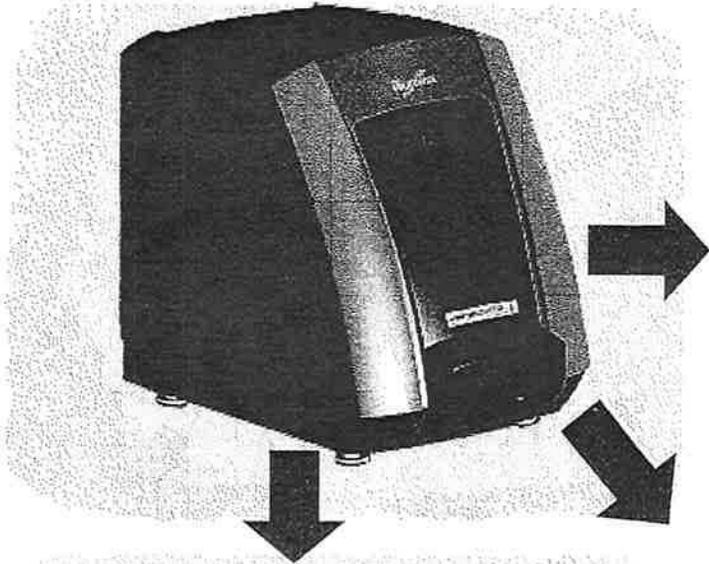
Comprehensive VeraCode product portfolio

- VeraCode Carboxyl Bead Sets
- VeraCode Universal Capture Bead Sets
- Custom GoldenGate Genotyping, 96 & 384-plex
- DASL Custom Gene Expression, 32 to 384-plex
- Custom GoldenGate Methylation, 48 to 384-plex

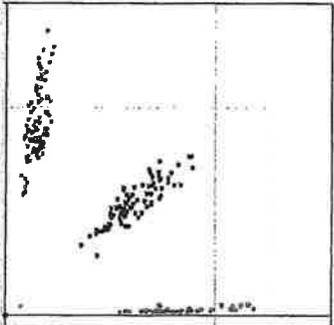
ILLUM-0175



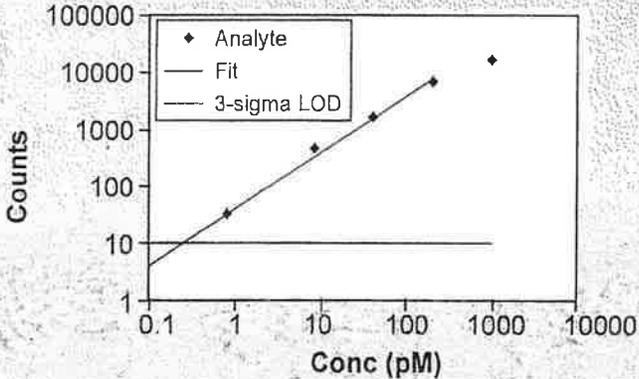
Analyzer for Multiple Applications



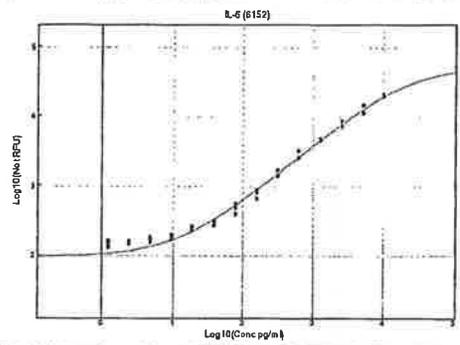
GENOTYPING



GENE REGULATION



PROTEIN EXPRESSION



ILLUM-0176



BeadXpress™ Reader

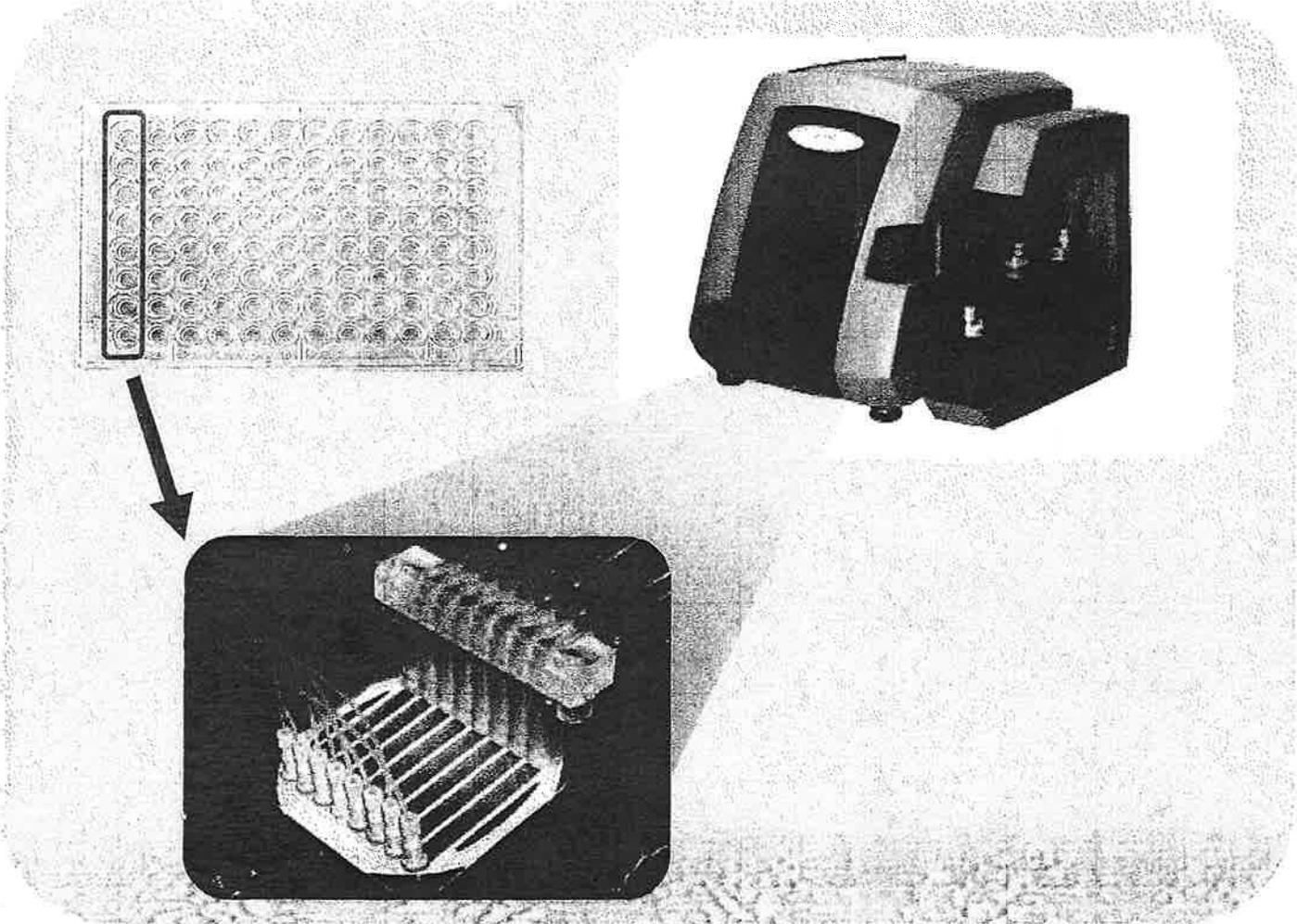


INSTRUMENT SPECIFICATIONS

SAMPLE DELIVERY FORMAT	<ul style="list-style-type: none"> Standard 96-well plate & Stripwell Plates
MULTIPLEXING PER SINGLE WELL	1 to 384
THROUGHPUT	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Designed to be compatible with standard laboratory automation
REGULATORY	<ul style="list-style-type: none"> Developed under Regulatory Design Control (DHF)

ILLUM-0177

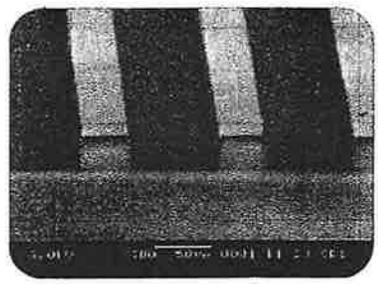
BeadXpress Reader



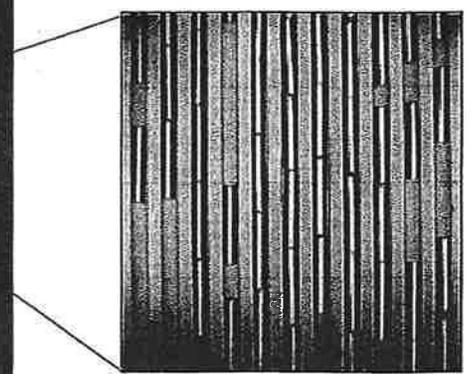
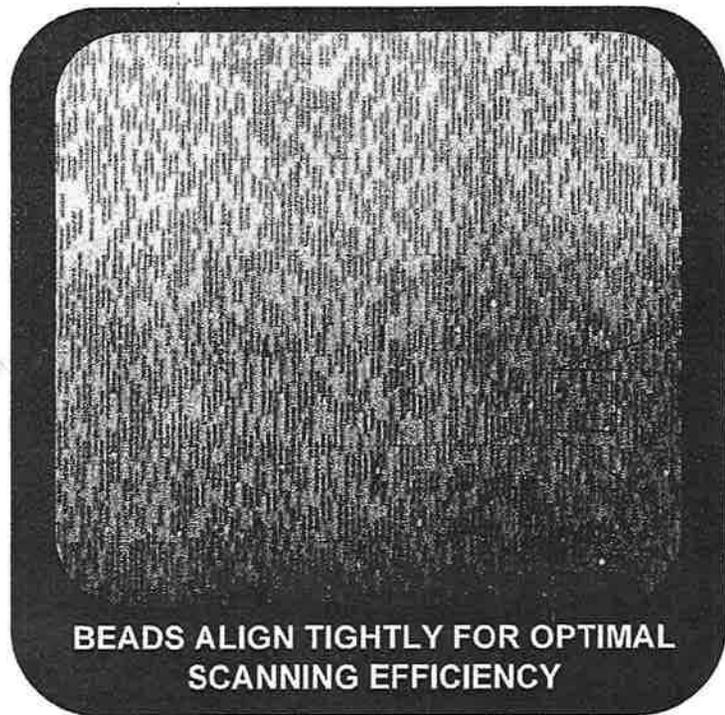
ILLUM-0178

VeraCode Technology

**CAPILLARY FORCE ATTRACTS
BEADS INTO GROOVES**

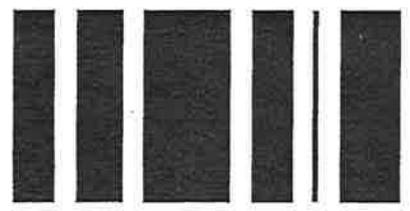
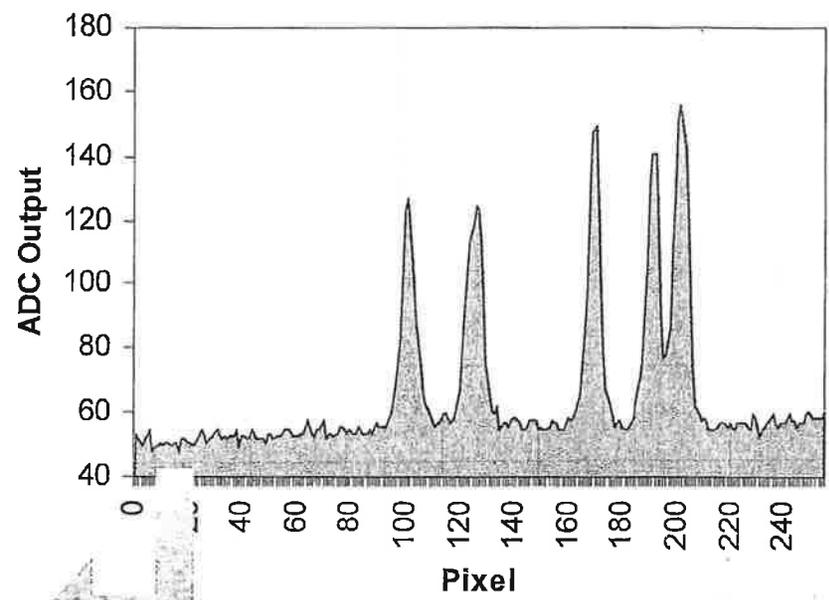
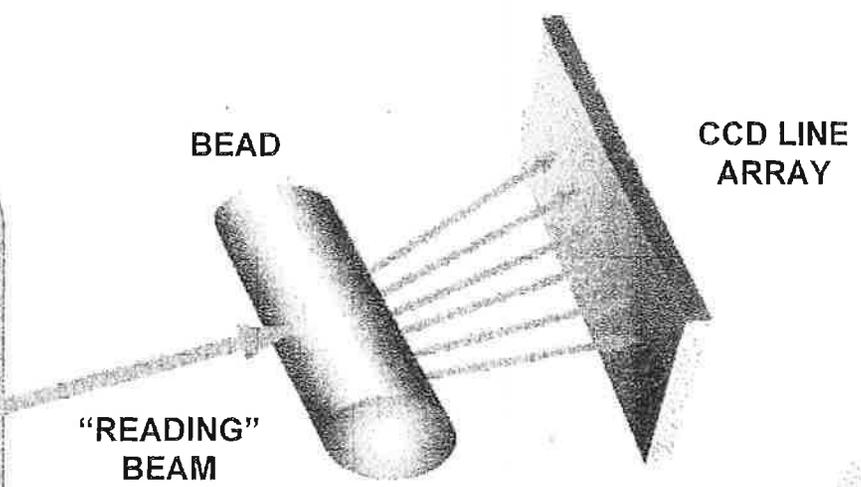


**GROOVE PLATE
CROSS-SECTION**



ILLUM-0179

Code Detection



ILLUM-0180

Data Analysis Streamlined with BeadStudio

The screenshot displays the BeadStudio software interface with several key components:

- Assay Results Table:** A table with columns for Assay ID, Assay Name, Assay Type, Assay Status, Assay Date, Assay Time, Assay Location, Assay Operator, Assay Instrument, Assay Protocol, Assay Version, Assay Batch, Assay Lot, Assay Expiry, Assay Calibration, Assay Validation, Assay Performance, Assay Accuracy, Assay Precision, Assay Sensitivity, Assay Specificity, Assay Linearity, Assay Range, Assay Dynamic Range, Assay Resolution, Assay Reproducibility, Assay Reliability, Assay Robustness, Assay Stability, Assay Consistency, Assay Variability, Assay Bias, Assay Drift, Assay Noise, Assay Interference, Assay Cross-reactivity, Assay Non-specificity, Assay Background, Assay Signal-to-Noise Ratio, Assay Signal-to-Background Ratio, Assay Signal-to-Interference Ratio, Assay Signal-to-Cross-reactivity Ratio, Assay Signal-to-Non-specificity Ratio, Assay Signal-to-Bias Ratio, Assay Signal-to-Drift Ratio, Assay Signal-to-Noise Ratio, Assay Signal-to-Interference Ratio, Assay Signal-to-Cross-reactivity Ratio, Assay Signal-to-Non-specificity Ratio, Assay Signal-to-Bias Ratio, Assay Signal-to-Drift Ratio.
- SNP Graph:** A scatter plot showing Norm R vs Norm Theta for SNP M667. The plot shows three distinct clusters of data points, indicating different genotypes.
- SNP Graph Alt:** A scatter plot showing Intensity (B) vs Intensity (A) for SNP M667. The plot shows three distinct clusters of data points, indicating different genotypes.
- Full Data Table:** A table with columns for Index, Name, Address, Chr, Position, GType, Score, Theta, R, GType, Score, Th. It lists data for Sample 73 (PCRI_101804-1001) and Sample 4 (PCRI_101804-1001).
- Samples Table:** A table with columns for Index, Sample ID, Sample Section, Call Rate, Genotype for M667, p05 Grn, p50 Grn, p95 Grn, p05 Red. It lists data for various samples and their genotypes.

ILLUM-0181

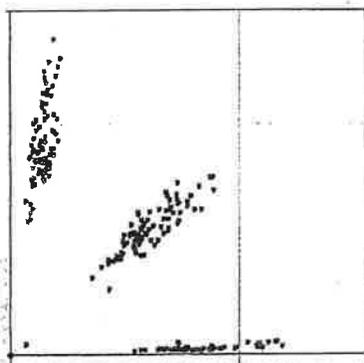
What's Next for BeadXpress

- 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-ting the Origins of the Domestic Cat – Efficiency of the GoldenGate[®] Assay for VeraCode[®] in Cat Genetics

ILLUM-0184

Leslie A. Lyons, PhD
Associate Professor
Department of Population Health & Reproduction (PHR)
School of Veterinary Medicine
University of California, Davis

Exhibit 303

$\Delta \pi$ EXHIBIT 303
Deponent: O'GRADY
Date: 12.4.14 Rptr: Fox
www.DEPOBOOK.COM

1-303

illumina.

BeadXpress System



The difference
between
good data
and great data
is in the code.

BeadXpress™ System and VeraCode™ Technology Launch Package

Prepared by M. Henshall
Market Manager, Molecular Diagnostics
.03/21/07
Updated 11/23/2008

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Overview

Introduction

On behalf of the BeadXpress Reader Team, the Physical Bead Team, the VeraCode GoldenGate Team, the R2 Assay Development Team, the Test & Calibration Team, Software, Customer Solutions and Marketing, welcome to the Launch Package for the BeadXpress System and VeraCode Technology.

Within this launch package, you will find details on our 2007 launch of:

- The BeadXpress Reader System
- GoldenGate Genotyping with VeraCode (96 & 384-plex)
- VeraCode Universal Capture Bead Sets
- VeraCode Carboxyl Bead Sets
- BeadXpress Accessories, Warranties and Training Programs

Compelling Reason to Buy

Illumina's VeraCode technology with the BeadXpress Reader leverages the power of digital holographic codes to provide a robust detection method for low-cost multiplex assays requiring high precision, accuracy and speed. VeraCode is a technology solution that grows with customers needs and remains relevant during dynamic changes in research pursuits. This technology offers many distinct advantages over competitive technologies, including:

- High Data Quality
Industry-leading measurement density and sensitivity due to inherent stringency of code detection
- Broadest Multiplexing Capability on the Market
Using digital holographic coding technology, the system enables development of the broadest range of multiplexing currently available on the market. Assays ranging from a single-plex up to a 384-plex per sample can be performed from a single well of a standard 96-well plate.
- Use of Codes for Increased Quality Metrics
Customers can utilize unique bead codes in the assay as identifiers for internal controls, as well as for unique identifiers such as reagent lots, test kits and sample ID.
- Assay Versatility

Customers will have the ability to perform a broad range of applications, including genotyping and protein-based assays on a single platform.

- Dual Color Laser Detection

The two-color laser detection of the BeadXpress Reader enables customers to have the ultimate flexibility in assay design. Customers can run either the two-color detection (ie., GoldenGate Assay) or single-color detection (ASPE), depending on their specific protocol.

Market Opportunity

Target Market

The unprecedented range in multiplexing and ability to support a multitude of applications such as genotyping and protein analysis, provides a very large market opportunity for the BeadXpress Reader. It is estimated that this combined market, serving genotyping, gene expression, and protein analysis, provides approximately \$800M available market, with a 15% CAGR. With instruments already addressing a significant portion of the market making up the high throughput/high complexity labs, Illumina can leverage the BeadXpress to capture the broader market of lower multiplex customers. Illumina's experience and technical expertise with SNP detection, coupled with the wide range of multiplexing capabilities of the BeadXpress, will make SNP genotyping the ideal assay for early adopters. Because 41% of the SNP detection market currently uses real time PCR (Frost & Sullivan, 2005), the VeraCode products are designed to demonstrate clear economic benefits, excellent performance and efficiency to the lab. Additionally, the broad range of BeadXpress multiplexing capabilities will allow us to adapt to market changes, and secure niche markets. The target market and customer base include:

- Researchers interested in focused analysis of markers of interest following a larger microarray discovery project. These include existing Illumina customers owning a BeadArray Reader, in addition to other competitive platforms.
- Researchers interested in performing SNP genotyping analysis of a broad range of multiplex reactions, typically higher than a 3-plex reaction, and/or a high volume of samples per project.
- Researchers interested in developing their own protein-based multiplex assays and/or genotyping assays.
- CLIA High Complexity certified laboratories interested in developing "laboratory developed tests" using RUO products for multiplex assays.

Competition



BeadXpress System

With the many existing and emerging multiplex technologies, Illumina faces strong competition in this rapidly growing market. The table below lists the top competitors and their platforms that the BeadXpress System will be competing directly against for market share. While each competitor has had success in the market, it is Luminex that poses the most direct challenge to BeadXpress, especially in terms of the multiplexing technology, a very large install base, and a formidable menu of tests. Since the commercial launch of the Luminex 100 System in 1999, close to 4,000 instruments have been sold to date. The technology, based on 100 distinctly colored microbead sets, has been used in numerous applications ranging from genotyping, gene expression, kinase selectivity, protein, and immunoassays. Luminex distributes its products through partnership agreements with more than 50 research and diagnostic companies. Most of these partners develop and market their own branded assays to run on the Luminex system. The sheer number of Luminex partners will make it challenging to compete against currently available product menus, numerous peer reviewed publications, and the coverage by sales representatives. Current partners in the research market include: Applied Cytometry Systems, Bio-Rad, BioSource, GenoSpectra, LINCO Research, Marligen Biosciences, MiraiBio, Qiagen, R&D Systems, Radix BioSolutions and Upstate.

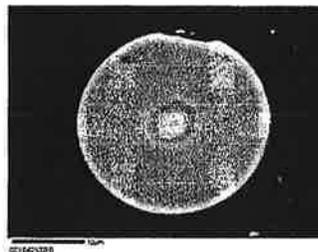
	ILLUMINA BEADXPRESS	LUMINEX	SEQUENOM	ABI SNPLEX	ABI TAQMAN
Max Multiplex per Sample (genotyping)	384 (432 w/controls)	50	36	48	1
Instrument Cost	\$98,500 (training included)	\$20,000 - \$65,000	\$300,000 (iPlex)	\$225,000	\$95,000
Price/SNP	\$0.85 - \$0.06	\$1.00 - \$0.15	\$0.20 - \$0.03	\$0.36 - \$0.08	\$0.80 - \$0.10
Pricing restrictions	customers developing homebrews will need to optimize reagents & workflow to determine pricing (like Luminex)	Very high volume for lowest pricing; optimized multiplex homebrew	Lowest price based on iPLEX Gold assay; 36-plex; 384 samples fully utilized per run	Lowest price based on high volume, and full utilization of 48-plex per sample	Only one site reporting lowest price; very high volume usage and low rxn volumes (2ul); not typical
# Apps. (GE, etc..)	Genotyping Protein Assays Gene Expression (coming soon!)	Genotyping Gene Expression Protein Assays	Genotyping Gene Expression	Genotyping	Genotyping Gene Expression
Strength	Unique code identifiers for increased precision & data quality; broadest multiplexing range and applications on the market	Flexibility; assay diversity & large install base. Recently purchased Tm Bioscience, giving them FlexMap beads, and GT assays.	Low price per SNP.	Utilizes strength of Tagman and sequencing; high accuracy	High quality data; gold standard for gene expression
Weakness	Development of gene expression application in progress; "Assay-in-a-box" approach for lower multiplex (like Sequenom) to be developed	Limited multiplex range; Limited genotyping assays possible on system (single color scan)	Cost per SNP scales significantly when lowering multiplex/sample; Customers report at max 90 to 95% call rates; limited multiplex	Low throughput; not readily scalable; long assay workflow; limited multiplex range.	High cost and low multiplex; not scalable for large projects

Product Information

Technology Overview – The Holographic Codes

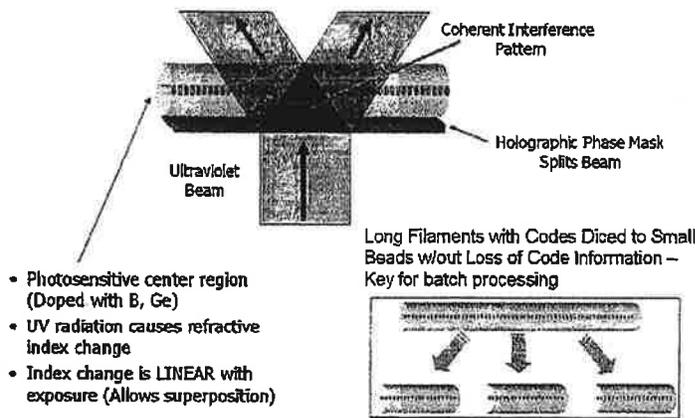
The single-most identifying feature of the VeraCode technology is the holographic codes inscribed within each microbead. It is this feature that immediately captures the attention of potential customers, opens a new realm of quality management and delivers highly accurate and robust data. The process of manufacturing these unique microbeads required the invention of proprietary instrumentation by our team in Connecticut. If you have the opportunity, it is an excellent learning experience to view this manufacturing process first hand.

VeraCode technology is based on cylindrically-shaped glass microbeads, measuring 240µm in length by 28µm in diameter. The center of each particle contains a region that can support a nanometer-scale, permanent change to index of refraction when exposed to ultraviolet light. Under certain exposure conditions, this index change can form a sinusoidal hologram which is imprinted via a local structural change of the glass matrix.



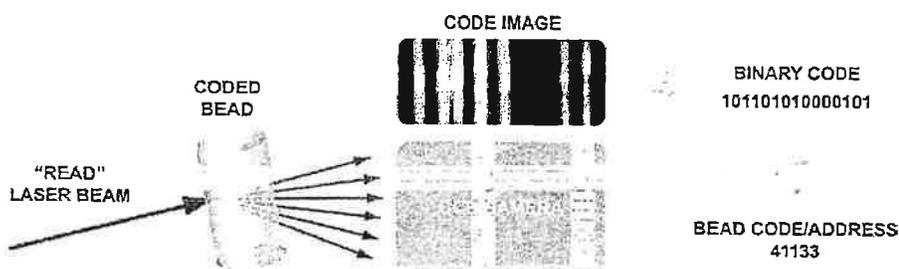
Each hologram embedded in the glass particle diffracts incident monochromatic light into a specific angle. Figure 1 illustrates this concept. Each diffraction angle represents a digital "bit" of information, and its presence or absence from the particle determines whether the corresponding bit is 1 or 0, respectively.

Principles of Holographic Writing Technique

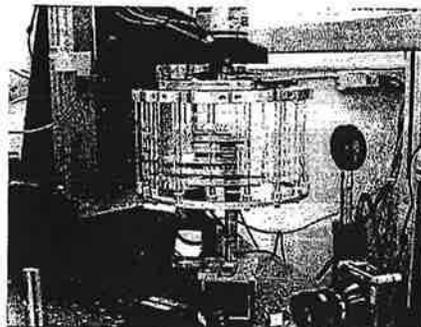
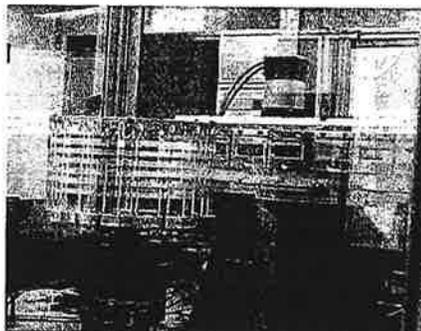


By successively writing a series of holograms into a particle, a specific pattern of 1's and 0's can be produced on the imaging electronics. These sets of diffraction angles provide an inscribed digital holographic code that uniquely identifies a particular bead.

Millions of unique bead types can be made by inscribing a limited number of unique combinations of overlapping holograms. For example, 20 bits, which has been demonstrated in the laboratory, provide 2^{20} unique codes. With this large a code space available, beads can be used for customizable tracking of not only the analyte in a particular assay, but also key information such as sample ID, laboratory ID, lot numbers, and reagent kits. In addition, the large number of available codes allow for the inclusion of multiple bits for error-checking, which greatly improves the robustness and reliability of the optical readout process.



Because bits are added one at a time in a programmable manufacturing cell, producing batches of the particles with an arbitrary code is relatively straightforward and can be accomplished with a small number of exposures.



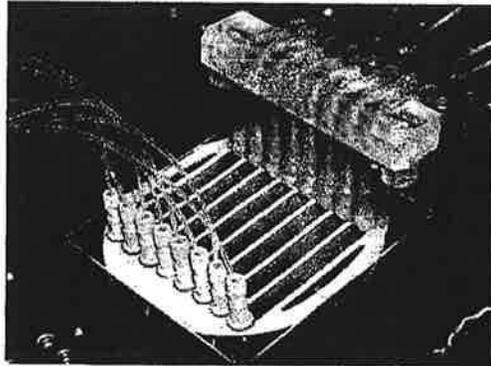
Another feature of VeraCode microbeads is the physical properties of the silica glass used to manufacture the beads. Due to the specifications for purity of the glass, there is minimal fluorescent background that could potentially interfere with the chemical readout of an assay. Silica glass is also an ideal substrate to attach biomolecules and a wide variety of techniques may be used to form linkers between the glass surface and the capture moiety via wet chemistry techniques. Oligonucleotide and protein (antibody) probes can be attached to the VeraCode

illumina

BeadXpress System

microbeads, and the performance of each of these functionalized particle types in biological assays.

Primary among the novel technologies developed for readout of VeraCode beads is the transparent "groove plate". The purpose of the groove plate is to spatially create an array of particles at high packing density, where the particles are aligned in a specific direction relative to the readout optics.



The groove plate forms the bottom of a fluidic cell that has eight chambers, one for each well in a column of a standard 96-well plate. This cell forms the heart of the reader system. The BeadXpress Reader accepts a standard 96-well microplate or 8-well strips in a standard stripwell carrier. The reader draws eight samples at one time from a column of the microplate. The internal fluidics of the systems delivers the beads to the eight sectored groove plate cell. 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 the microbeads are aligned, the entire cell is actuated across the optical system and the beads are scanned for fluorescent measurement and code classification.



Greater than 90% of the holographic codes are classified when aligned in the groove plate. The ability to efficiently pack microbeads into the groove plate is a key feature to keep sample readout time low.

BeadXpress and VeraCode Product Offering

To support broad adoption of this technology and highlight the flexibility of this platform, Illumina has developed a breadth of products and services to enable customers with the broadest multiplexing range in the industry and the development of numerous applications.

- BeadXpress Reader System

The BeadXpress Reader System is a high-throughput, dual-color laser detection system that allows you to scan large volumes of VeraCode assays in a wide range of multiplexed levels. The BeadXpress Reader provides powerful tools for nucleic acid and protein applications. Included with the purchase of a BeadXpress Reader is a one year limited warranty, a system reagent carrier for reagent bottles, the BeadXpress Starter Kit which includes a VorTemp incubating plate mixer and the VeraCode Bead Kitting System, and a full day on-site training provided by a Field Applications Scientist.

Specification	Requirements
Environmental Conditions	For Indoor Use Only Altitude up to 2000 M Temperature range 15°C to 30°C Humidity: 10 to 90% RH
Electrical Ratings	10 – 120 Vac, 2.0 A, 50/60 Hz, Class I or 200 – 240 Vac, 2.0 A, 50/60 Hz, Class I Installation Category (Over voltage) II
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	47 cm (w) x 77 cm (d) x 72 cm (h) for BeadXpress Reader 46 cm (w) x 40 cm (d) for PC, keyboard, and monitor Sturdy bench that is level within +/- 2 degrees
Access to Receiving Dock	76 cm (w) x 96.5 cm (d) x 86.5 cm (h) for the BeadXpress Shipping Crate 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 15 A for 110V version of the BeadXpress Reader 12 A for 220V version of the BeadXpress Reader This includes the power needs for the PC. The BeadXpress Reader itself draws < 2 A.
Sinks	Convenient access to a sink for waste disposal

- BeadXpress Accessories

Instrument accessory packages have been created to support the various protocols for VeraCode assays.

Accessory Kit	Description
BeadXpress Starter Kit	Required for all VeraCode assays and applications Included in the purchase of a BeadXpress Reader System Available in 110V and 220V Includes a VorTemp Incubating Plate Mixer and the VeraCode Bead Kitting System
GoldenGate Satellite Kit for BeadXpress	Required for running GoldenGate assays with VeraCode Existing customers who run GoldenGate on BeadStation do not need to purchase this kit Kit includes microplate shaker, high temp loop fastener, nylon hook, raised bar magnet, Hybex w/ microtube block, digital stroboscope, 96-well base adapter, and a combi heat sealer.
Optional GoldenGate Accessory Kit	This kit contains standard laboratory equipment that may be purchased by Illumina and are used in the GoldenGate Assay. These items may also be sourced by customers through their preferred laboratory equipment supplier. This package includes a refrigerated benchtop centrifuge, a thermocycler, a microplate carrier for M4 rotor, an alpha unit module for 96 well plates, conical insert (set of 4), standard 750ml bucket (set of 4)

• BeadXpress Extended Warranties

The Field Services team has developed several extended warranty options for the BeadXpress Reader System. This will enable customers to customize their service relative to meet their specific laboratory needs.

Warranty Plan	Description
Premium	Full coverage on parts and labor 48 hour guaranteed on-site response time 2 preventative maintenance visits per year Unlimited field service calls
Plus	Full coverage on parts and labor 3 day average on-site response time 1 preventative maintenance visit per year Unlimited field service calls
Basic	50% off the list price for parts 5 day average on-site response time 1 preventative maintenance visit per year -or- 1 emergency call per year No additional field service calls
Parts Only	Full coverage for parts only 5 day average on-site response time

• VeraCode Training Program

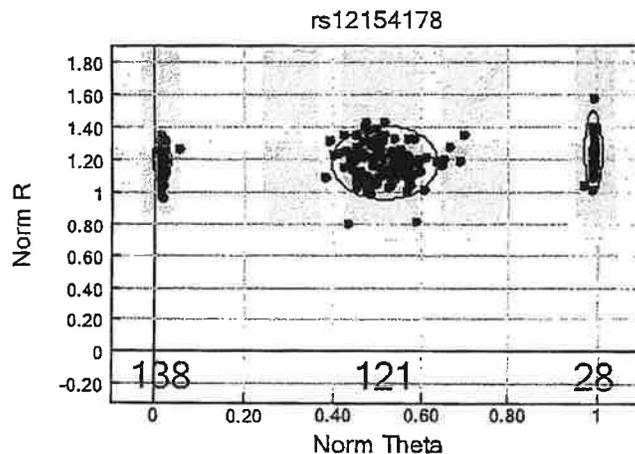
Included with the purchase of a BeadXpress Reader System is a full day of on-site VeraCode Basics training with a Field Applications Scientist. Additional training

programs have been developed to enable customers to improve their knowledge of the technology and adopt new applications.

Training Program	Description
VeraCode Basics	Single day, onsite training by a Field Applications Scientist Demonstration of VeraCode Bead Kitting Overview of VeraCode Universal and Carboxyl Beads Training on BeadXpress, VeraScan, and BeadStudio GoldenGate update on VeraCode for experienced users
Extensive GoldenGate Training	3 day, onsite training by a Field Applications Scientist Complete GoldenGate Assay protocol with VeraCode Training on BeadXpress, VeraScan and BeadStudio
Regional Training	Multiple customers at centrally located site (customer could host) 4 – 8 customers per site 3-day training by a Field Applications Scientist Demonstration of VeraCode Bead Kitting Overview of VeraCode Universal and Carboxyl Beads Complete GoldenGate Assay protocol with VeraCode Training on BeadXpress, VeraScan and BeadStudio
Illumina University	Training sessions scheduled 3–4 times per year at Illumina 6–8 customers per session 3 day training program Demonstration of VeraCode Bead Kitting Overview of VeraCode Universal and Carboxyl Beads Complete GoldenGate Assay protocol with VeraCode Training on BeadXpress, VeraScan and BeadStudio

• VeraCode Universal Capture Bead Sets

True flexibility in the development of multiplex SNP genotyping assays can now be achieved with VeraCode Universal Capture Bead Sets. These highly stable, uniquely coded bead sets are pre-coupled with capture oligonucleotides and enable researchers to develop their own assays based on their desired multiplex and preferred assay methodology. Customers achieve desired multiplex by simply pooling together beads of different codes using the VeraCode Bead Kitting System. Illumina will provide development guidelines in the Assay Manual following a multiplex PCR, multiplex ASPE protocol. However, customers are not limited to this single-color assay. The dual-color laser detection of the BeadXpress reader will allow customers to develop protocols requiring two color detection.

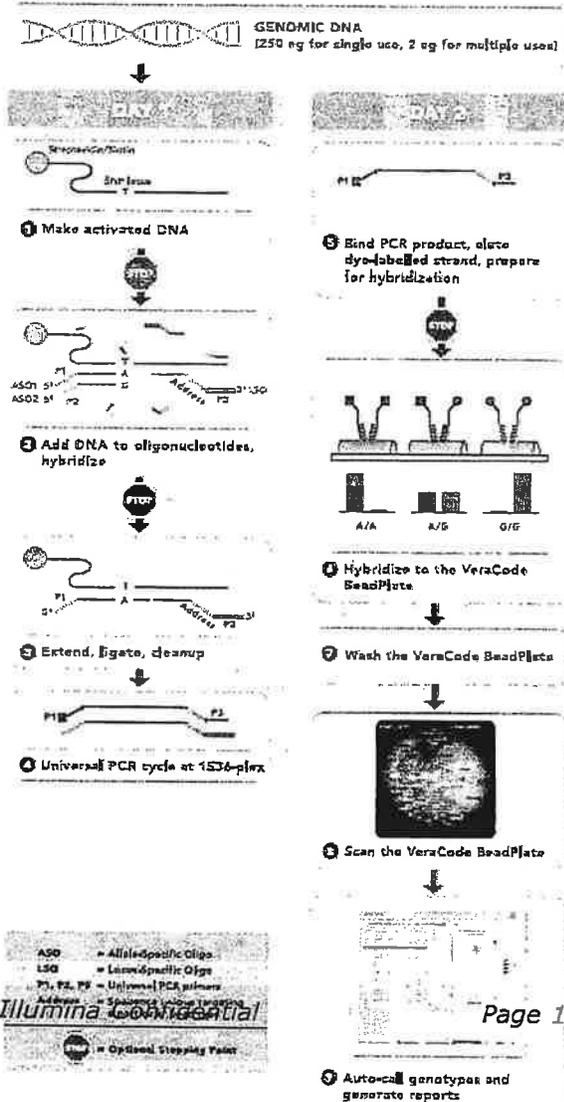


Beta Testing Results (4-plex ASPE rxn)
Factor V, Factor II, MTHFR panel
(>99.9% concordance)

• GoldenGate Genotyping with VeraCode (Custom 96 and 384-plex)

Taking advantage of the solution-based kinetics of the VeraCode microbeads, the workflow for the GoldenGate assay has been reduced to just two days. Customers who are already familiar with the GoldenGate protocol will be able to run assays almost immediately. The assay workflow is nearly identical, with an easier sample addition and hybridization step. GoldenGate Genotyping with VeraCode will be offered only as complete kits (OPA, bead plates, GGGT reagents). Customers will not be able to buy the kit components separately.

FIGURE 1: THE GOLDENGATE ASSAY WITH VERACODE



Typical Assay Performance at
96 and 384-plex

96-PLEX	
Call Rate	> 99.9%
Reproducibility	> 99.9%
Heritability	> 99.9%
DNA Success Rate	> 99%
Locus Success Rate	> 99%

384-PLEX	
Call Rate	> 99.9%
Reproducibility	> 99.9%
Heritability	> 99.9%
DNA Success Rate	> 99%
Locus Success Rate	> 98%

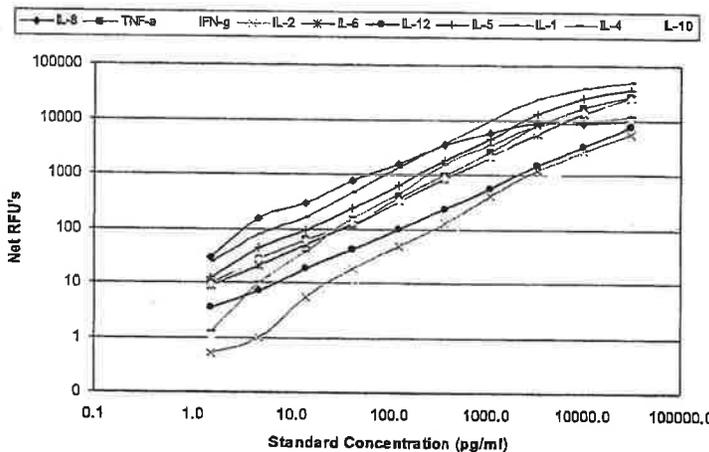
• VeraCode Carboxyl Bead Sets

The VeraCode Carboxyl Bead sets enable covalent attachment of proteins, peptides, nucleic acid and other ligands in a highly multiplexed format. Each VeraCode Carboxyl bead contains a unique code, and multiplex assays are achieved by pooling together different bead types. The carboxyl beads are highly stable and demonstrate low non-specific binding characteristics in multiplex assays. The simple and flexible immobilization chemistry enables rapid assay design for a variety of analytes, providing a truly open platform for laboratory developed tests. The VeraCode Assay Design Guide dedicates a chapter to assay design using the carboxyl beads, including bead kitting, immobilization and optimization techniques.

Analyte	Stdev	LOD (pg/ml)	Dynamic Range
INF-g		4.5	4.5-30,000
TNF-a		0.5	0.5-30,000
IL-1b		0.5	0.5-30,000
IL-2		0.5	0.5-30,000
IL-4		14	0.5-30,000
IL-5		0.5	0.5-30,000
IL-6		0.5	0.5-30,000
IL-8		4.5	4.5-10,000
IL-10		0.5	0.5-30,000
IL-12 (p70)		0.5	0.5-30,000

Results from Illumina's assay development team for multiplex detection of 10-plex cytokine standards in serum diluent.

Sensitivity: The sensitivity, or Limit of Detection (LOD), for each cytokine is defined as the corresponding concentration at three (3) standard deviations above the median fluorescence of at least eight replicates of the negative control (0pg/ml).



The table below shows the LOD and dynamic range for the 10-plex cytokine panel. The LOD ranged from 0.5 - 4.5 pg/ml. A three to four log dynamic range is demonstrated and shown.

- BeadXpress System Read Buffer

The BeadXpress System Read Buffer is required for loading and scanning samples on the BeadXpress Reader. Provided in a convenient 10X solution, there is sufficient solution for customers to run more than ten 96-well plates. Illumina's addition of a microbicide (ProClin), ensure stability for several weeks at room temperature.

Ordering Information and Pricing

Ordering Information

The BeadXpress System and VeraCode products have resulted in the generation of a bonanza of catalog numbers. All products will be loaded into iCom and will be available for customers to order within the next few weeks. Until all items are fully loaded, orders should be quoted by the Account Manager. Purchase orders should be submitted by the customer to our Orders department:

Email: orders@illumina.com

Fax: 858-202-4766

Phone: 1-800-809-4566

Catalog Numbers & Pricing

BEADXPRESS SYSTEM				
Catalog #	Product Name	Description	List Price NA_EU	List Price ROW
VC-101-1000	BEADXPRESS SYSTEM (110V)	This system includes the BeadXpress Reader (110V), reagent carrier, PC, VeraScan Software, the BeadXpress Starter Kit, one year limited warranty, installation by a Field Service Engineer and one day on-site VeraCode Basics Training by a Field Applications Scientist	\$98,500	\$118,200
VC-101-1001	BEADXPRESS SYSTEM (220V)	This system includes the BeadXpress Reader (220V), reagent carrier, PC, VeraScan Software, the BeadXpress Starter Kit, one year limited warranty, installation by a Field Service Engineer and one day on-site VeraCode Basics Training by a Field Applications Scientist	\$98,500	\$118,200
BEADXPRESS ACCESSORIES				
Catalog #	Product Name	Description	List Price NA_EU	List Price ROW
VC-120-1000	BEADXPRESS	The BeadXpress Starter Kit contains the	\$3,237	\$3,884

	STARTER KIT (110V)	basic essentials for developing assays utilizing the VeraCode digital microbead technology. The kit includes the VeraCode Bead Kitting System and a Vortemp Incubating Plate Mixer (110V)		
VC-120-1001	BEADXPRESS STARTER KIT (220V)	The BeadXpress Starter Kit contains the basic essentials for developing assays utilizing the VeraCode digital microbead technology. The kit includes the VeraCode Bead Kitting System and a Vortemp Incubating Plate Mixer (220V)	\$3,237	\$3,884
VC-120-1200	GOLDENGATE SATELLITE KIT FOR BEADXPRESS (110V)	The GoldenGate Satellite Kit for BeadXpress (110V) contains the essential hardware and accessories for running GoldenGate Assays developed with the VeraCode Technology and scanned on the BeadXpress Reader. Kit includes a high speed microplate shaker, a high temperature loop fastener, a nylon hook, a raised bar magnet, a heatblock (115V) with microtube block, a digital optical stroboscope, a 96-well base adaptor (120V), and a combi heat sealer (110v)	\$18,940	\$22,729
VC-120-1201	GOLDENGATE SATELLITE KIT FOR BEADXPRESS (220V)	The GoldenGate Satellite Kit for BeadXpress (220V) contains the essential hardware and accessories for running GoldenGate Assays developed with the VeraCode Technology and scanned on the BeadXpress Reader. Kit includes a high speed microplate shaker, a high temperature loop fastener, a nylon hook, a raised bar magnet, a heatblock (220V) with microtube block, a digital optical stroboscope, a 96-well base adaptor (220V), and a combi heat sealer (220V)	\$18,940	\$22,729
VC-120-1300	OPTIONAL GOLDENGATE ACCESSORIES KIT (110V)	This kit includes the standard laboratory equipment used for GoldenGate Assays developed with the VeraCode Technology and scanned on the BeadXpress Reader. The kit includes a refrigerated benchtop centrifuge (110V), a DNA Engine thermocycler (110V), a 96-well Alpha Unite Module, an M4 horizontal rotor, a microplate carrier for the M4 rotor, a 9x15mL conical insert (set of 4), and a 750mL standard bucket (set of 4).	\$94,683	\$113,620
VC-120-1301	OPTIONAL GOLDENGATE ACCESSORIES KIT (220V)	This kit includes the standard laboratory equipment used for GoldenGate Assays developed with the VeraCode Technology and scanned on the BeadXpress Reader. The kit includes a refrigerated benchtop centrifuge (220V), a DNA Engine thermocycler (220V), a 96-well Alpha Unite Module, an M4 horizontal rotor, a microplate carrier for the M4 rotor, a 9x15mL conical insert (set of 4), and a 750mL standard	\$94,683	\$113,620



		bucket (set of 4).		
GOLDENGATE GENOTYPING WITH VERACODE				
VC-201-0096	GOLDENGATE GENOTYPING KIT FOR VERACODE, 96-PLEX	This kit combines Illumina's proven GoldenGate Genotyping Assay with the cutting-edge VeraCode technology to deliver a highly robust system for custom SNP genotyping. The kit contains sufficient reagents to run 480 samples and includes a custom 96-plex OPA, five VeraCode 96-plex Bead Plates and GoldenGate Genotyping reagents for VeraCode.	\$5,990	\$7,188
VC-201-0384	GOLDENGATE GENOTYPING KIT FOR VERACODE, 384-PLEX	This kit combines Illumina's proven GoldenGate Genotyping Assay with the cutting-edge VeraCode technology to deliver a highly robust system for custom SNP genotyping. The kit contains sufficient reagents to run 480 samples and includes a custom 96-plex OPA, five VeraCode 384-plex Bead Plates and GoldenGate Genotyping reagents for VeraCode.	\$18,432	\$22,118
BEADXPRESS SYSTEM READ BUFFER				
VC-400-1001	BEADXPRESS SYSTEM READ BUFFER (10X), 500mL	Provided in a convenient 10X solution, this buffer is required for running the BeadXpress Reader System	\$25	\$30
BEADXPRESS EXTENDED WARRANTY PLANS				
SV-201-1004	PREMIUM BEADXPRESS EXTENDED WARRANTY	The Premium Warranty Plan for the BeadXpress Reader provides the most complete service program from Illumina. This plan includes full coverage on parts and labor, two preventative maintenance visits per year, 48-hour average on-site response time, demonstrations, non-critical and critical upgrades, unlimited web-ex access, and 1-3 day in-house applications training.	\$11,400	\$13,680
SV-201-1003	PLUS BEADXPRESS EXTENDED WARRANTY	The Plus Warranty Plan for the BeadXpress Reader includes full coverage on parts and labor, one preventative maintenance visit per year, three-day average on-site response time, critical and non-critical upgrades, demonstrations, and applications training.	\$9,500	\$11,400
SV-201-1002	BASIC BEADXPRESS EXTENDED WARRANTY	The Basic Warranty Plan for the BeadXpress Reader includes 50% off the list price for parts, one preventative maintenance visit per year or one on-site visit per year, five-day average on-site response time, critical upgrades, demonstrations and software installations.	\$8,550	\$10,260
SV-201-1001	PARTS ONLY BEADXPRESS EXTENDED WARRANTY	The Parts Only Warranty Plan for the BeadXpress Reader includes full coverage for parts only with five-day average on-site response time. Labor not included.	\$5,700	\$6,840
VERACODE TRAINING PROGRAMS				
TR-001-0010	EXTENSIVE	This training plan provides an in-depth, 3-	\$6,000	\$7,200

	GOLDENGATE TRAINING WITH VERACODE	day on-site training by a Field Applications Scientist on GoldenGate Genotyping using the VeraCode Technology. Training includes hands-on training of the GoldenGate protocol, use of the VeraScan software and operation of the BeadXpress Reader, and data analysis with BeadStudio.		
TR-101-0010	VERACODE GOLDENGATE TRAINING KIT	This training kit provides the necessary reagents to complete on site extensive GoldenGate training with VeraCode. The kit contains sufficient reagents to genotype 96 samples for a standard set of 96 polymorphisms from Illumina's DNA test panel. For customers who may not wish to conduct training with their custom GoldenGate panel or who wish to have material for internal cross training, the VeraCode GoldenGate Training Kit provides a standard package.	\$1,500	\$1,800
TR-001-0011	VERACODE BASICS TRAINING	This training program provides an overview of the basics for developing and running assays using the VeraCode Technology for the BeadXpress reader. This one day, on-site training is provided by a Field Applications Scientist and will walk customers through VeraCode Bead Kitting, basic tips for protocol development, setting up a Scan Settings file and sample sheet, operating the VeraScan software, running the BeadXpress Reader, and data analysis with BeadStudio.	\$3,000	\$3,600
TR-001-0012	VERACODE REGIONAL TRAINING	This training program provides a unique opportunity to receive hands-on training in a group environment. This 3-day training session will include between 4 to 8 customers and will walk through the VeraCode basics and the GoldenGate genotyping assay. It will also include operation of the BeadXpress reader using the VeraScan software, and data analysis with BeadStudio. This training will take place at a location convenient to the participating customers.	\$1,500	\$1,800
TR-001-0013	ILLUMINA UNIVERSITY TRAINING FOR VERACODE	This training program provides a unique opportunity to receive hands-on training at Illumina's corporate headquarters in an interactive group environment. This 3-day training session will include between 6 to 8 customers and will walk through the VeraCode basics and the GoldenGate genotyping assay. It will also include operation of the BeadXpress reader using the VeraScan software, and data analysis with BeadStudio.	\$1,500	\$1,800

VERACODE UNIVERSAL CAPTURE BEAD SETS				
VC-301-5440	VERACODE UNIVERSAL CAPTURE BEAD SET - 5440	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTTCGTAACCCGTGCGAAGTGCC), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-5632	VERACODE UNIVERSAL CAPTURE BEAD SET - 5632	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TACGATGGTACGGTCGCTGTGTA), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-5634	VERACODE UNIVERSAL CAPTURE BEAD SET - 5634	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGGTTAGCGATCATAACCGGCACT), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-5640	VERACODE UNIVERSAL CAPTURE BEAD SET - 5640	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TCCCGTTGTAGTCCGAAAGGG), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-5664	VERACODE UNIVERSAL CAPTURE BEAD SET - 5664	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TACCTGAGTTACCGGCGTTACGT), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-5760	VERACODE UNIVERSAL CAPTURE BEAD SET - 5760	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGCTGGATTGTCCGCACTCAAGT),	\$50	\$62



		enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.		
VC-301-6144	VERACODE UNIVERSAL CAPTURE BEAD SET - 6144	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTATGCTTCGCCGAGGACCACT), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6145	VERACODE UNIVERSAL CAPTURE BEAD SET - 6145	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGCAACGTGTCATTTCGCATCCTC), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6146	VERACODE UNIVERSAL CAPTURE BEAD SET - 6146	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TAGGAGTCCAACCGCATCTTGCA), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6147	VERACODE UNIVERSAL CAPTURE BEAD SET - 6147	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TCTCGGAACCTACTGCCGGATCA), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6148	VERACODE UNIVERSAL CAPTURE BEAD SET - 6148	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGTTGCCGACGGTTAAACCAGGT), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62

VC-301-6150	VERACODE UNIVERSAL CAPTURE BEAD SET - 6150	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TCGGTTAGCGAGTAATAGTGCCC) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6152	VERACODE UNIVERSAL CAPTURE BEAD SET - 6152	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TACTGCGCAACGGTTTCTGCGT) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6153	VERACODE UNIVERSAL CAPTURE BEAD SET - 6153	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TACCGAAAGTCCCGGCTGTGGAT) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6156	VERACODE UNIVERSAL CAPTURE BEAD SET - 6156	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TCTATCAGGGTCGCCATGTGTCA) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6160	VERACODE UNIVERSAL CAPTURE BEAD SET - 6160	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TCCTCTTGTCGGAAGTCCACACG) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6162	VERACODE UNIVERSAL CAPTURE BEAD SET - 6162	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TACGCCAGACTCCGGTCCAAGTT) , enabling researchers to develop their own SNP genotyping assays. By pooling with	\$50	\$62

		other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.		
VC-301-6168	VERACODE UNIVERSAL CAPTURE BEAD SET - 6168	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTAGGCGTTGGACCCTACCATCA), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6176	VERACODE UNIVERSAL CAPTURE BEAD SET - 6176	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TCACCGAACGGCAATGATCTGGT), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6177	VERACODE UNIVERSAL CAPTURE BEAD SET - 6177	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTGGCCGTACATCACTAACCGAC), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6180	VERACODE UNIVERSAL CAPTURE BEAD SET - 6180	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGA CTGCAACCCGGCTCTGTCTA), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6192	VERACODE UNIVERSAL CAPTURE BEAD SET - 6192	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGCGAACGGTCCTGTATTGCAGT), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6208	VERACODE UNIVERSAL CAPTURE BEAD SET -	This highly stable, uniquely coded bead set is pre-coupled with a capture	\$50	\$62

	6208	oligonucleotide (TGGTCAACCAGCTTGATACGCC), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.		
VC-301-6210	VERACODE UNIVERSAL CAPTURE BEAD SET - 6210	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TCTTGTAGGAGCTGCGGAAGACT) enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6216	VERACODE UNIVERSAL CAPTURE BEAD SET - 6216	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TCCACATGCTCTCGGTGTCGAAT) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6240	VERACODE UNIVERSAL CAPTURE BEAD SET - 6240	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TATTCGGATCGCCCTTCTGCAA), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6272	VERACODE UNIVERSAL CAPTURE BEAD SET - 6272	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGCGACGTGGACTGCTTCAAACG) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6273	VERACODE UNIVERSAL CAPTURE BEAD SET - 6273	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGAGGGAACGTGAATGCTGCTCT) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their	\$50	\$62

		multiplex assays using their preferred assay methodology.		
VC-301-6276	VERACODE UNIVERSAL CAPTURE BEAD SET - 6276	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGTCGGAGTAATTGTGCCACCA) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6288	VERACODE UNIVERSAL CAPTURE BEAD SET - 6288	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGTACTIONGAGTCCCAGTGGCAT) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6336	VERACODE UNIVERSAL CAPTURE BEAD SET - 6336	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTTCGTGCTGGCTGAGAGCGTAA) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6400	VERACODE UNIVERSAL CAPTURE BEAD SET - 6400	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTAGCGCCTATCTGCCAGGGACT) enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6402	VERACODE UNIVERSAL CAPTURE BEAD SET - 6402	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTCTGACTGGGAGATTCCGATGC) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6408	VERACODE UNIVERSAL CAPTURE BEAD SET - 6408	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTGAGCGCCTTCCCAACTGAGGA)	\$50	\$62

		, enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.		
VC-301-6432	VERACODE UNIVERSAL CAPTURE BEAD SET - 6432	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TAACCGGAGCCCAAGTTGCTGTC), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6528	VERACODE UNIVERSAL CAPTURE BEAD SET - 6528	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTCCGGTCTTGCATGAAGAGGAG), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6656	VERACODE UNIVERSAL CAPTURE BEAD SET - 6656	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGATGCGACGACGACTATTCCTGT), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6657	VERACODE UNIVERSAL CAPTURE BEAD SET - 6657	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGAGACGACAACCTTCTCGCAACC), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6660	VERACODE UNIVERSAL CAPTURE BEAD SET - 6660	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TCAAGTGATTCGCCCGGTTAATC), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62

VC-301-6672	VERACODE UNIVERSAL CAPTURE BEAD SET - 6672	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGTGCGAAATTCATCCGACCGCT) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6720	VERACODE UNIVERSAL CAPTURE BEAD SET - 6720	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTTACGAACCGATGAGCACCTAGTA) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-6912	VERACODE UNIVERSAL CAPTURE BEAD SET - 6912	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TAATCCGTA CTGTTGCCATCCGTA) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-7168	VERACODE UNIVERSAL CAPTURE BEAD SET - 7168	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGCCCATCCACTATTTCCGAGGTAA) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-7170	VERACODE UNIVERSAL CAPTURE BEAD SET - 7170	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTAATACGCCAGATGGTTGGTGCAT) , enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-7176	VERACODE UNIVERSAL CAPTURE BEAD SET - 7176	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TTATTGCACCACCGCTACTGAGAAT) , enabling researchers to develop their own SNP genotyping assays. By pooling with	\$50	\$62

		other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.		
VC-301-7200	VERACODE UNIVERSAL CAPTURE BEAD SET - 7200	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGGATATGTACCTACTGCAACGGA), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-7296	VERACODE UNIVERSAL CAPTURE BEAD SET - 7296	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGTGGCATCATAACCATAAACGCTCG), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-7680	VERACODE UNIVERSAL CAPTURE BEAD SET - 7680	This highly stable, uniquely coded bead set is pre-coupled with a capture oligonucleotide (TGTTACAATCCCTGGTCCGTATGC), enabling researchers to develop their own SNP genotyping assays. By pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology.	\$50	\$62
VC-301-0481	VERACODE PRE-POOLED 48-PLEX UNIVERSAL CAPTURE BEAD SET - 0481	This set of VeraCode Universal Capture beads is pre-pooled to contain 48 unique bead codes per tube. Each bead within the pool is pre-coupled with a unique capture oligonucleotide, enabling researchers to develop their own SNP genotyping assays. Either alone or by pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology. Sufficient for 6 x 96 samples	\$2,400	\$2,880
VC-301-0482	VERACODE UNIVERSAL CAPTURE BEAD SET - 0482	This set of VeraCode Universal Capture beads is pre-pooled to contain 48 unique bead codes per tube. Each bead within the pool is pre-coupled with a unique capture oligonucleotide, enabling researchers to develop their own SNP genotyping assays. Either alone or by pooling with other VeraCode Universal Capture Bead sets, researchers can develop their multiplex assays using their preferred assay methodology. Sufficient for 6 x 96 samples	\$2,400	\$2,880

VERACODE CARBOXYL BEAD SETS				
VC-311-8193	VERACODE CARBOXYL BEAD SET- A	This bead set enables covalent attachment of proteins, peptides, nucleic acid and other ligands in highly multiplexed format due to the carboxylated surface chemistry of the VeraCode Carboxyl beads. Set A contains separate vials of five different bead codes, Codes 8193, 8195, 8196, 8197 and 8198. Each vial is sufficient for 6 x 96 measurements	\$275	\$330
VC-311-8199	VERACODE CARBOXYL BEAD SET- B	This bead set enables covalent attachment of proteins, peptides, nucleic acid and other ligands in highly multiplexed format due to the carboxylated surface chemistry of the VeraCode Carboxyl beads. Set B contains separate vials of five different bead codes, Codes 8199, 8201, 8202, 8204, and 8205. Each vial is sufficient for 6 x 96 measurements	\$275	\$330
VC-311-8208	VERACODE CARBOXYL BEAD SET- C	This bead set enables covalent attachment of proteins, peptides, nucleic acid and other ligands in highly multiplexed format due to the carboxylated surface chemistry of the VeraCode Carboxyl beads. Set C contains separate vials of five different bead codes, Codes 8208, 8209, 8210, 8211, and 8212. Each vial is sufficient for 6 x 96 measurements	\$275	\$330
VC-311-8214	VERACODE CARBOXYL BEAD SET- D	This bead set enables covalent attachment of proteins, peptides, nucleic acid and other ligands in highly multiplexed format due to the carboxylated surface chemistry of the VeraCode Carboxyl beads. Set D contains separate vials of five different bead codes, Codes 8214, 8216, 8217, 8220, and 8225. Each vial is sufficient for 6 x 96 measurements	\$275	\$330
VC-311-8226	VERACODE CARBOXYL BEAD SET- E	This bead set enables covalent attachment of proteins, peptides, nucleic acid and other ligands in highly multiplexed format due to the carboxylated surface chemistry of the VeraCode Carboxyl beads. Set E contains separate vials of five different bead codes, Codes 8226, 8228, 8229, 8232, and 8234. Each vial is sufficient for 6 x 96 measurements	\$275	\$330
VC-311-8240	VERACODE CARBOXYL BEAD SET- F	This bead set enables covalent attachment of proteins, peptides, nucleic acid and other ligands in highly multiplexed format due to the carboxylated surface chemistry of the VeraCode Carboxyl beads. Set F contains separate vials of five different bead codes, Codes 8240, 8241, 8244, 8256, and 8257.	\$275	\$330

		Each vial is sufficient for 6 x 96 measurements		
VC-311-8258	VERACODE CARBOXYL BEAD SET- G	This bead set enables covalent attachment of proteins, peptides, nucleic acid and other ligands in highly multiplexed format due to the carboxylated surface chemistry of the VeraCode Carboxyl beads. Set G contains separate vials of five different bead codes, Codes 8258, 8259, 8260, 8262, and 8264. Each vial is sufficient for 6 x 96 measurements	\$275	\$330
VC-311-8265	VERACODE CARBOXYL BEAD SET- H	This bead set enables covalent attachment of proteins, peptides, nucleic acid and other ligands in highly multiplexed format due to the carboxylated surface chemistry of the VeraCode Carboxyl beads. Set H contains separate vials of five different bead codes, Codes 8265, 8268, 8272, 8274, and 8280. Each vial is sufficient for 6 x 96 measurements	\$275	\$330
VC-311-8288	VERACODE CARBOXYL BEAD SET- I	This bead set enables covalent attachment of proteins, peptides, nucleic acid and other ligands in highly multiplexed format due to the carboxylated surface chemistry of the VeraCode Carboxyl beads. Set I contains separate vials of five different bead codes, Codes 8288, 8289, 8292, 8304, and 8321. Each vial is sufficient for 6 x 96 measurements	\$275	\$330
VC-311-8322	VERACODE CARBOXYL BEAD SET- J	This bead set enables covalent attachment of proteins, peptides, nucleic acid and other ligands in highly multiplexed format due to the carboxylated surface chemistry of the VeraCode Carboxyl beads. Set J contains separate vials of three different bead codes, Codes 8322, 8324, 8325. Each vial is sufficient for 6 x 96 measurements	\$165	\$198

Discount Programs for VeraCode

Discounting for VeraCode consumables and reagents shall be volume driven. Customers running the GoldenGate Genotyping Assay with VeraCode can earn special pricing based on the sample quantities detailed in the table below.

Multiplex	# of Samples	Price Per Sample (NA & EU)	Price Per SNP (NA & EU)	Price Per Sample (ROW)	Price Per Sample (ROW)
96	480	\$12.48	\$0.130	\$14.98	\$0.156
	960	\$10.56	\$0.110	\$12.67	\$0.132
	≥1,440	\$8.64	\$0.090	\$10.37	\$0.108
	480	\$38.40	\$0.100	\$38.40	\$0.120



384	960	\$30.72	\$0.080	\$30.72	\$0.096
	≥1,440	\$19.20	\$0.050	\$19.20	\$0.060

BeadStation / BeadXpress Cross Platform Discount Program

Illumina provides a volume-based discount to its systems customers that will now extend across the BeadStation and the BeadXpress systems. This discount is applied to and calculated based on the purchase of GoldenGate Genotyping arrays, reagents, and Standard Content Panels, Direct Hybridization Gene Expression Arrays and Reagents, and DASL Gene Expression arrays, reagents and Standard Content Panels.

This discount is calculated based on the combined purchase value of the qualifying arrays, reagents, and standard panels from the previous 12 month rolling period. Discount level is updated weekly and applied to future purchases at the percentages listed upon attaining and maintaining the purchase value tiers as defined below.

Discounts are NOT applied to or calculated based on the purchase of Custom GoldenGate Oligo Pools (OPAs), Custom DASL Assay Pools (DAPs) or Infinium Whole-Genome Genotyping Arrays and Reagents on the BeadStation.

Discounts ARE applied to the entire GoldenGate Assay for VeraCode (including custom OPAs, VeraCode bead plates, and GoldenGate Reagents).

Value of Arrays, Reagents and Standard Content Panels Purchased (USD) over the last 12 months	Discount Applied to Future Arrays and Standard Content Panels
\$0 to \$250,000*	0%
\$250,001 to \$500,000*	10%
\$501,000 or more*	20%

*x1.5 for ROW

Discount Program Summary:

Silver Level Discount

- \$250K spent per rolling 12 month cycle across both the BeadStation and BeadXpress for GT and GX
- 10% Volume discount includes only GGGT, DASL, and Direct Hyb GEX
- Discount does not apply to Infinium, iSelect, nor OPAs for use with BeadStation

Gold Level Discount

- \$500K spent per year across both the BeadStation and BeadXpress for GT and GX
- 20% volume discount includes only GGGT, DASL, and Direct Hyb GEX
- Discount does not apply to Infinium, iSelect, nor OPAs for use with BeadStation

Advertising Calendar

Highlighted below in purple are the proposed ad placements and publications that you can expect to see appearing for VeraCode:

Genome Research	Jul	Aug	Sep	Oct	Nov	Dec
Issue	Jul	Aug		Oct		Dec
Ad	VeraCode	VeraCode		VeraCode		
Position		C2		C2		
Materials						
Due		1-Jul		1-Sep		

Drug Discovery News	Jul	Aug	Sep	Oct	Nov	Dec
Issue	Jul	Aug	Sep	Oct	Nov	Dec
Ad	VeraCode	VeraCode	Pharma	Pharma		
Close (IO & Mats)	15-Jun	13-Jul	17-Aug	15-Sep	20-Oct	16-Nov

GEN	Jun	Jul	Aug	Sep	Oct	Nov
Issue	15-Jun	Jul		15-Sep	15-Oct	
Ad	VeraCode	VeraCode		Pharma	Pharma	
Feature	Multiplexing Assays	Whole-Genome Amplification	Cell-based Assays, Biomarkers, Lead Optim.	MDX, Protein Therapeutics, micro RNA	PCR trends, Pathway analysis	
Show	APS	Chirality, SIM	DDT	Biotechnica	ASHG, Neuroscience	

Genome Technology	Jul	Aug	Sep	Oct	Nov	Dec
Issue	Jul/Aug		Sep	Oct		
Space	P4CB			P4CB		
Ad	VeraCode			VeraCode		
Position	Back Cover- PGX Perspectives			Back Cover- Tech Guide		
Feature	Proteomics Watch		Latest in Immuno-PCR, Tech Guide: Sequence Alignment	Clinical Genotyping: Tech Guide		
Show	AACCC, DDT		D2D, SBS	ASHG, DOT		



CAP Today	Apr	May	Jun	Aug	Oct	Nov
Issue	Apr	May	Jun	Aug	Oct	Nov
Ad	VeraCode	VeraCode	VeraCode	VeraCode	VeraCode	VeraCode
Feature	Molecular Pathology	Molecular Testing in MicroBio	AACC Preview	Blood Gas Testing, Cardiac Markers	HER2 testing, Hepatitis	Bone Marrow and Assess Platelets
Show		ASM, ASCO	AACC		AMP, NSH, ASC, AABB	ASH
Close						
Cost	5015	5015	5015	5015	5015	5015

Trade Shows, Meetings & Seminars

VeraCode will be presented at numerous research and diagnostic tradeshow throughout 2007. Whenever made available by conference organizers, Illumina shall host a seminar on the VeraCode technology, featuring customer presenters to showcase applications developed on VeraCode. R&D teams shall also be asked to assist with abstract submission for poster presentations and talks at these conferences to help increase visibility of the technology. Direct mail and/or email blasts shall be sent to pre-show registrants. Below is Illumina's tradeshow/meeting schedule for 2007.

Event	Date	Location	Activity
NA User Meeting	March 15 – 17	San Diego	Technology introduction; full literature
Society of Toxicology	March 25 - 29	Charlotte	Technology introduction; full literature
AACR	April 14	Los Angeles	Technology introduction; full literature
Webinar (VeraCode applications)	April	San Diego	Presentation from beta customers and CHEO on utilizing VeraCode Technology
EU User Meeting	April 26 - 27	Siena, Italy	Technology introduction; full literature
Seminar Series	April 30 – May 4	London, Paris, Munich	Technology introduction; full literature
FOCIS Annual Meeting	June 7 - 11	San Diego	Technology introduction; full literature
EHGC	June 19 - 20	Nice, France	Technology introduction; full literature
Webinar (VeraCode Applications)	July	San Diego	Customer presentation on VeraCode applications
AACC	July 17 - 19	San Diego	Feature Product at booth/workshop; technology introduction; applications
D2D	September 17 - 19	Philadelphia	Technology introduction; full literature
World Congress on Psychiatric Genetics XIII	October 7 - 11	New York	Technology introduction; full literature

ASHG	October 23 - 27	San Diego	Technology introduction; full literature
AMP	November 7 - 10	Los Angeles	Feature Product at booth/workshop; technology introduction; applications
Webinar (VeraCode Applications)	November	San Diego	Customer presentation on latest VeraCode application

Frequently Asked Questions

Q: Can you tell me about the VeraCode microbeads?

A: The VeraCode technology is based in cylindrical glass microbeads measuring 240µm in length x 28µm in diameter. Illumina uses a proprietary technology to inscribe digital holographic elements within each bead. When a laser beam shines through the bead, the holographic elements diffract the light, creating a code image.

Q: What's so special about having these beads with codes?

A: Beads with unique codes can be used to represent not only information such as the target of interest in multiplex assays, but also it can be used to track critical information such as sample ID, laboratory ID, reagent lots, etc. We are able to easily embed high density codes (24 bit), which means that there is virtually unlimited number of unique bead types that we can manufacture.

Q: What types of assays can be developed with the VeraCode beads?

A: The glass surface of the VeraCode beads make them ideal for a number of bioassays. Illumina has demonstrated several applications including genotyping, gene expression, and protein based assays. The VeraCode technology enables the development of solution-based assays, with the power of microarrays.

Q: How do you achieve multiplexing with the VeraCode beads?

A: Multiplexing is easily achieved by simply pooling together beads with unique codes. Illumina offers standard products to enable users to develop anything from a single-plex to several hundred-plex reactions per sample in a single well.

- Q: What products will you have at launch, and what level of multiplexing will I be able to achieve with those products?
- A: At launch, Illumina will be offering VeraCode Universal Beads (48 individual codes, 2 sets of 48-pre-pooled codes), VeraCode Carboxyl Beads (48 unique codes), and VeraCode GoldenGate 96 and 384-plex genotyping.
- Q: How are the VeraCode Universal Beads used?
- A: Each uniquely coded VeraCode Universal Bead has a unique oligonucleotide capture sequence attached and can be easily used for designing nucleic-acid based assays. We will be offering unique code types in individual tubes. As an example, if you wanted to develop a 3-plex reaction and wanted to use a single color detection assay, such as Allele Specific Primer Extension (ASPE), you would just pool together six different tubes of unique VeraCode Universal Oligo Beads (one bead type per allele).
- Q: How are the VeraCode Carboxyl Beads used?
- A: Like the VeraCode Universal Beads, the Carboxyl beads will be packaged such that a unique bead code will be in a single tube. However, the surface chemistry of the Carboxyl beads differ in that they have a carboxylated surface, enabling development of protein-based assays. To achieve multiplexing, users simply pool together different tubes of uniquely coded carboxyl beads after immobilizing with their proteins of interest.
- Q: What is the GoldenGate genotyping assay?
- A: This is Illumina's proprietary Research Use Only assay that enables genotyping of 96 or 384 SNPs in a single well. Although we call this our 96-plex and 384-plex assay, we are really performing a 144-plex and a 432-plex due to the addition of 48 controls that we use. This assay requires the two-color laser detection system of BeadXpress reader.
- Q: Could you describe in more detail how the 48 controls are used in the GoldenGate assay?
- A: The internal controls in the GoldenGate 96 and 384-plex assay lend a higher confidence level to the overall assay by enabling the ability to troubleshoot errors such as PCR and hybridization errors.
- Q: How are the VeraCode beads read?
- A: The BeadXpress Reader has been developed for the VeraCode



technology. The BeadXpress reader is a high-throughput, two color laser detection scanner that accepts a standard 96-well microplate, or 8-well strips from a 96-stripwell plate.

Q: What is the throughput of the BeadXpress reader?

A: Throughput is dependent upon the level of multiplexing and whether you are running a single color or dual color detection. Typical throughputs achieved are:

Multiplex	Single Color Detection	Dual Color Detection
10	140 samples/hr	120 samples/hr
144	90 samples/hr	68 samples/hr
432	44 samples/hr	30 samples/hr

Q: What software is used with BeadXpress?

A: VeraScan is the operating software for the BeadXpress Reader. This software enables users to set up each assay run quickly and accurately. A BeadXpress Scan Settings file and a sample sheet are incorporated into VeraScan for efficient assay set up. Data generated by VeraScan can be exported into the recently released BeadStudio version 3.0 for performing data analysis. The updated GT module can be used for analyzing the GoldenGate 96 and 384-plex with VeraCode, and for analyzing lower multiplex assays developed with the VeraCode Universal Capture Beads. A new Protein Module has been developed for data analysis of protein-based assays using the VeraCode Carboxyl Bead product.

Q: Will the BeadXpress reader be able to integrate with my laboratory's automation system?

A: The BeadXpress is designed to be compatible with standard laboratory automation for the upfront assay. We have developed a protocol utilizing a Tecan robot for the GoldenGate Genotyping Assay with VeraCode.

Q: What makes your product better than Luminex? They seem to be similar technologies.

A: The VeraCode technology with the BeadXpress reader demonstrates clear advantages over Luminex. Key differentiators include:

1. VeraCode dominates Luminex in multiplexing range in a single well.
2. The unique identification of VeraCode Beads enable tracking of aspects such as sample ID, reagent lot ID, and even laboratory ID.

3. The two color detection system of the BeadXpress reader expands the variety of assays that can be developed with the system. Luminex only has single color detection (green), since their red laser is dedicated to detecting their bead type.
4. VeraCode/BeadXpress is a multi-use system, enabling development of gene expression, genotyping and protein-based assays. The greater surface area of the beads, in combination with the multiple readings per bead, generates more robust data.
5. VeraCode beads are significantly more stable, they are not photosensitive like the Luminex beads.
6. Assay development is more straightforward with VeraCode beads. Customers do not have to worry about selecting the right "colored" bead to prevent overlapping signals.

Q: What support will be offer for Universal Oligo Beads?

A: Illumina will provide assay design guidelines in the VeraCode Assay Guide, and will provide basic molecular biology troubleshooting. This product is best suited to those comfortable with developing assays and want the advantages of complete flexibility. To assist these customers, Illumina is developing a web-based primer design tool that will help customers develop their multiplex PCR and multiplex ASPE primers for multiplex assays using the VeraCode Universal Capture Beads. We expect this design tool to be available on our website in May.

Q: Do you offer a 48-plex GoldenGate Genotyping Assay?

A: No. We are currently able to offer 96-plex and 384-plex GoldenGate genotyping. You may use or 48-plex pre-pooled Universal Capture Bead Set to develop your own assay if desired.

Q: 96 and 384-plex OPAs: can these be used interchangeably on the BeadStation as well?

A: Because the assay is slight different between the two platforms (VeraCode is shortened to just a 2-day assay), you can expect that the second set of controls for hybridization will not work.....otherwise, they can be used interchangeably. However, please note that the GoldenGate 96 and 384-plex with VeraCode is only sold as complete kits (OPA, VeraCode Bead Plate, GoldenGate Reagents).

Q: How does the OPA delivery time for VeraCode compare to the delivery time that we've been quoted for BeadArray?

A: Currently, you can expect the lead times for OPA orders to be the same as those for GoldenGate on the BeadArray platform.

Regulatory/Diagnostic Questions:

Q: Can the BeadXpress Reader be used for diagnostic testing?

A: The BeadXpress Reader is currently labeled as a Research Use Only Instrument, so it has not been reviewed by the FDA. But, we have had a lot of interest expressed by CLIA High Complexity Certified labs who are interested in developing homebrew assays with the technology.

Q: Does Illumina have ASRs for the VeraCode technology?

A: No. Illumina has General Purpose Reagents and Research Use Only products for the VeraCode technology.

Q: How much is the BeadXpress Reader?

A: The list price for the BeadXpress Reader will be about \$98,500

Note: Any and all pricing information given at clinical conferences (ie., AMP and AACC) must have come from an **Unsolicited Request**. Do not give pricing information to anyone unless specifically asked. This could have direct consequences with the FDA.

Q: What is Illumina's current regulatory status?

A: Illumina is currently working to achieve ISO 13485:2003 certification. We are developing all of the VeraCode products under design control and have Design History Files for each of our products.

Q: Can the GoldenGate Genotyping Assay be used for diagnostic testing?

A: The GoldenGate Genotyping Assay is a Research Use Only product. It has not been reviewed by the FDA.

Q: I work in a CLIA High Complexity Lab and would like to develop tests using the VeraCode technology. Will Illumina help me with designing and validating a test?

A: No. Illumina can provide technical support for working with the VeraCode Products and assist with troubleshooting, but the CLIA High Complexity Lab is responsible for designing and validating their own tests.

Regulatory Terminology

1. What is QA (Quality Assurance) vs. QC (Quality Control)?

Quality Assurance is a planned and systematic set of activities necessary to provide adequate confidence that requirements are properly established and products or services conform to specified requirements.

Quality Control is the process by which product quality is compared with applicable standards; and the action taken when nonconformance is detected. QC is therefore a subset of QA.

2. What is a 510k?

This refers to the section of the Food, Drug and Cosmetic Act which requires device manufacturers to submit information that verifies equivalency of the product to a predicate device and to notify FDA at least 90 days in advance, of their intent to market a medical device in the United States. For 510k submission and approval, the product must be equivalent to a product made (a predicate device) before 1976.

3. Define FDA and what it does

The public trusts the Food and Drug Administration (FDA) to ensure that:

1. Foods are safe, wholesome and truthfully labeled
2. Drugs for both humans and animals, and vaccines for humans are safe and effective
3. Blood used for transfusions is safe and in adequate supply
4. Medical devices, from scalpels to CT scanners are safe and effective.
5. Transplanted tissues are safe and effective
6. Equipment that uses radiant energy, such as X-ray machines and microwave ovens is safe
7. Cosmetics are safe and properly labeled

It is FDA's job to see that food is safe and wholesome, cosmetics won't hurt people, the medicines and medical devices are safe and effective, and that radiation-emitting products such as microwave ovens won't do harm. Feed and drugs for pets and farm animals also come under FDA scrutiny. The FDA ensures that all of these products are labeled truthfully with the information that people need to use them properly.

4. Define the nature of ISO and what it does

ISO (International Organization for Standardization) is a global network that identifies what International Standards are required by business, government and society. It develops these standards in partnership with the sectors that will put them in use, adopts them by transparent procedures based on national input and delivers them to be implemented worldwide.

5. What does "Approval, Licensure and Certification mean and how do they apply to Illumina and our plans?"

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Approval: FDA approval for Illumina to sell our products as a medical device would be in the form of a 510k of PMA.

ISO Certification: Certification with the International Organization for Standardization. Illumina plans to gain certification by proof to a notified body that we are in compliance with a standard such as ISO 13485.

License: The FDA will provide a written Medical device license to Illumina when we are found to be in compliance with the QSR

6. Define GMP and how it applies to Illumina

GMP are Good Manufacturing Practices followed by the pharmaceutical and biotech firms to ensure that the products produced meet specific requirements for identity, strength, quality, and purity.

In a nut shell, GMP is:

- Say what you are going to do – Document it.
- Do what the document says – Follow the document
- Prove that you have followed the document – By documentation

FDA regulates these industries to ensure GMPs are being followed. The current GMP requirements set forth in the Quality System regulation (QSR) are promulgated under section 820 of the Food, Drug and Cosmetic (FD&C) Act. They require that domestic or foreign manufacturers have a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices intended for commercial distribution in the United States.

Through compliance with the QSR, Illumina will be GMP compliant

7. Define QSR and how it applies to Illumina

QSR means: Quality System Regulation. The QSR is contained in Title 21 Part 820 of the Code of Federal Regulations. This regulation covers quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling control, device evaluation, distribution, installation, complaint handling, servicing, and records.

In order to sell medical devices in the United States, Illumina must be compliant to QSR.

8. Define GLP and how it applies to Illumina

GLP: Good Laboratory Practice is a quality system concerned with the organizational process and the conditions under which studies are planned, performed, monitored, recorded, reported and archived for use in clinical data reporting.

9. Define ASR and how it applies to Illumina

The FDA defines Analyte Specific Reagents in 21 CFR 864.4020 as “antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and

similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended to use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens.” In simple terms an analyte specific reagent is the active ingredient of an in-house test.

In order for Illumina to provide reagents for ASR utilization, we must:

- 1) Be QSR compliant (manufacture under GMP)
- 2) Provide materials without instructions on how to use our interpret system
- 3) Cannot provide a “closed” system for multiplex assays (unique detection system, unique software, unique reagents)

10. What is a PMA and how does it apply to Illumina

In order to sell a medical device within the United States for which there is no predicate device, a Pre-Market Approval submission must be submitted to the FDA. Because some of the biomarkers that Illumina might be interested in developing a test will for are truly novel and unique, a PMA submission may be necessary.

The information required for a PMA submission is far more stringent than that required for a 510k.

11. Why do we need to be compliant to regulations?

We must to be compliant to QSR/ISO regulations if we want to enter the medical diagnostics market domestically and internationally. This market is very heavily regulated by the FDA and ISO.

Compliance will also ensure that Illumina is using “best practices” in the manufacture of our products.

12. What do we need to do to be compliant?

Implementation of the Quality Plan as outlined in the Quality Manual will ensure compliance to ISO 13485 and the QSR.

13. What is a medical device?

A manufactured product that is used to:

1. Cope with human disease
2. Care for human injuries
3. Meet human anatomical needs
4. Maintain human physiological functions
5. Support or sustain human life
6. Control human conception
7. Disinfect human medical devices
8. Examine specimens taken from human bodies

Medical devices can include:

1. Instruments
2. Appliances
3. Implants
4. Machines

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5. Software
6. Materials
7. Calibrators
8. Apparatuses
9. In vitro reagents
10. Related articles

14. What and where is the Quality Manual

The purpose of the Quality Manual is to describe the methods and controls used to assure the quality of all services, products manufactured, processed and distributed by Illumina Incorporated. The Illumina Quality Manual can be found on the company intranet at the following location or with Document Control.

<http://intranet/engin/dc/Procedures/Quality Documents/11204017 Illumina Quality Manual.pdf>

15. What is the Quality Policy?

The quality policy addresses how Illumina will function as an organization to ensure that we provide high quality products. The Quality Policy is as follows and can be found in the Quality Manual and various locations posted around the Illumina facilities.

- We develop and manufacture innovative high quality products and services for the research and development, health care and life sciences markets.
- We deliver our products and services to our customers (internal and external) reliably on time.
- We provide employees with the necessary training and resources to meet or exceed customer expectations.
- We monitor processes and products to identify opportunities for continuous improvement.

16. What products will Illumina supply as medical devices?

The BeadXpress reader and the VeraCode Digital microbeads are being developed such that they can be offered downstream as an In Vitro Diagnostic product (IVD) with the development of a specific diagnostic test panel. The product will most likely Class II.

17. Will Illumina have two systems for manufacture of RUO and regulated products?

Illumina will have one Quality System that will apply to entire company as a whole.

18. Where can we get regulatory references?

The following are some examples of available websites that we can get regulatory information:

<http://www.iso.org>

<http://www.qsr.com>

<http://www.21cfrpart11.com>

<http://www.fda.gov/>

19. What is Design Control?

Design Control is a system of checks and balances to ensure that a product meets specified design requirements.

- The regulatory agencies describe design control as follows:

FDA Quality System Regulation - 820.30 DESIGN CONTROLS

Each manufacturer shall establish and maintain procedures to control the design of a device in order to ensure that specified design requirements are met.

ISO 13485 - 7.3 Designs and Development

The organization shall establish documented procedures for design and development.

20. What is Validation?

Validation is a process to establish **documented evidence** that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

The process requires a written and signed off protocol that contains acceptance criteria that the validated product or process must meet.

21. Where can I find quality type definitions?

There are several websites available to find quality definitions. The following are some example of places that you can find quality type information:

<http://www.iso.org>

<http://www.qsr.com>

<http://www.21cfrpart11.com>

<http://www.fda.gov/>

22. What is a lot and batch?

Lot or batch means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

23. What is CFR?

The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration. Each title (or volume) of the CFR is revised once each calendar year. A revised Title 21 is issued on approximately April 1st of each year. There are 1499 parts in title 21.

24. What is 21 CFR 820 and how does it apply to Illumina?

Part 820 of the Code of Federal Regulations refers to the regulations related to Medical Devices. Current good manufacturing practice (cGMP) requirements are set forth in this Quality System Regulation. The requirements in this regulation govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.

Illumina must to be compliant to 21 CFR part 820 in order to sell or products as In Vitro Devices and medical devices.

25. What is part 11?

In March of 1997 the FDA issued a set of regulations that provide criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. These regulations, which apply to all FDA program areas, were intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to protect the public health.

[Full name: part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11)]

26. What is CLIA?

The acronym stands for **Clinical Laboratory Improvement Amendments**. CLIA outlines the quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test (or on any material derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of disease or improvement of the health of human being) results regardless of where the test has been performed.

Laboratories with "CLIA High Complexity Certification" are able to design and validate their own laboratory developed tests for clinical use.

27. What is a control material, a reference standard, a proficiency sample?

Control material is a material with known composition or properties which can be used for the assessment of the performance of an analytical procedure or part thereof.

Reference standard is considered to be the best available method for establishing the presence or absence of the condition of interest. The reference standard can be a single method or a combination of methods to establish the presence of the target condition.

A proficiency sample is utilized to assess inter-laboratory concordance.

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- Mystic Core Team
- Physical Bead Core Team
- VIA Core Team

- Mystic GoldenGate Core Team
- Test & Calibration Core Team
- Software Development
- Engineering
- Reagent Manufacturing
- Finance
- Customer Solutions
- Tech Pubs & Marketing
- Sales

THANK YOU!!