Your Independent Source for Business & Financial News

LABORATORY INDUSTRY REPORT™

A DIVISION OF PLAIN LANGUAGE MEDIA

Vol. 17, Iss. 2, February 2017

HIGHLIGHTS

www.G2Intelligence.com

Upcoming Events

Conferences:

Lab Leadership Summit: Designing, Implementing & Managing a High-Profit Lab Outreach Program
May 11, 2017 – 8 a.m.-5 p.m.
Holiday Inn Airport, Atlanta, GA
www.lableadershipsummit.com

Lab Institute 2017
October 25-27
Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

Inside the Lab Industry: Silicon Valley Bank Reports Steady 2016 Dx Investments, Declining Exits

Investments in the diagnostics and tools (Dx/Tools) sector remained steady in 2016, according to Silicon Valley Bank's annual report, *Trends in Healthcare Investments and Exits 2017*. The report's authors found the industry is attracting new investors and is optimistic that the sector's prospects for big exits (valued at $50 million or more) will improve in 2017.

Investment Levels

Silicon Valley Bank (SVB) says that overall health care venture investing was "strong" in 2016, but did not reach the record levels set in 2015. However, in 2016, Series A investments in early-stage technologies set records in all health care sectors, including Dx/Tools.

Continued on page 10

Enforcement E¢onomi¢$: ROI on US Fraud & Abuse Program Continues to Decline

While still profitable, the business of enforcing health care fraud laws has been providing the federal government a steadily declining return on investment (ROI) in recent years. This long-term trend is among the key findings of the most recent annual report to Congress from the U.S. Departments of Health and Human Services and Justice on the financial performance of the Health Care Fraud and Abuse Control Program (Program).

Key Program Numbers from 2016

Here are some of the key numbers from fiscal year 2016:

- **975:** Criminal health care fraud investigations opened by the DOJ;
- **930:** Civil fraud investigations opened by the DOJ;

Continued on page 2

ROI on US Fraud & Abuse Program Continues to Decline, *from page 1*

- **480:** Criminal health care fraud cases filed by prosecutors;
- **658:** Defendants convicted;
- **765:** Criminal health care fraud actions resulting from OIG investigations;
- **690:** Civil fraud actions resulting from OIG investigations;
- **3,635:** Individuals the OIG excluded from participating in federal programs;
- **$282.1 million:** Mandatory funding amount (after $20.6 million in mandatory sequester reductions);
- **$681.0 million:** Discretionary funding amount.

ROI Continues Steady Decline

While the Program's successes are considerable, so are its costs. The result is steadily declining ROI. According to the report, for every dollar spent on the Program during the three-year period 2014-2016, investment return was $5.00—not bad but also significantly below ROI from previous years. Here's how that ROI compares to the ROI reported in the annual reports going back to 2011 (reported for three-year period ending in that FY):

ROI on Program Activities

FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
$7.20	$7.90	$8.10	$7.70	$6.10	$5.00

The ROI figures are based on a three-year rolling average to smooth over year-to-year variances caused by differences in number of cases settled or adjudicated during a particular year.

Takeaway: Although enforcement efforts remain aggressive, the return on investment has faced decline in recent years.

LIR

Kelly A. Hardy, JD, Editorial Director

Glenn S. Demby, Contributing Editor

Catherine Jones, Contributing Editor and Social Media Manager

Lori Solomon, Contributing Editor

Barbara Manning Grimm, Managing Editor

David van der Gulik, Designer

Randy Cochran, Corporate Licensing Manager

Myra Langsam, Business Development

Michael Sherman, Director of Marketing

Jim Pearmain, General Manager

Pete Stowe, Managing Partner

Mark T. Ziebarth, Publisher

Laboratory Industry Report (ISSN 1060-5118) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 1-888-729-2315
Fax: 1-855-649-1623
Web site: www.G2Intelligence.com.

The 6 Things Labs Need to Know About the Trump Travel Ban

Although the first Trump travel ban didn't survive, a new version is already in the works. Although we don't yet know the details, the expectation is that the new travel ban will look a whole lot like the old but for what one Senior White House Policy Advisor describes as some "technical changes" to satisfy the courts. One thing we do know is that the new travel ban will have a major and immediate impact on laboratory operations. Here are the six things lab managers need to know to meet the challenges posed by the travel ban.

1. What Is It?

The so called "travel ban" is an Executive Order (EO) issued on Jan. 27 temporarily barring individuals from designated countries (restricted countries) from entering the US. The EO imposed three different entry bans:

Duration	Entrant Status	Entrant Nationality
120 days	Refugees	All nationalities
Indefinite	Refugees	Syria
90 days	Citizens, both immigrant and non-immigrant	Iran, Iraq, Libya, Somalia, Sudan, Syria, Yemen

2. Does It Affect Your Lab?

The ban affects you directly if, like many other labs, you have employees (or want to recruit employees), contractors or business associates who are citizens of the restricted countries.

3. What Is Its Practical Effect?

The term "travel ban" is misleading. Technically, the EO doesn't prevent anybody from *leaving* the US; it simply bars them from getting back into the country later. Practical impact on your lab:

- It would deter individuals from restricted countries who are currently in the US, including your own employees, contractors and business associates, from leaving the country, e.g., traveling to an international conference;
- It would bar employees, contractors and business associates from restricted countries who are currently abroad from entering the US to do business with you.

The EO does not deport anybody; but there are concerns that subsequent orders may. [See the Box on page 4 for the EO's impact on visa holders.]

4. Does It Cover Green Card Holders?

Although having a green card will help individuals from restricted countries to gain entry into the US, it isn't a guarantee.

Explanation: On Jan. 29, the Department of Homeland Security issued a press release stating that in applying the EO it will "deem the entry of lawful permanent residents to be in the national interest." But the very next sentence opens a loophole. "Absent the receipt of significant derogatory information indicating a serious threat to public safety and welfare, lawful permanent residence status will be a dispositive factor in our *case-by-case determinations*" (emphasis added).

Translation: Although green card holders will get the benefit of the doubt, the DHS can still bar entry if it has evidence that the individual poses a serious threat.

5. Does It Cover Dual Citizens?

The EO doesn't apply if the citizen of the restricted country is also a legal US citizen. However, it does cover dual citizens of both a restricted and non-restricted country *outside the US*, including a US ally like the UK, Canada, Australia or Germany.

6. What Should You Do about It?

If like so many labs, you have employees (or business associates) from restricted countries, you want to keep them inside the US. But you need to be careful about how you do that:

Wrong: While it may be well intentioned, a policy of *not letting* employees from restricted countries travel abroad would likely be deemed a form of nationality discrimination banned by federal Equal Employment Opportunity laws. The fact that the policy is designed not to discriminate but protect employees against themselves is no defense. "In the area of civil rights, employees [must be left to] make their own personal risk decisions" without the employer's "paternalistic" interference, according to one court.

Right: Recognize that you can't prevent employees from travelling and respect their right to make their own personal decisions. But do everything in your power to encourage them to make the right decision. One of the first things to do is cancel all international trips involving affected lab personnel through the period in which the travel ban remains in effect.

Takeaway: Issue Written Statement of Support. In addition, you might want to do what so many other leading companies across the US have done in response to the EO and issue a written statement to affected employees. Although there is no one-size-fits-all formula, your statement should:

- *Express your support for immigration and employees affected by the EO;*
- *Explain the EO and risks of travelling abroad while it remains in effect;*
- *Make it clear that you will neither require nor expect affected employees to engage in international business travel for as long as the EO is in effect; and*
- *Assure affected employees that they will suffer no adverse employment consequences for not travelling.*

Suspension of Visa Interview Waiver Program

One part of the Jan. 27 Executive Order that has flown under the radar is the suspension of the State Department's Visa Interview Waiver program, which allows frequent visitors to the US to renew their visas without an in-person interview. The combination of restoring the interview requirement with expected government staff hiring freezes and cuts will make it harder to renew visas and may force visa holders to cut their stays short. Moreover, the visa issue affects visa holders from *all* countries, not just the seven countries covered by the travel ban.

What Labs Should Do: Labs can get out in front of the issue by warning employees with valid nonimmigrant visa status of the risk of significant delays in scheduling visa interviews and post-interview processing.

H-1B Visas. Many labs employ skilled temporary foreign workers under the H-1B visa program. Although the EO does not cover H-1B visas, the President has repeatedly criticized the program for allegedly crowding out American workers and plans to cap the number of visas granted are rumored to be in the works. Stay tuned…

Case of the Month: Feds Net Another Million-Dollar Settlement in 21st Century Oncology FISH Testing Case

A Florida-based urologist is the latest 21st Century Oncology defendant to fork over seven figures to settle charges of false billing for *fluorescence in situ hybridization* (FISH) tests.

In addition to being relatively pricey, FISH tests are deemed medically reasonable and necessary for Medicare coverage purposes in very limited situations.

The Original Whistleblower Suit

The case began in March 2013 when a medical assistant filed a *qui tam* lawsuit claiming that a lab owned by 21st Century billed Medicare and Tricare for medically unnecessary FISH tests. The suit claimed tests were ordered by four Fort Myers-based urologists who allegedly received bonuses from the integrated cancer center based on the number of tests ordered.

FISH tests are performed on urine to detect genetic abnormalities tied to bladder cancer. In addition to being relatively pricey, FISH tests are deemed medically reasonable and necessary for Medicare coverage purposes in very limited situations. 21st Century's billing pattern raised a number of red flags that the OIG would later list in its August 2014 guidance on improper billing of FISH tests, including abnormally high average allowed amount per beneficiary—21st Century's average was 1,193—16 times the average for a non-independent lab. And its average allowed per ordering physician was $107,700—or 24 times (!) the overall average for non-ILs.

The Settlements

So far, the case has yielded $24.86 million as a result of four separate settlements:

- Jan. 2016: 21st Century paid $19.75 million to settle the civil charges, $3.2 million of which went to the medical assistant who brought the whistleblower suit;
- Jan. 2016: Urologist Dr. David Spellberg paid $1.050 million to settle allegations he ordered medically unnecessary tests, including pricey computer assays billed at up to 10 times the standard rate for FISH tests;
- Aug. 2016: Urologist Dr. Robert Scappa paid $250,000 to settle charges of, among other things, receiving bonuses based on volume of FISH tests ordered; and
- Feb. 2017: In the most recent settlement, Dr. Meier Daller, the national leader in number of FISH tests ordered, agreed to pay $3.81 million to settle allegations regarding his role in the scheme.

One urologist, Dr. Steven Paletsky, has yet to settle. When and if he does, it will surely push the overall total recovery from the 21st Century case to over $25 million.

Takeaway: Latest settlement in FISH testing case demonstrates the significant financial impact of whistleblower lawsuits and continued enforcement focus on medical necessity of lab testing.

DIAGNOSTIC DEALS

A roundup of the key mergers, acquisitions, alliances, licenses and other strategic transactions from the past month

After January's flurry of deals, the M&A front has been relatively quiet so far this month. But relatively low volume of M&A deals has been more than offset by surges in strategic alliances and partnerships. Here's an overview of the key deals and trends.

M&A

Dollar-wise, the biggest M&A deal so far was the closing of Grifols's acquisition of Hologic's blood screening business. The acquired assets include a San Diego plant, development rights and Hologic's access to patented technologies under license agreements. In addition to the $1.85 billion purchase price, the sale enables Hologic to get out of blood screening, which Hologic CEO Steve MacMillan described as a "drag on our growth" and concentrate on its core women's health and molecular diagnostics business.

Both sides to the deal appeared vindicated a week later when Hologic issued its 2017 first quarter results reporting a 6 percent increase in year over year revenue by 8 percent growth in molecular diagnostics (from $129.6 million to $139.9 million) and "continued strength" across Aptima women's health products on the automated Panther and Tigris platforms. The report also made Grifols look pretty smart, especially the part citing a 7 percent rise in Hologic's blood screening revenues for the period ($65.2 million) thanks to "Zika-related sales and strong international ordering patterns."

Other than Quest's acquisition of northwest nonprofit PeaceHealth Laboratories' outreach lab operations, most of the other M&A activity for the month involved smaller start-ups, foreign ventures and genomics firms.

Last but not least, there are unconfirmed reports (from Reuters) that LabCorp is in talks to acquire contract research organization Pharmaceutical Product Development for over $8 billion. However, the Reuters report adds that there are other bidders for PDP. LabCorp demonstrated its affinity for CROs when it shelled out $6 billion for Covance in 2015.

Strategic Alliances

Among the most active companies in February so far is Quest Diagnostics which in addition to the PeaceHealth Laboratories acquisition noted above, cut a deal to secure its physician clients access to Veracyte's Affirma Gene Expression Classifier non-invasive test for diagnosing thyroid cancer [See related Veracyte story on page 11] and expanded its hospital partnership network to include New York City's Montefiore Health System.

Thermo Fisher was also busy starting the month by expanding its year-old deal with Invivoscribe Technologies to co-develop oncology tests for its Ion PGM Dx System to include in vitro assays for the TF Applied Systems Biosystems 3500Dx Genetic Analyzer. A week later, the biotech firm

announced a similar deal with Asuragen to co-develop diagnostic kits for the 3500Dx CS2 instrument. Following a busy January (See *LIR*, Diagnostic Deals, Jan. 23, 2017), Illumina stayed active announcing a new collaboration with Invivoscribe aimed at developing new in vitro diagnostic assays for the former's MiSeqDx next generation sequencing platform for the US market.

Trend-wise, the month was notable for collaborations pairing diagnostics companies with big pharma firms to develop new drug diagnoses and treatments, such as:

- Perthera's collaboration with Novartis to identify breast and lung cancer patients for pharmaceutical clinical trials;
- The collaboration between Exosome Diagnostics and Merck KgaA on oncology drug development; and
- GenomeDx Biosciences agreement with Astella using the former's genomic profiling tumor technology to identify patients who are candidates to use the latter's XTANDI prostate cancer drug.

MERGERS & ACQUISITIONS		
Acquiring Company	**Target**	**Deal Summary**
Quest Diagnostics	PeaceHealth, non-profit health system in Alaska, Wash, Ore	▪ Price: Undisclosed ▪ Status: To close in 2Q 2017 ▪ Quest acquires PeaceHealth Laboratories' outreach laboratory services operations ▪ PeaceHealth keeps 11 labs which Quest will professionally manage
Grifols	Hologic, Inc.'s blood screening assets	▪ Price: $1.85 billion cash gross proceeds ▪ Status: Closing of deal announced in Dec. ▪ G and H were partners in blood screening business with H doing R&D and manufacturing and G concentrating on commercialization ▪ H leaves blood screening to concentrate on its core women's health diagnostics and imaging business
Anatrace	Molecular Dimensions	▪ Price: Undisclosed ▪ Status: Closed ▪ Establishes Anatrace in European structural bio research market
Miragen Therapeutics	Signal Genetics	▪ Price: Undisclosed ▪ Status: Closing of Oct. merger agreement ▪ Signal absorbed into Miragen ▪ Miragen assumes Signal's Nasdaq listing under symbol "MGEN" ▪ Merged entity has roughly $60 million in cash and short-term investments
Integrated DNA Technologies	GeneWorks's oligonucleotide manufacturing business	▪ Price: Undisclosed ▪ Status: Closed ▪ Acquisition of Australian company via IDT Singapore subsidiary ▪ Latest in string of deals expanding IDT presence in Asia-Pacific, including 2015 acquisition of oligonucleotide business of Singapore's AITbiotech
Partnership between management group and pair of investment firms: ▪ Ampersand Capital Partners ▪ 1315 Capital	Novartis subsidiary Genoptix	▪ Price: Undisclosed ▪ Expected Closing Date: First quarter ▪ Novartis acquired G, which provides hematology and solid tumor molecular profiling for oncologists and pathologists, in 2011 for $470 million ▪ Novartis to keep G's biopharma business, to be renamed Navigate BioPharma Services
WuXi AppTec (large Chinese CRO)	HD Biosciences	▪ Price: Undisclosed ▪ Status: Closed ▪ Shanghai-based HD provides AGM-based target validation, plate-based pharmacology and other preclinical services ▪ Acquisition bolsters WX preclinical and biology services capabilities ▪ HD is latest in series of WX's strategic acquisitions which include XenoBiotic Labs and NextCODE Health

Continued on page 8

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Interpace Diagnostics	Viatar CTC Solutions	▪ Collaborate on preclinical research studies assessing indeterminate pancreatic cancer biopsies in patients with pancreatic cysts with hopes of developing Dx test(s)
Asterand Bioscience	MolecularMD	▪ Objective: Development of custom clinical trial assays and companion diagnostic products ▪ Dynamic: MolecularMD to access Asterands' human tissue resources to furnish latter's biopharma clients end-to-end workflow for biomarker and cancer drug target validation
Illumina	Invivoscribe	▪ Objective: Develop and commercialize in vitro diagnostic assays for Illumina's MiSeqDx next-generation sequencing platform ▪ Dynamic: Deal allows Invivoscribe to bring IVD assays and associated bioinformatics software through the US Food and Drug Administration for US sale and distribution
IncellDx	Celsee Diagnostics	▪ Research partnership to combine respective technologies for predicting patient responses to metastatic lung cancer immunotherapy
RPRD Diagnostics	Children's Minnesota	▪ Objective: Enable CM to develop a pharmacogenomic testing process ▪ Dynamic: CM to use RPRD's pharmacogenomics testing platform within its cancer and blood disorder clinic and neurology/psychology practice
NeuroPointDX	Ovid Therapeutics	▪ Objective: Identify biomarkers for developing a treatment for Angelman syndrome ▪ Dynamic: NeuroPointDX to use its metabolomics platform to analyze patient profile data from ongoing Phase II trial of OV101, a compound Ovid is developing to prevent disruption of tonic inhibition for both Angelman and fragile X in Angelman
Protagen	National Cancer Institute	▪ Objective: Identify and test biomarkers of patient response to cancer immunotherapy ▪ Dynamic: Protagen to transfer its SeroTag platform for measuring autoantibody levels for thousands of antigens simultaneously to NCI ▪ NCI to use platform to identify biomarkers predicting immunotherapy responsiveness, monitor patients receiving treatment and for early detection of immune-related adverse events
AMRI	Bruker Daltonics and HighRes Biosolutions	▪ Research alliance deploying mass spectrometry technology for drug discovery ▪ Dynamic: AMRI to implement BD's MALDI PharmaPulse system at its Integrated Drug Discovery Center with plans to run 100,000 samples per day using system ▪ BD and HR to train and work with AMRI researchers to develop protocols for high-throughput screening in drug discovery
Exosome Diagnostics	Merck KGaA	▪ Objective: New drug development for oncology, etc. ▪ Dynamic: Use of Exosome technology platforms for nucleic acid and protein detection from circulating exosomes ▪ Exosome gives Merck access to its newly launched Shahky instrument for exosomal protein capture and quantitative analysis
Perthera	Hope for Stomach Cancer	▪ Perthera to provide its Precision Cancer Analysis service for molecular profiling of tumors ▪ Profiling to be done by HSC staff on HSC patients at no cost to them
Perthera	Novartis	▪ Objective: Identify breast and lung cancer patients for clinical trials ▪ Dynamic: Novartis to access roughly 1,000 cancer patients who have used Perthera's Precision Cancer Analysis service for molecular profiling of cancers
Thermo Fisher Scientific	Asuragen	▪ Objective: Develop and commercialize capillary electrophoresis-based in vitro diagnostics ▪ Dynamic: Asuragen to use its AmplideX PCR/CE technology to develop diagnostic kits for Thermo Fisher's 3500 Dx Series Genetic Analyzer CS2 instrument
ThermoFisher Scientific	Invivoscribe Technologies	▪ Expansion of deal made a year ago to co-develop oncology tests for Ion PGM Dx System ▪ Sides have now agreed to collaborate on development and commercialization of *in vitro* assays for Applied Biosystems 3500Dx genetic analyzer
Epinomics	Stanford Univ's Park Institute for Cancer Immunotherapy	▪ Objective: Improve cancer immunotherapies via biomarkers and epigenomics tech ▪ Dynamic: Stanford team to utilize biomarkers defined by Epinomics' immune intelligence framework to improve outcomes and reduce adverse events in immunotherapy clinical trials
Guardant Health	Univ. of Texas MD Anderson Cancer Center	▪ Multi-year partnership ▪ Objective: Establish G's liquid biopsy tech as standard-of-care tool for guiding cancer patient treatment ▪ Dynamic: G to help MD Anderson build on-site liquid biopsy centers for developing new assays using G's cell-free DNA sequencing tech
GenomeDx Biosciences	Astellas	▪ Objective: Improve treatment of prostate cancer patients ▪ Dynamic: Researchers to determine whether use of GDx's technology can be used in genomic tumor profiling to identify prostate cancer patients who can benefit from XTANDI®, Astellas's prostate cancer treatment drug

Qiagen	Genomics England	■ GE to use Qiagen's HGMD Human Gene Mutation Database for its 100,000 Genomes Project ■ Objective: Provide reporting and analysis of genomic data to scientists and clinicians at GE medical centers across UK
Royal Phillips	Westchester Medical Center Health Network member Bon Secours Charity Health System	■ Value: $180 million ■ Multi-year deal under which Phillips will provide BSCHS broad range of diagnostic services and technologies as well as business consultation ■ BSCHS arrangement based on existing 15-year, $500 million Phillips-WMCHealth partnership
Tempus	Univ. of Michigan	■ Objective: Find new treatment options for pancreatic cancer patients at UM's cancer center ■ Dynamic: Tempus to furnish genomic and gene expression sequencing and analysis ■ T announced similar deal with Ohio Univ. Seidman Cancer Center last month ■ Other T academic medical center clients include Univ. of Penn. Abramson Cancer Center and Mayo Clinic
Quest Diagnostics	Veracyte	■ Quest gets access to Veracyte's Afirma Gene Expression Classifier, a lab-developed test that uses fine needle aspiration biopsies to evaluate thyroid nodules for cancer obviating need for surgery ■ Dynamic: Quest MD clients will be able to order Affirma and refer to Veracyte for genomic analysis ■ Effective Date: 2Q 2017 ■ Following deal announcement, 10 BCBS plans issued positive coverage determination for Affirma
Quest Diagnostics	Montefiore Health System	■ Latest in series of Quest-hospital partnerships ■ Objective: Quest to perform low complexity diagnostic lab tests freeing MHS to focus on core business ■ Dynamic: Some tests performed at Quest's Teterboro, NJ facility; rest performed at MHS hospitals under latter's direction
DISTRIBUTION AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
Premaitha Health	Integrated Gulf Biosystems	■ Product: Noninvasive prenatal Iona test ■ Territory: Middle East, including United Arab Emirates, Dubai and Saudi Arabia ■ Premaitha also appointed unnamed distribution partner for Kuwait
MDNA Life Sciences	BL&H	■ Product: Prostate Mitomic Test, MDNA's PCR-based liquid biopsy prostate cancer test ■ Territory: South Korea ■ Exclusive
Globavir Biosciences	Suyog Diagnostics	■ Product: PanGlob Dengue rRT-PCR kit for detecting dengue virus ■ Territory: India ■ Deal also calls for collaborating on launch of MulGlob, a multiplex test for multiple pathogens
Cynvenio Biosystems	Milenia Labs	■ Product: Cynvenio's ClearID Breast Cancer liquid biopsy test ■ Territory: Mexico ■ Exclusive
LICENSES		
Licensor	**Licensee**	**Deal Summary**
Pathoquest	Laboratoire Cerba (part of Cerba Healthcare group)	■ Product: P's IDTTect blood-based NGS test for precision diagnosis of infectious disease ■ Territories: Exclusive France, Belgium, Luxembourg ■ LC also gets right to use test on non-exclusive basis in other designated European countries, Africa and the Middle East ■ P also gets right to introduce test directly to microbiology laboratories within specific reference hospitals
Metabolon	Zhejiang Dian Diagnostics, independent Chinese medical laboratory firm	■ Product: Metabolon's Discovery HD4 metabolomics platform ■ Dian to install Discovery HD4 in its Hangzhou lab ■ Dian to commercialize Metabolon's metabolomics-based products and services throughout China
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier	**Client**	**Deal Summary**
Quest Diagnostics	Harvard Pilgrim Health Care	■ HPHC physicians get access to Quest's Data Diagnostics® point-of-care health analytics technology
Quest Diagnostics	PeaceHealth, non-profit health system in Alaska, Wash, Ore	■ As part of Quest's deal to acquire PeaceHealth Laboratories' outreach laboratory services operations, Quest inked contract to manage the 11 labs that PeaceHealth will keep

Continued on page 10

SUPPLY, SERVICE & TESTING AGREEMENTS, *Cont'd.*		
Supplier	**Client**	**Deal Summary**
OraSure Technologies subsidiary DNA Genotek	Chinese personal genomics firm WeGene	▪ OraSure to supply its Oragene-DNA, all-in-one system for self-collection of DNA in saliva DNA to WeGene ▪ WeGene to use kits for genetic testing and personalized healthcare services in East Asia ▪ Earlier in week, WeGene announced that it had settled its patent-infringement and breach-of-contract disputes with Ancestry.com involving its saliva DNA collection kits
Siemens Healthineers	Two hospitals in Turkey	▪ 5-year agreement with estimated value of $108 million (based on patient population of 90 million) ▪ Healthineers to design and run all medical labs in multiple disciplines, furnish equipment, provide maintenance and handle technical staffing
Indivumed	Regeneron Pharmaceuticals	▪ Indivumed to provide Regeneron tissue samples for cancer research ▪ Indivumed to handle molecular data collection and furnish Regeneron associated de-identified patient information obtained via its existing collaboration with Geisinger Health System

NEW PRODUCTS	
Company(ies)	**Product(s)**
Meridian Bioscience	▪ TruQuick, a menu of point-of-care tests for diagnosing tropical, infectious, sexually transmitted, respiratory, gastrointestinal, cancer and cardiac diseases
Genomenon	▪ Mastermind, a software tool for gene and variant curation
Swift Biosciences	▪ Accel-NGS XL Library Prep Kit for whole-genome sequencing on Pacific Biosciences instruments
Cofactor Genomics	▪ Pinnacle, an RNA-based oncology assay which analyzes a patient's individual cancer profile
Biodesix	▪ Expansion of existing GeneStrat liquid biopsy test to include ROS1 and RET mutations (in addition to EGFR sensitizing, EGFR resistance, KRAS, BRAF and EML4-ALK alterations)
Sygnis	▪ TrueHelix, a web-accessible bioinformatics platform for next-generation sequencing analysis services
Mawi DNA Technologies	▪ iSWAB-Microbiome, a tool for collecting and stabilizing microbial content and diversity within gut, rectal, vaginal, skin, oral or soil samples
Cancer Genetics	▪ Focus::HERSite, a genomic panel for hereditary breast and ovarian cancer syndrome
Takara Bio USA	▪ In-Fusion Cloning Primer Design Tool that researchers can access free online to join together linear fragments of DNA in a single, 15-minute reaction

Silicon Valley Bank Reports Steady 2016 Dx Investments, Declining Exits, *from page 1*

Deal Volume

SVB data shows that the Dx/Tools sector saw "meaningful" early-stage momentum in 2016, with 51 deals closing during the year, the most since 2013 which witnessed the closing of 39 deals. The value of these deals rose to a high of $478 million, the highest since 2014's $252 million in series A investment. Within the sector, Dx outpaced tools garnering 59 percent of the Series A dollars invested. Grail was the largest venture-backed Dx/Tools Series A deal ($125 million) seen.

"While Dx exits declined in 2016, we see a significant number of companies ramping revenue towards $30-$50 million. We think that level should attract acquirer interest."

— Jonathan Norris

Investor Diversity

Encouragingly, the most active investors in the device and Dx/Tools sectors grew more diverse (e.g., corporate venture, angel groups, incubators and accelerators, and private equity). Tech-focused venture capitalists became "very active" in Dx/Tools, with Data Collective (San Francisco) leading investors with eight active Dx/Tools deals in 2015-2016. These investments follow the trend of increasing use of big data and bioinformatics within the Dx/Tools sector. LabCorp and Illumina emerged as active corporate venture investors with, respectively, three and two active deals in the Dx/Tools space in 2015-2016.

Geography

Geographically, California remained the most active region for new investment in Dx/Tools with 19 deals in Northern California (valued at $1.193 billion) and seven deals in Southern California (valued at $345 million). Massachusetts was the second most active state for new investments in the Dx/Tools space with seven deals valued at $106 million.

Exits, IPOs & M&A

Within the overall health care industry, a slower pace of initial public offerings (IPOs) led to lower distributions in 2016. As a sector, though, Dx/Tools companies struggled to reach big exits and had no IPO activity. SVB analysts say, though, that "large investment bets" have been made in advancements in bioinformatics, potentially "setting the stage" for more big exits in the coming years. In addition to big data, SVB analysts are watching companies with new tools to enable drug development and high-end sequencing, as well as those working to make diagnostics less invasive (e.g., liquid biopsies).

"While Dx exits declined in 2016, we see a significant number of companies ramping revenue towards $30-$50 million," writes the report's lead author, Jonathan Norris, managing director at Silicon Valley Bank (Santa Clara, Calif.). "We think that level should attract acquirer interest."

In 2016, the Dx/Tools sector had just four mergers and acquisitions (M&As) and no IPOs, compared to eight M&As and five IPOs in 2015. Of the four big exits (deals valued at $50 million or more) in 2016, three were in the tools space and only one was a diagnostics deal. Despite the low number of deals, the total deal value went up ($175 million in 2016 versus $164 million in 2015), while the median years to exit (from the time of the close of its first institutional round of financing) increased in the Dx/Tools space to 7.7 years. For a review of the 2016 year in M&A, see *LIR*, Dec. 29, 2016.

While the IPO market was slow overall, the Dx/Tools sector may have been particularly hampered by the "poor" after-market performance of previous IPOs. SVB says all five 2015 Dx/Tools IPOs are trading below their IPO prices.

Takeaway: Experts are not expecting large swings in investment in the Dx/Tools sector during 2017, although they are optimistic that M&A activity will pick up in 2017.

Industry Newsmaker: Veracyte, Inc. Scores Big with Percepta and Affirma GEC

Veracyte, Inc. is a leader in developing noninvasive genomic diagnostic tests for lung cancer. And in February, Veracyte's share of this lucrative market grew significantly.

Percepta Gets Thumbs Up from Medicare

It started on Feb. 6 when Veracyte announced that Medicare Administrative Contractor Palmetto GBA had issued a local coverage determination making the firm's Percepta Bronchial Genomic Classifier the first genomic test covered by Medicare for improved lung cancer screening and diagnosis.

The US market for Percepta is $425 million to $525 million, according to company estimates. Approximately 50 percent of that market is comprised of Medicare patients.

Affirma GEC for Quest

But the month was just starting. The very next day, Veracyte had more good news regarding another one of its products, Affirma Gene Expression Classifier (GEC), a lab-developed test that uses fine needle aspiration biopsies to evaluate thyroid nodules for cancer, eliminating the need for surgery. On Feb. 7, Veracyte announced that it had made a deal with lab giant Quest Diagnostics allowing Quest's physician clients to order Affirma GEC for its patients and refer specimens to Veracyte for genomic testing. Quest will make the service available via its AmeriPath anatomic pathology business of Quest Diagnostics, for use on cytopathology results of biopsies that are indeterminate, i.e., not clearly benign or malignant.

Affirma GEC Gets Blue Cross Blue Shield Coverage

It would get even better for Veracyte. Two weeks after the Quest deal was announced, Veracyte reported that 10 separate Blue Cross Blue Shield plans had issued positive coverage decisions finding Affirma medically necessary for diagnosing thyroid cancer. Word of the BCBS decision, which could be worth $26.4 million in additional revenue to Veracyte, fueled a 1 percent increase in the company's shares in the next morning's Nasdaq trading.

For more on Veracyte, see *LIR*, June 6, 2016.