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LABORATORY INDUSTRY REPORT™

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HIGHLIGHTS

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Upcoming Events

Conferences:

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

Lab Reimbursement Summit 2018
December 8, 2017
Holiday Inn Airport (South)
Atlanta, GA
www.lableadershipsummit.com

PAMA-Geddon: CMS Slashes 2018 Part B Lab Rates

Resisting industry pleas for a delay, CMS is sticking to the Jan. 1 start date for the new PAMA payment system. Even worse, it's sticking to its misguided formula for pricing lab tests. Result: The CMS preliminary 2018 Clinical Laboratory Fee Schedule (CLFS) provides for disturbingly deep and widespread cuts in lab payments.

How Did We Get to This Point?

Nobody quibbles with the idea of basing Medicare payments on what payors actually pay for lab tests. The problem is figuring out what the prices actually are. The CMS approach is to gather pricing data from what it calls "applicable laboratories." The

Continued on page 2

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

Deal volume was high during the month. But most of the deals were small and research-based.

M&A

It took over 18 months but the Abbott-Alere merger finally closed on Oct. 3. Alere got quite the haircut to make the deal happen. To keep Abbott from getting cold feet, Alere had to take at least $500 million off its acquisition price. To secure FTC antitrust approval Alere had to sell off its Triage business to Quidel and Epocal blood diagnostics unit to Siemens. And then on the eve of closing, Alere had to pay $13 million to settle with the US Securities and Exchange Commission which was investigating the accounting practices of its foreign subsidiaries.

Abbott rival Quest Diagnostics was also active, acquiring Shiel Medical Laboratory in New York City from Fresenius as well as a pair of hospital outreach labs in neighboring Connecticut.

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PAMA-Geddon: CMS Slashes 2018 Part B Lab Rates, *from page 1*

problem is that it isn't counting hospital and community labs as "applicable laboratories." These are the labs with the leverage to command higher rates from payors. Consequently, excluding their data not only leaves out a huge part of the lab market but artificially skews everybody else's rates in a downward direction.

Such is the argument that the lab industry has been making ever since CMS proposed the PAMA formula. And the preliminary CLFS that CMS just issued bears out the argument in spades with approximately 75% of all lab tests targeted for cuts. It would be a lot worse but for CMS's 10% per year cap on reductions, which means that 58% of the rate cuts will be phased in over two years.

"If these draft rates were finalized, the impact would be devastating," according to American Clinical Laboratory Association President Julie Khani. "We fear the impact on laboratories serving the most vulnerable Medicare beneficiaries, laboratories serving rural areas, and those with high Medicare volumes would be the most severely impacted."

Reference Labs Suffer the Deepest Cuts

The big reference labs like Quest Diagnostics and LabCorp will be hit especially hard. In a note to investors, Piper Jaffray analyst William Quirk writes that the expected revenue decline of approximately 8% in the first three years is even worse than Wall Street's initial expectations of a 6% drop in 2018 followed by a flat 2019-2020. So it is hardly surprising that word of the CLFS sent the share prices of both firms sharply down.

Both labs have also issued statements criticizing the preliminary rates as not being market-based because they exclude payment data from hospital labs. According to Quest CEO Steve Rusckowski, "Hospitals and physician office labs comprise half of Medicare clinical lab fee schedule volume and lab spending, but only accounted for 8.5% of the reported lab volume used by CMS to calculate the rates."

Mixed Bag for Molecular Dx

Newfangled proprietary tests offered by a limited number of labs fared better than reference lab tests provided by large numbers of hospital and reference labs. A notable example is molecular diagnostic tests. Thus, while a few molecular tests did suffer deep cuts (including tests for Lynch syndrome (CPT 81435) and TRB gene rearrangement direct probe (CPT 81341)), molecular assays were hit with generally smaller declines and even a few rate increases.

Advanced Diagnostic Laboratory Tests (ADLTs)

Another category of tests to dodge the axe are the newfangled ADLTs, i.e., tests developed and offered by a single lab that use a unique algorithm to analyze multiple DNA, RNA or protein markers, and which provide new clinical diagnostic information that cannot be obtained by any other test. Two key ADLT test codes to get increases included:

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Molecular DX Test Winners & Losers

Test	Proprietary Manufacturer(s)	2017 Rate	Proposed 2018 PAMA Rate
CPT 81519 (Oncotype DX for breast cancer recurrence)	Genomic Health	$3,443.36	$3,873
CPT 81525 (Oncotype DX for colon cancer recurrence)	Genomic Health	$3,126	$3,116
CPT 0008M (Prosigna for breast cancer recurrence)	Nanostring	$3,443	$900
myRisk Hereditary Cancer (based on CPT 81211 and 81213)	Myriad Genetics	$2,781	$2,949
CPT 81490 (Vectra DA rheumatoid arthritis test)	Myriad Genetics	$591	$841
CPT 81450 (hematological malignancies)	--	$541.81	$648.40
CPT 81445 (targeted next-generation sequencing of 5 to 50 genes panels)	--	$602.10	$597.91
CPT 81432 (Invitae hereditary cancer panel)	Invitae	$931	$838
CPT 81528 (Cologuard colon cancer screen)	Exact Sciences	$512	$509
CPT 81420 (prenatal testing)	Illumina, Natera, et al.	$802	$759
CPT 81435 (Lynch syndrome test)	--	$802	$38

- CareDx's AlloMap for cardiac transplant rejection risk (CPT 81595): from $2,841 to $3,240; and
- Veracyte's Affirma Gene Expression Classifier for classifying thyroid nodules (CPT 81545): from $3,222 to $3,600.

Crosswalk Codes

CMS also issued crosswalk- and gapfilling-based preliminary rates for 58 HCPCS codes for which it received no private payor data.

CMS is taking public comments on the proposed rates through Oct. 23 with the expectation of issuing final rates in November. In the meantime, the lab industry has not given up on its efforts to persuade the agency to change the pricing formula to include hospital labs or at least delay the new PAMA rates from taking effect on Jan. 1.

FDA Watch: New Moves to Boost CLIA Transparency

The CLIA standards that a lab must meet are based on the complexity of the in vitro diagnostic tests it performs. The FDA's primary role in the CLIA system is to categorize IVDs.

Test Category	Get CLIA Certificate	Meet Quality Standards	Submit to Routine Inspections
Moderate complexity	✔	✔	✔
High complexity	✔	✔	✔
Waived	✔		

On Oct. 2, the FDA did two things to enhance the transparency of its CLIA activities.

1. Revised Categorization Guidance

The FDA issued updated guidance providing more details about the procedures it will use to categorize IVDs and respond to applications for CLIA waivers. The key details:

- The FDA will try to notify sponsors of an approved IVD's categorization within two weeks of approval;
- IVDs approved for home or over-the-counter use will be waived automatically;
- Makers of IVDs categorized as moderate complexity can apply for a CLIA waiver;
- To get the waiver, the maker must use clinical and flex studies to show that the test is simple to use and poses "insignificant risk of an erroneous result."

2. Publication of CLIA Waivers

The second thing the FDA did to beef up transparency is launch a pilot program under which it will publish summaries of its CLIA Waiver by Application (CW) decisions. In addition to enabling the public to see how the FDA reviewed the data, publishing the decision summaries will help test makers prepare their future CW applications, according to the agency.

NOTE TO USERS: To keep you abreast of FDA CLIA waivers, ***LIR*** will include CW decision summaries in the monthly FDA Watch column from now on.

Here's a rundown of the other key diagnostic product launches from late August through the third week of September.

A Zika Approval First

On Oct. 6, Roche's Cobas test for detecting Zika virus in plasma specimens of human blood and organ donors the first Zika detection test approved for use by blood collection facilities in screening blood supplies. Although the FDA has issued about two dozen emergency use authorizations for Zika assays, including two new EUAs this month (see chart below), it has yet to greenlight any Zika test for actually diagnosing patients.

Here's a look at key FDA diagnostics approvals in late September through mid-October:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Hologic	Approval of Panther Fusion Flu A/B/RSV assay running on Panther Fusion system
Cepheid	Approval of Xpert Xpress Strep A test is an automated real-time PCR assay for rapid detection of *Streptococcus pyogenes* in DNA from throat samples
Alere	Approval of Alere i Influenza A & B 2 test for rapid detection of influenza A and B infection
Chembio Diagnostics	Emergency use authorization for DPP Zika System for use in high- and moderate-complexity CLIA-certified labs
Roche	Approval of Cobas Zika test for detecting the virus in blood donations
Roche	Approval of Cobas Cdiff Nucleic acid test for detecting toxin B gene of toxigenic *Clostridium difficile*
Roche	Expanded approval of Ventana PD-L1 assay for use in non-small cell lung cancer and metastatic urothelial carcinoma in countries that recognize CE marking and have approved Roche's Tecentriq cancer immunotherapy
Sanguina	Approval of AnemoCheck assay for determining total hemoglobin and calculated hematocrit in whole blood
Siemens Healthcare Diagnostics	Emergency use authorization for Advia Centaur test for qualitative detection of Zika virus IgM antibodies in human serum and plasma
Agilent Technologies	Expanded approval of Dako PD-L1 IHC 28-8 pharmDx complementary diagnostic for use as companion diagnostic with Merck's Keytruda drug for 2 additional indications: urothelial carcinoma and squamous cell carcinoma of the head and neck
Agilent Technologies	Approval of GenetiSure Dx Postnatal Assay to detect genetic aberrations associated with developmental delay and intellectual disabilities

So far, the FDA has published two CLIA waiver summary decisions.

NEW FDA CLIA WAIVERS

Manufacturer(s)	Product(s)
Quidel	Waiver for Sofia RSV FIA test for use with Sofia analyzer
Quidel	Waiver for Sofia Influenza A+B FIA test for use with Sofia analyzer

New CE Marks & Global Certifications

Here's a summary of notable European CE certifications during the month:

NEW CE CERTIFICATIONS

Manufacturer(s)	Product(s)
Atomo Diagnostics	Approval of Atomo HIV Self Test
Abacus Diagnostica	Approval of molecular norovirus test
Bruker	Approval of Fungiplex Candida assay
Bruker	Approval of Micronaut-AM test plate
Hibergene	Approval of HG Meningococcus Direct CSF test
Siemens Healthineers	Approval of Atellica Solution platform

Other new international approvals included approval of Gencurix's GenesWell ddEGFR Mutation Test for use as a companion diagnostic by the South Korean Ministry of Food and Drug Safety.

Diagnostic Deals, *from page 1*

One deal that did not come off was Rosetta Genomics's $2.9 million sale of its PersonalizeDx business. On Oct. 10, Rosetta announced that buyer Pragmin Prognosis had failed to carry out its deal obligations leaving Rosetta to explore its legal options and search for a new buyer.

Strategic Alliances

As in M&A, quantity over quality was the prominent feature of alliance-making with research institutions and small genomics firms supplying most of the impetus. But there were a few commercial deals involving the big players, including:

- The collaboration between PerkinElmer and 10x Genomics combining the former's Chemagic nucleic acid extraction technology Sciclone automation platform with the latter's Chromium instrument;
- The co-marketing deal integrating Centogene's rare diseases database of annotated phenotype and genotype variants into Qiagen Clinical Insight bioinformatics platform; and
- Becton Dickinson's collaboration with Euroclone to develop and globally distribute molecular tests to detect new sexually transmitted diseases.

Here's a graphic summary of the key diagnostic deals from late September through mid-October:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Abbott	Alere	▪ Price: $4.6 billion in "aggregate consideration"—original (March 2016) price was $5.8 billion, which was cut to $5.3 billion in April 2017 ▪ Status: Closed Oct. 3 ▪ FTC approval contingent on sale of Alere's point-of-care testing businesses
Quidel	Alere's triage MeterPro and B-type Naturietic Peptide (BNP) assay businesses	▪ Price: $680 million, including $400 million purchase price, $240 million deferred for BNP + $40 million in contingent payments ▪ Status: Closed Oct. 6 ▪ Quidel also acquires Triage's San Diego facilities ▪ Quidel gains complete control over BNP
Siemens	Alere's Epocal point-of-care blood diagnostic unit	▪ Price: Undisclosed ▪ Status: Expected to close by end of Oct. ▪ Sale required for FTC approval of Abbott acquisition of Alere ▪ Siemens to also acquire 2 Alere facilities in Canada
Quest Diagnostics	Shiel Medical Laboratory (owned by Fresenius Medical Care)	▪ Price: Undisclosed ▪ Status: To close in Q4 ▪ Deal doesn't include Spectra Labs, Fresenius' dialysis lab services business ▪ Sides also agree to leverage Quest's lab data analytics to identify early-stage chronic kidney disease patients who may benefit from treatment to slow progression to end-stage renal disease
Quest Diagnostics	William W. Backus Hospital and Hospital of Central Connecticut outreach labs	▪ Price: Undisclosed ▪ Status: Closed ▪ Quest acquired outreach labs of Hartford HealthCare's Clinical Laboratory Partners in 2016
Konica Minolta	Ambry Genetics	▪ Price: Up to $1 billion cash, including $800 million upfront and up to $200 million over 3 years ▪ Status: Expected to close in 3Q ▪ European Commission OKs deal ▪ Ambry to become subsidiary of Konica Minolta and keep its name and continue its genetic testing operation from its current California HQ

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
DiaSorin	Siemens Healthineers	▪ Price: €47.5illion ($55.3 million) on debt- and cash-free basis ▪ Status: Closed first week of Oct. ▪ DiaSorin acquires Siemens's microtiter-based ELISA immunodiagnostics business and related assets ▪ Siemens to continue manufacturing and exclusively providing ELISA kits to DiaSorin for up to 3 years ▪ DiaSorin paid $300 million cash for Quest's Focus Diagnostics' immunoassay and molecular Dx products in March 2016
Angle	Axela (University of Toronto microarray spinout)	▪ Price: £3.7 million ($4.9 million) to be financed by placement of new shares ▪ Status: Acquisition agreement but no closing date announced ▪ Angle to acquire intellectual property, fixed assets, inventory, employees and interest in leased property from Axela
Bruker	Merlin	▪ Price: Undisclosed ▪ Status: Closing of previously announced deal ▪ Bruker acquires German-based antibiotic-resistance and -susceptibility testing firm
Brooks Automation	4titude	▪ Price: $65 million cash ▪ Status: Closed ▪ Brooks acquires UK-based scientific tools and consumables manufacturer that has grown 20% in past 2 years with revenues of roughly $14 million in past 12 months
Prescient Medicine	PGxL Laboratories	▪ Price: Undisclosed ▪ Status: Closed ▪ Prescient acquires Kentucky-based pharmacogenomics testing reference lab, including its LifeK-it Predict service for predicting opioid addiction risks based on patients' genetic profiles
Precision for Medicine	Epiontis	▪ Price: Undisclosed ▪ Status: Acquisition contingent on consummation of $3 million+ finance deal ▪ Precision acquires German specialty lab which uses proprietary PCR-based technology to provide epigenetic immune cell assays for clinical trial immune monitoring
ScreenCell	3D Signatures	▪ Price: $400,198 ▪ Status: Closed ▪ ScreenCell acquires stake in French biotech company consisting of 2 million common shares via private placement
Avista Capital Partners	Miraca Life Sciences	▪ Price: $175.6 million ▪ Status: To close in November ▪ MLS to be owned by newly formed holding company called Symphony Buyer ▪ MLS parent company Miraca Holdings to own 15% of Symphony Buyer's shares

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
PerkinElmer	10x Genomics	▪ Objective: Develop workflow to enable large-scale studies from samples like saliva and archived dried blood spots ▪ Dynamic: Combine PerkinElmer's Chemagic nucleic acid extraction technology and Sciclone automation platform with the 10x Genomics' Chromium instrument
Qiagen	Centogene	▪ Objective: Co-marketing deal integrating Centogene's CentoMD rare diseases database into Qiagen Clinical Insight bioinformatics platform and companion knowledge base ▪ Dynamic: Qiagen to become exclusive global commercial distributor of CentoMD while Centogene licenses Qiagen's software for its own rare diseases diagnostic testing
FDNA	Murdoch Children's Research Institution + Victorian Clinical Genetics Service	▪ Objective: Database integration and distribution ▪ Dynamic: Use FDNA's Face2Gene software to integrate and exclusively distribute MCRI's POSSUMweb database
EKF Diagnostic	Ortho Clinical Diagnostics	▪ Objective: Widen access to EKF's beta-hydroxybutyrate (BHB) ketoacidosis diagnosis assay ▪ Dynamic: BHB test to be made available as a validated MicroTip Partnership Assay under Ortho program providing validated third-party assays
Agena Bioscience	N-of-One	▪ Objective: Expand Agena's newly launched MassArray Insights molecular analysis reporting network ▪ Dynamic: N-of-One to help interpret cancer genomic data generated by Agena's MassArray system
Agena Bioscience	Molecular Health	▪ Objective: Expand Agena's newly launched MassArray Insights molecular analysis reporting network ▪ Dynamic: Molecular Health to use its MH Guide analysis platform to interpret raw data generated by Agena's MassArray system

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Strata Oncology	University of California, San Francisco	▪ Objective: Research precision medicine treatment of metastatic prostate cancer ▪ Dynamic: New StratifyProstate initiative to accelerate clinical trial enrollment by offering no-cost NGS testing to eligible metastatic prostate cancer patients who enroll
Inova	Veritas Genetics	▪ Objective: Provide whole-genome sequencing and interpretation services ▪ Dynamic: Partnership to launch MyMap, new service leveraging Veritas's MyGenome NGS testing and Inova's MediMap pharmacogenomic testing for whole genome screening
Indica Labs	MolecularMD	▪ Objective: Move preclinical research to diagnostic setting and deploy advanced imaging analysis workflows ▪ Dynamic: Leverage MolecularMD's diagnostic clinical testing solutions with Indica's digital biomarker analysis services
Knight Cancer Institute at Oregon Health & Science University	Biological Dynamics	▪ Objective: Early cancer detection research ▪ Dynamic: Biological Dynamics to provide OHSU researchers early access to its Biological Dynamics' NanoVerita and ExoVerita lab-on-a-chip systems
Knight Cancer Institute at Oregon Health & Science University	Tempus	▪ Objective: Breast, pancreatic and prostate cancer treatment research ▪ Dynamic: Tempus to provide molecular sequencing, analysis and decision support tools based on molecular, clinical and outcome data and OHSU to provide patient samples
Genomics England t	Thermo Fisher Scientific + Inivata	▪ Objective: Research use of liquid biopsy testing for improving disease management and outcomes for cancer patients ▪ Dynamic: In phase 1 of study, Inivata to use its InVision circulating tumor DNA test and Thermo Fisher to use its liquid biopsy technology to analyze quality of blood plasma samples from Genomics England's 100,000 Genomes Project ▪ Partners then to assess utility of liquid biopsy for t discovery of mutations that can lead to or indicate presence of cancer
Inivata	Addario Lung Cancer Medical Research Institute	▪ Objective: Early-stage non-small cell lung cancer treatment research ▪ Dynamic: Perform study using Inivata's InVision circulating tumor DNA test in early-stage non-small cell lung cancer patients after surgery
Rainbow Genomics	Baylor Genetics	▪ Objective: Provide clinical exome sequencing tests to patients in Asia ▪ Dynamic: Rainbow Genomics to offer screening and diagnostic exome sequencing-based tests developed by Baylor ▪ Rainbow to use Baylor's Consultagene service to offer genetic counseling in English, Mandarin, Cantonese and Japanese
1CellBio	Hangzhou Chengyuan Genomics Company	▪ Objective: Provide single-cell analysis research services for China market ▪ Dynamic: Reseller and licensing agreement under which Hangzhou will sell 1CellBio's InDrop instrument for single-cell RNA sequencing ▪ Deal includes 1CellBio's kits and consumables
Seegene	Hamilton	▪ Objective: Development of Seegene random access system ▪ Dynamic: Partnership integrating high multiplex real-time PCR testing on Hamilton's liquid handling platforms
Sema4	PWNHealth	▪ Objective: Provide telehealth genetic testing services to consumers ▪ Dynamic: PWN Health to supply physician oversight for Sema4's newly launched CarrierCheck genetic carrier screening test ▪ PWNHealth to review consumer's health history to ensure test is appropriate and offer genetic counseling services to approved consumers
Nanion Technologies	Cellular Dynamics International	▪ Objective: Co-market CDI's human induced pluripotent stem cell-derived tissue cells with Nanion's ion channel drug discovery and screening platform ▪ Dynamic: CDI to provide iPSC-derived differentiated cells and Nanion to provide on-site training for CardioExcyte with customers allowed to renew their contract or purchase the CardioExcyte 96 instrument at a discount at the end of the year
DxTerity	City of Hope Medical Center	▪ Objective: Develop blood test predicting if cancer patients would benefit from radiation therapy or are at risk for radiation toxicity ▪ Dynamic: Conduct RADIANT radiotherapy response study on patients receiving radiation treatment to abdominal-pelvic region

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Natera	Aarhus University (Denmark)	▪ Objective: Evaluate Natera's Signatera liquid biopsy assay for bladder cancer ▪ Dynamic: Conduct study of more than 400 plasma samples collected from bladder cancer patients over course of their treatment ▪ Aarhus to collect sequence data from patients' tumors while Natera designs custom circulating tumor DNA assays for each patient using its proprietary bioinformatics pipeline
UgenTec	R-Biopharm AG	▪ Objective: Create interpretation software for R-Biopharm's clinical PCR kits ▪ Dynamic: UgenTec to develop a standardized software for automated quantitatively interpreting results of R-Biopharm PCR assays
Becton Dickinson	Euroclone	▪ Objective: Develop and globally distribute molecular tests to detect new sexually transmitted diseases ▪ Dynamic: BD and Euroclone to develop and commercialize assays outside US beginning in 2018 and in US later
Opko Health (via BioReference Laboratories business)	The Garage	▪ Objective: Give physicians advanced tools to guide quality value-based care ▪ Dynamic: Combine Garage's Bridge technology platform with BioReference's diagnostics expertise
Indivumed	Helomics	▪ Objective: Jointly provide cancer specimen research and clinical data analysis products and services ▪ Dynamic: Customers of both companies get access to Indivumed's cancer database, biobank and European research laboratory, as well as Helomics' US-based analytical lab services for biospecimen analysis, CLIA testing capabilities and bioinformatics platform
Molecular Devices	Cytena	▪ Objective: Launch Cytena's CloneSelect single-cell printer in North America. ▪ Dynamic: Terms of partnership not disclosed

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
AroCell	Pathway Diagnostics	▪ Product: AroCell's TK 210 ELISA test ▪ Territories: UK and Ireland
Hema Diagnostic Systems (subsidiary of Generex Biotechnology)	Imerlab Sociedad Comercial Limitada	▪ Product: Hema's Rapid 1-2-3 Hema HIV Express test ▪ Territory: Chile ▪ Exclusive
Oxford Nanopore Technologies	Shanghai NanodigmBio	▪ Products: Oxford's sequencing products and services ▪ Territory: China (Shanghai) ▪ Oxford already has significant presence in China market
Vector Laboratories	MJS BioLynx	▪ Products: Vector's labeling and detection reagents (specific labels not disclosed) ▪ Territory: Canada ▪ Exclusive
Abacus Diagnostica	Launch Diagnostics	▪ Products: Abacus's GenomEra product line, including automated GenomEra CDX platform ▪ Territories: UK, Ireland, France, Belgium, Netherlands and Luxembourg
Illumina	Lucigen	▪ Products: Illumina's Epicentre portfolio of products ▪ Expansion of Lucigen's existing sale and manufacturing rights to entire Epicentre line ▪ Illumina named Lucigen exclusive global distributor of its Epicentre products in April 2017
Synthego	Thermo Fisher Scientific	▪ Products: Synthego's synthetic guide RNA products, which will be marketed and sold under the Thermo Fisher Invitrogen TrueGuide brand ▪ Territory: Worldwide
Biocept	Miraca Life Sciences	▪ Products: Biocept's Target Selector liquid biopsy tests and services ▪ Territory: US ▪ Exclusive
Streck	Orgentec Sasu	▪ Products: Streck's cell stabilization and molecular products ▪ Territory: France
Devyser	Dahui Biotech	▪ Products: Devyser's rapid prenatal aneuploidy diagnostic test kits ▪ Territory: China
GenePeeks	Bioiatriki	▪ Product: GenePeek's newly launched preconception screening test ▪ Territories: Greece and Cyprus

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
Sienna Cancer Diagnostics	Axlab	■ Product: Sienna's *in vitro* diagnostic test for detecting hTERT component of telomerase ■ Territories: Denmark and Sweden ■ Exclusive
Molecular Biology Systems	PreMed Lab	■ Product: MBS's NextGen PCR ultra-fast thermal cycler ■ Territory: China
Molecular Biology Systems	Camlab	■ Product: MBS's NextGen PCR ultra-fast thermal cycler ■ Territory: UK
Molecular Biology Systems	Ybux	■ Product: MBS's NextGen PCR ultra-fast thermal cycler ■ Territory: Czech Republic
Molecular Biology Systems	Isogen Life Science	■ Product: MBS's NextGen PCR ultra-fast thermal cycler ■ Territories: BeNeLux and Spain
Molecular Biology Systems	Pronto Diagnostics;	■ Product: MBS's NextGen PCR ultra-fast thermal cycler ■ Territory: Israel
Molecular Biology Systems	Albiogen	■ Product: MBS's NextGen PCR ultra-fast thermal cycler ■ Territory: Russia
Premaitha Health	Barker Medical	■ Product: Premaitha's Iona assay ■ Territory: South Africa
SpeeDx	Diagen	■ Products: SpeeDx's PlexPCR and ResistancePlus real-time PCR product lines ■ Territories: Denmark, Sweden and Norway
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Servicer	**Client**	**Deal Summary**
Twist Bioscience	Ginkgo Bioworks	■ Twist to synthesize a billion base pairs of synthetic DNA for Ginkgo ■ Ginkgo CEO calls deal a "historic purchase"

Investment Trends: New Report Sheds Light on Dx Tech Capital Flows

The health care industry raised $5 billion in venture fund investment in the first half of 2017 and is well on pace to smash the single year record of $7.5 billion set in 2015, according to Silicon Valley Bank (SVB). Here's an overview of the key findings in the SVB report.

Where the Money Is Flowing

Venture fund investment is focusing on biopharma and DX/Tools, the report notes. Traditional investors have "lost interest" in the device sector but nontraditional ventures like private equity, family offices, angel groups and corporate funds and other are still putting their money into it.

Early-stage, Series A investments across all sectors are on pace to exceed 2016 records. For the first half of 2017, Series A investment has been "strong" in the Dx/Tools sector. Nearly almost 40% of these deals did not disclose investors, notes report author Jonathan Norris, which suggests "significant angel investment."

Who's Getting In

Within Dx/Tools, the most active investors are tech-focused firms, including AME Cloud Ventures, Data Collective, Innovation Endeavors, Felicis Ventures and Khosla Ventures. Corporate investors like biotech (Lilly Ventures), tools (Illumina), general health care (GE Ventures) and tech

(Google's venture arm, GV) are also investing heavily in the sector, largely in Dx/Tools companies involved in artificial intelligence (AI)- and machine learning-based technology.

Since 2015, $2.2 billion has been invested in 44 deals involving Dx/Tools AI- and machine learning-based technologies companies. While the median deal size was $12 million, companies like Grail, Guardant Health and Human Longevity have raised multiple $100 million rounds. Eleven other companies have each raised over $30 million. Norris expects this "aggressive fundraising" to continue in the second half of 2017 and into 2018.

Who's Getting Out

There were no Dx/Tools exits (M&A or initial public offerings) in the first half of 2017 that Norris calls "troubling." But he does see future opportunities due to "significant" investments in the sector, including "big bets" placed on next-generation sequencing, liquid biopsy, AI- and machine learning-based technology activities.

"We expect to see some exceptional exit opportunities in the next two to five years, and possibly a $1 billion-plus M&A exit in 2017," writes Norris, with acquirers likely to include large pharmaceutical and tech companies.

Trend to Watch

Look for more investment in innovative early-stage device companies and, perhaps, reallocation by traditional venture funds to device. Since 2015, pre-market approval (PMA)/de novo 510(k) device acquisitions have generated larger upfront multiples and a quicker time to exit than iterative 510(k) pathway exits, Norris reasons. These returns are now approaching what we see from biopharma M&A.

Takeaway: The broad health care industry is poised for a strong 2017 in terms of investment. Look for large, future exits in the Dx/Tools sector.

The Dx Pipeline: A Roundup of the Month's Key New Product Launches

Here's a rundown of the key diagnostic product launches from late September through mid-October.

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
Episona	Consumer launch of epigenetic Seed test for male infertility (previously available only in fertility clinics) online for home use
Swift Biosciences	Accel-Amplicon Custom NGS Panels for research use
GenePOC	Group B Streptococcus Direct Swab molecular test in Europe
iGenomX	Riptide High-Throughput Rapid Library Prep
Fast Track Diagnostics	FTlyo Enteric (aka typhoid or paratyphoid) fever kit
Bruker	Fungiplex Candida assay (launched right after CE approval)

Continued on page 12

Company(ies)	Product(s)
Bruker	Micronaut-AM test plate (launched right after CE approval)
Xifin	Addition of NGS model to its LIS Anywhere laboratory information system
Illumina	Nextera DNA Flex whole-genome sequencing library preparation product
DNAnexus	DNAnexus CloudSeq suite of cloud-based tools supporting informatics infrastructure needs of customers using Illumina's NovaSeq systems
ResearchDx +	Resolvex A200, positive pressure workstation for LC-MS sample prep
Menarini Silicon	DEPArray HER2, FISH-based LDT
DiaSorin Molecular	Primer pairs, group C and group G Streptococcus for use in molecular LDTs
DiaSorin Molecular	Pneumocystis jirovecii primer pair for use in molecular LDTs
Hibergene	HG Meningococcus Direct CSF test (launched right after CE approval)
CogenDx	DxWound test for detecting infectious agents
NuGen Technologies	Addition of 96 unique dual index pairs to its library preparation kits
OnRamp BioInformatics	Rosalind genomics analysis platform for life science research
Lexogen	SLAM-seq metabolic RNA sequencing kits
Thermo Fisher Scientific	PureLink Fast Low-Endotoxin Plasmid Purification Medi and Maxi kits for research use
Blueprint Genetics	Whole-exome sequencing services for US customers