Your Independent Source for Business & Financial News

# LABORATORY INDUSTRY REPORT™

A DIVISION OF PLAIN LANGUAGE MEDIA

Vol. 17, Iss. 3, March 2017

## HIGHLIGHTS



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## 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 South,
Atlanta, GA
www.lableadershipsummit.com

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

## Trump Budget "Blueprint": 4 Ways It Will Impact Labs

President Trump's 2018 budget proposal includes a number of items likely to affect your laboratory. Here are the four things lab managers need to know about the proposal.

### What It Is & Is Not

The proposal is not a budget. Only Congress has the constitutional authority to make budgets and appropriations. But while presidents do not "make" budgets, they play a leading role in the process by establishing spending priorities. The 2018 budget proposal is best understood as a "blueprint" of President Trump's spending priorities.

And based on the deep cuts to the U.S. Department of Health and Human Services (HHS), including the National Institutes of Health (NIH), biomedical funding is clearly not one of the new president's spending priorities. In his introductory message to the budget proposal, President Trump explained that

*Continued on page 10*

## FDA Watch: Doubling of User Fees, LDT Maneuvering & Potential OK for First Diabetes POC Dx Test

### Trump Proposes Doubling FDA User Fees

The Trump 2018 budget proposal would double user fees that pharma and medical device companies pay the FDA to review their products from $1 to $2 billion. "Industries that benefit from FDA approval can and should pay for their share," according to the proposal. While the reasoning may be sound, a 100 percent increase in user fees would inflict disproportionate financial harm on biotech and other smaller, entrepreneurial firms operating on tight margins. In addition to gutting the revenue targets that the FDA painstaking negotiated with industry, the proposal would turn the understand-

*Continued on page 2*

FDA Watch: Doubling of User Fees, LDT Maneuvering & Potential OK, *from page 1*

ing that user fees are a supplementary rather than primary source of FDA review activities upside down. (For more details on the Trump budget and its impact on labs, see the related story on page 1.)

## Maneuvering on LDTs

The laboratory-developed tests (LDT) cauldron continues to bubble. Two weeks after the FDA issued a discussion paper outlining a new approach to oversight of LDTs (See *LIR*, January 2017), a group of 33 health care organizations including the American Cancer Society, asked Congressional leaders to push the process.

Meanwhile, a revised plan to regulate LDTs has surfaced in the US House of Representatives. The discussion draft of the Diagnostic Accuracy and Innovation Act, which was introduced as an alternative to the FDA LDTs plan, proposes creation of a new regulatory category for *in vitro* clinical tests (IVCTs) distinct from medical devices. Regulatory authority over IVCTs would be shared with the FDA overseeing test development and validation, CMS overseeing traditional lab activities necessary to perform testing, and states maintaining oversight of test results interpretation.

## FDA Mulls First POC Dx Test for Diabetes

Health professionals currently rely on point-of-care (POC) tests measuring HbA1c to monitor and manage glycemic control in diabetes patients. But the time needed to meet proficiency standards impairs the tests' diagnostic value. Now the FDA is considering what would be the first approved POC HbA1c diagnostic test for diabetes in the US. Alere's Afinion HbA1c Dx would be considered a moderate-complexity test, i.e., labs would have to perform proficiency testing and follow other quality controls. But Alere also makes a CLIA-waived version of Afinion for monitoring HbA1c that's subject to less scrutiny which some experts believe can be used not just to monitor glycemic control but actually detect diabetes earlier in the process.

## The Pipeline

On Feb. 2, Abbott Laboratories announced that its RealTime Zika assay had received expanded FDA Emergency Use Authorization (EUA) to include use on whole blood samples. The original EUA was limited to use on human serum, EDTA plasma and urine samples. (For more on the emerging Zika Dx market, see the related story on page 4.)

In addition to the expansion of the Abbott RealTime Zika EUA discussed above, at least 10 diagnostics products have received FDA clearance in February and March, including:

| Manufacturer(s) | Product(s) |
|---|---|
| Myriad Genetics | Approval of BRACAnalysis CDx as a complementary diagnostic to identify ovarian cancer patients with germline BRCA mutations likely to benefit from treatment with Zejula (niraparib) |
| Beckman Coulter Diagnostics | DxC 700 AU chemistry analyzer |

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LIR

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| Manufacturer(s) | Product(s) |
|---|---|
| Philips | ElastQ Imaging, noninvasive test of liver tissue stiffness |
| Accelerate Diagnostics Inc. | Marketing of PhenoTest BC Kit, which identifies organisms causing bloodstream infections and antibiotics to which the organism is likely to respond |
| BioMérieux Inc. | Expanded use of Vidas Brahms PCT Assay to decide whether to start antibiotic treatment of lower respiratory tract infections or stop such treatment of sepsis |
| Immunexpress | Approval of Septicyte Lab, RNA-based blood test to determine a patient's systemic inflammation was caused by infection |
| DiaSorin | Approval to market its Simplex C. difficile Direct Assay in US |
| Hologic | Pre-market approval of Aptima HCV Quant Dx assay on Panther system for hepatitis C viral load monitoring and confirmation of HIV diagnosis in US (not approved for sale in US) |
| Cepheid | Approval of Xpert Xpress Flu and Xpert Xpress Flu/RSV tests, first in Cepheid's planned line of 30 minute (or less) Xpress branded tests |

Great Basin Scientific also announced that it has submitted a new FDA Section 510(k) application for its Bordetella Direct Test, a sample-to-result PCR-based assay that detects the infectious agent that causes whooping cough (*Bordetella pertussis*) directly from a nasopharyngeal swab.

## New CE Marks

Diagnostic products receiving CE marking for Europe in February and March include:

| Manufacturer(s) | Product(s) |
|---|---|
| Roche | Cobas HPV assay on the Cobas 6800/8800 systems for cervical cancer screening |
| HTG Molecular Diagnostics | HTG EdgeSeq ALKPlus assay EU for analyzing mRNA ALK gene rearrangements in lung tumor specimens |
| Nucleix | Bladder EpiCheck test for monitoring bladder cancer patients |
| DiaCarta | ColoScape, a PCR-based kit that detects mutations associated with colorectal cancer |
| Medical Innovation Ventures (aka Mediven) | PCR kit to detect different serovars of leptospira (i.e., the bacteria that causes leptospirosis) |
| Pressure BioSciences | Barocycler 2320Extreme instrument, a sample preparation machine for proteomic analysis |
| Agilent Technologies | Expansion of use for its Dako PD-L1 IHC 22C3 pharmDx, a companion diagnostic for Merck's Keytruda, in Europe |

In addition, Illumina announced that an expanded version of its VeriSeq NIPT software for analyzing fetal aneuploidies has met EU's *in vitro* diagnostic directive requirements and that it will apply the CE mark to the software. Genedrive reported that it's seeking CE marking for its hepatitis C test, the Genedrive HCV ID Kit.

## Outside North America

Roche Diagnostic Canada said that it has secured the approval of Health Canada for its Cobas EGFR Mutation Test v2 for marketing in that country.

And Chinese firm Amoy Diagnostics announced that it is seeking approval from Japan's Pharmaceuticals and Medical Devices Agency for its OncoGuide AmoyDx ROS1 fusion kit for identifying advanced non-small cell lung cancer patients with ROS1 gene fusions.

# Emerging Markets: The Rapid Rise of Commercial Zika Diagnostics

The rapid emergence of the Zika threat is creating a new *in vitro* diagnostics market that did not exist a year ago. Here's a quick overview of the Zika market, how it developed and where it stands today.

## Incubation of the Market

Zika is a mosquito-borne virus first discovered in Uganda in 1947. The first major Zika outbreak occurred in the Pacific in 2007; by 2016, local infections were occurring in over 20 countries across the Americas, according to World Health Organization estimates. The primary means of diagnosing Zika is specialized laboratory blood testing to detect the two breeds of mosquitoes that spread the virus. As late as May 2016, those tests were performed almost entirely by the CDC and a handful of state and public health departments. But as the threat crept closer to American shores, commercial labs in the US stepped up efforts to develop a diagnostic test for Zika.

## The FDA Stimulus

The Food and Drug Administration (FDA) served as the engine of growth by using its authority to approve experimental tests for limited emergency uses. The FDA began issuing Emergency Use Authorizations (EUAs) in February 2016 for two forms of Zika diagnostic tests:

- Molecular/Nucleic Acid Amplification Tests; and
- Zika Virus Antibody/Serological Tests.

The first EUAs were for antibody tests detecting the Zika mosquito breeds performed by the CDC and state health departments. Those same mosquito breeds also transmit dengue and yellow fever. Because there was, at the time, no test to distinguish Zika from dengue, the serological tests were of limited diagnostic use. However, Nirmidas Biotech, a startup Palo Alto firm founded by Stanford University has reportedly developed a serological test for rapidly distinguishing Zika virus infection from Dengue virus infection in both acute and convalescent patients, according to a March 6, 2017 article published in *Nature Medicine*.

## Commercial Breakthroughs

In April 26, a breakthrough occurred when the FDA approved its first test developed by a commercial lab molecular test for Zika by issuing an EUA for Zika Virus RNA Qualitative Real-Time RT-PCR test, a molecular test from Quest Diagnostics subsidiary Focus Diagnostics. EUAs to other commercial labs followed—Altona, Hologic, Siemens, Luminex, Roche, Abbott, among others—in quick succession.

The most recent commercial breakthrough took place in February when Abbott Laboratories' RealTime Zika assay became the first whole blood molecular test to receive FDA approval. The approval is an expansion of the EUA that the FDA issued in November 2016 approving RealTime for use on human serum, EDTA plasma and urine samples to whole blood samples.

For details on the 14 EUAs the FDA has issued for in vitro Zika diagnostics visit our website: https://www.g2intelligence.com/fda-euas-for-zika-testsas-of-march-15-2017

## DIAGNOSTIC DEALS

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

Two-thirds of the way through the month, March has seen a relatively high volume of strategic deals but mostly of the marginal variety, particularly with regard to M&A activity.

### M&A

The headline M&A deal for the month was LabCorp's acquisition of the ownership interests of Washington-based Pathology Associates Medical Laboratories (PAML) in five joint ventures: Colorado Laboratory Services, Kentucky Laboratory Services, MountainStar Clinical Laboratories, PACLAB Network Laboratories and Tri-Cities Laboratory. Under the terms of the deal, which does not include PAML's California joint ventures, LabCorp will furnish outreach testing and reference lab services currently provided by PAML while PAML's joint owners, Catholic Health Initiatives and Providence Health & Services, continue to provide in-patient hospital lab services.

Strategic acquisitions by LabCorp are nothing new. After all, the diagnostic giant has been locked in something of an M&A race with rival Quest Diagnostics for several years. However, the PAML deal is a bit of a role reversal from recent practice. Acquisition of health system outreach labs has largely been Quest's *modus operandi* (for example, Quest's February acquisition of northwest nonprofit PeaceHealth Laboratories' outreach lab operations) with LabCorp focusing instead on acquiring specialty labs to bolster the sophistication of its product lines.

Other items of March M&A news that you may have missed were a pair of revelations disclosed by PerkinElmer in its recent SEC filing regarding 2016 deals, including the fact that the company:

- Paid $63.5 million in cash to acquire Bio Scientific;
- Had also acquired Delta Instruments for $8.8 million.

### Strategic Alliances

While M&A activity was relatively slow, strategic partnerships and alliances continued to chug along at a rapid pace. Key deals from March include:

- The one-year extension of the collaboration between Quest and Vermillion for commercialization of the latter's OVA 1 ovarian cancer test;
- The strategic research partnership among Illumina, IBM Watson and Munich Leukemia Laboratory integrating IB Watson for Genomics with Illumina's BaseSpace and tumor sequencing process to simplify genomic data interpretation;
- Royal Phillips's collaboration with OneLife (which includes a minority equity stake in OneLife) combining proprietary technologies to develop pregnancy and early child care diagnostics products.

Continuing recent patterns, March featured a number of strategic alliances between diagnostics firms and big pharma, such as SenzaGen's granting AstraZeneca the right to use its GARD platform for rapid genomic allergen detection for development of a genomic test differentiating allergens from irritants for use in drug development research.

## Key Coverage Determinations

Although several companies secured favorable diagnostic coverage determinations in March, the big winner was Vermillion, manufacturer of the OVA1 ovarian cancer early detection test—the test covered in the expanded commercialization agreement between Vermillion and Quest mentioned above. On March 1, Vermillion announced that Aspira Labs, the wholly-owned subsidiary that manufactures the test, had secured a major contract for OVA1 with Blue Cross Blue Shield of Michigan. Less than a week later, Aspira Labs was granted Medi-Cal (the California Medicaid program) out-of-state provider status, effectually expanding OVA1 access to 12 million new patients.

## Key Product Developments

Diagnostic firms whose products achieved significant approvals in March included:

- **OncoCyte**, which reported that its early lung cancer detection test achieved favorable results in a 300-patient study ahead of a planned launch for the second half of 2017;
- **Agendia**, whose MammaPrint 70-gene signature test measuring risk of breast cancer recurrence received a1A label, the highest medical evidence level granted under German Association of Gynecological Oncology guidelines; and
- **Beckman Coulter Diagnostics**, which announced the FDA clearance and commercial launch of its DxC 700 AU chemistry analyzer.

Here's a graphic rundown of the key deals from March (so far):

**MERGERS & ACQUISITIONS**

| Acquiring Company | Target | Deal Summary |
|---|---|---|
| Ampersand Capital Partners and 1315 Capital | Genoptix (from Novartis) | ▪ Price: Undisclosed (Novartis paid $411 million for Genoptix in 2011)<br>▪ Status: Expected to close in Q1<br>▪ Former Prometheus Laboratories CEO Joseph Limber will be Genoptix CEO<br>▪ Novartis to keep Genoptix's biopharma business, which will be renamed Navigate BioPharma Services |
| BioreclamationIVT | TransCell Science | ▪ Price: Undisclosed<br>▪ Status: Expected to close in Q1<br>▪ TransCell is a privately held CRO specializing in primary cell-based phenotypic screening assays |
| Laboratory Corporation of America Holdings | Pathology Associates Medical Laboratories, LLC—jointly owned by Providence Health & Services and Catholic Health Initiatives | ▪ Price: Undisclosed<br>▪ Status: Deal signed to be implemented in stages<br>▪ LabCorp also acquires PAML's interest in 5 joint ventures<br>▪ Providence, CHI and hospital joint venture owners will continue providing in-patient hospital lab services<br>▪ LabCorp will provide outreach testing services and reference lab services currently provided by PAML and joint ventures |

| | | |
|---|---|---|
| Johnson & Johnson | Abbott Medical Optics | ■ Price: $4.33 billion<br>■ Status: Closing of September 2016 buyout agreement<br>■ Acquired portfolio of AMO ophthalmic products generates annual revenues of $1.1 billion |
| MedDay Pharmaceuticals | Profilomic | ■ Price: Undisclosed<br>■ Status: Closed<br>■ MedDay bolsters its SPECMET cerebrospinal fluid-based metabolomics research platform by acquiring Profilomic's lab equipment, database and metabolomics and lipidomics research team |
| OncoDNA | BioSequence | ■ Price: Undisclosed<br>■ Status: Closed<br>■ OncoDNA acquires Spanish personalized cancer genomics firm that it designated 2 years ago as exclusive distributor of its clinical oncology molecular diagnostics products in Spain<br>■ OncoDNA to leverage BioSequence deal to expand into Portugal and Latin America |
| Aviva Systems Biology | GenWay Biotech | ■ Price: Undisclosed<br>■ Status: Closed<br>■ Acquisition advances Aviva's strategy to become leading provider of proteomic solutions<br>■ GenWay has ISO13485 accreditation for development, validation and production of antibodies and proteins for use in US FDA-regulated and CE marked products |
| Angeon Group (private equity investment group) | InstantLabs Medical Diagnostics | ■ Price: Undisclosed<br>■ Status: Closed<br>■ Angeon acquires controlling equity interest<br>■ InstantLabs Medical Diagnostics name changed to InstantLabs |
| Instrumentation Laboratory (subsidiary of Werfen) | Accriva Diagnostics | ■ Price: Undisclosed<br>■ Status: Closed (end of January)<br>■ Acquisition of Accriva's in vitro diagnostic blood testing at the Point-of-Care line positions IL as a market leader in hospital-based POC Hemostasis testing<br>■ Acquired product line spans coagulation, platelet aggregation, CO-Oximetry and incision devices |
| **STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS** | | |
| **Partner 1** | **Partner 2** | **Deal Summary** |
| Quest Diagnostics | Vermillion | ■ Objective: Commercialization of Vermillion's OVA1 ovarian cancer test<br>■ Dynamic: 1-year extension of existing services agreement with option to renew for additional year<br>■ Vermillion agrees to provide Quest monthly confirmation of number of OVA1 tests performed, listing ordering Quest labs and accounting for amounts owed and payments received under agreement<br>■ Quest gets right to access records to verify accuracy of above information |
| Roche | Poplar Healthcare | ■ Objective: Expansion of Roche's molecular Dx testing network<br>■ Dynamic: Expansion of existing deal to make Poplar a designated Roche Molecular Center of Excellence for 5 years |
| Weill Cornell Medicine | Memorial Sloan Kettering Cancer Center | ■ Objective: develop liquid biopsy tests to predict cancer spread and recurrence<br>■ Dynamic: Entitled the Sohn Collaborative for Liquid Biopsy at Weill Cornell Medicine, project to investigate biomarkers predicting if cancer will spread and to which organs<br>■ Supported by $600K grant from Sohn Conference Foundation |
| Metrion Biosciences | Concept Life Sciences | ■ Objective: Develop integrated services to support ion channel drug discovery<br>■ Dynamic: New services will combine Metrion's knowhow in ion channel assay development, validation and compound screening with Concept's chemistry and toxicology expertise |
| GeneNews Limited | Multi-specialty physician group in Midwest (name withheld) | ■ Partnership under which GeneNews to provide its BreastSentry®, ColonSentry®, earlyCDT®-Lung and Prostate Health Index products to medical group's patients |
| NeoGenomics | Definiens | ■ Objective: Discover new cancer biomarkers<br>■ Dynamic: Expands existing research alliance to assays for clinical trials and clinical testing<br>■ Definiens to provide automated quantitative biomarker solutions to support immunohistochemistry services NeoGenomics provides to its pharma services and clinical clients |
| SenzaGen | AstraZeneca | ■ Objective: Create genomic test to differentiate respiratory allergens from irritants for use in new drug development<br>■ Dynamic: Use SenzaGen's GARD platform for rapid genomic allergen detection and AstraZeneca's inhaled substance libraries to develop a genomic signature to identify molecules causing respiratory tract irritancy |

*Continued on page 8*

| STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS, *Cont'd* | | |
|---|---|---|
| **Partner 1** | **Partner 2** | **Deal Summary** |
| Illumina and IBM | Munich Leukemia Laboratory | ▪ Objective: Leukemia and lymphoma treatment research<br>▪ Dynamic: Use IBM Watson and Illumina NovaSeq platform to develop new cognitive technology platform for use in personalizing treatments<br>▪ In January, IBM agreed to integrate Watson for Genomics with Illumina's BaseSpace and tumor sequencing process to simplify genomic data interpretation |
| Illumina | Analytik Jena | ▪ Objective: Develop and commercialize automated ultra high-throughput sample preparation system<br>▪ Dynamic: Work together to create specially configured versions of AJ's CyBio Felix automated liquid handling platform to enable the preparation of up to 6 reaction plates with Illumina's Infinium XT reagents |
| Almac Diagnostics | European Organization for the Research and Treatment of Cancer | ▪ Objective: Streamline patient inclusion in clinical trials of molecularly targeted treatments, and standardize NGS and gene expression analysis<br>▪ Dynamic: Almac to create molecular profiles of EORTC cancer patient samples |
| Royal Philips | LabPON | ▪ Objective: Development of new pathology database<br>▪ Dynamic: Each side to contribute its data and knowhow to create "deep learning" algorithms that can be used to develop a state-of-the-art database that can be used to study, diagnose and treat cancer and other diseases |
| Royal Philips | Onelife Health | ▪ Objective: Create pregnancy and early child care solutions<br>▪ Dynamic: Use Onelife's Femisphere app for guiding pregnancy and first year after birth treatment decisions as a platform<br>▪ App complements Philips uGrow tool for capturing data from smart baby monitors and other connected devices to provide personalized feedback to new parents<br>▪ Royal Phillips acquires minority interest in OneLife |
| Angsana Molecular & Diagnostics | Ignyta | ▪ Objective: Cancer therapy research<br>▪ Dynamic: Angsana to provide cancer screening out of its Hong Kong and Singapore labs for Phase 2 clinical trial in Asia for entrectinib, a tyrosine kinase inhibitor<br>▪ Screening will use Angsana's RNA-based cancer panel to detect TRK and other fusions in study subjects |
| Tempus | Duke University | ▪ Objective: Find new treatment options for brain cancer<br>▪ Dynamic: Tempus to furnish sequencing and analysis for Duke clinical study using engineered poliovirus for treating glioblastoma patients<br>▪ Other T academic medical center research partners include Ohio Univ., Univ. of Penn. Abramson Cancer Center and Mayo Clinic |
| ZS Genetics | Hitachi High Technologies America | ▪ Objective: Develop and commercialize ZS's DNA sequencing platform<br>▪ Dynamic: Combine ZS's sequencing technologies with HTA's expertise in electron microscopy |
| Bluejay Diagnostics | Hitachi Chemical | ▪ Objective: Develop noninvasive, point-of-care test to detect the antibody immunoglobulin E (IgE) in tears which can be used to determine if conjunctivitis caused by allergen<br>▪ Dynamic: Bluejay gets access and exclusive development, marketing and manufacturing rights to Hitachi's Allerwatch device for diagnosing allergic conjunctivitis<br>▪ Deal covers Americas and Europe—device already marketed in Japan |
| GenePeeks | 3 Sisters Surrogacy and The Donor Solution | ▪ Objective: Provide preconception genetic screening to prospective parents<br>▪ Dynamic: Donor and 3 Sisters clients get access to GenePeeks' Virtual Progeny Analytics screening technology that uses DNA from 2 would-be parents to predict a child's genome before conception<br>▪ Service to be provided via GenePeeks' CLIA-certified lab |
| Akesogen | Emory University School of Medicine | ▪ Objective: Identify predictive markers for diseases more common in older people<br>▪ Dynamic: Collaborate on Emory Healthy Aging Study to build a patient database that can be used to detect genomic markers for Alzheimer's and other diseases |
| NantHealth and Allscripts | Cancer Treatment Centers of America | ▪ Objective: Creation of Pathways, a new clinical decision support service platform for MDs<br>▪ Dynamic: Merger of NantHealth's Eviti clinical decision support tool and Allscripts' Sunrise electronic health record system |
| Cynvenio Biosysterms | Color | ▪ Objective: Provide combined version of each firm's liquid biopsy and hereditary cancer tests<br>▪ Dynamic: Combined product can be used to test breast cancer patients for alterations in 30 genes on Color's hereditary cancer panel + somatic cancer mutations in 27 genes covered in Cynvenio's ClearID breast cancer test<br>▪ Cynvenio recently gave Milenia Labs exclusive rights to market ClearID in Mexico |

| | | |
|---|---|---|
| Interpace Diagnostics Group, Inc. | Viatar CTC Solutions Inc. | ▪ Objective: Use of liquid biopsies for early pancreatic cancer detection, prognosis and disease monitoring<br>▪ Dynamic: Combined use of Viatar's circulating tumor cell collection technology with Interpace's PancraGEN™ assay for assessing indeterminate pancreatic cancer biopsies in patients with pancreatic cysts |
| Northwell Health | NYC Health + Hospitals | ▪ Objective: Cut lab costs for in-network hospitals<br>▪ Dynamic: Construct $47.7 million shared, centralized laboratory in Queens, NY |
| **DISTRIBUTION AGREEMENTS** | | |
| **Property Owner** | **Distributor** | **Deal Summary** |
| Novigenix | Dr Risch Medical Laboratory | ▪ Product: Colox, Novigenix's PCR-based blood test for early detection of colorectal cancer<br>▪ Territories: parts of Switzerland and Liechtenstein<br>▪ Unilabs holds Colox distribution rights in French Swiss market |
| Biodesix | Progenetics | ▪ Products: Biodesix's GeneStrat and VeriStrat liquid biopsy tests<br>▪ Territory: Israel<br>▪ Progenetics also Israeli distributor of Biocept, Trovagene and OncoDNA liquid biopsies<br>▪ Bioyong Industries recently named distributor of VeriStrat in China |
| Biolog | MediLoc Laborsysteme | ▪ Products: Biolog's Gen III MicroPlate panel for identifying bacterial species and other cell analysis products<br>▪ Territories: Germany and Austria |
| Luxcel Biosciences | HD Biosciences | ▪ Products: Luxcel's mitochondria assays and technologies, including respirometric screening technology assay for differentiating specific mitochondrial toxicity from nonspecific toxicity, for preclinical drug safety testing,<br>▪ Territory: Not disclosed<br>▪ Co-marketing and sales deal |
| **LICENSES** | | |
| **Licensor** | **Licensee** | **Deal Summary** |
| IntegraGen | Laboratoire Cerba | ▪ Product: IG's oncology biomarker for microRNA hsa-miR-31-3p used for predicting response to metastatic colorectal cancer treatments<br>▪ Territories: France, Belgium, Netherlands, Luxembourg, Middle East and Africa<br>▪ LC gets right to develop tumor expression assay based on biomarker<br>▪ Marketing to start in Q2 |
| Nerviano Medical Sciences | Trovagene | ▪ Product: PCM-075, Nerviano's investigational drug for acute myeloid leukemia<br>▪ Territory: Global<br>▪ Trovagene gets exclusive commercialization and development rights<br>▪ Deal signals Trovagene's strategic repositioning from diagnostics to therapeutics |
| Atlantic Cancer Research Institute | BioVendor – Laboratorní Medicína | ▪ Product: ACRI's Vn96 synthetic peptide for extracellular vesicle isolation<br>▪ BioVendor, a Czech biotech, gets non-exclusive right to use Vn96 to develop *in vitro* diagnostics and research-use-only immunoassays |
| University of California, San Francisco | MioDx | ▪ Products: Technologies for monitoring patient response to immunotherapy—one measures response to immune checkpoint inhibitor therapies, the other assesses risk of adverse events associated with immunotherapy treatments<br>▪ Territories: Not disclosed |
| **SUPPLY, SERVICE & TESTING AGREEMENTS** | | |
| **Supplier** | **Client** | **Deal Summary** |
| Biocept | Catalyst Pharmaceuticals | ▪ Catalyst to use Biocept's Target Selector liquid biopsy platform to screen for early signs of small cell lung cancer in subjects of clinical trial for Firdapse, a drug used to treat rare diseases |
| Accumen Inc. | Arizona Hospital and Healthcare Association | ▪ 3-year agreement making Accumen affiliated lab services partner of AzHHA |
| True Health Diagnostics | Cigna | ▪ True Health made in-network provider of laboratory testing services, effective March 15 |
| **NEW PRODUCTS** | | |
| **Company(ies)** | | **Product(s)** |
| Myriad Genetics | | ▪ US launch of EndoPredict test for early-stage breast cancer that assesses risk of cancer recurrence after surgery and identifies patients who can safely skip chemotherapy |

*Continued on page 10*

| NEW PRODUCTS, *Cont'd* | |
|---|---|
| **Company(ies)** | **Product(s)** |
| Thermo Fisher Scientific | ▪ Thermo Scientific iCAP Triple-Quadrupole Inductively Coupled Plasma Mass Spectrometry (iCAP TQ ICP-MS) system |
| MagBio Genomics | ▪ cfKapture 21 kit for isolating cell-free DNA in plasma samples |
| Sygnis | ▪ True Advance, a new service to validate DNA samples and address other quality issues in NGS and liquid biopsy testing |
| Canon Biomedical | ▪ Added series of 21 new cystic fibrosis genotyping assays to its Novallele line |
| GenomOncology and med fusion | ▪ Expansion of med fusion's LungSEQ and 50SEQ Plus FISH lab services to include PD-L1 expression testing |
| BioReference Laboratories (via its GenPath Women's Health unit) | ▪ ClariTest, a noninvasive prenatal test to be performed at Illumina labs until company develops its own NIPT testing capacity |
| IncellDx | ▪ OncoTect iO Quantitative, a single-cell PD-L1 assay kit for research use only |
| Agilent Technologies | ▪ 6545XT AdvanceBio, a new mass spectrometry instrument for biomolecule characterization in drug development research |
| Agilent Technologies | ▪ GenetiSure Dx Postnatal Assay for cytogenetic testing |
| Sage Science | ▪ SageHLS, a platform that extracts and purifies large DNA fragments directly from bacterial and tissue cultures, blood samples or other cell sources |
| Courtagen Life Sciences | ▪ Expanded its Spotlight test menu for epilepsy, developmental delay, endocrinology, and mitochondrial disease by adding 10 new gene panels |
| Zymo Research | ▪ Discovery Series, a new generation of its DNA and RNA purification kits |
| Invivoscribe Technologies | ▪ 3 new in vitro diagnostic assays for company's Ion PGM Dx System |
| Natera | ▪ Evercord, a service enabling expectant parents to collect, store and retrieve newborn's cord blood and tissue in case it's needed later for therapeutic use (to launch in Q2) |
| Eurofins Genomics | ▪ EXTREmers, DNA synthesizer platform for oligonucleotides |
| Repositive | ▪ Autism Data Collection database |
| Horizon Discovery Group | ▪ HDx cell-free DNA Reference Standard in Synthetic Plasma, a tool for extracting DNA for liquid biopsy testing |

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"defense and public safety" budget increases would be offset by "finding greater savings and efficiencies across the Federal Government. … We are going to do more with less, and make the Government lean and accountable to the people."

## The Potential Impact

Not surprisingly, the spending priorities outlined in the proposal have attracted sharp criticism from the industry. "The Trump administration's proposed budget would cripple the science and technology enterprise through short-sighted cuts to discovery science programs and critical mission agencies alike," according to Rush Holt, CEO of the American Association for the Advancement of Science. "Investments in federal research and development make significant contributions to economic growth and public well-being," Holt's statement continues. "The administration's proposed cuts would threaten our nation's ability to advance cures for disease, maintain our technological leadership, ensure a more prosperous energy future, and train the next generation of scientists and innovators."

*"In the last 15 years, NIH-funded research has built the foundation for many of America's biotechnologies, such as developments in cancer treatments, genomics, and medical diagnostics."*

— Darrell Kirch, M.D.

Let's take a closer look at the three elements in the proposal most likely to impact labs and the diagnostic industry.

### 1. NIH Budget Cuts

The proposal requests $69 billion for HHS, $15.1 billion (or 17.9 percent) less than current levels. The NIH stands to lose $5.8 billion (almost 20 percent) in funding. The proposed funding of $25.9 billion is below 2003 funding levels. By comparison, 2013 sequestration cuts reduced the NIH budget by 5 percent, a fraction of what the Trump administration is proposing. Even still, sequestration, the institute said, led to 700 fewer competitive research grants in fiscal year 2013.

"In the last 15 years, NIH-funded research has built the foundation for many of America's biotechnologies, such as developments in cancer treatments, genomics, and medical diagnostics," says Darrell Kirch, M.D., president of the Association of American Medical Colleges, in a statement. "Medical research takes years to translate from the bench to the bedside and cannot be turned on and off like a faucet. The proposed cuts would set back progress toward critical advancements that could take decades to regain, prevent new ideas from being explored, and have a chilling effect on those who would potentially enter the biomedical research workforce."

The Trump administration says the budget proposal "reduces administrative costs and rebalance[s] Federal contributions to research funding." While details are scarce in the two pages dedicated to HHS, the budget proposal also mentions "a major reorganization of NIH's Institutes and Centers."

### 2. More Money for Fraud Enforcement

In addition to the NIH cuts, the diagnostics industry would be impacted by the proposed increase in federal enforcement funding, particularly Medicare and Medicaid fraud initiatives under the Health Care Fraud and Abuse Control Program (HCFAC). The proposed budget would raise HCFAC discretionary funding for 2018 by $70 million to $751 million.

The Blueprint declares the administration's commitment to "investing in activities to prevent fraud, waste, and abuse and promote high quality and efficient health care" and points to the high return on investment associated with fraud enforcement activities.

"Additional funding for HCFAC program has allowed the Centers for Medicare & Medicaid Services in recent years to shift away from a 'pay-and-chase' model toward identifying and preventing fraudulent or improper payments from being paid in the first place," the Blueprint explains.

### 3. Higher FDA User Fees

Diagnostics would also be impacted by the proposal's attempt to "recalibrate" medical product user fees, which could include doubling of what pharmaceutical companies and medical device manufacturers (including diagnostics companies) pay in review costs. The FDA had decreased user frees in 2017 to what the Regulatory Affairs Professionals Society says are the lowest fees since 2013.

The White House says the proposed increase in fees is "designed to achieve regulatory efficiency and speed." However, given the current shortage of FDA reviewers and the federal hiring freeze, experts are skeptical, the increase in fees would achieve its stated goal.

### 4. Public Health Emergency Funding

The proposed Budget also "[r]eforms key public health, emergency preparedness, and prevention programs"—such as changing preparedness grants to "reduce overlap," save expense and channel funding to states most in need.

Additionally, the budget calls for a new Federal Emergency Response Fund to address public health crises such as the Zika Virus outbreak. Finally, the Centers for Disease Control and Prevention would get a $500 million block grant designed to provide more flexibility and address state-specific needs.

*Takeaway: If enacted, the Trump administration cuts to the NIH could have profound negative effects on biomedical research and would increase FDA user fees. While Congress will ultimately decide the budget, the White House proposal would be detrimental to the biomedical industry, including the diagnostics sector. Advocates for science and medical research remain hopeful that Congress will maintain its bipartisan history of "protecting" research investments, as Congressional members from both parties have expressed public concern over the proposed NIH cuts.*