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LABORATORY

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Upcoming Events

Conference:

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

Market Trends: Quest-Walmart, LabCorp-Walgreens Add Momentum to Mass Retailing of Lab Services

Mass commercialization of health care in general and laboratory services in particular is heating up with a pair of co-branding deals between leading lab chains with national retail giants. What makes the deals so eye-popping isn't so much the model but the fact that the participants are all household names.

The Quest-Walmart Deal

At the end of June, Quest Diagnostics announced plans to open co-branded lab service centers at 15 Walmart stores in Florida and Texas by year's end. The centers will initially furnish testing services with plans to encompass other basic health care services going forward. "By providing lab testing and healthcare services where people also shop, we will make it easier for Walmart customers to get the quality diagnostic insights they need in convenient locations," noted Quest CEO Steve Rusckowski.

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Industry Buzz: The Diagnostic Market's M&A Highlights from 1H 2017

As usual, the Big 3 of Abbott, Quest and LabCorp were the driving force of M&A activity in the diagnostics industry in the first half of 2017.

Abbott Continues to Make News

Each company announced or completed multiple acquisitions during the period, including the January closing of what remains the year's biggest deal Abbott's \$25 billion purchase of St. Jude Medical. Already a leader in stents and mitral valve repair (via its MitraClip device), acquisition of St. Jude's heart failure and vascular disease products portfolio makes Abbott arguably the strongest player in the \$30 billion cardiovascular device market and one of the biggest overall medical device manufacturers in the world.

Continued on page 2

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Abbott is also at the center of the biggest story of the year so far—the on again, off again and now on again—Alere merger. After taking their dispute to federal court, the sides announced on April 14 that the deal would go through after all. But to make it happen, Alere had to discount the purchase price from \$5.8 billion to \$5.3 billion to compensate Abbott for the erosion of its stock value since the deal was first announced back in Feb. 2016. In July, Alere secured shareholder approval of the deal and divested its triage, blood gases and other assets to pave the way for anti-trust approval. Meanwhile, Abbott CEO Miles White said he was “quite confident” that the deal would close by the end of the year.

Other Movers and Shakers

Another headline 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.”

Quest also had a busy H1, acquiring outreach lab operations from PeaceHealth Laboratories (in the northwest) and Dignity Health Sierra Nevada Memorial Hospital, as well as a pair of clinical labs in Texas.

Molecular Diagnostics & Life Sciences

GenomeWeb reports that overall M&A deal volume in molecular diagnostics and life sciences for the first half of the year was down 14% from H1 2016. But while deal volume was down—30 vs. 35 deals—prices remained high, with a pair of billion-dollar acquisitions. The biggest is Thermo Fisher Scientific’s \$7.2 billion acquisition of contract development and manufacturing organization (CDMO) Patheon. Thermo Fisher says the deal, which is expected to close by the end of 2017, will secure its access to the \$40 billion CDMO market and create \$120 million in synergies (\$90 million in cost and \$30 million in revenues synergies), prompting the company to increase its 2018 adjusted earnings per share by \$0.30. The other nine-figure acquisition in the period was PerkinElmer’s \$1.3 billion purchase of Euroimmun.

H1 2017’s Top 5 M&A Deals in the MDx/Omics Life Science Tools Space

| Buyer | Seller | Price |
|------------------------------|-------------|----------------------|
| Thermo Fisher Scientific | Patheon | \$7.2B |
| PerkinElmer | Euroimmun | \$1.3B |
| Cathay Fortune International | Epigenomics | \$186.3M |
| Agilent | Multiplicom | \$70.6M |
| Invitae | AltaVoice | Up to \$15M in stock |

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FDA Watch: Another First as Agency Approves NGS Oncology Companion Dx for Multiple Therapies

The FDA made a stir in May by approving a cancer drug (Keytruda (pembrolizumab) PD-1/PD-L1 inhibitor from Merck) administered on the basis of a tumor's genomic features rather than its location in the patient's body. Barely a month later, came a new surprise from the agency: premarket approval to Oncomine Dx Target Test, Thermo Fisher Scientific's next generation sequencing-based companion diagnostic for non-small cell lung cancer (NSCLC) diagnostic that simultaneously screens for biomarkers associated with three FDA-approved therapies. The test was approved to detect multiple gene mutations (BRAF, ROS1, and EGFR) from a single tissue specimen. The results of the test aid in selecting targeted therapies, including IRESSA (gefitinib) for EGFR L858R and Exon 19 deletions, Tafinlar + Mekinist (dabrafenib in combination with trametinib) for BRAF V600E, or XALKORI (crizotinib) for ROS1 fusion.

Thermo Fisher says that the test kit enables quicker matching for targeted therapies, through a single test rather than sequential testing. The company also says the test will be available in the U.S. beginning in July 2017. LabCorp's Diagnostics and Covance Businesses, NeoGenomics Laboratories, and Cancer Genetics, are the first laboratories offering the test. The test is run on Thermo Fisher's Ion PGM Dx System, which received FDA 510(k) clearance in parallel for use on formalin-fixed, paraffin-embedded (FFPE) tissue samples.

"This first iteration of the test is just the beginning since the diagnostic claims of the Oncomine Dx Target Test may be expanded in the future based on the existing panel," said Joydeep Goswami, Thermo Fisher's president of clinical next-generation sequencing and oncology, in a statement. "Thermo Fisher has entered into discussions with several pharmaceutical companies looking to use the panel for FDA-approved targeted therapy applications beyond lung cancer."

The Oncomine Dx Target Test also currently targets an additional 20 NSCLC-associated gene variants currently being investigated in clinical trials that may be actionable in the future. The company expects that as other drugs are approved, the FDA will expand approvals on the panel.

NGS Companion Dx Tests Approved by the FDA

In late June the FDA also granted approval to Illumina (San Diego, Calif.) for a companion diagnostic test to identify metastatic colorectal cancer patients that could be treated with the targeted therapy Vectibix.

The test, which was developed in partnership with the pharmaceutical company Amgen, marks the third NGS-based companion diagnostic that the FDA has approved and Illumina's first companion diagnostic and premarket approval in the field of oncology. In December 2016 the agency approved Foundation Medicine's FoundationFocus

CDxBRCA test to identify advanced ovarian cancer patients with BRCA1 and BRCA2 gene mutations likely to benefit from Clovis Oncology's PARP inhibitor Rubraca (rucaparib).

"The Extended RAS Panel on the MiSeqDx System enables labs to implement an in-house solution for precision oncology and signifies that NGS has reached a milestone as a clinical diagnostic platform to aid therapeutic decision-making in oncology," said Garret Hampton, Ph.D., executive vice president of clinical genomics at Illumina, in a statement.

Here's a look at key FDA diagnostics approvals in late June through July:

NEW FDA APPROVALS

| Manufacturer(s) | Product(s) |
|--------------------------|---|
| Great Basin | Approval of stool bacterial pathogens panel for simultaneous detection of bacterial pathogens <i>Salmonella</i> , <i>Shigella</i> , Shiga Toxin-producing <i>E. coli</i> and <i>Campylobacter</i> |
| Illumina (with Amgen) | Approval of extended RAS Panel, a companion DX run on its MiSeqDx system to analyze variants in KRAS and NRAS genes to determine if patients will benefit from Amgen's Vectibix (panitumumab) |
| Abbott | Approval of RealTime CMV molecular test for amplifying 2 select regions of CMV genome |
| Hologic | Approval to market Aptima Herpes Simplex Virus 1 & 2 molecular assay on its fully automated Panther system |
| Techlab | Approval of <i>E. Histolytica</i> Quik Chek, rapid assay for qualitatively detecting <i>E. histolytica</i> in fecal samples |
| Thermo Fisher Scientific | Approval of Oncomine Dx Target Test, NGS-based based companion diagnostic for analyzing alterations in panel of genes predictive of response across 3 non-small cell lung cancer treatments |
| Thermo Scientific | Approval to market CEDIA Buprenorphine II assay |
| Bio-Rad Laboratories | Approval to market BioPlex 2200 Syphilis Total & RPR (rapid plasma reagin) assay for diagnosing syphilis infection |

In addition, DxNA announced that it has applied for 510(k) clearance of GeneSTAT, its real-time PCR system and test for Valley Fever.

New CE Marks & Global Certifications

Here's a summary of notable European CE certifications:

NEW CE CERTIFICATIONS

| Manufacturer(s) | Product(s) |
|---------------------|---|
| NGeneBio | Approval of its BRCAAccuTest and clinical analysis software |
| Roche | Approval of Cobas methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) and <i>Staphylococcus aureus</i> (SA) nucleic acid test for use on firm's Liat PCR point-of-care platform |
| GenMark Diagnostics | Approval of its ePlex BCID gram-positive and gram-negative panels |
| Hologic | Approval of upgrade to its existing Panther Fusion diagnostic system and for Panther Fusion flu and respiratory testing assays |
| Luminex | Approval of Aries Norovirus Assay for rapid detection and differentiation of norovirus genogroup I and II from stool specimens of people with acute gastroenteritis symptoms |
| Mobidiag | Approval of Amplidiag Viral GE gastrointestinal virus PCR-based test for simultaneous detection of diarrhea-causing enteric viruses |

Other international certifications during the period included:

- ▶ Health Canada's approval of 3M's second-generation molecular assay for detecting *Listeria* in food and environmental testing;
- ▶ Approval of Vela Diagnostics' Sentosa SQ HIV genotyping assay in Australia and its Sentosa SQ melanoma panel in Singapore; and
- ▶ South Korea's approval of Altona Diagnostics' RealStar Zika Virus RT-PCR Kit.

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

After a relatively slow March and April, business has picked up noticeably in May, June and July with deal volume increasing across all transaction model sectors. Here are the highlights from the past 4 weeks.

M&A

The most active seller of the month was Alere. Soon after announcing shareholder approval of the Abbott merger, Alere sold off strategic assets to clear the deck for antitrust approval of the deal. On July 17, Alere announced the sale of its Triage businesses to Quidel for \$400 plus \$40 million in contingent payments. The deal includes real estate, i.e., the triage business's San Diego facilities, Alere's MeterPro cardiovascular and toxicology assets and B-type Natriuretic Peptide (BNP) assay. A week later, Alere announced that Siemens had agreed to buy its Epcal point-of-care blood diagnostic unit for an undisclosed price. The Quidel and Siemens sales are both contingent on consummation of the Alere-Abbott merger.

The other big story in M&A for the month was the appearance of a new and potentially significant player: Konica Minolta, which inked an agreement to purchase genetic testing firm Ambry Genetics for up to \$1 billion in cash. According to a company spokesman, the deal represents the digital giant's first step in leveraging its medical imaging capabilities to build a presence in the precision medicine market, first in Japan and then in Europe.

Strategic Alliances

In a month with intense deal volume, the collaborations pitting big labs with mass retailers were the sexiest of the new strategic alliances. There were not one but two such deals announced during the month—the first pairing Quest and Walmart followed a week later by a second deal co-starring LabCorp and Walgreens. (See the related story on page 1).

As per usual, most of the partnerships and alliance made in July involved genomics and molecular diagnostics. Notable examples:

- ▶ The 5-year partnership of Exploit Technologies and Biocartis to develop molecular breast cancer diagnostic tests to be run on the latter's PCR-based Idylla platform;
- ▶ Trovagene's latest venture into the Chinese market via collaboration with Chinese genomics service provider Novogene to commercialize Trovagene's Next Collect device, which is currently approved for research use only; and
- ▶ EntroGen's collaboration with the USC Norris Comprehensive Cancer Center to evaluate the clinical utility of the former's liquid biopsy real-time PCR test in lung cancer patients.

Here's a graphic rundown of all the key diagnostic deals in late June and early July:

| MERGERS & ACQUISITIONS | | |
|--------------------------|--|---|
| Acquiring Company | Target(s) | Deal Summary |
| Siemens. | Alere's Epocal point-of-care blood diagnostic unit | <ul style="list-style-type: none"> Price: Undisclosed Status: To close by end of Sept. Sale contingent on consummation of Abbott Alere merger |
| Quidel | Alere's triage MeterPro cardiovascular and toxicology assets and B-type Natriuretic Peptide (BNP) assay business | <ul style="list-style-type: none"> Price: \$400 million + \$40 million in contingent payments paid as mix of cash and loans Status: To close by end of Sept. Sale contingent on consummation of Abbott Alere merger |
| Roche | mySugr | <ul style="list-style-type: none"> Price: Undisclosed Status: Closed Privately held mySugr produces a mobile devices logbook to help people track their blood sugar, medications and activity levels |
| Konica Minolta | Ambry Genetics | <ul style="list-style-type: none"> Price: Up to \$1 billion cash, including \$800 million upfront and up to \$200 million over 3 years Status: Expected to close in 3Q Ambry to become subsidiary of Konica Minolta and keep its name and continue its genetic testing operation from its current California HQ |
| Thermo Fisher Scientific | Linkage Biosciences | <ul style="list-style-type: none"> Price: Undisclosed Status: Closed SF-based Linkage, known for its LinkSeq product line, becomes part of Thermo Fisher's One Lambda transplant Dx business |
| Quest Diagnostics | Laboratory businesses Med Fusion and Clear Point in Lewisville, Texas | <ul style="list-style-type: none"> Price: Undisclosed Status: Closing of previously announced deal Quest acquires business' 200,000 sq. foot facility and becomes a preferred provider to several organizations that are former owners of one or both businesses |
| Quest Diagnostics | Outreach laboratory services business of Cape Cod Healthcare | <ul style="list-style-type: none"> Price: Undisclosed Status: Non-binding letter of intent subject to negotiation of terms and regulatory approval, which is expected to occur by Jan. 1, 2018 Deal comes on heels of Quest's acquisition of PeaceHealth Laboratories' outreach lab services operations |
| SOL Group | Personal Genomics | <ul style="list-style-type: none"> Price: Undisclosed Status: Italy-based SOL acquires 51% stake SOL to finance expansion of PG's tests for genetic disorders and early cancer diagnosis |
| Eurofins | Genoma Laboratory Group | <ul style="list-style-type: none"> Price: Undisclosed Status: Expected to close in July Eurofins gains entry to Italian testing market and strengthens its position in specialty diagnostics across Europe Deal follows Eurofins' acquisition of GATC Biotech, which is also expected to close in July |
| Philips | Spectranetics Corp | <ul style="list-style-type: none"> Price: €1.9 billion (\$2.16 billion) + debt Acquisition of Spectranetics' guidance tech for heart disease expands Philips' image-guided therapy line Deal not expected to increase Philips' return on invested capital for 5 years |
| Philips N.V. | Electrical Geodesics Inc. | <ul style="list-style-type: none"> Price: Purchase price based on £29 million (\$36.7 million) valuation of EGI Status: Expected to close in 3Q Philips drawn by EGI's EEG platform technology, which gathers brain-activity data from many more electrodes than conventional EEG products |
| PerkinElmer | Euroimmun Medical Laboratory Diagnostics (based in Germany) | <ul style="list-style-type: none"> Price: Approximately \$1.3 billion cash Status: Expected to close in 4Q Acquisition of Euroimmun, recognized as a global leader in autoimmune testing and emerging force in infectious disease and allergy testing, expands PerkinElmer's reach into autoimmune and allergy diagnostic markets, and enables it to offer "new infectious disease capabilities to customers in China," according to a company spokesman |
| Invitae | Ommdom (health software developer) | <ul style="list-style-type: none"> Price: Roughly \$6 million in Invitae common shares in exchange for all Ommdom outstanding capital stock Status: Closed Acquisition of Ommdom's CancerGene Connect platform for collecting and managing genetic family histories expands its existing suite of technologies for using genetic information in mainstream medical care |

| STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS | | |
|--|--|---|
| Partner 1 | Partner 2 | Deal Summary |
| Asia Genomics | CellMax Life | <ul style="list-style-type: none"> Objective: Make CellMax's cancer tests available throughout Southeast Asia Dynamic: Partnership in which Asia Genomics will make tests available immediately through hospitals and clinics in region, and directly to consumers "where appropriate" |
| Trovogene | Novogene (Chinese genomics service provider) | <ul style="list-style-type: none"> Objective: Develop tests for Chinese market Dynamic: Novogene to validate Trovogene's Next Collect urine collection and nucleic acid preservation device, which is currently approved for research only, for commercial use in China |
| Nestle Health Science | Enterome | <ul style="list-style-type: none"> Objective: Develop microbiome diagnostics for inflammatory bowel disease, liver disorders and other indications Dynamic: 50/50 joint venture forming startup company called Microbiome Diagnostics Partners |
| Biocartis | Exploit Technologies | <ul style="list-style-type: none"> Objective: Develop molecular breast cancer and other tests to be run on Biocartis' PCR-based Idylla platform Dynamic: 5-year alliance Biocartis responsible for commercializing tests under its own label ETPL to act as a development partner via Singapore's Diagnostics Development Hub |
| Counsyl | Angsana Molecular & Diagnostics Laboratory | <ul style="list-style-type: none"> Objective: Commercialize Counsyl's expanded carrier screening test in Hong Kong Dynamic: Samples to be processed at Counsyl's CLIA-certified San Francisco lab |
| Bionano Genomics | Genoptix | <ul style="list-style-type: none"> Objective: Co-develop diagnostic assays for hematologic oncology indications Dynamic: Exclusive deal combining Bionano's Saphyr system for visualizing the structure of a genome and Genoptix's expertise in hematology and oncology |
| Rennova Health | Certainty Health | <ul style="list-style-type: none"> Objective: Develop smartphone-based platform for offering molecular tests for precision treatment of psychiatric disorders Dynamic: Rennova to offer genetic tests developed by its Advanced Molecular Services Group subsidiary directly to consumers via mobile platform |
| Quest Diagnostics | Wal-Mart Stores | <ul style="list-style-type: none"> Partnership to bring Quest's laboratory testing services to 15 Walmart locations in Florida and Texas by end of 2017 |
| Adaptive Biotechnologies | Janssen Pharmaceuticals | <ul style="list-style-type: none"> Objective: Study clinical effectiveness of Janssen's Darzalex drug for treating multiple myeloma (MM) Dynamic: Adaptive will use its NGS-based ClonoSeq assay to measure minimal residual disease in MM patients treated with Darzalex in clinical trials |
| BGI | University of Debrecen in Hungary | <ul style="list-style-type: none"> Partnership to establish a next-generation sequencing laboratory and collaborate on genomics research projects |
| MDxHealth | QUT bluebox (commercialization arm of Queensland University of Technology) | <ul style="list-style-type: none"> Objective: Develop liquid biopsy epigenetic assay for early detection of oral cancer Dynamic: MDxHealth to have first option to license the commercial diagnostic rights Proceeds to support firm's urologic cancer diagnostics R&D platform as well as University research activities |
| Thermo Fisher Scientific | OpGen | <ul style="list-style-type: none"> Objective: Commercialize OpGen's Acuitas molecular products and informatics system for fighting multidrug-resistant infections Dynamic: OpGen to combine its Acuitas Rapid Test for Pathogen ID with Thermo Fisher's real-time PCR solutions |
| Human Longevity | Merck KGaA | <ul style="list-style-type: none"> Objective: Identify treatment-response biomarker signatures in advanced melanoma patients Dynamic: HL to generate and analyze genomic sequencing data from clinical trial participants' tumors and germline DNA |
| EntroGen | University of Southern California Norris Comprehensive Cancer Center | <ul style="list-style-type: none"> Collaboration to evaluate clinical utility of EntroGen's liquid biopsy real-time PCR test in lung cancer patients |
| FlowJo | Becton Dickinson | <ul style="list-style-type: none"> Objective: Co-marketing Dynamic: Companies to market FlowJo Envoy cloud-based data-analysis software with BD's FACSymphony a cell analyzer for simultaneous measurement of up to 50 characteristics of a single cell |
| FlowJo | Cytapex Bioinformatics | <ul style="list-style-type: none"> Partnership to provide bioinformatics consulting and services in flow cytometry data analysis using the FlowJo application |

| STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS | | |
|--|--|--|
| Partner 1 | Partner 2 | Deal Summary |
| Siemens Healthineers | Fast-track Diagnostics | <ul style="list-style-type: none"> Objective: Expansion of Siemens's molecular testing product line Dynamic: Siemens to add a range of Fast Track's CE-marked kits and multi-syndromic panels to its own Versant kPCR Molecular System menu Jackson scientists to form genomics research collaborations with WMU investigators in US and China |
| LifeLabs | GenXys Health Care Systems | <ul style="list-style-type: none"> Objective: Offer pharmacogenetic testing services in Canada Dynamic: LifeLabs to analyze patient cheek swab samples to look for 60 genetic variations that can affect drug metabolism and response Results to be added to GenXys' TreatGx^{plus} software |
| Trovagene | AstraZeneca | <ul style="list-style-type: none"> Objective: Evaluate whether blood and urine testing in combination is as effective as tissue testing in identifying epidermal growth factor receptor T790M mutation status Dynamic: AstraZeneca to use Trovagene's Trovera EGFR urine liquid biopsy test to conduct biomarker study |
| HTG Molecular Diagnostics | Qiagen | <ul style="list-style-type: none"> Objective: Develop sequencing-based companion diagnostic assay Dynamic: Qiagen to pay low single digit millions of dollars for initial phase development work performed by HTG and share in net profits generated by initial phase |
| CloudHealth Genomics (based in Shanghai) | Mongolian Health Initiative | <ul style="list-style-type: none"> Collaboration to advance precision medicine research for nutritional deficiencies and nutrition-related diseases |
| Tempus | University of Michigan's Comprehensive Cancer Center | <ul style="list-style-type: none"> Objective: Use molecular data to identify most effective care for breast cancer Dynamic: Tempus to use bioinformatics and machine learning to analyze molecular, phenotypic, therapeutic and outcome data from UM patients Tempus has similar collaborations with University of Chicago, Duke, University of Pennsylvania, Ohio's University Hospitals Seidman Cancer Center and Mayo Clinic |
| GeneDx (owned by Opko Health) | University of California | <ul style="list-style-type: none"> Objective: Track physician utilization of genetic tests Dynamic: Expansion of current agreement to cover more than 400 tests for rare hereditary disorders |

| DISTRIBUTION, SALES & MARKETING AGREEMENTS | | |
|--|------------------------------|---|
| Property Owner | Distributor | Deal Summary |
| Molecular Biology Systems (MBS) | Isogen Life Sciences | <ul style="list-style-type: none"> Product: MBS's NextGen PCR thermal cycler Territories: Belgium, Netherlands, Luxembourg and Spain Exclusive |
| OneOme | Total Quality Medicine (TQM) | <ul style="list-style-type: none"> Products: OneOme's PCR-based RightMed genetic test to be incorporated into TQM's GeneTest line of personalized medicine products Territory: Mexico |
| Dovetail Genomics | Tree Code | <ul style="list-style-type: none"> Products: Dovetail's genome assembly services Territories: Singapore, Malaysia, Thailand, Vietnam, Indonesia, Philippines and Myanmar |
| OncoDNA | Shchurko | <ul style="list-style-type: none"> Products: OncoDeep solid tumor test, OncoTrace and OncoSelect liquid biopsy tests, OncoStrat&Go and OncoKDM data reporting software Territory: Belarus |
| Streck | Golden Bat Far East | <ul style="list-style-type: none"> Products: Streck's cell stabilization, molecular and core products Territory: Philippines |
| MDxHealth | IPS Genomix | <ul style="list-style-type: none"> Product: SelectMDx for Prostate Cancer test Territories: Lebanon, Egypt, United Arab Emirates, Saudi Arabia, Oman, Bahrain, Qatar and Jordan |
| GenePOC | Cardinal Health | <ul style="list-style-type: none"> Products: GenePOC's revogene instrument and associated assays Territory: US Exclusive |
| OncoDNA | Zogen | <ul style="list-style-type: none"> Products: OncoDNA products for molecular profiling of liquid biopsies and solid tumor tissue for personalized medicine Territory: Mexico |
| Canopy Biosciences. | Cosmo Bio | <ul style="list-style-type: none"> Products: Canopy's genetic engineering products Territory: Japan |

| DISTRIBUTION, SALES & MARKETING AGREEMENTS | | |
|--|-----------------------|--|
| Property Owner | Distributor | Deal Summary |
| Genomic Vision | APG Bio | <ul style="list-style-type: none"> Products: Genomic Vision's products and services to be offered to life science researchers Territories: China, Hong Kong and Macau |
| GenePeeks | Alliance Global Group | <ul style="list-style-type: none"> Products: GenePeeks' Preconception Screen Territories: Middle East and Africa |
| Cynvenio Biosystems | Bio-Medical Science | <ul style="list-style-type: none"> Products: Cynvenio's ClearID line of liquid biopsy tests Territory: South Korea |
| Cynvenio Biosystems | ProgeniTest | <ul style="list-style-type: none"> Products: Cynvenio's ClearID line of liquid biopsy tests Territory: Argentina |
| Cynvenio Biosystems | Karyo | <ul style="list-style-type: none"> Products: Cynvenio's ClearID line of liquid biopsy tests Territory: Greece |
| Cynvenio Biosystems | Pronto Diagnostics | <ul style="list-style-type: none"> Products: Cynvenio's ClearID line of liquid biopsy tests Territory: Israel |
| Biodesix | Positive Bioscience | <ul style="list-style-type: none"> Products: Biodesix's GeneStrat and VeriStrat Territory: India All testing to be done at Biodesix's Boulder, Colorado lab |
| SpeeDx (Australia) | Cepheid | <ul style="list-style-type: none"> Products: SpeeDx's PlexPCR and ResistancePlus multiplex real-time PCR products Territories: UK, Germany, France and Italy Expansion of current deal allowing Wallace to distribute Amplidiag in South Africa |

| LICENSES | | |
|--|-------------------|---|
| Licensor | Licensee | Deal Summary |
| SISCAPA Assay Technologies | Waters | <ul style="list-style-type: none"> Property: Stable isotope-labeled standards technology to be used by Waters for standardizing quantitative mass spec assays Territory: Undisclosed Non-exclusive |
| Inventors from Max Delbrück Center for Molecular Medicine, Genetic Information Research Institute and Paul Ehrlich Institute | Horizon Discovery | <ul style="list-style-type: none"> Property: Transposon-based gene-editing technology Territory: Undisclosed Exclusive |

| SUPPLY, SERVICE & TESTING AGREEMENTS | | |
|---|---|--|
| Supplier | Client | Deal Summary |
| GenomOncology | University of California, San Francisco | <ul style="list-style-type: none"> UCSF to use GenomOncology's informatics platform to analyze and report results from its UCSF500 NGS cancer panel |
| Illumina | Genomics England | <ul style="list-style-type: none"> GE to use Illumina's BaseSpace Variant Interpreter for tumor and matched normal samples characterized as part of 100,000 Genomes Project |
| Personal Genome Diagnostics said today that it will now | US Department of Veterans Affairs | <ul style="list-style-type: none"> PGD to provide its PlasmaSelect 64 liquid biopsy test to advanced cancer patients being treated at VA facilities |



GET THE LATEST ON COMPLIANCE

Lab Compliance Essentials 2017: Managing Medicare Fraud & Abuse Liability Risk

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Contact Jen at **1-888-729-2315** or Jen@PlainLanguageMedia.com for details on this special offer.

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

Thermo Fisher, HTG Molecular Diagnostics and Roche were among the large lab companies with product launches over the past 4 weeks. Here's a rundown of other key new products that came out.

NEWLY LAUNCHED PRODUCTS & SERVICES

| Company(ies) | Product(s) |
|---|--|
| University of California, San Francisco's Center for Next-Gen Precision Diagnostics | Metagenomic next-generation sequencing test for neurological infections |
| Biocept | Liquid biopsy test for detection and monitoring of a key biomarker in blood of breast cancer patients |
| Norgen Biotek | Small RNA Library Prep Kit for Illumina sequencing instruments and sequencing services on Illumina instruments |
| Exact Diagnostics | Verification panels for IVD use |
| LGC | Meridian2 liquid dispensing system |
| Li-Cor Biosciences | LED-based D-DiGit Gel Scanner to help researchers eliminate risk of ethidium bromide exposure and workspace contamination from nucleic acid gel analysis experiments |
| MDxHealth | US launch of AssureMDx for Bladder Cancer liquid biopsy as a laboratory-developed test |
| HTG Molecular Diagnostics | US and Europe launch of EdgeSeq Path Assay |
| Canopy Biosciences | Service for high-throughput gene-expression analysis |
| Roche | Addition of 22q11.2 deletion testing to Harmony Prenatal Test menu to screen for 22q11.2 deletion syndrome |
| Bioarray | PGS+PGD Single Biopsy kit for screening aneuploidies and identifying embryos with pathological mutation from single sample |
| SeraCare Life Sciences | New version two of iQ NGS QC Management software |
| Oxford Nanopore Technologies | PCR-cDNA Sequencing kit |
| Oxford Nanopore Technologies | Direct cDNA Sequencing kit to prepare cDNA for nanopore sequencing |
| Children's Hospital Los Angeles | OncoKids, NGS-based panel that detects mutations, gene amplification and gene fusions |
| Premaitha Health | Updated version of Iona noninvasive prenatal test to include first trimester combined test risk score option in software |
| Premaitha Health | Sage, non-invasive prenatal testing solution |
| TATAA Biocenter | GrandPerformance assays for expression profiling single circulating tumor cells |
| OmniSeq | Immune Report Card, immune profiling test to help oncologists select immunotherapy options |
| DNA Software | PanelPlex, cloud-based product for multiplexing molecular diagnostics for infectious disease |
| Grifols | Erytra Eflexis, automated, mid-sized analyzer for pretransfusion compatibility testing using DG Gel technology |
| Thermo Fisher Scientific | ISQ EC Single Quadrupole mass spectrometer |
| Thermo Fisher Scientific | Chromeleon Chromatography Data Software |
| Thermo Fisher Scientific | Q Exactive HF-X Hybrid Quadrupole Orbitrap mass spectrometer |
| Prevention Genetics | Genetic tests for both female and male infertility |
| Cytek Biosciences | Aurora advanced flow cytometry system |
| Phosphorus | Three new advanced test panels for hereditary cancers |
| Centogene | CenoNIPT test for non-invasive prenatal testing |
| NeoGenomics | Expansion of NeoTYPE cancer profiles to include Tumor Mutation Burden and microsatellite instability testing |

■ Market Trends, from page 1

Quest is no stranger to mass retail collaboration. But its previous deals have been mostly with grocery stores, including over 100 company-branded patient service centers (PSCs) at Albertsons companies' stores (Safeway, Vons, Randalls and Tom Thumb) across California, Colorado, Maryland, Oregon, Texas, Virginia and Washington.

The LabCorp-Walgreens Deal

The second blockbuster will see LabCorp operate co-branded PSCs at 7 Walgreens locations in Denver, North Carolina and Deerfield, Illinois (site of Walgreens HQ). The PSCs, which are expected to open by the end of the year, will provide specimen collection services.

LabCorp has been a pioneer of the PSC model and was, according to company press statements, the first national lab chain to make its services available through retail outlets. The Walgreens deals adds to LabCorp's portfolio of roughly 1,750 PSCs offering over 4,800 women's health, genomics, oncology and companion diagnostics test across the country.

Expansion of labs services into the retail environment is a natural extension of pharmacy diversification, says Morgan Stanley analyst Ricky Goldwasser.

The Brick and Mortar Model

Both of the new deals follow the typical model for lab-mass retail collaboration in which co-branded PSCs are established at store locations. By leveraging their retail partners' real estate and marketing assets labs generate incremental volumes and greater exposure. Stores benefit from the extra foot traffic and added customer convenience. Thus Walmart hailed the Quest deal as enabling it to extend its current health care offerings (which include vaccines and free blood pressure readings) and make its stores ia "one-stop shop" for customers' everyday health and wellness needs.

Expansion of labs services into the retail environment is a natural extension of pharmacy diversification, says Morgan Stanley analyst Ricky Goldwasser. For example, CVS's 1,081 MinuteClinics and Walgreen's 374 in-store clinics offer labs a "premier" retail footprint, while sharing overhead expenses could yield incremental savings, if labs relocate PSCs from other sites, like medical office buildings. Goldwasser says that in addition to the potential overhead savings, relocation to more consumer-friendly sites can also drive increases in testing volume. She highlighted in a recent research note that an estimated 10 percent to 20 percent of lab requisitions go unfilled. If retail PSCs can capture 10 percent of the unfilled requisitions, it would yield a 150 bps pickup in test volumes, or an incremental increase in earnings per share growth of one percent to two percent, according to Goldwasser.

The Cloud Model

Of course, the mass retail strategy is not confined to brick and mortar settings. Not surprisingly, Amazon has been among the most active in adapting the model for online retail. So far, most lab tests on Amazon have been sold through third parties. But last November, Good Start Genetics

Both models have also been adapted for direct-to-consumer (DTC) applications allowing customers to order tests without a physician's order in states where such arrangements are permitted by law.

became the first genetic testing firm to establish a direct partnership with Amazon to provide physician-ordered tests online, namely Good Start's VeriYou next generation sequencing test for couples planning to have kids. The dynamic: Customers must register online, furnish family history and provide consent. A licensed physician then reviews the data and decides whether to order the test. The customer can then buy the test on Amazon for \$149.

DTC Applications

Both models have also been adapted for direct-to-consumer (DTC) applications allowing customers to order tests without a physician's order in states where such arrangements are permitted by law.

The ill-fated Walgreens-Theranos partnership was a notable example of the former to a brick and mortar setting. Online examples include Quest's newly launched QuestDirect empowering consumers in Colorado and Missouri to order designated tests online without a physician's order.

Takeaway: Collaboration between labs and mass retail will continue and likely expand into the retail pharmacy segment. Look for brick and mortar PSC and online arrangements to proliferate, both DTC and physician-ordered.



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