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# LABORATORY

# INDUSTRY REPORT™

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## Market Trends: Lab-Retail Collaboration Remains Strong Despite Theranos Debacle

The Theranos debacle hasn't dissuaded retailers from partnering with labs.

### LabCorp & Walgreens

Walgreens, Theranos's ex-retail partner, has moved on and entered into an agreement with another blood-testing firm. But instead of an unproven start-up, the nation's second-largest pharmacy store has gone with a known entity, LabCorp.

*Continued on page 2*

## Diagnostic Deals 2018 Year In Review: A roundup of the key mergers, acquisitions, alliances, licenses and other strategic transactions from the past month

While overall deal volume for 2018 increased, the year was relatively light in the dramatic transactions that were so prolific in the previous two years. Here's a quick overview of deals and predominant trends during the year.

### M&A

The number of mergers and acquisitions in the molecular diagnostics and omics life science tools space rose 12% in 2018, according to research conducted by GenomeWeb. However, its research shows that the values of those deals were generally smaller than deals completed in 2017.

That's not surprising given that the lead-up to the PAMA market-based system for lab tests had been the primary driver in the lab space over the past two years as large labs looked to acquisitions to offset the anticipated Medicare reimbursement losses. Accordingly, most of the strategic mergers and acquisitions were already completed when PAMA officially took effect on Jan. 1, 2018.

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## ■ Lab-Retail Collaboration Remains Strong Despite Theranos Debacle, *from page 1*

Walgreens recently announced that it will open 600 blood-testing sites in its drugstores over the next four years, inclusive of the 17 locations that have opened since the initiative launched in June 2017.

### Quest & Walmart

Walgreens is hardly the only giant retailer to offer lab services. Last year, Walmart entered into an agreement with Quest Diagnostics to bring co-branded lab drug testing services to 15 Walmart in-store pharmacy locations in Florida and Texas.

### Quest & Albertsons

Quest also has a retail collaboration with Albertsons, the parent company of supermarket chains Randalls, Safeway, Tom Thumb and Vons. As of Dec. 1, there were Quest Diagnostic Patient Service Centers at 183 Albertsons locations in 11 states. Each Quest Diagnostic Patient Service Center has its own entrance inside the store, frosted privacy windows, a customer waiting area and a private restroom for patients' use. Walk-ins are welcome, but scheduled patients get priority.

### CVS & MinuteClinic

The largest pharmacy healthcare provider in the country, CVS also offers lab testing. However, these services are part of larger offerings through its MinuteClinic; lab testing is only available in conjunction with a standard service.

MinuteClinic, originally founded in 2000 as QuickMedx, was the first "retail clinic" in the US. Today, it's a full-blown division of CVS operating more than 1,000 in-store clinics across 32 states and the District of Columbia.

MinuteClinic offers in-clinic and send-out labs and tests. In-clinic labs and tests include A1C, Adeno test, blood sugar test, flu test influenza A & B, lipid panel, mono test, pregnancy test, strep test, and urine dip stick. Send-out labs and tests include follow-up strep test and urine culture.

### Why Go There?

On the surface, offering lab testing services in retail environments may seem odd. But it's part of a larger trend to offer customers and patients greater convenience.

The arrangement also provides a new source of revenue for large clinical lab operators and retailers. In addition, it's a way for retailers to differentiate themselves from the competition.

At the same time, it is indicative of a shift in focus in the healthcare market—a shift that has created what would have previously been considered unusual, if not highly questionable, partnerships. CVS's \$69 billion acquisition of health insurer Aetna, which closed in late November, is an example of this.

As the healthcare market continues to evolve, look for more partnerships with the potential to impact the lab industry. 

■ **Diagnostic Deals: 2018 Year In Review, from page 1**

Even so, many deals were made during the year and some pretty big ones at that. The year saw the closing two deals valued in the billions, both involving the same company: Roche. By contrast, there were four nine-figure M&A deals that closed in 2017, all at higher prices than the richest deal of this year, i.e., the \$2.48 billion paid by Roche for Foundation Medicine. Here are the 2018 top 10 M&A deals, including transactions that have been announced but not yet closed as of year-end:

### Top 10 Lab M&A Deals of 2018

Rank	Buyer	Target	Reported Price
1	Roche	Foundation Medicine	\$2.48 billion
2	Roche	Flatiron Health	\$1.98 billion
3	Illumina	Pacific Biosciences	\$1.2 billion*
4	Thermo Fisher Scientific	Gatan	\$925 million
5	Sonic Healthcare	Aurora Diagnostic	\$540 million*
6	Myriad Genetics	Counsyl	\$375 million
7	Bio-Techne	Exosome Diagnostics	\$250 million upfront + up to \$325 contingent on milestones
8	Agilent Technologies	Advanced Analytical Technologies	\$250 million
9	Qiagen	NeuMoDX	\$234 million*
10	Quest	Oxford Immunotec Global	\$170 million

\* Announced in 2018 with closing scheduled for 2019

### Strategic Alliances

Strategic alliance activity was also more robust this year, particularly in the new molecular, AI and NGS segments. Biopharma was a major theme with numerous deals featuring collaborations between pharma and test makers to develop companion diagnostics for new drug treatments. Product integration was also a prolific pattern in alliance making.

In addition to its \$1.2 billion acquisition of Pacific Biosciences, which has not yet closed, Illumina initiated a number of alliances this past year and [launched an incubator for genomic startups](#). Past activity suggests 2019 will also be a busy year for Illumina.

Here's a summary of key diagnostic deals from late November through December:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Sonic Healthcare	Aurora Diagnostic	<ul style="list-style-type: none"> <li>Price: \$540 million</li> <li>Status: Agreement signed with no closing date announced</li> <li>Acquisition and absorption of Florida anatomic pathology provider expands Australia-based Sonic's US market presence</li> </ul>

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
NeoGenomics	Genoptix	<ul style="list-style-type: none"> <li>Price: \$125 million cash + 1 million shares of NeoGenomics common stock</li> <li>Status: Closed</li> <li>Acquisition boosts NeoGenomics' position in oncology market</li> </ul>
Strand Life Sciences	Quest Diagnostics	<ul style="list-style-type: none"> <li>Price: Undisclosed</li> <li>Status: Closed</li> <li>Bangalore-based Strand acquires Quest's India diagnostics business including 3 reference labs, 45 touchpoints and leading pharmaceutical clients</li> </ul>
Quest Diagnostics	Boyce and Bynum Pathology Laboratories	<ul style="list-style-type: none"> <li>Price: Undisclosed</li> <li>Status: Agreement signed with no closing date announced</li> <li>Boyce and Bynum Pathology Professional Services, Inc., target's owner, to become exclusive pathology provider for Quest in Missouri and a preferred pathology provider in greater Midwestern region</li> </ul>
10x Genomics	Spatial Transcriptomics	<ul style="list-style-type: none"> <li>Price: Undisclosed</li> <li>Status: Closed</li> <li>10x acquires Swedish developer of two-dimensional gene expression technology for tissue sample sections</li> </ul>
Q-State Biosciences	Pairnomix	<ul style="list-style-type: none"> <li>Price: Undisclosed</li> <li>Status: Closed</li> <li>Firms merge to create company focused on precision medicine and drug discovery for central nervous system diseases</li> </ul>
LGC	SeraCare Life Sciences	<ul style="list-style-type: none"> <li>Price: Undisclosed</li> <li>Status: Closed</li> <li>Acquisition of quality control materials for infectious disease testing and NGS markets boosts LGC's position in clinical quality control tools market and expands its calibration verification materials and proficiency testing offerings</li> </ul>
Cancer Genetics	NovellusDx	<ul style="list-style-type: none"> <li>Cancellation of merger announced in Sept.</li> </ul>

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
LabCorp	Walgreens	<ul style="list-style-type: none"> <li>Objective: Expansion of LabCorp at Walgreens retail alliance into California Inland Empire</li> <li>Dynamic: Open nine new LabCorp patient service centers within Walgreens stores in greater Riverside, California area by year's end</li> </ul>
IncellDx	Zomedica	<ul style="list-style-type: none"> <li>Objective: Identify circulating tumor cells from canine cancers</li> <li>Dynamic: Develop assay that combines biomarkers from Zomedica's canine cancer research programs with IncellDx's BioINK reagents</li> </ul>
Biocept	Prognos	<ul style="list-style-type: none"> <li>Software license and lab data supply agreement</li> <li>Dynamic: Biocept to provide Prognos de-identified data from its liquid biopsy testing</li> <li>Prognos to leverage its AI tools to help pharma clients ensure that patients get the right therapies</li> </ul>
Bristol-Myers Squibb	H3 Biomedicine	<ul style="list-style-type: none"> <li>Objective: Evaluate therapeutic potential of H3's RNA splicing platform</li> <li>Dynamic: Joint research using H3 RNA platform to study development of cancer immunotherapies</li> <li>Bristol-Myers responsible for development and commercialization of resulting drug candidates</li> <li>H3 eligible for unspecified upfront payment + development, regulatory and sales milestones + royalties</li> </ul>

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Bristol-Myers Squibb	Boston Medical Center	<ul style="list-style-type: none"> <li>Objective: Identify prognostic and predictive immuno-oncology biomarkers across different cancers</li> <li>Dynamic: Multi-year research study on tissue and circulating biomarkers and role of microbiome in predicting benefit from immune checkpoint inhibitors</li> </ul>
Roche	Merck	<ul style="list-style-type: none"> <li>Objective: Create pan-cancer CDx test to assess if patients have mismatch repair deficiency in their tumors and are eligible to use Merck's Keytruda checkpoint inhibitor</li> <li>Dynamic: Immunohistochemistry-based CDx will operate on Roche BenchMark Ultra instrument</li> </ul>
Roche	Daiichi Sankyo	<ul style="list-style-type: none"> <li>Objective: Create immunohistochemistry-based CDx for Daiichi investigational breast cancer drug</li> <li>Dynamic: Roche to develop, manufacture and commercialize CDx for identifying HER2 low-expressing metastatic breast cancer patients for enrollment in a phase III study evaluating Daiichi's HER2-targeting antibody drug conjugate</li> </ul>
Guardant Health	AstraZeneca	<ul style="list-style-type: none"> <li>Objective: Develop blood-based CDx tests for AstraZeneca oncology drugs</li> <li>Dynamic: Guardant to develop and seek FDA approval for CDx test to help identify non-small cell lung cancer patients likely to respond to AstraZeneca's third-generation EGFR inhibitor Tagrisso</li> </ul>
Biocartis	AstraZeneca	<ul style="list-style-type: none"> <li>Objective: Expedite lung cancer molecular diagnostics results</li> <li>Dynamic: Conduct a European prospective lung cancer study using Biocartis' Idylla EGFR mutation test</li> </ul>
BiomX	Janssen Research & Development	<ul style="list-style-type: none"> <li>Objective: Discover microbiome-based biomarkers to identify responders to a Janssen inflammatory bowel disease treatment</li> <li>Dynamic: Use BiomX's XMarker platform to stratify responders and non-responders to undisclosed Janssen IBD treatment</li> </ul>
Proteomics International	Janssen Research & Development	<ul style="list-style-type: none"> <li>Objective: Use Proteomics' PromarkerD test for diabetic kidney disease in drug development</li> <li>Dynamic: Firms to evaluate test's effectiveness in predicting kidney function decline and drug response in patients from Janssen's clinical trials</li> </ul>
Centogene	Chiesi	<ul style="list-style-type: none"> <li>Objective: Identify genetic mutations that cause disease</li> <li>Dynamic: Centogene to perform a European epidemiological study focused on prevalence of a rare lysosomal storage disorder caused by mutations in MAN2B1 gene</li> <li>Chiesi to use its CentoCard dried blood spot collection kit to collect samples to sequence MAN2B1 gene to identify disease-causing mutations</li> </ul>
Foundation Medicine	QED Therapeutics	<ul style="list-style-type: none"> <li>Objective: Develop CDx for QED's drug candidate infigratinib for bile duct cancer</li> <li>Dynamic: Infigratinib and new CDx to be incorporated into Foundation's genomic profiling assay for all solid tumors</li> </ul>
Qiagen	Novartis	<ul style="list-style-type: none"> <li>Objective: Develop molecular CDx to guide use of Novartis investigational PI3K inhibitor in breast cancer patients</li> <li>Dynamic: CDx to cover DNA extraction, detection of clinically relevant mutations and final reporting and fill void in market for FDA-approved therapies targeting PIK3CA mutations in HR+/HER2- advanced breast cancer</li> </ul>
Qiagen	NeoGenomics	<ul style="list-style-type: none"> <li>Objective: Expedite development and launch of CDx tests for pharma</li> <li>Dynamic: Master service agreement under which Qiagen will provide investigational-use-only tests to NeoGenomics and other labs "enabling them to verify, set up and run our companion diagnostics in clinical trials and in anticipation of regulatory approval"</li> </ul>

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Sysmex	MolecularMD	<ul style="list-style-type: none"> <li>Objective: Develop CDx for precision medicine</li> <li>Dynamic: Non-exclusive partnership leveraging the firms' technology and global regulatory experience to accelerate CDx and drug commercialization</li> </ul>
Sema4	Sanofi + Mount Sinai Health System	<ul style="list-style-type: none"> <li>Objective: Asthma research</li> <li>Dynamic: 5-year research study</li> </ul>
Indivumed	Institute of Molecular and Cell Biology (IMCB) at the Agency for Science, Technology and Research (A*STAR) in Singapore	<ul style="list-style-type: none"> <li>Objective: Launch cancer library initiative to support development of precision diagnostics and personalized cancer treatments</li> <li>Dynamic: Leverage Singapore's clinical network to collect omics data to be stored in the Asian-centric Cancer Database and made available for local research</li> </ul>
Synlab Pharma	Biotype	<ul style="list-style-type: none"> <li>Objective: Provide clinical trial service for microsatellite instability and DNA polymerase epsilon/polymerase delta 1 mutation detection for European market</li> <li>Dynamic: Service to use using Biotype's Modaplex technology</li> </ul>
Shivom	Lifebit	<ul style="list-style-type: none"> <li>Objective: Launch AI-powered platform for identifying appropriate patients for clinical trials</li> <li>Dynamic: Firms to combine their technologies to offer DNA data platform allowing users to perform immediate genome-wide association study analyses, and access proprietary software and AI tools for data analysis</li> </ul>
GeneCentric	University of North Carolina at Chapel Hill	<ul style="list-style-type: none"> <li>Objective: Study patient responses to immunotherapeutic drugs, including PD-1 and PDL-1 inhibitors, based on bladder cancer subtypes</li> <li>Dynamic: Researchers to investigate links between certain bladder cancer changes, disease progression and clinical response to anti-PD-1 and anti-PDL-1 checkpoint inhibitor therapy</li> </ul>
Mobidiag	Autobio Diagnostics	<ul style="list-style-type: none"> <li>Objective: Create joint venture in China</li> <li>Dynamic: Mobidiag to grant joint venture an exclusive license for human infectious disease assays (except for sepsis assays)</li> <li>Joint venture to register the Mobidiag Novodiag platform and assays for meningitis, respiratory infections and gastroenteric infections, with the National Medical Products Administration (formerly called the China Food and Drug Administration)</li> </ul>
BGI Research	China National GeneBank (CNGB) + Australia's Macquarie University	<ul style="list-style-type: none"> <li>Objective: Establish a synthetic biology research partnership</li> <li>Dynamic: Five-year partnership under which parties will collect genomics technologies and resources and promote their use by the research community</li> </ul>
NIPD Genetics	Medicover	<ul style="list-style-type: none"> <li>Objective: Support NIPD Genetics' noninvasive prenatal tests and development of new tests</li> <li>Dynamic: Bring NIPD's Veracity and Veragene noninvasive prenatal tests to Medicover's network and other new markets</li> <li>Design and develop new genetic tests in prenatal, postnatal, neonatal, oncology and other spaces</li> </ul>

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	Distributor	Deal Summary
HalioDx	Hyupjin	<ul style="list-style-type: none"> <li>Products: HalioDx's Immunoscore assay</li> <li>Territory: South Korea</li> </ul>
HalioDx	IDB Resources	<ul style="list-style-type: none"> <li>Products: HalioDx's Immunoscore assay</li> <li>Territory: Singapore, Malaysia, Thailand</li> </ul>
HalioDx	IPS Genomix	<ul style="list-style-type: none"> <li>Products: HalioDx's Immunoscore assay</li> <li>Territory: Lebanon, Jordan, Saudi Arabia, UAE, Egypt, Oman, Qatar</li> </ul>
HalioDx	MicroDiagnostics	<ul style="list-style-type: none"> <li>Products: HalioDx's Immunoscore assay</li> <li>Territory: Greece</li> </ul>
HalioDx	South Genetics	<ul style="list-style-type: none"> <li>Products: HalioDx's Immunoscore assay</li> <li>Territory: Argentina, Chile, Uruguay</li> </ul>
Jeta Molecular	Inno-train Diagnostik	<ul style="list-style-type: none"> <li>Products: QTRACE, Jeta's qPCR reagent and software suite</li> <li>Territory: US and most of Europe (excluding France)</li> </ul>
Lucence Diagnostics	iGenetic Diagnostics	<ul style="list-style-type: none"> <li>Products: Lucence's LiquidHallMark liquid biopsy panel</li> <li>Territory: India</li> </ul>
Synthego	Eurofins Genomics	<ul style="list-style-type: none"> <li>Products: Synthego's synthetic single guide RNA (sgRNA) products</li> <li>Territory: 44 countries</li> </ul>

LICENSES		
Licensor	Licensee	Deal Summary
DarwinHealth	Encheng Group	<ul style="list-style-type: none"> <li>Property: Darwin's precision cancer medicine tests</li> <li>Exclusive rights in Hong Kong, Macao and Taiwan</li> </ul>
ERS Genomics	Lonza Pharma & Biotech	<ul style="list-style-type: none"> <li>Property: ERS's CRISPR-Cas9 genome editing technology</li> <li>Lonza licenses for use in its bioproduction products and services and in induced pluripotent stem cells for research</li> </ul>

SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Service	Client	Deal Summary
Seegene	Biogroup-LCD	<ul style="list-style-type: none"> <li>Seegene to supply \$8.9 million worth of PCR-based diagnostic kits, including tests for sexually transmitted infections, women's health and gastrointestinal infections</li> </ul>
Primerdesign (molecular testing division of Novacyt)	Genesis Diagnostics	<ul style="list-style-type: none"> <li>Exclusive supply agreement with Primerdesign to develop and supply 384-well plate molecular assay panels, including respiratory, women's health, sexually transmitted diseases, wound and urinary tract infections, to Genesis to use in its Pennsylvania-based clinical service lab</li> </ul>

## FDA Watch: Agency Floats Plan to Simplify 510(k) Premarket Review

Last month, the FDA floated a plan to overhaul and modernize the 510(k) premarket review pathway allowing for faster, safer approval of medical devices, including diagnostics. Here's a quick recap.

### The 510(k) Pathway

Device and diagnostics manufacturers can use the 510(k) pathway to get expedited approval for new products that they can show are substantially equivalent to products that were grandfathered in when Congress created the pathway in 1976. *Translation:* Technology that's 40 or more years-old is being used as the standard for letting new products into the market.

There's a perception that we've gone too far in stretching what's "equivalent," and that new 510(k) approvals should be compared to the benefits and risks of modern technology, notes Philadelphia attorney Janice Hogan who represents companies in the 510(k) process.

### The New Proposal

The FDA recognizes the problem and has taken steps to address it. In April 2018, the agency suggested that substantial equivalency of new products be evaluated based on objective performance criteria rather than predicate devices. The November guidance advances that objective via establishment of an alternative 510(k) pathway (to be called the "Safety and Performance Based Pathway") that allows manufacturers of certain-well-understood device types to rely on objective safety and performance criteria to demonstrate substantial equivalence.

The proposal also calls for modernization by way of embarrassment via publication of manufacturers and products relying on predicate technology over 10-years-old.

### Impact on the Lab Industry

Hogan suggests that the new rules will have less impact on diagnostics than therapeutics given the former's current reliance on newer predicates. What's more, adds Hogan, 510(k) may become moot for diagnostics if some version of the *Diagnostic Accuracy and Innovation Act* (DAIA) (see [NIR, September, 2018](#)) is passed. *Explanation:* DAIA would establish a new pathway for diagnostic tests instead of continuing to include them in the definition of a medical device within the scope of the 510(k) process.

Although it has bi-partisan support, Hogan cautions that DAIA is far from being a done deal. And unless and until it passes, new diagnostics will still have to go through the 510(k) process reach the market.

Although it has bi-partisan support, Hogan cautions that DAIA is far from being a done deal. And unless and until it passes, new diagnostics will still have to go through the 510(k) process reach the market.

### New FDA Approvals

Here's a look at the key FDA approvals announced at the end of November through December:

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## NEW FDA APPROVALS

Manufacturer(s)	Product(s)
GenMark Diagnostics	510(k) clearance for ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel
Becton Dickinson	510(k) clearance for BD Max enteric viral panel, molecular test for detecting and differentiating pathogens causing viral gastroenteritis
Hycor Biomedical	510(k) clearance for Noveos allergy testing system and related assay for dust mite allergen detection
Myriad Genetics	Expanded use for BRACAnalysis CDx in identifying advanced ovarian cancer patients eligible for AstraZeneca's Lynparza (olaparib) as first-line maintenance therapy after responding to platinum-based chemotherapy
BioMérieux	510(k) clearance for BPA and BPN bottles used in quality control testing of platelets at blood banks using firm's BACT/ALERT Virtuo blood culture system
Meridian Bioscience	Clearance to market Alethia CMV Assay Test System Vitros XT 7600 Integrated System cytomegalovirus assay for newborns
Ortho Clinical Diagnostics	Expanded use of Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator on firm's Vitros ECi/ECiQ Immunodiagnostic Systems
Invivoscribe Technologies	Expanded use for LeukoStrat CDx FLT3 Mutation Assay for use with with Xospata (gilteritinib), Astellas Pharma drug for patients with relapsed acute myeloid leukemia and FLT3 mutation
Loxo Oncology	Approval for Vitrakvi (larotrectinib), TRK inhibitor is for the treatment of solid tumors characterized by an NTRK gene fusion and no acquired resistance mutation
Mesa Biotech	Approval and CLIA waiver for Accula RSV respiratory syncytial virus test
DiaSorin Molecular	Clearance for Simplexa GBS Direct assay for use on firm's Liaison MDX instrument for qualitative detection of group B <i>Streptococcus</i> nucleic acid

## New CE Marks &amp; Global Certifications

Notable European CE certifications:

## NEW CE CERTIFICATIONS IN EUROPE

Manufacturer(s)	Product(s)
Novacyt	CE marking for Genesig BK virus (BKV) and Epstein-Barr virus (EBV) diagnostic kits
Cepheid	CE-IVD clearance for rapid molecular assay to measure viral load of hepatitis B in infected patients
Quidel	CE marking for point-of-care Sofia 2 Lyme+ fluorescent immunoassay
Quidel	CE marking for TriageTrue High Sensitivity Troponin I Test for determining troponin I levels as an aid in diagnosing myocardial infarction
Systaaq Diagnostic Products	CE marking for real-time PCR-based hepatitis B diagnostic

Manufacturer(s)	Product(s)
HiberGene Diagnostics	CE marking for HG Flu A/B <i>Combo</i> test
PredictImmune	CE-IVD marking for PredictSure IBD test for inflammatory bowel disease
AusDiagnostics	CE-IVD marking for molecular diagnostic assay to detect hemochromatosis
Speedx	CE-IVD marking for Resistance GC, qPCR assay to detect <i>Neisseria gonorrhoeae</i> and sequences in <i>gyrA</i> gene of bacteria linked to ciprofloxacin susceptibility
Asuragen	CE marking for AmpliX DM1 Dx kit for diagnosis of myotonic dystrophy type I (DM1)
PerkinElmer	CE-IVD marking for Vanadis NIPT system

Other international clearances announced in the past month:

Manufacturer(s)	Country(ies)	Product(s)
Atomo Diagnostics	Australia	Therapeutic Goods Administration approval for Atomo Self Test, self HIV test
Genobio	South Korea	Korean Ministry of Food and Drug Safety approval for GenoCTC isolation kit
Oxford Immunotec Global	China	China Food and Drug Administration approval for T-Cell Select, immune cell separation reagent kit
OpGen	Colombia	Instituto Nacional de Vigilancia de Medicamentos y Alimentos approval to market QuickFISH rapid pathogen identification products

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

Most of the new product launches in late November through December were in the molecular and genomics space. For the second month in a row, Qiagen was among the most active companies with a trio of launches. Here's the visual rundown:

### NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
DiaSorin Molecular	Trio of new primer pairs for use in LDTs, including: <ul style="list-style-type: none"> <li>■ <i>Legionella</i> species</li> <li>■ <i>Chlamydomphila pneumoniae</i></li> <li>■ <i>Mycoplasma pneumoniae</i></li> </ul>
Viracor Eurofins	16S Next-Generation Sequencing Bacterial Meningitis test
Lexogen	New version of TeloPrime Full-Length cDNA Amplification Kit

Company(ies)	Product(s)
Enpicom	Expanded version of ImmunoGenomix platform
Microbiologics	Group A <i>Streptococcus</i> and Respiratory Panels
Expedeon	Two new high-fidelity polymerases: <ul style="list-style-type: none"> <li>▪ MagniPhi DNA Polymerase</li> <li>▪ QualiPhi DNA Polymerase</li> </ul>
Proteona	Enhanced Single-Cell Analysis with Protein Expression (ESCAPE) RNA sequencing as a service and early access kit
Indigo Biosciences	Gene expression assay kit featuring optimized "Upocyte" hepatocytes
ZeptoMetrix	Two new pneumonia verification panels for molecular quality control: <ul style="list-style-type: none"> <li>▪ NATrol Pneumonia Panel-Atypical Bacteria &amp; Viruses</li> <li>▪ NATrol Pneumonia Panel-Quantifiable Bacteria</li> </ul>
Cellecta	Five DriverMap Predesigned RNA-Seq panels: <ul style="list-style-type: none"> <li>▪ Human Cell Marker Panel</li> <li>▪ Human Hallmark Signatures Panel</li> <li>▪ Human LINCSx Panel</li> <li>▪ Human Pan-Cancer Pathway Panel</li> <li>▪ Human Transcription Factor Signature Panel</li> </ul>
Thermo Fisher Scientific	Invitrogen Collibri Stranded RNA Library Prep Kits for Illumina Systems
Thermo Fisher Scientific	Invitrogen Silencer Select lncRNA siRNAs library
Allele Biotech	Initial batch of six induced pluripotent stem cell (iPSC) lines
Insight Genetics	Insight TNBCtype test for categorizing triple negative breast cancers (TNBC) into distinct molecular subtypes
Qiagen	European launch of QiaScreen HPV PCR test
Qiagen	CLC Genomics Workbench 12 sequencing analysis software
Qiagen	QiaAct Myeloid UMI Panel for GeneReader NGS system
Swift Biosciences	Normalase Kit, an enzymatic library normalization kit for NGS library prep
SoftGenetics	MaSTR probabilistic mixture analysis software
OncoDNA	Updated version of OncoDeep solid tumor analysis tool
SoftGenetics	New Sequence Repeat Expansion Analysis app for its GeneMarker software
Arima Genomics	Arima-HiC sample preparation kit

## Earnings Report: Top Payers Announce Q3 Earnings

The country's five largest commercial payers posted strong results for the third quarter of fiscal year 2018.

COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total Q3* 2018	YOY	Wall Street Estimate	
<b>Aetna</b>	\$15.5 billion	+3%	\$15.25 billion	After expenses, Aetna's net income grew 19% in Q3 2018 to \$1 billion, compared to \$838 million in Q3 2017.
<b>Anthem</b>	\$23 billion	+4%	\$23 billion	Including expenses and nonoperating gains, Anthem ended Q3 2018 with \$960 million in net income, up 29% from \$747 million in Q3 2017.
<b>Cigna</b>	\$11.5 billion	+9%	\$11.2 billion	After including expenses and nonoperating gains, Cigna ended Q3 2018 with net income of \$772 million, up nearly 38% from \$560 million in Q3 2017.
<b>Humana</b>	\$14.2 billion	+7%	\$13.98 billion	At Humana, revenues outpaced expenses and climbed 6.6% YOY to \$13.2 billion, up from \$12.4 billion in Q3 2017. Humana ended Q3 2018 with net income of \$644 million, up from \$499 million in Q3 2017.
<b>UnitedHealth Group</b>	\$56.6 billion	+12.4%	\$56.3 billion	Year-to-date, UnitedHealth's profits are \$8.9 billion after expenses – an increase of 29% compared to the first nine months of 2017.

\* **Bold face:** Companies that met or exceeded Q3 Wall Street revenues targets

\* *Italics:* Companies that missed Wall Street revenues targets



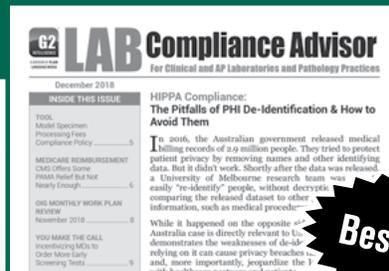
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