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Upcoming Events

Lab Leadership Summit

Designing, Implementing & Managing a High-Profit Lab Outreach Program

Friday, April 27, 2018

www.lableadershipsommit.com

Lab Institute 2018

Oct. 24-26, Washington, DC

www.labinstitute.com

Industry Buzz: ACLA Goes for Kill in PAMA Lab Fees Challenge Case

Attorneys for the American Clinical Laboratory Association asked the federal court for summary judgment in its lawsuit challenging the legality of the new PAMA-based Medicare Part B fee schedule for lab tests. Specifically, ACLA contends that the HHS exceeded its authority and ignored the PAMA legislation by omitting hospital and reference labs from pricing data used to set fee rates for lab services under the law. (For more about the lawsuit, see [GCA, Dec. 11, 2017](#).) If the court does grant summary judgment it would essentially be saying that it has enough of a basis to rule that ACLA's claims are legally valid without holding a trial. If it denies the motion, a trial will be necessary—unless, that is, HHS brings and wins its own summary judgment motion. 

Dx Earnings Report: Strong Q4 as Lab Companies End Year with a Bang

Big PAMA cuts may lay ahead in 2017, but the diagnostics industry had a robust 2017. While the entire year was strong, success was the most widespread in the fourth quarter with all but a few companies posting gains at levels above Wall Street expectations.

Gainers

Of the 28 companies to report final or preliminary Q4 earnings as of the date we went to press, all but two reported growth during the period. Among the gainers, only one failed to make its Wall Street target, Oxford Immunotec, which downgraded its expected earnings to between \$24.9 and \$25.4 million, below both previous guidance of \$26.4 million and the consensus Wall Street estimate of \$26.1 million.

Among the 21 companies with fiscal years coinciding with the calendar year, 20 reported growth for the entire year. The lone

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exception was Fluidigm which was down 2% in 2017 despite robust 11% growth in the fourth quarter. Of the companies reporting up years, only one posted annual growth below expectations: Quidel, which despite riding the Triage acquisition to 118% growth in the fourth quarter and 45% for the entire year, came in slightly below estimated annual revenues—\$277.7 million vs. \$278.0 million.

The Big Boys

For the fourth straight quarter, almost all of the billion-dollar labs at least met, and in a few cases, smashed their expected gains. The latter included:

- ▶ Thermo Fisher which followed a spectacular Q3 with an even more impressive fourth quarter featuring 22% growth at \$6.05 billion, (vs. the Wall Street target of \$5.7 billion) and ending the year with 14% growth at \$20.92 billion;
- ▶ Abbott Laboratories which got a lift from the Alere acquisition to the tune of 52% growth and \$7.59 billion in revenues (\$200 million above Wall Street estimates) but also posted solid comparable operation basis growth of 7%;
- ▶ PerkinElmer which posted fourth quarter and yearly revenues comfortably ahead of estimates thanks not only to the Euroimmun acquisition but also strong growth in organic revenues; and
- ▶ Danaher which posted 11% overall growth including an eye-popping 13% increase in diagnostic revenues to beat its \$4.98 billion target by \$21 million.

For the third straight quarter, almost all of the billion-dollar labs at least met, and in a few cases, smashed their expected gains. The latter included:

- ▶ Thermo Fisher which had a monster Q3 featuring not only 14% growth at \$5.12 billion, (vs. the Wall Street target of \$5.03 billion) but completion of the \$7.2 billion Patheon acquisition;
- ▶ LabCorp which exceeded its \$2.55 billion target by \$11 million—while strategic acquisition revenues lifted the figures, the firm also posted a 10% gain in diagnostic sales;
- ▶ Danaher which posted 10% overall growth including an eye-popping 20% increase in diagnostic revenues, allowing it to beat its \$4.47 target by \$6 million.

LabCorp and Quest were also able to meet their Q4 and 2017 Wall Street revenue targets but just barely.

Decliners

Only two labs posted revenue declines in Q4: Myriad Genetics and Pacific Biosciences. But even these clouds came with silver linings:

Other companies that struggled in terms of revenues:

- ▶ Although down 1% for the quarter, Myriad's losses were much less than projected allowing the firm to beat its Wall Street revenue projections—\$194 million posted vs. \$188.8 million expected; and

- Pacific Biosciences' \$24.9 million in Q4 revenues, though down 3% year over year, were \$3 million ahead of Wall Street; moreover, the firm was up 3% for the entire year and at a higher than expected rate (\$93.5 million posted vs. \$90.3 million projected).

Diagnostics Earning Reports 4Q 2017, Total 2017
(At least \$10 million in sales—of companies to report as of press date)

COMPANY	4th QUARTER			2017 TOTALS	DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street		
Abbott Laboratories	\$7.59 billion	+52% (7% on comparable operation basis)	\$7.39 billion	\$27.39 billion, up 32% on reported basis and 5% on comparable operations basis	Report numbers incorporate revenues from newly acquired Alere; Dx up 4% to \$1.22 billion driven by 9% growth in core lab tests to \$1.1 billion, 7% growth in POC tests to \$145 million and 4% growth in molecular tests to \$122 million
Becton Dickinson	\$3.08 billion	+5%	\$3.05 billion	Sept. to Dec. 2017 = Q1 of FY 2018	Dx revenues up 14% to \$381 million driven by molecular and core microbiology
BioMérieux	€613.8 million	+4%	NA	€2.29 billion, up roughly 10%	32% growth in molecular bio driven by BioFire FilmArray line
Bio-Techne	\$154.2 million	+17%	\$146.3 million	Sept. to Dec. 2017 = Q2 of FY 2018	Dx revenues declined 4%
Bruker	\$530.5 million	+13%	\$504.0 million	\$1.77 billion, up 10% and above Wall Street estimate of \$1.74 billion	Organic growth of 4% net of 4% in acquisition boosts and 5% in positive foreign currency effects
CareDx (Expected)	\$12.3 to \$12.5 million	+13% to 15%	\$12.1 million	\$48.1 to \$48.3 million, up 18% to 19%	Significant growth in Dx revenues from \$7.4 to \$8.4 million in Q4 expected fueled by Oct. launch of AlloSure transplant test
Danaher	\$5.09 billion	+11%	\$4.98 billion	\$18.33 billion, up 9% YOY and above Wall Street's \$18.22 billion estimate	Dx revenues up 13% to \$1.62 billion driven by strong immunoassay, urinalysis and clinical chemistry
Exact Sciences (Expected)	\$86.9 to \$87.9 million	+148%	\$65.0 million		Expected 115% increase in Cologuard colon cancer tests
Fluidigm	\$27.7 million	+11%	NA	\$101.9 million, down 2%	Losses in single-cell genomics instruments nullify gains in high-throughput genomics and mass cytometry
Foundation Medicine (Expected)	\$48.9 million	+70%	\$39.2 million	\$152.9 million, up 31%	Molecular information services expected to generate \$117.1 million of 2017 revenues
GenMark Diagnostics (Expected)	\$16.0 million	+7%	\$15.2 million	\$52.5 million, up 6% and above Wall Street estimate of \$51.7 million	Strong sales of newly FDA approved ePlex and eSensor XT-8 molecular Dx systems
Hologic	\$791.1 million	+8%	\$785.9 million	Sept. to Dec. 2017 = Q1 of FY 2018	Total Dx revenues fall 13% to \$284.6 million—double rate of decline in Q4, mainly due to effects of divested blood screen business which counteracted strength of Aptima women's health line in molecular segment;
Illumina	\$778 million	+26%	\$750.2 million	\$2.75 billion, up 15% and ahead of \$2.73 billion Wall Street estimate	NovaSeq instruments and 30% increase in sequencing consumables, including NovaSeq consumables drive growth
Invitae	\$25.4 million	+170%	\$24.6 million	\$60 million	Driven by recent acquisitions, including \$4 million from Good Start Genetics and \$2 million from CombiMatrix
Laboratory Corp. of America	\$2.70 billion	+13%	\$2.69 billion	\$10.21 billion, up 8% and beating \$10.19 average estimate	Acquisitions contribute 10% but organic revenues also grew 3%, including 9% growth in Dx

COMPANY	4th QUARTER			2017 TOTALS	DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street		
Luminex	\$78.2 million	+8%	\$77.0 million	\$306.6 million, up 13% and above \$305.3 million Wall Street estimate	Driven by 31% growth in MDx sample-to-answer portfolio
MDxHealth	Not yet broken out			\$40.5 million, up 35%	ConfirmMDx for prostate cancer accounts for 91% of sales; also launched AssureMDx for Bladder Cancer, liquid biopsy bladder cancer test
Meridian Bioscience	\$52.3 million	+12%	\$49.0 million	Sept. to Dec. 2017 = Q1 of FY 2018	Dx revenues up 11% to \$33.8 million driven by strong respiratory season and double-digit growth in foodborne and <i>H. pylori</i> lines
Myriad Genetics	\$194.0 million	-1%	\$188.8 million	Sept. to Dec. 2017 = Q2 of FY 2018	Molecular tests down 3% to \$179.2 million and hereditary cancer sales down about 8% to \$126.9 million
NanoString Technologies (Expected)	\$21 million			\$113 to \$115 million, which would beat \$112.5 million Wall Street estimate	Prosigna IVD kits fuel growth; in Q4, company eliminated 30 positions to refocus on development of new platforms
NeoGenomics	\$67.8 million	+12%	\$66.3 million	\$258.6 million, up 6% and over \$257.2 million consensus Wall Street estimate	Driven by 19% growth in genetic testing and 7% growth in overall clinical testing to \$59.1 million; PAMA losses anticipated to be only 0.4%, <\$1 million
OraSure Technologies	\$52.0 million	+46%	\$47.8 million	\$167.1 million, up 30% above Wall Street estimate of \$163.4 million	Infectious disease testing up 3% (\$14 million), risk assessment testing down 5% (\$3.1 million), molecular collection systems up roughly 350% (\$29.8 million)
Oxford Immunotec (Expected)	\$24.9 to \$25.4 million		\$26.1 million		Projected earnings downgrade from earlier guidance; no reasons provided but may be due to sharper than expected decline in tick-borne disease testing revenues
Pacific Biosciences	\$24.9 million	-3%	\$21.9 million	\$93.5 million, up 3% and above \$90.3 million Wall Street estimate	Company unable to make up for roughly \$12.6 million in 2016 contract revenues lost in 2017
PerkinElmer	\$641.6 million	+13%	\$618.6 million	\$2.26 billion, up 7% and above Wall Street estimate of \$2.23 billion	Organic revenues, i.e., excluding Euroimmun acquisition, up 6% including 23% bump in Dx to \$193.4 million (counting Euroimmun)
Qiagen	\$396.9 million	+8%	\$393.3 million	\$1.42 billion, up 6% and beating average estimate of \$1.41 billion	Driven by OmicSoft acquisition although growth of 5% on adjusted basis; Molecular DX up 4% to \$193 million, over 50% firm's total sales; applied testing up 9%
Quest Diagnostics	\$1.94 billion	+4%	\$1.94 billion	\$7.71 billion, up 3% and above \$7.69 billion consensus Wall Street estimate	PAMA cuts expected to cut 2018 revenues 4%, some of which company will look to offset via new acquisitions and recent tax law changes
Quidel	\$114.9 million	+118%	\$114.7 million	\$277.7 million, up 45% but below consensus estimate of \$278.0 million	Spike result of Triage acquisition; Molecular Dx up 67% to \$4.5 million driven by 221% growth in Solana; Specialized Dx also up 4% to \$14.2 million
Roche (Dx Division)	\$3.51 billion	+4%	NA	\$12.93 billion, up from \$12.29 billion in 2016	Growth driven by 4% increase in molecular Dx, 15% increase in HPV and 1% increase in blood screening
Thermo Fisher Scientific	\$6.05 billion	+22%	\$5.7 billion	\$20.92 billion, up 14% and just over consensus estimate of \$20.59 billion	Acquisitions contribute 11% growth but organic revenues also up 8%, including 10% increase in Specialty Dx led by transplant; Labs up 43% to \$2.4 billion, thanks, in part, to Patheon acquisition
Waters	\$687 million	+9%	\$669 million	\$2.31 billion, up 7% and above \$2.29 billion Wall Street estimate	Balanced growth with especially strong sales in mass spec business

* **Bold face:** Companies that met or exceeded Q4 Wall Street revenues target

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

Based on the early returns, the market analysts that predicted 2018 would see a slowdown in strategic Dx deal making appear to be right. But while deal volume was low on both the M&A and alliance front, there were a few splashes.

M&A

February witnessed the first major new M&A deal of 2018, Roche's announced \$1.9 billion acquisition of Flatiron Health, a NYC-based oncology electronic health records. Roche Pharmaceuticals CEO Daniel O'Day called the purchase, which is scheduled to close in the first half of 2018, "an important step in our personalized healthcare strategy," citing Flatiron's positioning "to provide the technology and data analytics infrastructure needed not only for Roche, but for oncology research and development efforts across the entire industry."

Qiagen and Quest Diagnostics also got on the 2018 M&A board, the former by announcing its entry into the multiplex infectious disease testing market via acquiring Barcelona-based PCR technology firm STAT-Dx for a purchase price of up to \$197 million. Meanwhile, Quest boosted its mobile services capabilities by announcing plans to purchase Mobile Medical Examination Service for an undisclosed price.

One industry giant you should not expect to see a lot of on the M&A front in 2018 is Abbott, which said that it plans to spend the year absorbing the huge debts it took on as a result of last year's spending spree including, of course, the Alere merger. But investors showed no signs of concern with Abbott's \$20 billion in long-term debt, especially after the firm announced earnings way above expected levels—both for the fourth quarter and all of 2017. While the 52% and 32% growth rates, respectively, were ballooned by the Alere deal, comparable operations-basis growth was also rock solid at 7% for Q4 and 5% for the year.

Strategic Alliances

After a furious January, alliance-making and partnership activity hit the skids this month in terms of both deal volume and value. Among the few notables:

- ▶ Quest's agreement to offer Thermo Fisher Scientific's non-small cell lung cancer panel via its Texas oncology center of excellence and under which Quest will have preferred access to Thermo Fisher's OncoPrint-branded clinical and biopharma technology pipeline;
- ▶ The collaboration spun out of last year's acquisition of Ambry Genetics by Konica Minolta pitting Ambry and Konica-owned Invivo aimed at developing customized genomics and imaging services for development of new oncology drugs and biotechnology applications; and
- ▶ The partnering of Mayo Clinic with informatics firm SkylineDx designed to leverage the former's proprietary algorithm for metastasis risk factor identification to develop new tests to guide clinical decision making for melanoma treatment.

Here's a summary of the key diagnostic deals from late January through most of February:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Roche	Flatiron Health	<ul style="list-style-type: none"> Price: \$1.9 billion Status: Expected to close in first half 2018 Roche already 13% stakeholder in Flatiron Acquisition of Flatiron's oncology technology assets boosts Roche's personalized healthcare infrastructure
Qiagen	STAT-Dx	<ul style="list-style-type: none"> Price: Up to \$191 million—\$147 million cash + milestone payments of up to \$44 million Status: Expected to close in Q2 2018 Qiagen enters multiplex infectious disease testing market by acquiring Barcelona-based developer of real-time PCR technology for molecular NGS simultaneous detection of oncology, respiratory, gastrointestinal and other infections
LGC	Lucigen	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed LGC acquires Wisconsin-based producer of molecular biology enzymes, reagents and kits
Eurofins Scientific	Labo Van Poucke	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Eurofins gets into Belgian market by acquiring local family-owned lab with €5 million (\$6.2 million) in 2017 revenues
Quest Diagnostics	Mobile Medical Examination Service	<ul style="list-style-type: none"> Price: Undisclosed Status: Expected to close Q1 2018 Acquiring provider of home-based health risk assessments and related services expands Quest's position in home and mobile services
DiscernDx	Applied Proteomics	<ul style="list-style-type: none"> Price: \$1.85 million Status: Closed Liquidation sale in which DiscernDx acquires all assets of San Diego-based proteomics firm launched in 2007
Elsevier (part of RELX Group)	Via Oncology	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Elsevier acquires Pittsburgh-based provider of decision support and cancer care management services
STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Thermo Fisher Scientific	Quest Diagnostics	<ul style="list-style-type: none"> Objective: Offer Thermo Fisher's OncoPrint Dx Target Test diagnostic panel for non-small cell lung cancer Dynamic: Quest to perform test at its Lewisville, Texas oncology center of excellence Quest to also have early access to Thermo Fisher's pipeline of novel platforms and assays to assist with development of OncoPrint-branded solutions for clinical and biopharma applications
Roche	Wisconsin Diagnostic Laboratories of Milwaukee	<ul style="list-style-type: none"> Strategic alliance WDLM named Roche Molecular Center of Excellence
Science Exchange	OnRamp Bioinformatics	<ul style="list-style-type: none"> Objective: Deliver bioinformatics services and tools Dynamic: Science Exchange to provide R&D support to OnRamp Bio for its user interface, automated analyses and genomic data management products
Somalogic	Leeds Centre for Personalised Medicine and Health	<ul style="list-style-type: none"> Objective: Research capacity of protein measurements to impact patient care in different clinical areas Dynamic: Leverage Somalogic's SomaScan proteomic platform to measure large numbers of proteins in blood and other patient samples Latest step in Somalogic's larger strategy to develop SomaScan as clinical tool
Sciex	IROA Technologies	<ul style="list-style-type: none"> Objective: Provide system for identification and quantitation of metabolites in biological samples Dynamic: Joint promotion of system that combines IROA's workflow for isotopic ratio outlier analysis with Sciex's Swath data-independent acquisition workflow on next-generation metabolomics and Triple-TOF systems
Medidata	Syapse	<ul style="list-style-type: none"> Objective: Develop products to improve patient access to oncology clinical trials Dynamic: Partners to initially focus on creating products to help trial sponsors design eligibility criteria, identify community health systems trial sites and find patients to enroll in trials

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Syapse	Seoul National University Hospital + Megazone	<ul style="list-style-type: none"> Objective: Deliver precision oncology services to Asian market—S. Korea, Japan, Vietnam Dynamic: Seoul National University Cancer Hospital to install Syapse data-aggregation platform in its 28 centers across Korea Megazone, an Amazon Web Services consulting partner in Asia, to provide IT support
Agilent	Science Exchange	<ul style="list-style-type: none"> Objective: Promote access to Agilent-enabled services to global research community Dynamic: Create new, privacy-protected online portal that Agilent customers can use to search and request a quote for Agilent-enabled research services directly from Agilent.com Science Exchange's verification program used to qualify listed providers Partners to co-market new portal starting Feb.
Agilent	University of Southern California Michelson Center for Convergent Bioscience	<ul style="list-style-type: none"> Objective: Create an Agilent Center of Excellence in Biomolecular Characterization Dynamic: Center will be place where scientists and engineers can work together on multidisciplinary approaches to improve healthcare through new drugs, diagnostics and medical devices
Ambry Genetics	Invicro	<ul style="list-style-type: none"> Objective: Offer customized genomics and imaging services for biotechnology and pharmaceutical industry, with specialized focus on oncology and neurodegenerative diseases Dynamic: Combine Invicro's imaging services and software with Ambry's genomics services Both firms owned by Konica Minolta via latter's 2017 acquisition of Ambry but operate as independent subsidiaries
Avalon GloboCare	Da An Gene (China)	<ul style="list-style-type: none"> Objective: Accelerate exosome-based in vitro diagnostic product development and commercialization Dynamic: Strategic alliance combining Avalon's exosome technology with Da An Gene's proprietary core technology platform of fluorescent-quantitative PCR diagnostic reagents
Oxford Biodynamics	Holos Life Sciences	<ul style="list-style-type: none"> Objective: Develop non-invasive epigenetic biomarkers linked to sports-related concussions Dynamic: Holos to supply participants' blood samples and Oxford to provide its EpiSwitch epigenetic biomarkers development platform which partners will use to establish and monitor epigenetic changes and potential physiological reprogramming caused by a sports-related concussion
Access Bio	Atomo Diagnostics	<ul style="list-style-type: none"> Objective: Provide point-of-care HIV testing in global markets Dynamic: Atomo to make its AtomoRapid lateral flow platform available for use with Access Bio rapid test detecting HIV antibodies from single drop of blood from a fingertip
Foundation Medicine	European Organisation for Research and Treatment of Cancer (EORTC)	<ul style="list-style-type: none"> Objective: Provide cancer genomic profiling tests to determine patient eligibility for clinical trials Dynamic: Foundation Medicine to use its genomic profiling assays to provide testing services for EORTC's Screening Patients for Efficient Clinical Trial Access (SPECTA) program
Biodesix	Colorado Cancer Center	<ul style="list-style-type: none"> Objective: Develop a blood-based assay to identify non-small cell lung cancer patients likely to respond to certain immunotherapies Dynamic: CU Cancer Center research lab to analyze prospectively collected tissue samples with matched plasma from NSCLC patients Biodesix to use results in its development of test for PD-L1
SkylineDx	Mayo Clinic	<ul style="list-style-type: none"> Objective: Develop diagnostic tests to improve clinical decision-making for melanoma patients Dynamic: Leverage Skyline's informatics expertise to further optimize Mayo Clinic algorithm identifying risk factors for metastasis
Nebion	Qlucore	<ul style="list-style-type: none"> Objective: Provide data analysis support for clinical research Dynamic: Deepening of collaboration began in 2014 allowing for combined use of Qlucore's Omics Explorer and Nebion's Geneinvestigator by scientists for data storage, pre-processing, analysis, interpretation and comparisons with public datasets, among other applications
PlexBio	Denka	<ul style="list-style-type: none"> Objective: Accelerate detection of infectious disease and multidrug resistance Dynamic: Expand existing collaboration to include codevelopment of a molecular diagnostic platform for infectious disease testing New system to leverage PlexBio's multiplex nCode MicroDisc technology and initially focus on tests for sepsis and multidrug resistance
Prometheus Research	Stanford University	<ul style="list-style-type: none"> Objective: Create genetic registry as part of sleep medicine study Dynamic: Prometheus to join and collate highly disparate data from multiple sources in support of Stanford Technology Analytics and Genomics in Sleep (STAGES) study collecting and analyzing sleep data alongside biological samples from 30,000 patients

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Tempus	NYU School of Medicine	<ul style="list-style-type: none"> Objective: Develop personalized pancreatic cancer treatments Dynamic: Tempus to analyze data from roughly 500 pancreatic cancer patients and use NGS tests to generate additional genomic data to identify genetic patterns for use in predicting patient response to different therapies Recent academic collaborators of Tempus include Vanderbilt, Ohio Univ., Univ. of Penn. Abramson Cancer Center and Mayo Clinic
Biocartis	Immunexpress	<ul style="list-style-type: none"> Objective: Develop Immunexpress' Septicyte tests for use on Biocartis' Idylla platform Dynamic: Tests based on biomarker signatures that gauge response of patient's immune system to infections Immunexpress to lead commercialization, starting with US and Europe
UgenTec	MDxHealth	<ul style="list-style-type: none"> Objective: Develop artificially intelligent software to support interpretation of molecular test results for MDxHealth's ConfirmMDx and SelectMDx prostate cancer tests Dynamic: "This [automation step] will... also provide our SelectMDx IVD customers with an advanced software they can use [to] support and standardize drafting of result reports," according to MDxHealth CEO
DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	Distributor	Deal Summary
SenzaGen	Eurofins BPT Munich	<ul style="list-style-type: none"> Products: SenzaGen's GARD skin allergy tests Territory: Global Covers both GARDskin allergic contact dermatitis test, and GARDpotency add-on test subcategorizing sensitizing compounds as strong/moderate/non-sensitizing
OncoDNA	NM Genomix	<ul style="list-style-type: none"> Products: OncoDNA's tumor profiling products (specific products not disclosed) Territory: Bulgaria
OncoDNA	Genext	<ul style="list-style-type: none"> Products: OncoDNA's OncoDeep solid tumor test, OncoTrace and OncoSelect liquid biopsy tests, OncoStrat&Go solid and liquid biopsy combination, OncoKDM data interpretation and reporting software Territory: Russian Federation
BioPorto	Roche	<ul style="list-style-type: none"> Product: BioPorto's neutrophil gelatinase-associated lipocalin (NGAL) test for use on Cobas c 501 and Cobas c 502 analyzers Territory: Global
BioGx	Launch Diagnostics	<ul style="list-style-type: none"> Products: Assays produced by BioGx's European subsidiary Territories: UK, Ireland
BioGx	AxonLab	<ul style="list-style-type: none"> Products: BioGx's entire CE-IVD product line, plus laboratory-use-only products Territories: Austria, Belgium, Czech Republic, Germany, Slovenia, Switzerland, Croatia
Sysmex	McKesson Medical-Surgical	<ul style="list-style-type: none"> Product: Sysmex's new automated hematology analyzer Territory: Not disclosed Exclusive distribution deal
VHLGenetics	PharmaDNA	<ul style="list-style-type: none"> Products: Genetic assays Territories: Estonia, Latvia, Lithuania
VHLGenetics	Progènes	<ul style="list-style-type: none"> Products: Animal applications Territory: France
VHLGenetics	Agrotis	<ul style="list-style-type: none"> Products: Genetic assays under Laboratory Genetics and Services brand name Territory: Italy
VHLGenetics	Inno Laboratório Veterinário	<ul style="list-style-type: none"> Products: Cat and dog products Territory: Portugal
Amoy Diagnostics	Medikonía	<ul style="list-style-type: none"> Products: Amoy Diagnostics' molecular diagnostic tests Territories: Macau, Hong Kong
Technogenetics	Immunodiagnostic Systems	<ul style="list-style-type: none"> Technogenetics' automated assay kits for detecting and monitoring autoimmune and infectious diseases Territory: Global 10-year term Products to be sold under IDS brand
Lucigen	GeneSuz Biochemical & Genetics	<ul style="list-style-type: none"> Products: Not specified Territory: Turkey
Lucigen	Diagnostech	<ul style="list-style-type: none"> Products: Not specified Territory: South Africa

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	Distributor	Deal Summary
Lucigen	Albiogen	<ul style="list-style-type: none"> Products: Not specified Territory: Russia
Lucigen	Gene Target Solutions	<ul style="list-style-type: none"> Products: Not specified Territory: Australia
LICENSES		
Licensor	Licensee	Deal Summary
Dynamic Combinatorial Chemistry	DNA Script	<ul style="list-style-type: none"> Property: Novel DNA building block for use in enzymatic DNA synthesis Exclusive
University of California, San Francisco	Vela Diagnostics	<ul style="list-style-type: none"> Property: Two methods for enriching rare sequences Vela to use the technologies to develop oncology and infectious disease tests, including for cell-free DNA and RNA testing and microbiology tests
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Service	Client	Deal Summary
Thermo Fisher Scientific	OpGen	<ul style="list-style-type: none"> OpGen to use Thermo Fisher's real-time PCR technology in its Acuitas AMR Gene Panel tests
Abbott	Angle	<ul style="list-style-type: none"> Abbott to supply PathVysion HER-2 DNA FISH kits for Angle study investigating analysis of circulating tumor cells Aim of Angle study is to demonstrate that its Parsortix system can be used to harvest CTCs from blood of metastatic breast cancer patients
Illumina	Harvard Pilgrim Health Care	<ul style="list-style-type: none"> Illumina to provide noninvasive prenatal testing to women with average-risk pregnancies Value-based contract under which Harvard Pilgrim will cover NIPT for average-risk pregnancies and Illumina will reimburse Harvard Pilgrim if one-year costs of testing exceed pre-established baseline
Exosome Diagnostics	FedMed	<ul style="list-style-type: none"> Exosome Diagnostics to provide its ExoDx Prostate test via FedMed, a US PPO with 40 million members as a covered benefit

FDA Watch: Personalized Medicine Approvals Continue to Flow

As the agency wrapped up comments on proposed changes to CLIA waiver procedures, new product approvals were the big story of February.

Record Year for Personalized Medicine Approvals

First, the big picture. In 2017, the FDA approved 16 new personalized medicine products, 34% of all new of all new drugs, agents, or therapeutic biologics approved during the year, reports the Personalized Medicine Coalition (PMC). Key approvals included:

- ▶ Expanded approval of Keytruda to all tumor types, the first approval of an oncology drug based on a biomarker rather than location in the body;
- ▶ The first approval of DTC marketing of health-related genetic tests—23andMe's Personal Genome Service Genetic Health Risk tests;
- ▶ Approval of personalized medicine biosimilar for Herceptin (trastuzumab); and
- ▶ Joint FDA approval and CMS coverage decision for Foundation Medicine's NGS-based FoundationOne CDx test.

A Blood Test Breakthrough

Continuing the new approval momentum, on Valentine's Day, the FDA announced a new milestone: the first agency approval of a blood test for use in diagnosing concussions. The Brain Trauma Indicator, marketed by Banyan Biomarkers Inc., measures two proteins associated with concussion when detected in high levels via CT scan. The new assay is blood-based and has been approved for use by physicians in ruling out concussion. Abbott is among the other firms reported to be developing their own blood test for detecting the proteins without CT scan.

Flu Tests

Meanwhile, as the U.S. struggles with its nastiest flu season in years, the FDA approved five different products for the qualitative detection of influenza, including:

- ▶ QuickVue Influenza A+B, an assay from Quidel that detects and differentiates between influenza types A and B in 10 minutes, which the agency reclassified as a class II rapid influenza diagnostic test;
- ▶ Two different rapid, instrument influenza detection and A vs. B differentiation tests from Alere, now part of Abbot;
- ▶ Xpert Xpress Flu, Cepheid's new test system and molecular test for detecting A and B influenza from either nasopharyngeal or nasal swabs; and
- ▶ Mesa Biotech's Accula Flu A/Flu B test which runs on the firm's Accula system.

Other New FDA Approvals

Meanwhile, here's a rundown of the other key new FDA approvals announced from mid-January through late February:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Guardant Health	Expedited access pathway designation for Guardant360 liquid biopsy assay
Banyan Biomarkers Inc.	Brain Trauma Indicator, first blood test approved for diagnosing concussion
Quidel	QuickVue Influenza A+B assay to detect and differentiate influenza types A and B, approved after being reclassified as a class II rapid influenza diagnostic test
Roche	Approval of multiplex Factor II and Factor V test which does real-time PCR analysis for mid- to high-volume labs, for use on Cobas 4800 system
Becton Dickinson	Approval of automated BD Onclarity HPV molecular test to detect 14 types of high-risk human papilloma virus from specimens collected in the BD SurePath liquid-based cytology vial for cervical cancer screening
Becton Dickinson	Approval of Phoenix automated microbiology system for <i>in vitro</i> quantitative determination of antimicrobial susceptibility
Vela Diagnostics	Approval of Sentosa SA201 HSV-1/2 PCR herpes simplex virus test detecting viral DNA from oral or anal skin lesions
Alere	Approval of Alere i Influenza A & B for qualitative detection and differentiation of influenza A and influenza B in patients with respiratory infection symptoms
Alere	Approval of Alere i Influenza A & B 2, rapid, instrument-based isothermal test for qualitative detection and differentiation of influenza A and influenza B in patients with respiratory infection symptoms

NEW FDA APPROVALS, Cont'd.

Manufacturer(s)	Product(s)
Alere	Approval of Alere i Strep A, rapid, instrument-based isothermal test for qualitative detection of Group A Strep from throat swab specimen
Alere	Approval of Alere i RSV, rapid, instrument-based isothermal test for qualitative detection and differentiation of respiratory syncytial virus viral RNA in patients with respiratory infection symptoms
Cepheid	Approval of Xpert Carba-R Assay, automated real-time PCR diagnostic test for qualitative detection of gene sequences from rectal or perirectal swab specimens or isolates of pure cultures of gram-negative bacteria that are not susceptible to carbapenem
Cepheid	Approval and CLIA waiver for Xpert Xpress Flu test used in near-patient settings to detect both A and B strains of influenza from either nasopharyngeal or nasal swabs
Techlab	Approval of Campylobacter Chek test for detecting campylobacteriosis
Techlab	Approval of Campylobacter Quik Chek test for detecting campylobacteriosis
Myriad Genetics	Expanded approval of BRACAnalysis CDx test for identifying breast cancer patients with germline BRCA mutations and who are thus most likely to benefit from Lynparza
Inova Diagnostics	Approval of Quanta Flash Calprotectin assay for detection of fecal calprotectin in human stool samples
Mesa Biotech	Approval and CLIA waiver for Accula Flu A/Flu B test to detect and distinguish influenza A and B from nasal swab specimens
Siemens Healthineers	Approval of blood urea nitrogen (BUN) and total carbon dioxide (TCO2) point-of-care tests to diagnose kidney diseases and metabolic imbalances run on firm's handheld Epc blood analysis system
Meso Scale Diagnostic	Approval of conventional C-reactive protein assay, based on firm's Multi-Array technology
Sebia	Approval of Hydrashift 2/4 daratumumab assay for evaluating multiple myeloma patients treated with Darzalex
Hologic	Approval of Aptima HBV Quant Assay for quantitation of hepatitis B viral load on firm's Panther system
Qiagen	Expanded approval of Ipsogen JAK2 RGQ PCR Kit to diagnosis of all myeloproliferative neoplasms
Qiagen	Extended indications for use of firm's Therascreen EGFR RGQ PCR kit to guide the use of Boehringer Ingelheim's Gilotrif (afatinib) for first-line treatment of patients with metastatic non-small cell lung cancer harboring non-resistant EGFR mutations
Bio-Rad Laboratories	Approval of IH-Incubator L and IH-Centrifuge L instruments for use with firm's IH-System Gel Reagents for manual blood typing
Diazyme Laboratories	Approval of fully automated two-reagent EZ Vitamin D assay for use on validated clinical chemistry analyzers

During the period, the following FDA CLIA waivers were announced:

NEW FDA CLIA WAIVERS

Manufacturer(s)	Product(s)
ACON Laboratories Inc.	Mission Cholesterol Pro Monitoring System (Mission Cholesterol Pro Test Cartridges)
Cepheid	Xpert Xpress Flu test
Mesa Biotech	Accula Flu A/Flu B

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS

Manufacturer(s)	Product(s)
Qiagen	Approval of Therascreen PITX2 RGQ PCR kit
Sophia Genetics	Approval of molecular diagnostics test to detect leukemia and other hematological diseases
GenDx	Approval of chimerism monitoring products for use in stem cell or bone marrow transplantation
Roche	Approval of Cobas TV/MG test for use on Cobas 6800/8800 systems
Mesa Biotech	Approval of PCR point-of-care infectious disease testing platform

Other international clearances announced in the past month:

Manufacturer(s)	Product(s)	Product(s)
Thermo Fisher Scientific	Canada	Class III Medical Device System License to firm's BRAHMS business for four automated immunofluorescent assays used as prenatal screening aids
Siemens Healthineers	Canada	Approval to market its Symbia Intevo Bold SPECT/CT system
Premaitha Health	Brazil	Approval of Iona noninvasive prenatal test as <i>in vitro</i> diagnostic
Qiagen	Japan	Approval of QuantiFeron-TB Gold Plus (QFT-Plus) as <i>in vitro</i> diagnostic to detect tuberculosis infection
Amoy Diagnostics	China	Approval of SuperARMS EGFR mutation analysis test as companion diagnostic for EGFR TKI-based non-small cell lung cancer drugs
NGeneBio	South Korea	Approval of BRCAaccuTest for clinical use
GenDx	South Korea	Approval of NGSgo human leukocyte antigen typing workflow for use in transplant medicine
Curetis	Singapore	Approval of Unyvero test cartridge for diagnosing pneumonia in hospital patients
Vela Diagnostics	Singapore	Approval of Real-Time PCR-based Sentosa SA ZIKV RT-PCR Test for <i>in vitro</i> diagnostic use



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