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DX Earnings Report: Lab Companies Finish 2018 Strong but Growth Slows for Established Firms

The diagnostics industry capped a robust 2018 with most companies posting strong fourth quarter results. Of course, every silver lining has a cloud. While widespread, gains were smaller than in 2017, particularly among the blue blood establishment. This includes testing behemoths like Abbott, LabCorp and Quest that felt the sting of PAMA and other reimbursement cuts.

Gainers

Of the 28 companies that had reported Q4 earnings by the date we went to press, all but three reported growth during the period. And

Continued on page 2

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

The past few weeks have brought snow to parts of the country that don't usually see the white stuff, and a flurry of diagnostic deals. Although some pundits continue to speculate about a business slowdown, the outlook remains positive as winter inches toward spring. Here's a quick overview of the past month's activity.

M&A

Thermo Fisher Scientific has been actively selling off its anatomical pathology business. Tokyo-based PHC Holdings (formerly known as Panasonic Healthcare Holdings) will acquire the business for \$1.14 billion in cash, in order to expand its growing healthcare and diagnostic portfolio.

Meanwhile, Thermo Fisher Scientific is moving into other areas, acquiring a 9% stake in molecular diagnostics company

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■ Dx/Tools Venture Capital Keeps Flowing Despite Decline in Early-Stage Investment, *from page 1*

although only two of the firms reporting Q4 growth fell short of their average Wall Street estimate, they were notable, including Abbott, which reported flattish 1% growth in molecular diagnostics sales, and Qiagen which is still settling in after divesting business lines to concentrate on core NGS and molecular testing.

Some of the firms that met their Wall Street targets had a less than stellar Q4, including Luminex which despite exceeding its \$79.4 million top-line target by a solid \$1.7 million, shocked the market by coming in way short on the bottom line with \$0.04 rather than the expected \$0.09 earnings per share. It was also a relatively tough quarter for LabCorp which hit its \$2.79 billion target on the nose thanks to 10% growth in its recently acquired Covance drug development business which offset a 3% decline in core diagnostics revenues.

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The Hottest Companies

Recent acquisitions also helped Becton Dickinson (C.R. Bard), Danaher (Cepheid), Myriad Genetics (Counsyl) and PerkinElmer (Euroimmun) post double-digit growth (exception: Danaher grew 5%). Arguably, though, the most impressive performances came in the form of organic growth by the relatively small molecular and genomics test firms including:

- ▶ Exact Sciences which grew 71% for the year (\$454.5 million) thanks to the red-hot Cologuard colon cancer test;
- ▶ Consumer genetic testing firm Invitae which posted 78% growth for the quarter and over 200% growth for the year;
- ▶ NeoGenomics where genetic cancer and other testing volume continues to grow by double digits almost every quarter; and
- ▶ Veracyte which increased sales by 32% for the quarter and 28% for the year and is now just under \$100 million in revenues.

Decliners

Three companies had declining sales in the quarter, including:

- ▶ Meridian Bioscience was down 2% to \$51.5 million overall (2% in diagnostics), which company officials attributed to “volume pressures in molecular products and pricing in certain gastrointestinal lines” which offset the modest gains in immunoassay and blood chemistry diagnostics revenues;
- ▶ Quest Diagnostics declined 1% thanks to PAMA Medicare price cuts, increased payor denials and uncollectible patient balances—although Quest did grow 2% for the overall year, its \$7.53 billion in revenues came below the Wall Street estimate of \$7.57 billion; and
- ▶ OraSure Technologies fell 3% in the quarter which belied its solid 9% growth for the entire year (\$181.7 million, or \$2.4 million above the \$179.3 million average Wall Street estimate).

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Keep in mind that the reported results don't include perennial revenue loser Pacific Biosciences which is in the process of being acquired by Illumina.

Diagnostics Earning Reports 4Q 2018, Total 2018 (At least \$10 million in sales—of companies to report as of press date)					
COMPANY	4th QUARTER			2018 TOTALS	DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street		
Abbott Laboratories	\$7.77 billion	+2% (7% on comparable operation basis)	\$7.82 billion	\$30.58 billion, up 12% but below \$30.65 billion Wall Street estimate	DX Q4 revenues up 3% (7% organic) to \$1.96 billion; Yearly DX revenues up 34% (7% organic) to \$7.50 billion with 5% growth in molecular + 8% growth in core lab
Agilent Technologies	\$1.28 billion	+6%	\$1.27 billion	Results are for firm's Q1 2019	DX & Genomics up 13% to \$235.0 million thanks to strong pharma + clinical markets
Becton Dickinson	\$4.16 billion	+35% (counting newly acquired C.R. Bard)	\$4.11 billion	Results are for firm's Q1 2019	DX systems relatively flat at \$382 million despite strength in instrumented microbiology platforms, including blood culture and ID-AST, and BD Max molecular platform
Bio-Techne	\$174.5 million	+13%	\$170.2 million	Results are for firm's Q1 2019	DX & Genomics up 6% to \$39.3 million with inclusion of Exosome Diagnostics EPI assay in NCCN guidelines poised to drive further growth
Danaher	\$5.36 billion	+5%	\$5.32 billion	\$19.89 billion, up 9% and above Wall Street \$19.84 billion estimate	DX for year up 7% to \$6.26 billion driven by double-digit Cepheid growth and strong sales in China
Exact Sciences	\$143.0 million	+64%	\$134.8 million	\$454.5 million, up 71% and above Wall Street \$445.7 million estimate	Cologuard colon cancer tests up to 292K for Q4 (4.1% market share) and 934K for year—although average revenue per test down 2% to \$486 in Q4
Fluidigm	\$32.3 million	+17%	\$30.6 million	\$113.0 million, up 11% and above \$111.2 million Wall Street estimate	Mass cytometry grows 48% to \$19.1 million offsetting 11% dip in microfluidics instruments, consumables and services to \$13.2 million
GenMark Diagnostics	\$19.4 million	+21%	\$19.1 million	\$70.8 million, up 35% and above \$70.4 million Wall Street estimate	ePlex systems up 110% to \$12.1 million for Q4 (42 placed)
Genomic Health	\$104.6 million	+22%	\$101.5 million	\$394.1 million, up 18% and above \$391.1 million Wall Street estimate	Increases attributable in part to switch to ASC 606 accounting standard; Oncotype tests up to 35,530 v. 31,990 in Q4 and 136,380 vs. 126,730 for year
Hologic	\$830.7 million	+5%	\$817.9 million	Results are for firm's Q1 2019	DX revenues up 4% to \$296.6 million driven by 11% growth in molecular diagnostics (\$164.3 million) + 13% growth in blood screening (\$14.2 million) which offset 4% dip in cytology + perinatal (\$118.1 million)

Continued on page 4

■ Dx/Tools Venture Capital Keeps Flowing Despite Decline in Early-Stage Investment, *from page 3*

Diagnostics Earning Reports 4Q 2018, Total 2018 (At least \$10 million in sales—of companies to report as of press date)					
COMPANY	4th QUARTER			2018 TOTALS	DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street		
illumina	\$867 million	+11%	\$863.5 million	\$3.33 billion, up 22%	Sequencing systems up 21% to \$159 million for Q4 including 100+ NovaSeq instruments + \$466 million in sequencing consumables
Invitae	\$45.4 million	+78%	\$40.8 million	\$147.7 million, more than double 2017 + above \$143.1 million Wall Street estimate	Q4 Average revenue per test up \$518 vs. \$490 in Q3; 290K billable tests accounting for \$144.6 million in revenues for year
Laboratory Corp. of America	\$2.79 billion	+2%	\$2.79 billion	\$11.33 billion, up 8% including \$7.03 DX (up 2%)	Q4 DX revenues hurt by PAMA (100 basis points), bad weather + divestitures; Covance up 25% to \$4.31 billion for year
Luminex(1)	\$81.1 million	+4%	\$79.1 million	\$315.8 million, up 3% and above \$313.6 million Wall Street estimate	Assay revenues for Q4 dip 11% to \$37 million; net losses for quarter driven by loss of LabCorp Women's Health + costs of closing MilliporeSigma deal
Meridian Bioscience	\$51.5 million	-2%	\$53.1 million	Results are for firm's Q1 2019	DX down 2% to \$36.7, including 16% dip in molecular tests and pricing pressure on GI products; immunoassay + blood chemistry up testing up 2%
Myriad Genetics	\$216.8 million	+15%	\$216.7 million	Results are for firm's Q2 2019	Molecular DX up 17% to \$203 million driven by 4% growth in hereditary cancer (\$126.7 million) + 12% growth in newly acquired (via Counsyl acquisition) prenatal
NeoGenomics (2)	\$76.5 million	+25%	\$71.4 million	\$276.7 million, up 15% + above \$271.3 million Wall Street estimate	Testing up 23% (\$65.9 million) in Q4 and 14% (\$241.9 million) for year thanks to volume growth, including Genoptix
OraSure Technologies	\$50.2 million	-3%	\$47.8 million	\$181.7 million, up 9% + above \$179.3 Wall Street estimate	Q4 loss due to dips in product sales including molecular collection systems (-15%, \$24 million) + genomics (-18%, \$23.5 million); for year, molecular collection grew 15% to \$86.5 million, genomics grew 11% to \$79.8 million + microbiome grew 92% to \$6.7 million
PerkinElmer	\$756.3 million	+18%	\$746.6 million	\$2.78 billion, up 23% + above \$2.77 billion Wall Street estimate	4Q DX up 53% to \$296.5 million driven by reproductive health, immunodiagnostics + Euroimmun acquisition; yearly DX up 59% to \$1.69 billion
Qiagen	\$403.2 million	+2%	\$408.6 million	\$1.50 billion, up 6% but just below \$1.51 billion Wall Street estimate	Molecular DX up 5% to \$194 million in Q4 + up 8% to \$732 million for year; applied testing for year flat at \$137 million

Diagnostics Earning Reports 4Q 2018, Total 2018 (At least \$10 million in sales—of companies to report as of press date)					
COMPANY	4th QUARTER			2018 TOTALS	DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street		
Quest Diagnostics	\$1.84 billion	-1%	\$1.88 billion	\$7.53 billion, up 2% but below \$7.57 billion Wall Street estimate	5.5% dip in revenues per requisition in Q4 due to PAMA, increased payor denials, uncollectible patient balances + accounting adjustment; test volume for year up 1.1% and lab pricing headwinds just below 1.5%
Quidel	\$132.6 million	+15%	\$132.1 million	\$522.3 million, up 88% and above \$521.6 million Wall Street estimate	In Q4, cardiac immunoassay up 34% (\$62.9 m), rapid immunoassay up 3% (\$50.4 m), molecular DX up 30% (\$5.8 m); for full year, cardiac immunoassay up from \$47 to \$266.5 m, rapid immunoassay up 11% (\$165.1 m), molecular DX up 43% (\$19.4 m)
Roche Diagnostics	\$3.5 billion	+10%	NA	\$12.88 billion, up 7%	Yearly growth driven by increases of 5% in molecular DX (\$2.02 billion), 4% in virology (especially HIV screening), 9% in blood screening + 8% in HPV screening
Siemens Healthineers	\$3.76 billion	+3%	NA	Results are for firm's Q1 2019	DX up 4% to \$1.096 billion driven by sales of Atellica Solution platform
Thermo Fisher Scientific	\$6.51 billion	+8%	\$6.23 billion	\$24.36 billion, up 16% + above \$24.08 billion Wall Street estimate	In Q4, Specialty DX up 4% (5% organic) to \$950 million led by transplant DX + Immuno-DX while Lab products + services up 8% to \$2.6 billion; for year, Specialty DX up 7% to \$3.72 billion + Lab products + services up 28% to \$10.04 billion
Twist Bioscience	\$11.5 million	+267%	\$9.7 million	Results are for firm's Q1 2019	\$7.7 million from synthetic biology + \$3.8 million from genomics
Veracyte	\$25.8 million	+32%	\$24.4 million	\$92.0 million, up 28% and above \$90.6 million Wall Street estimate	Genomic test volume up 28% in Q4 + 22% for year (31,710 tests)
Waters	\$715 million	+4%	\$702.8 million	\$2.42 billion, up 5% and above \$2.41 billion Wall Street estimate	Growth driven by demand for liquid chromatography systems which offset flat mass spectrometry sales

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

Notes

(1) While beating Wall Street average estimates for revenues, Luminex's \$0.04 EPS for Q4 surprisingly missed the Wall Street target of \$0.09, sending share prices sharply down

(2) NeoGenomics' high growth partly attributable to acquisition of Genoptix

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FDA Watch: Agency Finalizes Guidance on Coordinated Antimicrobial Drug & Test Development

Last month, the FDA issued [final guidance](#) to help manufacturers of antimicrobial drugs and antimicrobial susceptibility tests (ASTs) devices coordinate development and bring the products to market at roughly the same time.

What the Guidance Says

The challenge for co-developers is that antimicrobial drugs and ASTs are subject to different regulatory pathways and timelines. While pledging to keep review independent, the guidance states that the FDA “intends to facilitate clearance of the AST device coincident with or shortly after drug approval, as appropriate.” The guidance calls on sponsors to collaborate early to ensure simultaneous or near simultaneous of the drug and the device.

“Drug sponsors may benefit from this collaboration by having access to AST device technology during clinical studies of the antimicrobial drug, and AST device manufacturers may benefit by having access to clinical isolates obtained during the drug development process that may aid in device validation,” according to the agency.

Coordinated development may be appropriate for a variety of AST devices, including dilution panels, disc diffusion or elution, gradient diffusion devices and molecular tests that can identify mutations linked to decreased antimicrobial susceptibility. The FDA advises drugmakers to make their therapies available to multiple device manufacturers early on to facilitate parallel development and commercial availability of the tests and treatment. Meanwhile, it suggests that device makers:

- ▶ Use the agency’s Q-Submission Program to garner its feedback throughout the process;
- ▶ Submit a coordinated development plan for the test shortly after the drugmaker submits a new drug application; and
- ▶ Submit for 510(k) clearance for the device four-to-six weeks before the drug is slated for approval.

New FDA Approvals

Here’s a look at the key FDA approvals announced at the end of January through February:

NEW FDA APPROVALS	
Manufacturer(s)	Product(s)
HemoCue	510(k) clearance for HemoCue Hb 801 System to assess hemoglobin levels at point of care in and quantitatively measure hemoglobin in capillary or venous whole blood
Bio-Rad Laboratories	Clearance for QXDx BCR-ABL %IS Kit, liquid biopsy assay and Droplet Digital PCR system for monitoring treatment response in chronic myeloid leukemia
BioDirection	Breakthrough device designation for Tbit System for traumatic brain injury
Fujirebio Diagnostics	Breakthrough device designation for Lumipulse G -Amyloid Ratio (1-42/1-40) quantitative test for assessing older patients for cognitive decline

NEW FDA APPROVALS	
Manufacturer(s)	Product(s)
Grifols	Clearance for Procleix assay to detect Babesia, a malaria-like parasite transmitted by tick bites and donated blood
Opko Health	Approval for point-of-care Sangia Total Prostate Specific Antigen (PSA) quantitatively measuring total PSA in whole blood
C2N Diagnostics	Breakthrough device designation for brain amyloidosis blood test for use as a screen for brain amyloid pathology in patients assessed for Alzheimer's disease
Kurin	510(k) clearance for Kurin Lock blood culture collection product with a peripheral IV infusion set
Oxford Gene Technology	<i>de novo</i> classification for 8 Cytocell Aquarius Haematology fluorescence in situ hybridization probes for acute myeloid leukemia and myelodysplastic syndromes
Sysmex America	Clearance for XN-L Automated Hematology Analyzer, which classifies whole blood and body fluid parameters by via electrical impedance, laser light scattering and fluorescent labeling
Beckman Coulter	Clearance for use of HbA1c Advanced assay on firm's DxC 700 AU clinical chemistry analyzer
Thermo Fisher Scientific	Clearance for use of Sensititre MIC and Breakpoint Susceptibility System for clinical susceptibility testing
ILine Microsystems	Clearance for use of microINR System to determine patient's International Normalized Ratio (INR)
Immualysis	Clearance for use of Sefria PCP Oral Fluid Enzyme Immunoassay with firm's Quantisal II oral fluid collection device
Qualigen	Clearance for use of FastPack IP Sex Hormone Binding Globulin Immunoassay running on firm's FastPack system

New CE Marks & Global Certifications

Notable European CE certifications during the period:

NEW CE CERTIFICATIONS IN EUROPE	
Manufacturer(s)	Product(s)
Hologic	CE marking for Aptima HIV-1 Quant Dx Assay for testing dried blood spots
Hologic	CE marking for Aptima HIV-1 Quant Dx Assay for early diagnosis of HIV in infants
Abbott	CE marking for Determine HBsAg 2 rapid diagnostic test for detecting hepatitis B surface antigen
Altona Diagnostics	CE-IVD marking for AltoStar HCV RT-PCR Kit 1.5 to detect and quantify hepatitis C virus-specific RNA with genotypes 1 to 6
Qiagen	CE marking for hepatitis B and hepatitis C assays

Other international clearances announced during the period:

International Clearances		
Manufacturer(s)	Country(ies)	Product(s)
Bioneer	South Korea	Ministry of Food and Drug Safety approval for AccuPower HIV-1 Quantitative RT-PCR Kit to quantify HIV-1 viral RNA from blood samples using firm's ExiStation system
Promega	Japan	Ministry of Health, Labour and Welfare approval for companion diagnostic for Merck's cancer immunotherapy Keytruda (pembrolizumab) based on Promega's microsatellite instability (MSI) technology

■ Diagnostic Deals, from page 1

Yourgene Health (formerly known as Premaitha Health) by exercising warrants it held in the company. Thermo Fisher could take ownership of up to 17% in Yourgene if it chooses to exercise other warrants it holds. The agreement between the companies calls for Yourgene to exclusively promote its noninvasive prenatal testing products on Thermo Fisher’s Ion Torrent next-generation sequencing systems in the Southeast Asia markets for three years.

Among deals that closed this period are the acquisition of molecular solutions company Invisible Sentinel by BioMérieux, and the acquisition of Boyce & Bynum Pathology Laboratories by Quest Diagnostics. Details for these and other M&As are provided in the chart below.

Strategic Alliances

Among new strategic alliances are several involving genetic testing, a field that continues to grow. And not all alliances are between businesses.

Horizon Discovery has entered into an exclusive strategic partnership with Rutgers University to develop and commercialize novel gene editing technology, known as base editing. The technology, which will augment Horizon’s research tools and services, potentially has applications in the development of new cell therapies. Details about this and other alliances are provided in the chart below.

Here’s a summary of key diagnostic deals from late January through late February:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
PHC Holdings	Thermo Fisher Scientific’s anatomical pathology business	<ul style="list-style-type: none"> • Price: \$1.14 billion cash dilutive to full-year 2019 adjusted EPS of approximately \$.10 • Status: Definitive agreement with expected closing in 2Q • Anatomical pathology business is part of Thermo Fisher’s Specialty Diagnostics segment with \$350 million in annual revenues via sales of microscope slides, instruments and consumables • PHC Holdings is a diagnostics, diabetes care, life sciences and healthcare IT company based in Tokyo
BioMérieux	Invisible Sentinel	<ul style="list-style-type: none"> • Price: Roughly \$75 million to strengthen its position in food pathogen testing and • Status: Closed • Acquisition of US-based food testing firm bolsters BioMérieux’s position in food pathogen testing and spoilage organism detection
Quest Diagnostics	Boyce & Bynum Pathology Laboratories	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of diagnostic and clinical lab services in Midwest • Separate agreement makes Boyce & Bynum Pathology Professional Services the exclusive pathology provider for Quest in Missouri and a preferred pathology provider in greater Midwestern region
Beckman Coulter Life Sciences	Labcyte	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of privately held liquid handling firm and developer of Echo, acoustic droplet ejection technology that uses sound energy for contactless transfer of samples and reagents
Icon	MolecularMD	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of molecular diagnostic lab specializing in development of precision medicines in oncology

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
ArcherDX	Baby Genes	<ul style="list-style-type: none"> • Price: Undisclosed but purchase made with cash reserves • Status: Agreement signed but no closing date announced • Baby Genes to operate as wholly owned subsidiary and market its genetic carrier screening tests under name ArcherDX Clinical Services • Existing ArcherDX R & D functions to remain in firm's Boulder, CO lab • Commercial genetic profiling services for both companies to be consolidated in Baby Genes' Golden, CO lab
Gestalt Diagnostics	Peak Medical	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of lab integration services firm bolsters Gestalt's digital pathology integrations services division

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner 2	Deal Summary
Ares Genetics (subsidiary of Curetis)	Qiagen	<ul style="list-style-type: none"> • Objective: Develop bioinformatics products and services for antimicrobial resistance (AMR) research based on ARESdb database • Dynamic: Qiagen gets exclusive license for AMR product development and commercialization + non-exclusive license to develop and commercialize molecular research assays using ARESdb content with its own NGS and PCR technologies
Genspeed	Virogates	<ul style="list-style-type: none"> • Objective: Develop rapid point-of-care test for medical risk classification • Dynamic: Test designed to detect C-reactive protein, biomarker of inflammation, and suPAR, protein biomarker of inflammation and immune system activity, from finger prick within 10 minutes
Genomenon	Diploid	<ul style="list-style-type: none"> • Objective: Improve genome interpretation for rare disease diagnostics • Dynamic: Diploid to integrate Genomenon's Mastermind genomic search engine into its Moon diagnostic software • Non-exclusive also covers future products
Genomica	HuaSin	<ul style="list-style-type: none"> • Objective: Develop fully automated HPV genotyping assay platform for China market • Dynamic: HuaSin gets exclusive rights to develop and produce platform using Genomica's technology • HuaSin to seek China Food and Drug Administration ahead of a 2021 launch
GenomeDx Biosciences (now called Decipher Biosciences)	Dendreon Pharmaceuticals	<ul style="list-style-type: none"> • Objective: Identify patients likely to respond to Dendreon's prostate cancer therapy Provenge (sipuleucel-T) • Dynamic: Decipher assay to be used to assess biological behavior of tumors from patients in phase III study of Provenge • Study also to evaluate tumor gene expression signatures potentially associated with Provenge response

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner 2	Deal Summary
AbCellera	Novartis	<ul style="list-style-type: none"> • Objective: Discover antibody-based drug candidates from natural immune responses • Dynamic: AbCellera to use its antibody discovery platform to up to 10 targets Novartis selects • Novartis to provide AbCellera technology access payments, research funding, downstream milestone payments and royalties on net product sales
BioMérieux	Entasis Therapeutics (spinoff of AstraZeneca)	<ul style="list-style-type: none"> • Objective: Develop drug to combat carbapenem-resistant A. baumannii infections • Dynamic: Incorporate BioFire FilmArray multiplex pneumonia panel tests into Entasis clinical trials

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Continued on page 10

■ Diagnostic Deals, from page 9

Partner 1	Partner 2	Deal Summary
RenalytixAI	Akesogen	<ul style="list-style-type: none"> Objective: Partnership to increase testing capacity and support pharmaceutical services Dynamic: Form joint venture called Renx AI Labs to provide services directly to health systems and pharmaceutical companies in US
Fluidigm	Indica Labs	<ul style="list-style-type: none"> Objective: Co-market digital pathology image analysis and management tools Dynamic: Cooperative marketing of Indica's HALO image analysis products with Fluidigm's Hyperion imaging mass cytometry platform and related reagents and software
Xifin	Glidian	<ul style="list-style-type: none"> Objective: Create platform to help labs reduce prior authorization-related denials Dynamic: Integrate Glidian's automated prior authorization capabilities with Xifin's revenue cycle management and LIS solutions, Xifin RPM and Xifin LIS
Numares	Mayo Clinical Laboratories	<ul style="list-style-type: none"> Objective: Develop tests that use nuclear magnetic resonance spectroscopy to detect cardiovascular disease, kidney disease, liver cancer and other diseases Dynamic: Tests to analyze metabolic constellations, or clusters of risk factors, derived from clinical diagnostic tests performed on patient samples First test expected to measure lipoproteins
OptraScan	Neuberg Diagnostics	<ul style="list-style-type: none"> Objective: Bring OptraScan's digital pathology and telepathology services to Neuberg histology network in India, Middle East and Africa Dynamic: Partnership, named Neuberg Digipath, to also launch OptraScan's Global TelePath Network in United Arab Emirates, India, and South Africa
SQI Diagnostics	University Health Network	<ul style="list-style-type: none"> Objective: Develop rapid, multiplex test and companion point-of-care device for identifying lung transplant candidates Dynamic: Technology to leverage predictive biomarkers developed at UHN to evaluate suitability of a lung for transplant
SeqWell	Gencove	<ul style="list-style-type: none"> Objective: Develop low-pass whole-genome sequencing and genotype imputation product Dynamic: Integrate SeqWell's PlexWell multiplexed NGS library preparation technology with Gencove imputation and analysis software
Western Digital	University of California, Santa Cruz	<ul style="list-style-type: none"> Objective: R&D partnership to accelerate genomic sequencing workflows with computational storage technology Dynamic: UC Santa Cruz Genomics Institute and Baskin School of Engineering to use Western Digital's storage architecture to test their theory that moving computational power closer to data storage can speed analysis of massive genomic data sets
Horizon Discovery	Rutgers University	<ul style="list-style-type: none"> Objective: Commercialize gene editing technology developed in Rutgers med school lab Dynamic: Horizon makes non-material payment to Rutgers for option to exclusively license base editing platform, which modifies genes by creating single point mutations in DNA without making double-stranded breaks, for use in all therapeutic applications
MRM	Biodesix	<ul style="list-style-type: none"> Objective: Develop mass spectrometry-based assays for lung cancer Dynamic: MRM Proteomics grants Biodesix rights to use its iMALDI technologies to develop blood-based tests for lung cancer

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Property Owner	Distributor	Deal Summary
Minomic	Cirrus Dx	<ul style="list-style-type: none"> Products: Minomic's MiCheck prostate cancer test Territory: US To be offered as LDT after internal validation studies completed
MDxHealth	LifeLabs	<ul style="list-style-type: none"> Products: MDxHealth's SelectMDx noninvasive liquid biopsy assay Territory: Canada Exclusive

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Property Owner	Distributor	Deal Summary
Mawi DNA Technologies	Alliance Global	Products: Mawi's iSWAB biosampling technologies Territory: Kuwait, Bahrain, Qatar, Yemen, Oman, UAE, Iran, Jordan, Syria, Lebanon, Iraq, Palestine, Africa, Turkey, Pakistan, Sri Lanka, Afghanistan, Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan, Turkmenistan, Azerbaijan, Thailand, Philippines, Vietnam, the Maldives, Mongolia, Singapore, Indonesia, Brunei, Myanmar, Malaysia
Sienna Cancer Diagnostics	Mediwell	Products: Sienna's bladder cancer diagnostic Territory: Singapore Non-exclusive
Natera	Thermo Fisher Scientific's One Lamda	Products: Natera's cell-free DNA-based kidney transplant rejection test Territory: US
Amoy Diagnostics	Sanomics	Products: Amoy Dx's multigene mutation detection kit Territory: Hong Kong and Macau Renewal of existing deal through 2025

LICENSES

Licensor	Licensee	Deal Summary
Broad Institute	Promega	Property: Broad's CRISPR-Cas9 Promega to combine CRISPR-Cas9 technology with its own products for knock-in of genetic reporters into genomes of any cell or cell line Non-exclusive

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/Service	Client/User	Deal Summary
Quest Diagnostics	Houston Medical Center and Perry Hospital	• Quest to provide full lab management services, lab equipment, supplies and procurement processes to the 2 hospitals

The DX Pipeline: A roundup of the month's key new product launches

After a slow January, new product development picked up steam in February. Here's a rundown of the key new launches:

NEWLY LAUNCHED PRODUCTS & SERVICES

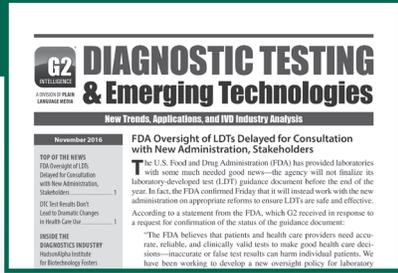
Company(ies)	Product(s)/Service(s)
Myriad Genetics	Enhanced version of Prequel Prenatal Screen
Strattec Molecular	InviMag FFPE DNA kit for purification of pure and PCR inhibitor-free DNA on firm's InviGenius PLUS platform
Clear Labs	Software update for Clear Safety NGS platform which includes Salmonella serotyping
Arrow Diagnostics	ArrowforNGS Microbiota Solution A/B, library preparation kits for bacterial 16S rRNA gene sequencing
Varigen Biosciences	Custom cloning of bacterial or fungal biosynthetic gene clusters of up to 100 kb-long
Bode Technology	New forensic genealogy service for law enforcement investigators and crime labs

Continued on page 12

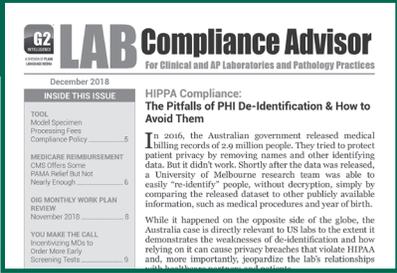
■ The DX Pipeline, from page 11

NEWLY LAUNCHED PRODUCTS & SERVICES	
Company(ies)	Product(s)/Service(s)
Promega	Maxwell RSC miRNA Plasma and Serum kit
Invitae	Addition of non-invasive prenatal screening (NIPS) to its carrier screening test
Illumina	S Prime Reagent Kits for NovaSeq 6000 next-generation sequencing instrument
MGI (subsidiary of BGI)	MGISP series of automated sample preparation workstations
ArcticZymes (subsidiary of Biotec Pharmacon)	T4 DNA ligase, its first commercial ligase enzyme
OncoDNA	OncoNTRK assay for solid or liquid biopsies analysis of tumors with potential NTRK gene fusions
Baylor Genetics	Clinical whole-genome sequencing for diagnosis of rare genetic and inherited disorders
Caris Life Sciences	MI Transcriptome, whole-transcriptome assay to sequence transcriptome of tumors
Tecan	NGS DreamPrep, automated NGS library prep instrument
Saphetor	VarSome Pro, a paid, enhanced version of free VarSome genomic annotation software tool for researchers
Oxford Nanopore Technologies	Direct cDNA (SQK-DC109) and PCR-cDNA (SQK-PCS109) cDNA sequencing kits
Viracor Eurofins	Baloxavir marboxil (Xofluza) Influenza A Antiviral Resistance PCR test for resistance to antiviral Xofluza (baloxavir marboxil)
Fluidigm	REAP-seq (RNA expression and protein sequencing) protocol for use with firm's C1 sample prep system for single-cell genomics
Ncardia	DiscoverHit drug screening platform service to help researchers access disease-relevant biology earlier in drug-discovery process
Biocept	Research-use-only (RUO) assay to run its Target Selector circulating tumor DNA assays in house

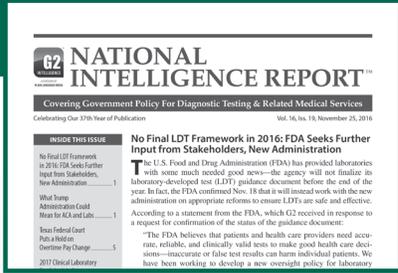
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