

LABORATORY INDUSTRY REPORT™

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DX Earnings Report: Lab Companies Continue to Grow but at a Slower Rate

The diagnostics industry got off to a so-so start with PAMA reimbursement cuts, a weak flu season relative to 2018 and currency translation slowing the pace of year-over-year revenue growth.

Gainers

Of the 40 companies in our sample, 30 reported at least some growth during the period. But growth rates were mostly below what they were in the same period last year among not only mature labs like Abbott (17% in Q1 2018 v. 2% in Q1 2019),

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Upcoming Events

Lab Institute 2019

*Save-the-Date and
Save up to \$600!*

November 6-8, 2019, Arlington, VA

www.LabInstitute.com

Reimbursement Summit 2019

Practical Strategies for Maximizing Revenue and Minimizing Claim Denials in 2019

September 12, 2019, Charlotte, NC

www.LabLeadershipSummits.com

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

Although not as frantic as the previous month, the pace of deal making remained rapid through the end of May to mid-June. Here's a quick overview of the trends and key deals.

Mergers & Acquisitions

In addition to the mergers, acquisitions, and asset sales detailed in the chart below, Illumina announced that it's pushing back until Q4 the expected close date of its \$1.2 billion acquisition of Pacific Biosciences due to ongoing review by UK regulators about competition concerns. After initial review by the UK Competition and Markets Authority (CMA), the investigation has moved to Phase 2, where a group of independent CMA panel members will consider the implications of the acquisition. Despite this obstacle, Illumina remains confident that the deal will move forward.

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■ DX Earnings Report, from page 1

Illumina (31% v. 8%), PerkinElmer (25% v. less than 1%), Roche (5% v. less than 1%) and Thermo Fisher (23% v. 5%).

Six companies reported flat sales, i.e., gains or declines of less than 1%, including billion-dollar companies Becton Dickinson, Quest and Roche. The other two firms with flat revenues were Bio-Rad and Luminex.

Although 26 of 35 companies hit or exceeded average Wall Street revenues estimates, that ratio is significantly below Q1 2018 when 31 of 35 companies accomplished the same feat. And one of the 26 companies that met Wall Street targets in the previous quarter (OraSure Technologies) actually had revenue losses of 28%, which was just slightly less than the 29% losses analysts were expecting.

The Hottest Companies

Ten companies raised their 2019 full year earnings guidance on the basis of Q1 sales, including Bruker, CareDx, Exact Sciences, Guardant Health, Hologic, NeoGenomics, PerkinElmer, Thermo Fisher, Twist Bioscience and Veracyte. Other strong performers during the quarter included:

- Bio-Techne which grew 14% thanks to continued strength in genomic testing sales;
- Fluidigm whose revenues increased 19% thanks to surging sales of its Helios and Hyperion imaging mass cytometry systems
- Consumer genetic testing firm Invitae which posted 47% growth despite the 10% headwinds effect of PAMA Medicare cuts; and
- NeoGenomics where genetic cancer and other testing volume continues to grow by double digits almost every quarter.

Decliners

Companies on the list of decliners included mammoths like LabCorp (-2%) and Becton Dickinson (down less than 1%). The seven other firms with lower YOY revenues were Enzo Biochem (-22%), Meridian Bioscience (-11%), OpkoHealth (-13%), OraSure Technologies (-28%), Pacific Bioscience (-15%), Quidel (-13%) and Waters (-3%).

Diagnostics Earning Reports for Q1

(Period ended March 31, 2019)

(At least \$10 million in sales)

COMPANY	1st QUARTER			DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street	
Abbott Laboratories	\$7.51 billion	+2% (7% on organic basis)	\$7.47 billion	DX revenues flat at \$1.84 billion with core lab up 4% to \$1.06 billion, molecular down 8% to \$108 million, POC up 5% to \$135 million, rapid diagnostics (mostly Alere) down 4% to \$537 million

COMPANY	1st QUARTER			DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street	
Agilent Technologies	\$1.28 billion	+6%	\$1.27 billion	DX & Genomics up 13% to \$235.0 million thanks to strong pharma + clinical markets
Becton Dickinson (FY Q2)	\$4.20 billion	flat	\$4.24 billion	DX systems down 5% at \$389; overall life sciences down 4% to \$1.05 billion due in part to relatively mild flu season as compared to 2018
Bio-Mérieux	€632.5 million (\$707.8 million)	+4% (8% currency neutral basis)	NA	Clinical applications, including microbio, molecular bio and immunoassays up 4% to €525.9 million with microbio growth driven by strong Bact/Alert blood culture and Vitek sales
Bio-Rad Laboratories	\$554 million	flat	\$550	Clinical DX down 5% to \$334.1 million despite strong autoimmune and blood typing product sales
Bio-Techne (FY Q3)	\$184.9 million	+13%	\$164.0 million	DX & Genomics up 15% to \$47.1 million driven by Advanced Cell Diagnostics RNAscope product sales; EPI tests performed up 14%
Bruker	\$461.4 million	+7%	\$450.1 million	CALID, including mass spectrometry and microbio, up 13% to \$148.2 million
CareDx	\$26.0 million	+84%	\$24.3 million	Testing services up 103% to \$21.5 million driven by AlloSure and AlloMap sales
Danaher	\$4.88 billion	+5%	\$4.79 billion	Growth driven by 10% increase in life sciences to \$1.63 billion; DX core revenues up in mid-single digits led by immunoassays and automation; Cepheid slightly down due to relatively weak flu season as compared to 2018
Enzo Biochem	\$19.7 million	-22%	NA	Clinical services down 34% to \$11.7 million due to reduced reimbursement rates, higher insurance claims rejections and changes to payor protocols for genetic testing
Exact Sciences	\$162.0 million	+79%	\$153.0 million	Cologuard colon cancer tests up 79% to 334K for Q1 (4.6% market share) and 934K for year—although average revenue per test down \$2 to \$483 and average cost per test increased \$4 to \$128
Fluidigm	\$30.1 million	+19%	\$29.2 million	Mass cytometry more than doubles at \$18.8 million 48% to \$19.1 million thanks to strong demand for Helios and Hyperion systems, which offsets 30% dip in microfluidics-related revenues to \$11.4 million
GenMark Diagnostics	\$21.5 million	+4%	\$20.9 million	ePlex systems up 72% to \$15.7 million (39 new systems placed during quarter)
Genomic Health	\$108.8 million	+17%	\$106.7 million	Invasive breast cancer testing up 12% to \$79.8 million; prostate cancer testing up 47% to \$8.5 million; test results delivered up 16% to 37,580

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■ DX Earnings Report, from page 3

COMPANY	1st QUARTER			DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street	
Guardant Health	\$36.7 million	+120%	\$31.7 million	Precision oncology up 103% to \$28.8 million; development services up from \$2.5 million to \$7.8 million driven by companion Dx program with AstraZeneca
Hologic	\$818.4 million	+4%	\$806.1 million	Global DX up 6% to \$296.7 million driven by 11% growth in molecular diagnostics to \$167.8 million + 19% growth in blood screening to \$13.4 million which offset 2% dip in cytology + perinatal (\$115.5 million)
Illumina	\$846 million	+8%		Consumables up 14% to \$481 million but Microarrays down 3.3% to \$147 million
Invitae	\$40.6 million	+47%	\$47.2 million	10% decline in Medicare reimbursement for cancer testing due to PAMA and lower average revenue per test (\$455)
Laboratory Corp. of America	\$2.79 billion	-2%	\$2.83 billion	DX down 3% to \$1.72 billion due in large part to PAMA reimbursement cuts although sales up 0.4% on organic basis; Covance flat at \$1.07 billion
Luminex	\$82.4 million	Flat	\$83.1 million	Lower than expected respiratory product sales and loss of women's health products to LabCorp as well as weak flu season
Meridian Bioscience (FY Q2)	\$50.2 million	-11%	\$51.7 million	DX down 16% to \$33.5 million, including 29% dip in molecular tests to \$7.1 million and 11% dip in immunoassay and blood chemistry to \$26.4 million
Myriad Genetics (FY Q3)	\$216.6 million	+18%	\$217.5 million	Molecular DX up 18% to \$200.5 million driven by 4% growth in hereditary cancer (\$117.6 million) + 7% growth in newly acquired (via Counsyl acquisition) prenatal testing \$30.6 million; Polaris prostate cancer test revenues up 8% to \$6.9 million; EndoPredict breast cancer test up 22% to \$2.8 million; Declining products included GeneSight (-3%) and Vectra DA (-25%)
NantHealth	\$23.7 million	+6%	NA	Sequencing and molecular tests down from \$840K to \$814K; GPS molecular DX and Liquid GPS tests down due in part to new policy restricting access without promise of insurance reimbursement or patient direct payment
Natera	\$66.8 million	+7%	\$65.5 million	Driven by 12% growth in Panorama to \$37.2 million and 24% growth in Horizon to \$22.7 million; total tests processed up 22% to 200,194
NeoGenomics	\$95.6 million	+51%	\$90.6 million	Test orders up 48% to 155,963, tests performed up 31% to 234,317 and average revenues per test up 15% to \$368
OpkoHealth	\$222.5 million	-13%	\$241.3 million	4Kscore prostate cancer tests down 8% and PAMA cuts hurt BioReference Laboratories business

COMPANY	1st QUARTER			DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street	
OraSure Technologies	\$30.1 million	-28%	\$29.9 million	Molecular collection systems down 42% to \$10.6 million; genomics down 53% to \$8.0 million; infectious disease testing down 13% to \$12.3 million due to 11% decline in OraQuick tests for HIV and HCV; declines primarily result of previously announced loss of major consumer genetics customer
Pacific Bioscience	\$16.4 million	-15%	\$21.6 million	\$13.5 million in product and \$3.0 million in service revenues
PerkinElmer	\$648.7 million	Flat	\$645.1 million	DX up 5% to \$259.9 million driven by prevalence of infectious and autoimmune diseases, especially in emerging markets, but Discovery & Analytical Solutions down 2% to \$388.8 million
Qiagen	\$348.7 million	+2%	\$350.7 million	Molecular DX up 10% to \$168 million and life sciences up 3% to \$181 million
Quanterix	\$12.3 million	+64%	\$10.2 million	Neurology firm expands into oncology space which now accounts for 17% of revenues
Quest Diagnostics	\$1.89 billion	flat	\$1.87 billion	Test volume up 4% driven by tuberculosis, Cardio IQ, drug monitoring and hemopathology blood cancer testing which helped offset 10% reimbursement losses from PAMA cuts
Quidel	\$148.0 million	-13%	\$155.2 million	Hurt by weak flu season; Cardiac immunoassay down 4% to \$65.9 million; Rapid immunoassay down 23% to \$62.5 million including \$17.4 million decrease in flu revenue; Molecular DX up 12% to \$5.7 million, including 24% increase in Solana sales; Specialized DX down 7% to \$13.9 million
Roche Diagnostics	\$2.90 billion	flat	NA	DX sales up 1% including 3% growth in immunodiagnostics and 7% growth in molecular diagnostics which offset 2% decline in clinical chemistry and 12% decline in point of care. Strong performers included cervical cancer diagnosis (up 52%) and blood screening (up 14%)
Siemens Healthineers (FY Q2)	\$3.93 billion	+9%	NA	DX up 5% to \$1.16 billion driven by sales of Atellica Solution platform (780 shipped during quarter)
Thermo Fisher Scientific	\$6.12 billion	+5%	\$6.02 billion	Specialty DX up 1% to \$960 million; Lab products + services up 4% to \$2.51 billion
Twist Bioscience	\$13.6 million	+119%	\$12 million	\$8 million from synthetic biology + \$5.5 million from genomics and targeted NGS
Veracyte	\$29.5 million	+47%	\$20.0 million	Genomic test volume up 33% to 9,162 tests
Waters	\$513.9 million	-3%	\$545.3 million	Hurt by currency translation and weak TA instruments sales in China and Europe

* Companies that met or exceeded average Q1 Wall Street revenue estimates



FDA Watch: First Zika Assay Gets Green Light for Marketing

Over the past several years, the FDA has issued Emergency Use Authorization (EUA) for over a dozen different tests for Zika. But on May 23, 2019, the FDA did something it had never done before: It authorized marketing of a diagnostic test for the Zika virus—specifically, Seattle-based InBios' ZIKV Detect 2.0 IgM Capture Elisa for detecting immunoglobulin (IgM) antibodies in human blood, an assay previously cleared for emergency use only.

The ZIKV Detect 2.0 IgM Capture ELISA is designed to identify proteins (antibodies) produced by the body's immune system when it tests for Zika virus infection in the blood. IgM antibodies indicate an early immune response. The test is for use only in patients with clinical signs and symptoms consistent with Zika virus infection, and/or who meet the CDC's Zika virus epidemiological criteria, such as a history of residence in or travel to a geographic region with active Zika transmission at the time of travel. The FDA authorization doesn't cover testing of blood or plasma donors.

Moving beyond EUA to marketing authorization is a seminal shift in FDA policy. Comfort with the effectiveness of the InBios Zika assay enabled the agency to take the next step. According to InBios, the assay was evaluated via testing 807 unique specimens—353 from test subjects at sites where Zika is endemic and 256 subjects at non-endemic sites. In samples from patients collected seven days or later after the onset of symptoms, the InBios Zika kit correctly identified over 90% of patients confirmed positive for Zika IgM and over 96% of patients confirmed negative.

The authorization doesn't impact the availability of the 14 other Zika nucleic acid diagnostics available under EUAs.

For the rest of the story, go to:

<https://www.g2intelligence.com/fda-watch-first-zika-assay-gets-green-light-for-marketing/> 

■ Diagnostic Deals, from page 1

In other news, Thermo Fisher Scientific and Roper Technologies terminated an agreement under which Thermo Fisher would have acquired Gatan, a wholly-owned subsidiary of Roper and manufacturer of instrumentation and software used to enhance and extend the operation and performance of electron microscopes. The would-be deal was valued at approximately \$925 million in cash when it was announced last year.

Although its agreement with Roper turned out to be a bust, Thermo Fisher has been busy. This period, it acquired HighChem, a Slovakia-based developer of mass spectrometry software, for an undisclosed amount. The software company will be integrated into Thermo Fisher's chromatography and mass spectrometry business.

Strategic Alliances

Thermo Fisher was busy during the period announcing entry into four new partnership arrangements, including one with Predictive Laboratories to further female infertility research. Predictive Laboratories will implement several Thermo Fisher reproductive health tests for whole-exome sequencing.

Other notable deals included the partnering of DiaSorin and Qiagen to develop a new ultrasensitive test for Lyme Disease.

Here's a summary of key diagnostic deals announced from late May through the third week of June:

MERGERS, ACQUISITIONS & ASSET SALES

AQUIRING COMPANY	TARGET(S)	DEAL SUMMARY
Invitae	Singular Bio	<ul style="list-style-type: none"> • Price: \$55 million—approximately 2.5 million shares of Invitae common stock + \$5.7 million in cash • Status: Expected to close in July or August • Singular employees that stay with company to get up to \$90 million in Invitae contingent stock awards • Acquisition of firm specializing in single-molecule, cell-free DNA analysis for non-invasive prenatal testing advances Invitae's strategy to push into NIPT space
Ascenda Biosciences	Provista Diagnostics	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of proteomic diagnostic firm which produces Videssa Breast test assessing whether women with indeterminate mammograms need a biopsy
BioMérieux	Suzhou Hybiome Biomedical Engineering	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • BioMérieux increases its equity holdings in Chinese immunoassay producer in which it acquired majority stake in 2018 from 54% to 67%
Thermo Fisher Scientific	HighChem	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Slovakia-based developer of mass spectrometry software to be integrated into Thermo Fisher's chromatography and mass spectrometry business
Covance Drug Development (Lab Corp)	Envigo	<ul style="list-style-type: none"> • Price: \$485 million • Status: No closing date announced • Covance acquires Envigo's nonclinical researcher services while Envigo's Research Models Services business acquires LabCorp's Covance Research Products business
Bio-Techne	B-MoGen Biotechnologies	<ul style="list-style-type: none"> • Price: Purchase of 100% of B-Mogen stock financed with cash on hand for undisclosed price • Status: Closed • Bio-Techne to include B-Mogen's technology in its own cell and gene therapy products
Meridian Bioscience	GenePOC	<ul style="list-style-type: none"> • Price: \$50 million + up to \$70 million more in contingent milestone payments • Status: Closing of deal announced in April • Acquisition of Quebec City-based molecular diagnostics firm

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■ Diagnostic Deals, from page 7

AQUIRING COMPANY	TARGET(S)	DEAL SUMMARY
Beckman Coulter Life Sciences	Cytobank	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of single-cell data analysis and software-as-a-service company enables allows Beckman Coulter to offer a high-end data analytics solution for pharma/biopharma and academic research
Lumos Diagnostics	RPS Diagnostics	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed <p>Merged company to keep Lumos name and focus on international launch of RPS' FebriDx blood-based POC test for identifying febrile acute respiratory infections (ARI) and differentiating viral and bacterial infections</p>
Schott	Minifab	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Expected to close in 2019 • German producer of glass substrates for microarrays and microfluidic components made of glass acquires Australian microfluidics company • Combined firms to create centers of excellence for polymer in Australia and glass in Germany
PerkinElmer	Cisbio Bioassays	<ul style="list-style-type: none"> • Price: \$219.8 million • Status: Closed • PerkinElmer acquires life sciences + DX kits and reagents manufacturer with \$50 million in 2018 revenues
Todos Medical	Amarantus Bioscience Holding	<ul style="list-style-type: none"> • Price: Undisclosed • Status: To close when Todos' stock is listed on a national stock exchange • Todos exercises option to acquire remaining 80% of its Breakthrough Diagnostics joint venture with Amarantus • Parties entered into joint venture in December 2018 to develop LymPro, a blood-based lymphocyte proliferation assay, as diagnostic test for Alzheimer's
Constellation Alpha Capital	DermTech	<ul style="list-style-type: none"> • Price: Undisclosed price paid in Constellation stock shares • Status: Closed • Under merger terms, skin cancer diagnostics firm to become wholly owned subsidiary of Constellation
Erasmus University Medical Center	GenomeScan	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Erasmus MC acquires undisclosed number of shares in genomics service provider • Both parties to collaborate with Leiden University Medical Center (LUMC), an existing GenomeScan shareholder, in molecular diagnostics and research

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

PARTNER 1	PARTNERS (2+)	DEAL SUMMARY
Thermo Fisher Scientific	Predictive Laboratories	<ul style="list-style-type: none"> • Objective: Female infertility research • Dynamic: Predictive Labs to implement Thermo Fisher reproductive health tests, including Applied Biosystems CarrierScan assay, Ion ReproSeq PGS assay, CytoScan Dx assay and Ion AmpliSeq Exome RDY for whole-exome sequencing
Thermo Fisher Scientific	Newomics	<ul style="list-style-type: none"> • Objective: Develop new microflow LC-MS workflows for validating disease biomarkers • Dynamic: Combine Thermo Fisher's microflow LC-MS systems and Nanospray Flex ion source with Newomics' multi-nozzle emitters

PARTNER 1	PARTNERS (2+)	DEAL SUMMARY
Thermo Fisher Scientific	Evosep	<ul style="list-style-type: none"> • Objective: Develop high-throughput clinical research proteomics workflows for profiling large plasma sample cohorts • Dynamic: Combine the Thermo Scientific Q Exactive HF-X mass spectrometer and the Evosep One liquid chromatography solution to develop standardized and high-throughput analytical protocols for proteomics, translational research and pharmaceutical applications
Thermo Fisher Scientific	Biognosys	<ul style="list-style-type: none"> • Objective: Develop data-independent acquisition (DIA) mass spectrometry-based workflows for quantification of target proteins in plasma and other body fluids • Dynamic: Extend existing collaboration aimed at developing methods for analyzing plasma and other body fluids
Qiagen	DiaSorin	<ul style="list-style-type: none"> • Objective: Develop ultra-sensitive in vitro test for Lyme disease • Dynamic: Test to combine Qiagen's QuantiFeron (interferon-gamma release assay) technology with DiaSorin's Liaison automated analyzers • Companies plan to market assay for use alongside DiaSorin's existing Lyme disease tests, Liaison Borrelia IgG and IgM • Companies also plan to run multi-site clinical validations during 2020 Lyme disease season and apply for regulatory approval in US and Europe later that year
Resolution Bioscience	Janssen Pharmaceuticals	<ul style="list-style-type: none"> • Objective: Develop Resolution's HRD liquid biopsy test as companion diagnostic for niraparib, a PARP inhibitor being investigated to treat patients with metastatic castration-resistant prostate cancer • Dynamic: Resolution HRD is a blood-based, cell-free DNA assay that detects single nucleotide variants, copy number variants, and deletions in genes related to homologous recombination deficiency (HRD) • If approved, new CDx assay would be first test to find gene deletions from cfDNA and distinguish between single copy and homozygous gene deletions through a blood draw
Caris Life Sciences	Debiopharm International	<ul style="list-style-type: none"> • Objective: Develop companion diagnostic for new oncology drug being developed by Debiopharm • Dynamic: Use Caris' Molecular Intelligence (MI) Transcriptome assay for mRNA analysis to detect rare fibroblast growth factor receptor (FGFR) fusions and identify eligible patients for Debiopharm's FUZE phase II clinical trial of Debio 1347, a selective FGFR inhibitor
Foundation Medicine	Bayer	<ul style="list-style-type: none"> • Objective: Develop NGS companion diagnostics • Dynamic: Strategic global collaboration initially focusing on creating a test to identify patients eligible for treatment with larotrectinib (Vitrakvi), a TRK inhibitor approved in the US for patients with NTRK fusions regardless of tumor type or location
Mayo Clinic	Regeneron Pharmaceuticals	<ul style="list-style-type: none"> • Objective: Sequence the exomes and genotype 100,000 patient DNA samples from Mayo's biobank • Dynamic: Regeneron to pay for the sequencing and genotyping • Both partners to have access to the data for research purposes
University of California	GlaxoSmithKline	<ul style="list-style-type: none"> • Objective: Establish Laboratory for Genomics Research (LGR) to investigate disease-causing gene mutations and develop new technologies using CRISPR to accelerate discovery of new drugs • Dynamic: Five-year collaboration in which GSK to provide up to \$67 million in funding, facilities for 24 full-time university employees and up to 14 full-time GSK employees • Initial focus on immunology, oncology and neuroscience

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■ Diagnostic Deals, from page 9

PARTNER 1	PARTNERS (2+)	DEAL SUMMARY
GeneNews	Oncore Pharma	<ul style="list-style-type: none"> • Objective: Commercialize GeneNews ColonSentry test in all countries outside US and Canada—specifically, deploy 1.75 million ColonSentry tests in next five years • Dynamic: Five-year exclusive licensing and services deal under which GeneNews to receive a fixed fee per test, a special royalty payment equal to 10% of Oncore's yearly profits and 1 million shares of Oncore stock • All ColonSentry tests to be processed in GeneNews' Virginia laboratory • Initial focus on Netherlands, Belgium, Luxembourg, Germany, France, Switzerland, Austria, Spain, Monaco, Italy, Portugal, UK, Ireland, Norway, Sweden, Finland, Denmark, Israel and UAE
LabCorp	Mount Sinai Health System	<ul style="list-style-type: none"> • Objective: Establish the Mount Sinai Digital and Artificial Intelligence-Enabled Pathology Center of Excellence • Dynamic: To achieve integration, Mount Sinai to implement Philips' IntelliSite Pathology Solution, which LabCorp is in the process of implementing at its own labs • Center of Excellence, to be housed within Mount Sinai's Department of Pathology, Molecular and Cell-Based Medicine, to begin by using new digital pathology tools for interpretation of genitourinary cancers, primarily prostate tumors and head and neck cancers
Sanford Health	Harvard Medical School + Brigham and Women's Hospital	<ul style="list-style-type: none"> • Objective: Determine best practices for using genetic screening to improve population health • Dynamic: Four-year collaboration with experts in genomic medicine from Harvard and Brigham and Women's to help guide Sanford researchers use and interpret data collected via Sanford Chip, a new \$49 pharmacogenomic laboratory developed test to identify genetic risk factors for medication use and prescription
Decode Genetics	Intermountain Healthcare	<ul style="list-style-type: none"> • Objective: Genetics research • Dynamic: Partners to perform whole-genome sequencing on 500,000 patients in Utah and Idaho in a population health initiative called HerediGene
Cartana	Lunaphore Technologies	<ul style="list-style-type: none"> • Objective: Develop hardware for automated sequencing and imaging cycles. • Dynamic: Integrate Cartana's in situ RNA sequencing (ISS) technology with Lunaphore's microfluidic tissue processor technology
Hamilton	Enable Biosciences	<ul style="list-style-type: none"> • Objective: Fully automate the processing of Enable's ultra-sensitive immunoassay technology in a hands-free workflow with Hamilton's automated workstation • Dynamic: Firms to automate the processing of up to 96 liquid biopsy samples at one time using Enable Bio's Antibody Detection by Agglutination PCR (ADAP) technology for immunoassays
NuView Life Sciences	Aperture Bio	<ul style="list-style-type: none"> • Objective: Evaluate NuView's NV-VPAC1 urogenital cancer test • Dynamic: Companies to assess use of the test on Aperture's automated RAPID-B platform, which uses robotic flow cytometry to identify and count targeted cellular material in body fluids
Owlstone Medical	International Association of Heat and Frost Insulators and Allied Workers (IAHFIW)	<ul style="list-style-type: none"> • Objective: Identify and verify breath-based biomarkers for early detection of malignant mesothelioma, an asbestos-caused disorder common in construction and other union workers • Dynamic: Use Owlstone's Breath method to measure volatile organic compounds (VOCs) in breath • Three-year project with phase 1 to focus on identifying VOCs in breath of people diagnosed with malignant mesothelioma, and phase 2 to launch a blind study to verify the sensitivity, specificity and positive and negative predictive values of selected VOC biomarkers identified in phase 1

PARTNER 1	PARTNERS (2+)	DEAL SUMMARY
Biocartis	Kite (Gilead Sciences)	<ul style="list-style-type: none"> • Objective: Develop molecular-based assays supporting Kite's therapies on Biocartis' Idylla platform • Dynamic: Collaboration part of Biocartis' ongoing strategy of expanding its presence in the oncology market via a series of immunotherapy and liquid biopsy assays on the Idylla platform
Biotage	Shandong Yingsheng Biotechnology	<ul style="list-style-type: none"> • Objective: Develop clinical mass spectrometry applications for China market • Dynamic: Biotage to provide systems and consumables from its analytical chemistry portfolio to be sold by Yingsheng under its own brand together with Yingsheng's other products
Mobidiag	Autobio Diagnostics	<ul style="list-style-type: none"> • Objective: Develop observational research analytics tools to assess treatment outcomes for precision oncology • Dynamic: New Automobi Molecular Diagnostics joint venture to seek Chinese regulatory approval for Novodiag platform and assays and establish local facilities to manufacture system parts and disposables • Autobio has invested €8 million and holds a 65% stake in the venture; Mobidiag owns the remaining 35% under a €4.3 million investment • Autobio has also made a €10 million equity investment in Mobidiag itself
Bruker	PreOmics	<ul style="list-style-type: none"> • Objective: Commercialize consumables and software for Bruker's 4D Proteomics technology • Dynamic: Codevelopment and comarketing agreement covering PreOmics' inStageTip (iST) sample prep technology on Bruker's TimsTOF Pro
Bruker	Genedata	<ul style="list-style-type: none"> • Objective: Develop NGS host cell protein analysis platform • Dynamic: Make Genedata's Expressionist software platform support Bruker's TimsTOF Pro 4D omics format
Invitae	Horizon Therapeutics	<ul style="list-style-type: none"> • Objective: Support Invitae's urea cycle disorder genetic (UCD) testing program • Dynamic: Invitae to perform genetic testing and Horizon to provide unspecified financial support for program aimed at improving diagnosis of UCD
Luminex	EDP Biotech	<ul style="list-style-type: none"> • Objective: Develop and commercialize blood-based colorectal test using Luminex's xMAP technology • Dynamic: Test, called ColoPlex, uses multiplexed immunoassay technology and machine learning to detect early state colorectal cancer and precancerous polyps

DISTRIBUTION, SALES & MARKETING AGREEMENTS

PROPERTY OWNER	DISTRIBUTOR	DEAL SUMMARY
Parallel BioAssays	Bioké	<ul style="list-style-type: none"> • Products: Parallel BioAssays' SnapChip microarray products • Territory: Belgium, Netherlands, Luxembourg
Patia	Premier Medical Laboratory Services	<ul style="list-style-type: none"> • Products: Patia's type 2 diabetes risk assay DIABETESpredict which combines genetic risk analysis with behavioral and lifestyle assessments • Territory: US • Exclusive
Biomerica	Maxhealth	<ul style="list-style-type: none"> • Products: Biomerica's EZ Detect colorectal cancer screening test • Territory: China • Exclusive • Maxhealth agrees to meet annual minimum purchase requirements totalling \$17 million over seven years and pay Biomerica \$1 million upfront upon meeting certain undisclosed conditions

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■ Diagnostic Deals, from page 11

LICENSES

Licensor	Licensee	Deal Summary
ERS Genomics	Bioneer	<ul style="list-style-type: none"> Property: CRISPR-Cas9 genome editing technology Bioneer gets right to use technology to develop and commercialize CRISPR-edited cell-based disease models
Integrated DNA Technologies	Editas Medicine	<ul style="list-style-type: none"> Property: Newly released CRISPR Alt-R Cas12a (Cpf1) enzyme for human therapeutic applications Exclusive

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/ Servicer	Client/User	Deal Summary
Agilent Technologies	SomaLogic	<ul style="list-style-type: none"> Multi-year supply agreement for Agilent to provide customized high-fidelity oligo microarrays for the nucleic acid detection step in SomaLogic's Somascan assay

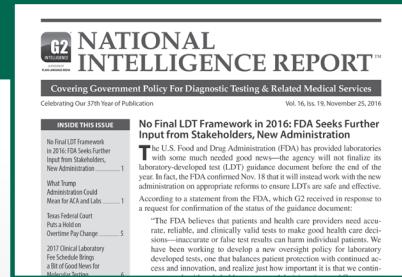
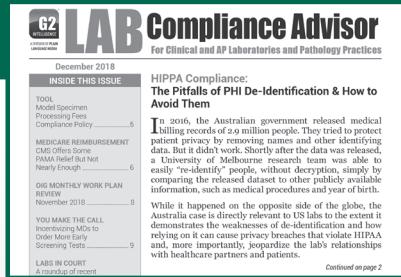
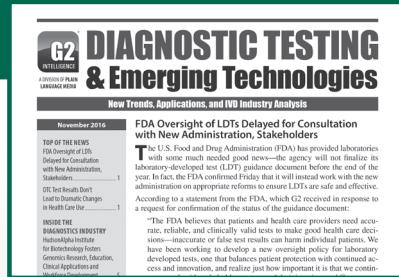
NEW CLINICAL STUDIES

DX Partner	Other Partner(s)	Description of Study
BrainBox Solutions	None	<ul style="list-style-type: none"> HeadSMART (Head injury Serum markers and Multimodalities for Assessing Response to Trauma) to support regulatory filings for marketing approval of the TBI test

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