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DX Earnings Report: Markets Soften, Payors Harden but Growth Continues

Lab business is getting tougher. While PAMA cuts are hurting Medicare revenues, pressure from private payors may be even more intense both at the pricing front end and claims denial back end. Economic growth in Europe and Asia has slowed. And the consumer genomics market continues to lag.

But, so far at least, labs are hanging tough. Many lab companies did a good job of preparing for PAMA by acquiring new companies and revenue sources. And even as the PAMA firewalls prove their value, organic growth remains steady, albeit somewhat slower than last year at this time. That's the

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Upcoming Events

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November 6-8, 2019, Arlington, VA

www.LabInstitute.com

Reimbursement Summit 2019

Practical Strategies for Maximizing
Revenue and Minimizing Claim Denials
in 2019

October 3, 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

Big picture-wise, health care industry mergers and acquisitions during the second quarter were up 7.3% from the first quarter and topped 250 deals for the eighth quarter in a row, according to PricewaterhouseCoopers. Deal value was also up 10.3%. Diagnostic deal making during the quarter was largely consistent with that pattern. Here are the highlights of a busy month spanning late July to late August.

Mergers & Acquisitions and Asset Sales

The predominant trend in diagnostics M&A in 2019 has been an increase in the number of deals and a decrease in their size. But arguably the biggest deal of the year came down on

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big picture takeaway from recent earnings reports from the second quarter of 2019. Here's a more detailed analysis.

Gainers

The first key point is that sales are up across the board. All but five of the 40 companies in our sample reported at least some revenue growth during the period, as compared to Q2 2018. The bad news is that the rate of growth is down, especially for the blue bloods who last year at this time were first digesting significant new acquisitions:

Company	Q2 2019 Nonorganic Revenue Growth	Q2 2018 Nonorganic Revenue Growth
Abbott	2%	17%
LabCorp	0.3%	13%
PerkinElmer	3%	29%
Quest	2%	3%
Thermo Fisher	4%	22%

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Earnings v. Expectations

Thirteen of the 37 companies that had clear consensus Wall Street estimates missed their target during the quarter, as compared to only 5 in 2018. The top-line misses included many of the industry's most significant companies such as Abbott, Bio-Techne, Illumina, LabCorp, Meridian Bioscience, Myriad Genetics, PerkinElmer and Qiagen. The silver lining is that, with the exception of Myriad and Bio-Techne, all of these companies met or exceeded earnings per share (EPS) targets.

The flip side is that seven of the 22 companies that met revenues targets fell short on the bottom line. Of course, most of these companies are in the genomics space, including cancer screening company Personalis that just went public. Overall, companies that met or exceeded Wall Street EPS targets outnumbered companies that fell short 28 to 8.

Also boding well is that 14 companies raised their full-year revenue guidance on the basis of their Q2 results, including firms that had disappointing quarters like:

- Abbott, which fell just \$2 million short of meeting its \$8.0 billion revenue target;
- LabCorp, which also missed top line earnings estimates by \$2 million; and
- Bio-Rad Laboratories, which had -1% growth for the period.

Decliners

Four firms revised their revenue and/or estimates downward, including Illumina, OraSure Technologies, PerkinElmer and Waters.

But no company had a tougher quarter than Myriad Genetics which despite 11% growth, came in well short of its top (\$215.4 million vs. \$221.0 million) and bottom line (\$0.41 EPS vs. \$0.47) targets. Myriad CEO Mark Capone cited the “unprecedented” impact of laboratory benefit management programs which he said reduced test revenues by about \$50 million and adjusted EPS by approximately \$.51. Although Capone said he expects the pricing situation to stabilize in Q1 FY2020, revenue and EPS projections left investors disappointed and triggered a sell-off of Myriad stock.

Diagnostics Earning Reports for Q2 (period ended June 30, 2019)

(At least \$10 million in sales)

COMPANY	FY 2019 Q2			DX SEGMENT PERFORMANCE
	Total Revenue (vs. Wall Street)	YOY Revenues	Adjusted EPS (vs. Wall Street)	
Abbott Laboratories*	\$7.98 billion (\$8.0 billion)	+2% (8% on organic basis)	+\$0.82 (+\$0.80)	DX revenues up 4% to \$1.17 billion, molecular down 12% to \$107 million, POC up 4% to \$145 million, rapid diagnostics (mostly Alere) flat to \$484 million
Adaptive Biotech.	\$22.1 million (\$19.3 million)	+91%	-\$1.23	Sequencing, including clonoSeq testing, up 43% to \$11.9 million
Agilent Technologies (FY Q3)*	\$1.27 billion (\$1.24 billion)	+6%	+\$0.76 (+\$0.72)	DX and genomics group revenues grow from \$237 to \$263 million thanks to strength in nucleic acid solutions division
Becton Dickinson (FY Q3)	\$4.35 billion (\$4.35 billion)	+2%	+\$3.08 (+\$3.05)	DX systems up 2% to \$362 million. Double-digit growth in BD Max platform and ID-AST microbiology solutions
Bio-Rad Laboratories	\$572.6 million (\$566.2 million)	-1%	+\$1.57 (+\$1.33)	Clinical DX up 1% to \$357.1 million driven by quality controls, immunology and diabetes product lines
Bio-Techne (FY Q4)	\$191.7 million (\$197.8 million)	+7%	+\$1.25 (+\$1.33)	DX & Genomics up 4% to \$48.5 million
Bruker	\$490.2 million (\$477.8 million)	+11%	+\$0.33 (+\$0.30)	CALID, including mass spectrometry and microbio, up 10% to \$140.5 million
CareDx*	\$31.5 million (\$28.0 million)	+76%	-\$0.19 (-\$0.19)	Testing services up 84% to \$25.7 million driven by 11% increase in AlloSure and AlloMap sales
Danaher*	\$5.16 billion (\$5.08 billion)	+4%	+\$1.19 (+\$1.16)	Growth driven by 6% increase in life sciences to \$1.71 billion; DX core revenues up \$7 million to \$1.62 billion led by immunoassays and automation; Cepheid up 20% thanks to strength in infectious disease testing thanks in part to lingering of flu season into April
Exact Sciences*	\$199.9 million (\$182.1 million)	+90%	-\$0.30 (-\$0.56)	Average revenue for Cologuard stays at \$479 per test and average cost per test falls \$2 to \$123. Company announces acquisition by Genomic Health by end of 2019
Fluidigm	\$28.2 million (\$30.6 million)	+7%	-\$0.10 (-\$0.21)	Mass cytometry up 28% to \$17.5 million but continuing struggles in microfluidics (down 16% to \$10.7 million) acts as drag causing company to issue soft revenues guidance
GenMark Diagnostics	\$18.4 million (\$17.9 million)	+23%	-\$0.23 (-\$0.21)	ePlex systems up 70% to \$12 million (45 new systems placed during quarter)

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COMPANY	FY 2019 Q2			DX SEGMENT PERFORMANCE
	Total Revenue (vs. Wall Street)	YOY Revenues	Adjusted EPS (vs. Wall Street)	
Genomic Health*	\$114.1 million	+19%	+\$0.42	US sales of Oncotype DX Prostate up 42% to \$9.6 million; total Oncotype tests up from 33,590 to 38,470 and breast cancer volume up 13%
Guardant Health*	\$54.0 million (\$36.4 million)	+178%	-\$0.13 (-\$0.36)	Precision oncology up 136% to \$42.1 million; development services up 664% to \$11.9 million driven by companion Dx program with AstraZeneca
Hologic (FY Q3)*	\$852.4 million (\$835.7 million)	+3%	+\$0.63 (+\$0.61)	Global DX up 4% to \$305.4 million driven by 11% growth in molecular diagnostics to \$170.9 million but cytology + perinatal down 1% to \$120.3 million
Illumina**	\$838 million (\$866.2 million)	+1%	+\$1.35 (+\$1.34)	6% growth in sequencing offset by 21% decline in microarray revenues driven by continuing weakness in direct-to-consumer genetic testing market resulting in substantial lowering of guidance
Invitae	\$53.5 million (\$50.7 million)	+43%	-\$0.54 (-\$0.46)	Samples accessioned up 52% to over 111,000 + cost per sample down 10% to \$252; PAMA remains drag on revenues
LabCorp*	\$2.88 billion (\$2.90 billion)	+0.3%	+\$2.93 (+\$2.90)	DX down 2.9% as a result of PAMA + 1.1% dip in direct-to-consumer genetic tests; although overall sales up 0.3% on organic basis; but revenue per requisition up 1% despite 1.5% PAMA drag on revenues
Luminex	\$83.1 million (\$81.7 million)	+4%	-\$0.11 (-\$0.01)	Assay revenues down 22% to \$31.4 million but services double to \$6 million; flow cytometry contribution of \$13.2 million partially offsets loss of LabCorp revenue + costs of integrating newly acquired MilliporeSigma flow cytometry business
Meridian Bioscience (FY Q3)	\$48.4 million (\$49.8 million)	-6%	+\$0.16 (+\$0.09)	DX down 9% to \$33.1 million, including 21% dip in molecular tests to \$5.9 million and 6% dip in immunoassay and blood chemistry to \$28.9 million
Myriad Genetics (FY Q4)	\$215.4 million (\$221.0 million)	+11%	+\$0.41 (+\$0.47)	Molecular DX up 9% to \$196.9 million, including flat sales in hereditary cancer (\$119.0 million), 19% decline in Vectra (\$12.2 million), 10% decline in Prolaris prostate (\$6.3 million), EndoPredict breast cancer up 11% (\$3.0 million), GeneSight down 12% (\$29.8 million)
NanoString Technologies	\$30.3 million (\$29.0 million)	+21%	-\$0.57 (-\$0.52)	Consumables up 15% to \$11.8 million + Prosigna IVD kit up 4% to \$2.6 million with growth in Europe offset by lower sales in North America
Natera	\$74.4 million (\$66.8 million)	+18%	-\$0.48 (-\$0.58)	Product revenues up 8% to \$65.1 million driven by 2% growth in Panorama to \$36.5 million and 14% growth in Horizon to \$24.3 million; total tests processed up 20% to 195,168
NeoGenomics*	\$101.7 million (\$97.3 million)	+50%	+\$0.07 (+\$0.06)	Growth driven by 2018 Genoptix acquisition + market share gains; test requisitions up 32% to 144,983 + average revenues per test up 12% to \$355
OpkoHealth	\$226.4 million (\$225.6 million)	-13%	-\$0.10 (-\$0.11)	PAMA cuts (first quarter of no Medicare reimbursement for 4Kscore prostate cancer tests) + higher rate of denials for lab and genomic tests although GeneDX was strong with 16% growth in test volume + 12% growth in hospital- + health-system-based test orders

COMPANY	FY 2019 Q2			DX SEGMENT PERFORMANCE
	Total Revenue (vs. Wall Street)	YOY Revenues	Adjusted EPS (vs. Wall Street)	
OraSure Technologies**	\$38.8 million (\$41.5 million)	-11%	+\$0.07	Infectious disease testing down 16% to \$13.3 million due to 18% decline in OraQuick tests for HIV + HCV (\$13.0 million); Risk assessment testing down 7% to \$3.1 million; Molecular collection systems up 1% to \$17.3 million; genomics down 53% to \$8.0 million
Oxford Immunotec*	\$19.6 million (\$19.4 million)	+18%	+\$0.02 (-\$0.04)	Product revenues up 24% to \$18.7 million due not just to strong demand but shift of higher seasonal testing volumes previously recognized in Q3; services down 44% to \$922,000 due to exit from blood donor screening business
Pacific Biosciences	\$24.6 million (\$20.8 million)	+14%	-\$0.16 (-\$0.16)	\$21.3 million in product + \$3.4 million in service and other revenues
PerkinElmer**	\$722.5 million (\$729.8 million)	+3%	+\$1.00 (+1.00)	DX up 6% to \$288.6 million driven by Euroimmune's 17% growth, the highest since being acquired two years ago; reproductive health up in high single digits driven by strength in genomics
Personalis	\$15.8 million (\$14.9 million)	+80%	-\$2.39 (-\$0.30)	Cancer sequencing firm's first quarterly report after closing \$140 million IPO in June
Qiagen	\$381.6 million (\$382.2 million)	+1%	+\$0.34 (+0.32)	Molecular DX up 5% to \$188 million driven by 6% increase in QuantiFERon-TB tests but molecular companion diagnostics co-development project revenues down 21% to \$11 million
Quanterix	\$13.5 million (\$11.5 million)	+57%	Not reported	Products up 69% to \$8.8 million + services and other revenues up 50% to \$4.8 million, including 40% growth in lab services
Quest Diagnostics	\$1.95 billion (\$1.94 billion)	+2%	+\$1.73 (+1.68)	Test volume up 4.4% (2.9% excluding acquisitions) but firm expects +\$200 million in future losses due to PAMA and price pressures from other payors
Quidel	\$108.3 million (\$108.3 million)	+5%	+\$0.36 (+0.34)	Rapid immunoassays up 30% to \$21.8 million including \$6 million increase in flu revenue; Cardiac immunoassays down 3% to \$68 million; Molecular DX up 7% to \$4.2 million, including 26% increase in Solana sales; Specialized DX up 13% to \$14.3 million
Roche Diagnostics (FY H1)*	\$30.86 billion	+8%	+\$11.40	Total DX sales for 2Q up 1% to \$3.47 billion, including 5% growth in molecular DX (\$1.06 billion). 1H growth driven by 16% increase in blood screening and strong demand for Cobas 6800/8800 systems; Centralized + POC solutions up 3% at \$3.86 billion including 7% growth in immunodiagnostics
Siemens Healthineers (FY Q3)	\$3.98 billion	+8%	+\$0.39	DX up 3% to \$1.16 billion (€1.04 billion) driven by sales of Atellica Solution platform (1,230 shipped so far in 2019)
Thermo Fisher*	\$6.32 billion (\$6.30 billion)	+4%	+\$3.04 (+3.00)	Specialty DX up 1% to \$943 million; Lab products + services up 3% to \$2.63 billion
Trinity Biotech	\$22.5 million	-10%	-\$0.26	Clinical lab revenues down 3% to \$20.4 million + POC down 90% to \$2.1 million
Twist Bioscience (FY Q3)*	\$13.6 million (\$12.8 million)	+109%	-\$0.92 (-0.82)	\$8 million from synthetic biology (including \$2.2 million from Gingko Bioworks) + \$5.6 million from next generation sequencing products

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COMPANY	FY 2019 Q2			DX SEGMENT PERFORMANCE
	Total Revenue (vs. Wall Street)	YOY Revenues	Adjusted EPS (vs. Wall Street)	
Veracyte*	\$30.1 million (\$28.9 million)	+32%	-\$0.05 (-\$0.27)	Genomic test volume up 26% to 9,663 tests, including over \$1 million in Percepta bronchial genomic classifier—744 tests
Waters**	\$599.2 million (\$601.4 million)	+ under 1%	+\$2.14 (+\$2.11)	Hurt by currency translation and weak sales in Europe; modest growth in mass spec

Companies that met or exceeded average Q2 Wall Street revenue estimates

* Companies that raised their revenue guidance as a result of Q2 performance

** Companies that lowered their revenue guidance as a result of Q2 performance 

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

Here's a summary of the key product launches announced from late July through the third week of August, 2019:

NEWLY LAUNCHED PRODUCTS & SERVICES	
COMPANY(IES)	PRODUCT(S)/SERVICE(S)
Integrated DNA Technologies	oPools Oligo Pools of high-quality DNA oligonucleotides up to 350 nucleotides-long
Loop Genomics	LoopSeq Bacterial Genome Sequencing sample preparation kit for de novo bacterial genome assembly using synthetic long reads on Illumina sequencers
Dovetail Genomics	Omni-C assay based on Hi-C method for chromosome conformation capture
Streck	Three new real-time PCR antibiotic resistance kits for research use only covering MCR, expanded OXA and TEM/SHV/GES
Streck	RNA Complete BCT, direct-draw whole-blood collection tube capable of maintaining the draw-time concentration of extracellular vesicles for up to 7 days at room temperature storage
Novogene	NovoPM 2.0 Cancer Panel, NGS panel that analyzes 484 solid tumor-related genes and introns in 43 genes
ChunLab	TrueBac ID cloud-based platform for bacterial identification of more than 12,000 species
Twist Bioscience	Long oligonucleotides product line
Mesa Biotech	Respiratory syncytial virus (RSV) test run on its Acula sample-to-answer point-of-care PCR system
Oxford Nanopore Technologies	Gridlon Mk1, an upgrade to the Gridlon X5 sequencing platform
BioDot	Rainmaker picoliter volume printing platform
Clear Labs	New Listeria testing and environmental mapping capabilities on its Clear Safety NGS platform
Menarini Silicon Biosystems	VRNxT automated volume reduction tool for removing manual sample reduction steps in cellular biology workflows
3M	3M Molecular Detection Assay 2 - STEC Gene Screen (stx and eae) to detect the genes for Shiga toxin types 1 and 2
3M	3M Molecular Detection Assay 2 - STEC Gene Screen (stx) to detect Shiga toxin genes
NanoString Technologies (in collaboration with MODEL-AD consortium)	New nCounter gene expression panels for use in Alzheimer's research 

■ Diagnostic Deals, from page 1

July 30 when Exact Sciences announced that it inked an agreement to acquire fellow cancer technologies firm Genomic Health for \$2.8 billion in cash and stock.

What makes the acquisition stunning isn't the price tag but the participants. The deal brings together three of the most dynamic products in the genomics cancer testing market: Exact's Cologuard stool test for colorectal cancer and Genomic Health's OncotypeDX tests for breast and prostate cancer. Collectively, these three products represent approximately 40% of all solid tumor incidence. Exact's Chairman and CEO Kevin Conroy touted the deal as "a pivotal step toward building the leading cancer diagnostics company in the world." And he may not be exaggerating. If the deal gets regulatory approval and closes by the end of the year as expected, the combined company is forecasted to generate \$1.6 billion in pro forma revenue in 2020.

Strategic Alliances

After a big July, the number of strategic alliances this month tailed off significantly. Key deals that were announced included a new three-year collaboration among Thermo Fisher Scientific, the Ontario Institute for Cancer Research and Genome Canada for the development of a trio of NGS-based assays for pancreatic, prostate and breast cancer detection and targeted treatment.

Meanwhile, two more firms took the plunge into the China market. On Aug. 20, Vancouver-based Enlighta announced that it was partnering with Chinese bioinformatics firm LHC to market No Cancer, an AI-based blood test system for early cancer detection in China and other parts of Asia. That same day, Genomenon said it was exporting its Mastermind genomic search engine to China via a new partnership with Shanghai Shanyi Biological Technology Co.

Back on the home front, Abbott and St. Louis-based Intoximeters unveiled their agreement to co-market their respective drug and alcohol testing technologies to law enforcement for use in cracking down on intoxicated drivers. The featured products include Abbott's SoToxa Mobile Test System, an oral fluid testing tool enabling rapid roadside detection of marijuana, cocaine, opiates, methadone, amphetamine and benzodiazepines, and Intoximeters' Alco-Sensor brand breath alcohol-tests.

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

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■ Diagnostic Deals, from page 7

MERGERS, ACQUISITIONS & ASSET SALES

AQUIRING COMPANY	TARGET(S)	DEAL SUMMARY
Exact Sciences	Genomic Health	<ul style="list-style-type: none"> • Price: \$2.8 billion in cash and stock • Status: Expected to close by end of 2019 • Genomic Health common shareholders to get per share price of \$27.50 in cash and \$44.50 in shares of Exact stock, subject to 10% collar based on Exact's volume-weighted average price for 45 trading days ending July 26 • Create cancer DX megafirm that unites Exact's Cologuard with Genomic Health's Oncotype DX
Thermo Fisher Scientific	HighChem	<ul style="list-style-type: none"> • Price: \$14 million • Status: Closed • Thermo Fisher acquires Slovakia-based mass spectrometry software provider
Siemens Healthineers	Minicare	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of Dutch developer of handheld technology for immunoassay testing at the point of care
GeneCentric Therapeutics	Select ImmunoGenomics	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of advanced immunogenomic, data analysis, and biomarker development services provider to support immuno-oncology drugs development
Salveo Diagnostics	ImmunArray + Nudge	<ul style="list-style-type: none"> • Price: \$50 million--\$15 million cash + \$35 million common stock • Status: Closed • 3-way merger of chronic disease testing firm (Salveo), autoimmune diagnostics firm (ImmunArray) and personalized health coaching engagement platform (Nudge)
MilliporeSigma	BSSN Software	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of lab informatics company based in Darmstadt, Germany
LineaRx (subsidiary of Applied DNA Sciences)	Vitatex	<ul style="list-style-type: none"> • Price: Upfront payment of \$300,000 worth of LineaRx equity at valuation of \$25 million valuation + milestone payments of up to \$200,000 cash + \$800,000 in stock • Status: Closed • LineaRx acquires assets + intellectual property of developer of invasive circulating tumor cell (iCTC) analysis technologies
Eurofins Genomics	Blue Heron Biotech	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of firm specializing in gene synthesis and DNA design
Cellink	Cytena	<ul style="list-style-type: none"> • Price: €30.3 million (\$33.8 million), including €11.4 million in cash + 674,678 newly issued shares valued at €18.9 million • Status: No closing date announced • Acquisition of German developer of printer technology for isolating and dispensing single cells for genomics research and biopharma production • Cytena to keep its current management team after closing
Precision for Medicine	ProMedDx + GLAS	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of ProMedDx, which specializes in biofluid specimens, + GLAS, which specializes in tissue-based samples, expands Precision's biomarker services offerings

MERGERS, ACQUISITIONS & ASSET SALES

AQUIRING COMPANY	TARGET(S)	DEAL SUMMARY
Caprion Biosciences	HistoGeneX	<ul style="list-style-type: none"> • Price: Undisclosed • Status: No closing date announced • Merger creating a new firm offering immune monitoring and biomarker services to biopharma companies
Progentec Diagnostics	Karate Health	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Merger creating new firm operating under the Progentec name offering testing and digital technologies for diagnosing and managing lupus, multiple sclerosis and other autoimmune diseases
NEC	Oncolmmunity	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of Norwegian bioinformatics firm and developer of ImmuneProfiler personalized cancer medicine platform
Cambridge Pathology	Novacyt	<ul style="list-style-type: none"> • Price: £400,000 (\$499,000) • Status: Closed • Novacyt sells off its clinical lab business to focus on sale allows to focus on its core Primerdesign and Lab21 businesses
LifeSpan BioSciences	Everest Biotech	<ul style="list-style-type: none"> • Price: Undisclosed • Status: Closed • Acquisition of firm specializing in production of antigen affinity purified goat polyclonal antibodies expands LSBio's monoclonal and polyclonal primary antibodies offerings

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

PARTNER 1	PARTNERS (2+)	DEAL SUMMARY
Enlighta	LHHC Medical Technology	<ul style="list-style-type: none"> • Objective: Sell No Cancer AI-based blood test system for early cancer detection in Asia • Dynamic: LHHC to establish testing + blood collection sites in China and other Asian markets • Companies to also launch direct-to-consumer electronic network for customers to upload and access their No Cancer data
Genomenon	Shanghai Shanyi Biological Technology Co.	<ul style="list-style-type: none"> • Objective: Make Genomenon's Mastermind genomic search engine to available to labs in China • Dynamic: Genomenon forms partnership with Chinese provider of sequencing interpretation, variant validation + other molecular tech services
Genomind	NeuroFlow	<ul style="list-style-type: none"> • Objective: Deliver services related to care of depression, anxiety, PTSD, substance abuse + other mental health disorders • Dynamic: Combine NeuroFlow's IntegrateHealth platform with Genomind's Professional PGx Express genetic testing service to enable physicians to use the former to administer the latter and communicate test results to patients
Abbott Laboratories	Intoximeters	<ul style="list-style-type: none"> • Objective: Market Abbott's SoToxa Mobile Test System oral fluid drug test kit to law enforcement for use in cracking down on intoxicated drivers • Dynamic: Intoximeters to market SoToxa alongside its own Alco-Sensor brand breath alcohol-testing products

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■ Diagnostic Deals, from page 9

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

PARTNER 1	PARTNERS (2+)	DEAL SUMMARY
Thermo Fisher Scientific	Genome Canada + Ontario Institute for Cancer Research	<ul style="list-style-type: none"> Objective: Develop targeted NGS-based assays + analysis software Dynamic: 3-year, \$4.5 million collaboration to develop one assay for rapid diagnosis of pancreatic cancer + two for targeted treatments of prostate + breast cancer
NanoString Technologies	Mayo Clinic Laboratories	<ul style="list-style-type: none"> Objective: Develop high-risk breast cancer + leukemia tests Dynamic: Perform cross-site study using NanoString's GeoMx Digital Spatial Profiler + nCounter technologies to investigate the immune architecture of high-risk hormone receptor positive HER2-negative breast tumor samples Do second study evaluating if use of nCounter fusion assays is scalable + cost-effective alternative to conventional leukemia FISH testing
Xylonix	BioGemex	<ul style="list-style-type: none"> Objective: Develop predictive cancer immunotherapy treatment response diagnostic Dynamic: Jointly develop XDX-01, a pretreatment point-of-care diagnostic to predict patient reaction to T-cell mediated cancer immunotherapies in solid tumors Assay to be cartridge-based modular system scaled with Xylonix's XDX-01 serum biomarker
Q-State Biosciences	2bPrecise (unit of Allscripts Healthcare Solutions)	<ul style="list-style-type: none"> Objective: Create clinical-genomic datasets to support precision medicine Dynamic: 2bPrecise to contribute its cloud-based technology platform for integrating genomic data into clinical workflows Q-State to supply whole-genome + whole-exome sequencing, transcriptomics analysis + phenotyping services
Mission Bio	Onconova	<ul style="list-style-type: none"> Objective: Do clinical trials using Mission Bio's Tapestri platform for targeted single-cell DNA analysis to study Onconova's cancer therapy Dynamic: Onconova to use Tapestri platform in phase III clinical trial examining rigosertib, a small molecule mimetic firm is developing to target RAS mutation in myelodysplastic syndromes (MDS)
Expedeon	Sona Nanotech	<ul style="list-style-type: none"> Objective: Develop multiplex point-of-care lateral flow diagnostic tests Dynamic: Expedeon to provide gold nanoparticles, bioconjugation technologies and expertise; Sona to provide lateral flow assay development services
Sophia Genetics	ADC Therapeutics	<ul style="list-style-type: none"> Objective: Identify genomic markers associated with clinical response to ADC's experimental lymphoma drug Dynamic: Sophia to conduct somatic mutation analysis on genes in cell-free DNA samples from the blood of refractory diffuse large B-cell lymphoma patients participating in ADC's Phase II clinical trial for experimental drug ADCT-402, loncastuximab tesirine Sophia to use its informatics platform to match genomic markers with clinical response to treatment
Predictive Laboratories (subsidiary of Predictive Technology Group)	Preeclampsia Foundation	<ul style="list-style-type: none"> Objective: Study genetic factors associated with preeclampsia Dynamic: Conduct sequencing analysis study to grow Foundation's Preeclampsia Registry + generate data that Predictive will use to develop a proprietary test for early detection of women at risk for preeclampsia

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

PARTNER 1	PARTNERS (2+)	DEAL SUMMARY
Biodesix	Immodulon Therapeutics	<ul style="list-style-type: none"> Objective: Identify proteomic markers linked to pancreatic cancer Dynamic: Use Biodesix's Diagnostic Cortex biomarker discovery platform to analyze circulating proteome of advanced pancreatic cancer patients treated with Immodulon's IMM-101 candidate immunotherapy
Syapse	Pfizer	<ul style="list-style-type: none"> Objective: Improve precision oncology treatment + research Dynamic: Collect real-world data on molecular testing patterns and therapy choices made by physicians for cancer patients within the healthcare system

DISTRIBUTION, SALES & MARKETING AGREEMENTS

PROPERTY OWNER	DISTRIBUTOR	DEAL SUMMARY
Verax Biomedical	Fisher Healthcare	<ul style="list-style-type: none"> Products: Verax's Platelet PGD Test Territory: US Exclusive
T2 Biosystems	Undisclosed	<ul style="list-style-type: none"> Products: T2's rapid diagnostic technologies, including T2Bacteria + T2Candida Panels Territory: Australia, Fiji, New Zealand Exclusive T2 also announced that it has made 5 other exclusive distribution deals in 2019 covering Estonia, Greece, Ireland, Saudi Arabia, South Africa
IncellDx	Kindstar Global	<ul style="list-style-type: none"> Products: 3 IncellDx single-cell immuno-oncology tests, including OncoTect iO Tumor Treatment Profile, OncoTect iO Bladder + OncoBreast Territory: China Exclusive
Curetis	Ako Med	<ul style="list-style-type: none"> Products: Curetis' Unyvero A50 instrument system + test cartridges antigens, antibodies + immunoassays Territory: Serbia, North Macedonia, Bosnia and Herzegovina, Montenegro Two separate 3-year exclusive agreements
Patia	GX Sciences	<ul style="list-style-type: none"> Products: Patia's DiabetesPredict type 2 diabetes risk test Territory: US GX agrees to acquire a minimum of 25,000 tests from Patia until 2021 for a minimum of €1.2 million (\$1.3 million)
NanoCollect Biomedical	Millennium Science	<ul style="list-style-type: none"> Products: NanoCollect's Wolf Cell Sorter, N1 single-cell plate dispenser, consumables + software Territory: Australia + New Zealand Exclusive

LICENSES

Licensor	Licensee	Deal Summary
The Broad Institute	MilliporeSigma	<ul style="list-style-type: none"> New licensing framework covering CRISPR genome editing intellectual property under each side's respective control Broad to now offer licenses to its own and MilliporeSigma's CRISPR IP portfolio to potential licensees for internal research uses and commercial research tools and kits MilliporeSigma's IP for CRISPR technology now available royalty-free to non-profit academic institutions, non-profit business communities and governmental agencies for internal research

Continued on page 12

■ Diagnostic Deals, from page 11

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/Service	Client/User	Deal Summary
Uman Diagnostics (Quanterix subsidiary)	Bio-Techne	Supply antibodies to Bio-Techne for use on its Ella immunoassay platform for quantification of neurofilament light (Nf-L)
Beacon Laboratory Benefit Solutions	Biocept	Lab services provider agreement
Integrated DNA Technologies	Clear Labs	Integrated DNA to be primary supplier of next-generation sequencing oligo products for Clear Lab's NGS-based food safety platform

NEW CLINICAL STUDIES

DX Partner	Other Partner(s)	Description of Study
Group K Diagnostics (GKD)	Health Network Laboratories	Trial to validate the accuracy, effectiveness and clinical implications of GKD's MultiNostic liver function test



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November 2016
FDA Oversight of LDTs Delayed for Consultation with New Administration, Stakeholders

The U.S. Food and Drug Administration (FDA) has provided laboratories with some much needed good news—the agency will not finalize its laboratory-developed test (LDT) guidance document before the end of the year. In fact, the FDA confirmed Friday that it will instead work with the new administration on appropriate reforms to ensure LDTs are safe and effective.

According to a statement from the FDA, which G2 received in response to a request for confirmation of the status of the guidance document:

“The FDA believes that patients and health care providers need accurate, reliable, and clinically valid tests to make good health care decisions— inaccurate or false test results can harm individual patients. We have been working to develop a new oversight policy for laboratory developed tests, one that balances patient protection with continued access and innovation, and realize just how important it is that we continue to work with the new administration on appropriate reforms to ensure LDTs are safe and effective.”

INSIDE THIS ISSUE

- TOP OF THE NEWS: FDA Oversight of LDTs Delayed for Consultation with New Administration, Stakeholders
- DIAGNOSTICS INDUSTRY: Relationship Strategy for Biotechnology Firms
- GENETICS: Research, Education, Clinical Applications and Market Development

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 For Clinical and AP Laboratories and Pathology Practices

December 2018
HIPAA Compliance: The Pitfalls of PHI De-identification & How to Avoid Them

In 2006, the Australian government released medical billing records of 2.9 million people. They tried to protect patient privacy by removing names and other identifying data. But it didn't work. Shortly after the data was released, a University of Melbourne research team was able to easily “re-identify” people, without decryption, simply by comparing the released dataset to other publicly available information, such as medical procedures and year of birth.

While it happened on the opposite side of the globe, the Australia case is directly relevant to US labs to the extent it demonstrates the weaknesses of de-identification and how relying on it can cause privacy breaches that violate HIPAA and, more importantly, jeopardize the lab's relationships with healthcare partners and patients.

INSIDE THIS ISSUE

- TOOL: Model Specimen Processing Fees Compliance Policy
- MEICARE REIMBURSEMENT: CMS Offers Some FRACAS Related But Not Nearly Enough
- QIG MONTHLY WORK PLAN REVIEW: November 2018
- YOU MAKE THE CALL: Incorporating MDx to Order More Early Screening Tests
- LABS IN COURT: A knowledge of intent

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No Final LDT Framework in 2016: FDA Seeks Further Input from Stakeholders, New Administration

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INSIDE THIS ISSUE

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- What Happens: Administration Could Mean for ACA and Labs
- State Federal Court Pays Attention: Overtime Pay Change
- 2017 Clinical Laboratory Fee Schedule: Bringing a Bit of Good News for Medication Services

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