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LABORATORY

INDUSTRY REPORT™

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Upcoming Events

Lab Institute 2018

Surviving Disruption: Rethinking Business Models, Technologies, and Competitive Strategies in a Changing Lab Market

Oct. 24-26, Washington, DC

www.labinstitute.com

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Oct. 24, Washington, DC

■ *Lab Reimbursement Summit 2019: What You Need to Know and Do to Get Ready for the New 2019 Clinical Lab Fee Schedule*
Dec. 6, 2018, Las Vegas, NV

www.lableadershipsommits.com

DX Earnings Report: Q2 Lab Earnings Stay Strong but Not Quite at Q1 Levels

Q2 is shaping up to be another strong quarter—albeit not as stellar as Q1. Salient trends:

- ▶ Big labs continue posting impressive organic growth even as they enjoy the surge of new revenues from recent acquisitions designed, in part, to cushion the impact of PAMA cuts in Medicare rates;
- ▶ Currency translation and the strong US dollar had a significant effect on foreign firms and those that rely heavily on global markets;
- ▶ Seasonally, the prolonged winter and delayed spring in the Eastern US was a boost for flu and respiratory tests but a bust for Lyme and other warm weather illness tests.

Continued on page 2

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

Forget the lazy days of summer—lab companies have been moving forward with deals. Here's a look at key activity from mid-July through the third week of August.

M&A

Roche acquired an additional 12.5 million shares of Foundation Medicine at \$137 per share, valued at \$1.72 billion, moving the company closer to its total purchase price of \$2.4 billion. When the deal closes, Foundation Medicine will become a wholly-owned subsidiary of Roche.

Another notable deal was the closing of Myriad Genetics' acquisition of Counsyl. In addition to the M&A deals listed in the chart, there were three new strategic product and technology asset acquisitions worth noting:

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■ DX Earnings Report, from page 1

Here's a full rundown. (*Note:* Foundation Medicine and MDxHealth had not yet reported their Q2 earnings on the date we went to press.)

Gainers

Continuing recent trends, gainers outnumbered decliners by nearly 7:1 with 34 of 40 companies reporting higher Q2 revenues vs. the same period in 2017. Gains were not only widespread but frequently higher than expected. Thus, among the gainers, only five failed to make their Wall Street targets (as compared to three in Q1):

- ▶ Exact Sciences which despite 78% growth fueled by Cologuard sales missed its \$104.7 million target by \$1.8 million;
- ▶ Meridian Bioscience which grew 3% but came up \$400K shy of its \$52.1 million target;
- ▶ Quest Diagnostics which for the second quarter in a row narrowly missed its target despite posting respectable 3% growth;
- ▶ Pacific Biosciences which posted its first positive growth quarter in over a year but still fell \$2.2 million below its \$23.8 million target; and
- ▶ Struggling Waters whose \$596.2 million in Q2 revenues were up 7% year over year but \$1.8 million shy of where Wall Street expected them to be.

Four firms upwardly adjusted their full-year EPS and/or revenue guidance during the quarter, half as many as in Q1. One firm reduced its EPS guidance—Waters, which backed off from last quarter's adjustment increase.

Decliners

The number of firms reporting revenue declines in Q2 increased from five to six. For the first time in a while, both Pacific Biosciences and Waters got off the decliners list. But they were replaced by new entrants, including:

- ▶ EnzoBioChem which followed Q2's 3% growth with a 5% decline this quarter;
- ▶ NanoString Technologies which lost 28% due to the loss of pharma collaboration revenues—a loss that was anticipated and allowed the firm to meet its \$25 million Wall Street target; and
- ▶ NantHealth, which is in the process of restructuring its operations, lost 6% but still managed to double sequencing sales and narrow its net loss to \$.21 per share.

Meanwhile, two of the other decliners were repeats from Q1:

- ▶ Opko Health which lost 10% due in part to PAMA cuts but still boosted exosome sequencing tests and surpassed its \$261.7 million target by \$2 million; and
- ▶ Siemens Healthineers, the fledgling Siemens spinout which lost 5% in just its third quarter of operation.

On the flip side, a pair of Q1 decliners were able to turn things around this quarter, including:

- ▶ Fluidigm which bounced back from 1% in losses to post 11% in gains; and

- ▶ Myriad Genetics which followed up the previous quarter 2% decline with 6% to the plus side.

The Billion-Dollar Labs

Of the billion-dollar labs, only Quest Diagnostics missed its Wall Street target. But the miss was narrow and belied by the positive growth of 3% despite PAMA cuts that were estimated to impact 12% of its business. The predominant theme among the other giants was massive growth swollen by revenues from recent acquisitions but backed up by rock solid performance in core sectors, including:

- ▶ Abbott—17% in reported revenues from Alere and St. Jude acquisitions + 8% organic growth;
- ▶ Thermo Fisher Scientific—22% increase in reported revenues from Pantheon acquisition + 8% organic growth;
- ▶ PerkinElmer—29% reported growth from Euroimmun acquisition + 10% organic growth;
- ▶ Becton Dickinson—41% reported growth from CR Bard acquisition + 5% organic growth; and
- ▶ LabCorp—13% reported growth from acquisitions + 8% organic growth.

Diagnostics Earning Reports Q2 2018 (At least \$10 million in sales)

COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total Q2* 2018	YOY	Wall Street Estimate	
Abbott Laboratories	\$7.77 billion	+17%	\$7.71 billion	Organic growth not counting Alere and St. Jude purchases of 8%; DX sales of \$1.87 billion v. \$1.27 billion in Q2 2017 lifted by 8% growth in molecular tests spearheaded by infectious disease
Agilent Technologies	\$1.20 billion *(Q3)	+8%	\$1.20 billion	CrossLabGroup up 10% to \$426 million, Diagnostics & Genomics up 9% to \$237 million; mass spec + cell analysis strong; raises guidance from \$4.86 billion to \$4.88 billion in revenues and EPS to \$2.71 (up 2¢)
Becton Dickinson	\$4.28 billion *(Q3)	+41%	\$4.24 billion	Up 5% on comparable, currency-neutral basis excluding CR Bard acquisition; DX systems revenues up 7% to \$362 million driven by BD Max platform + core microbio; raises guidance to over 31.5% revenue growth
BioMérieux	\$677.1 million	+3%	NA	8% organic growth; 6% decline in immunoassays due to price pressures in US partly offset by growth of Vidas line in other markets
Bio-Rad	\$575.9 million	+14%	\$548.4 million	Clinical diagnostics up 10% (6.5% currency-neutral) to \$354 million driven by blood typing, immunology + quality control products
Bio-Techne	\$180.3 million *(Q4)	+15%	\$174.8 million	9% organic growth; diagnostics up 2% to \$33.1 million; protein platforms up 21% offsetting drop in glucose controls
Bruker	\$443.7 million	+7%	\$436.9 million	3% organic growth; scientific instruments up 7% and mass spec up in single digits
CareDx	\$17.8 million	+48%	\$15.5 million	Stellar growth in Allosure kidney transplant tests driving 67% spike in testing revenues; product revenues up 6%; licensing revenues up 10%
Danaher	\$4.98 billion	+10%	\$4.92 billion	6% organic growth (net of Cepheid); diagnostics up 8% to \$1.55 billion with Cepheid properties growing in high single-digits, slightly down from previous quarters; EPS guidance adjusted upward to \$3.64 to \$3.71 range

COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total Q2* 2018	YOY	Wall Street Estimate	
EnzoBioChem	\$25.6 million *(Q3)	-5%	NA	Bad weather coupled with losses of major insurance payor + major genetic test medical practice client contribute to loss
Exact Sciences	\$102.9 million	+78%	\$104.7 million	Cologuard stays hot with 59% spike in tests—215,000 ordered at average of \$479 per test
Fluidigm	\$26.4 million	+11%	\$26.3 million	19% increase in mass cytometry + high-throughput genomics to \$11.4 million partially offset by decline in single-cell genomics products
GenMark Diagnostics	\$14.9 million	+20%	\$14.5 million	Growth driven by 39 new ePlex analyzer placements; net earnings of -37¢ per share miss -32¢ target
Genomic Health	\$95.6 million	+14%	\$92.1 million	Oncotype DX breast cancer tests up 4% + prostate tests up 32% in US
Hologic	\$824 million *(Q3)	+2%	\$800.4 million	Diagnostics up 4% to \$294.3 million with 7% growth in molecular offsetting 2% decline in blood testing; cytology + perinatal basically flat at \$121.1 million
Illumina	\$830 million	+25%	\$786.6 million	NovaSeq + new iSeq drive growth in sequencing segment; increases 2018 guidance to 20% revenue growth + \$5.10-\$5.20 EPS
Invitae	\$37.3 million	+160%	\$31.7 million	Test volume up 139% to 73,000 samples, 59,000 of which were billable; Medicare CPT code 81433 ovarian + breast cancer revenues up to \$2.3 million
Laboratory Corp. of America	\$2.87 billion	+13%	\$2.85 billion	Diagnostics up 5% to \$1.72 billion with acquisitions revenues + currency translation offsetting PAMA price cuts, which cut revenue per requisition 0.7%
Luminex	\$79.6 million	+4%	\$79.6 million	Strong growth in diagnostics led by sample-to-answer molecular products; loss of LabCorp NuSwab account expected to harm profitability
Meridian Bioscience	\$51.7 million *(Q3)	+3%	\$52.1 million	Diagnostics revenues up 1% to \$36.4 million driven with declines in <i>Clostridium difficile</i> + foodborne products wiping out single-digit growth in <i>Helicobacter pylori</i> + double-digit growth in respiratory and Magellan LeadCare testing products
Myriad Genetics	\$200.9 million *(Q4)	+1%	\$195.8 million	Molecular test revenues flat at \$187.6 million due to 12% fall in hereditary cancer test sales to \$126.8 million but GeneSight revenues up 33% to \$33.9 million, ProLaris prostate cancer test revenues up 133% to \$7 million, EndoPredict tests up 40% to \$2.8 million
NanoString Technologies	\$25 million	-28%	\$25 million	Pharma collaboration revenues down over 300% YOY; consumables up 16% to \$12.8 million with Prosigna IVD kit sales contributing \$2.5 million; IO 360 remains fastest growing panel launch in firm history; full year revenue guidance increased to \$79 million-\$81 million
NantHealth	\$22 million	-6%	\$23 million	Net loss narrows to \$.21 per share; sequencing molecular sales nearly double to \$924,000; software falls 10% to \$19.5 million
Natera	\$63.1 million	+21%	\$61.2 million	Tests up 29%, including 27% increase prenatal Panorama test (\$33.3 million, 113,000 tests) + 36% increase in Horizon carrier screening test (41,800 tests)
NeoGenomics	\$67.7 million	+9%	\$66.2 million	14% growth in test volume offsets 4% PAMA related decline in test revenue to \$318 per test yielding overall 7% increase in total test revenues to \$59.5 million; pharma services revenues increase 22% to \$6.7 million
Opko Health	\$263.7 million	-10%	\$261.7 million	Despite 13% growth in test volume, PAMA cuts drive 1% decline in BioReference Laboratories revenues YOY (but \$5 million above 1Q) as firm reorganizes to boost efficiency; exosome sequencing test volume up 38%
OraSure Technologies	\$43.6 million	+8%	\$42.2 million	Global sales drive 42% increase in OraQuick HIV testing products to \$12.6 million; OraQuick HCV products down 58% to \$3.2 million due to loss of foreign govt. contract; molecular collection systems up 7% to \$17.2 million
Oxford Immunotec	\$29.3 million	+12%	\$28.6 million	Growth driven by 17% increase in global tuberculosis sales to \$25 million; tick-borne testing down 9% to \$4.4 million due to scale down of blood donor screening operation

COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total Q2* 2018	YOY	Wall Street Estimate	
Oxford Nanopore	£13.8 million (\$18.4 million)	+204%	NA	Growth driven by increase in nanopore sequencing tools customers + sales of consumables
<i>Pacific Biosciences</i>	\$21.6 million	+7%	\$23.8 million	First quarter of positive growth in over a year; 90%+ growth in Sequel usage offset by 50%+ decline in RS II system consumables; instrument revenue up 20% to \$8.5 million
PerkinElmer	\$703.4 million	+29%	\$693 million	10% organic growth not counting Euroimmun revenues; diagnostics revenues up 66% (10% organic) to \$272.7 million; new genomics business keeps growing at 100%+ clip due, in part, to low base it started with
Qiagen	\$377.2 million	+8%	\$375.6 million	Molecular diagnostics up 10% to \$187 million, just below 50% of total sales, led by double-digit growth in QuantiFERon latent TB test (expected to generate \$300 million in 2018 sales); companion diagnostics co-development deals boost personalized health sales
<i>Quest Diagnostics</i>	\$1.92 billion	+3%	\$1.95 billion	Narrowly misses target for second Q in a row; diagnostics services growth driven by acquisitions which offset PAMA price cuts; acceptance of AbbVie's new Mavyret treatment for hepatitis C drives sharp declines in genotyping + resistance testing; Vitamin D testing down due to increase in coverage denials; prescription drug monitoring revenues strong but slightly below expectations
Quidel	\$103.3 million	+269%	\$103.2 million	Driven by \$69.9 million in cardiac immunoassay revenues including sales from newly acquired Triage and BNP; rapid immunoassay products down from \$22 to \$16 million due to early end of flu season; specialized diagnostics down from \$13.1 to \$12.7 million; 103% growth in Solana products drives \$700K growth in molecular to \$3.9 million
Roche	\$28.34 billion *(H1 2018)	+7%	NA	Roche Diagnostics up 8% + total DX sales up 9% to \$3.43 billion driven by centralized point of care solutions and success of new Cobas t 511 and t 711, molecular diagnostics (up 6%) and blood and HPV screening (up 30%); virology up 4% including 7% growth in HIV monitoring + 229% growth in Cobas Liat point of care testing sales
Siemens Healthineers	\$3.87 billion	-5%	NA	Decline driven by negative currency translation; DX revenues down 4% to \$1.01 billion despite strong growth in China, Europe and other global markets
Thermo Fisher Scientific	\$6.08 billion	+22%	\$5.89 billion	8% organic growth + 12% growth from new acquisitions + 2% growth from currency translation; Lab revenues up 42% to \$2.55 billion including 9% organic + net of Patheon revenues; increases 2018 guidance to revenues of \$23.68-\$23.86 billion and EPS of \$10.80-\$11.01 EPS
Trinity Biotech	\$25 million	-2%	NA	Lab revenues decline \$100K to \$21 million with gains in diabetes + autoimmunity offset declines in Lyme disease due to late spring in Northeast; 4% decline in point-of-care (\$3.8 million) due to lower HIV sales in US
Veracyte	\$22.8 million	+24%	\$20.6 million	Genomic test volume up 18% (7,686 tests), including triple revenues from Percepta bronchial genomic classifier; increases 2018 revenues guidance to \$87-\$89 million (\$83-\$86 million)
<i>Waters</i>	\$596.2 million	+7%	\$598 million	Growth driven by strong sales in China + TA sales + positive currency translation; mass spec rebounds from weak start in first part of year; reduces full year guidance to non-GAAP EPS of \$8.05 to \$8.20

* **Bold face:** Companies that met or exceeded Q1 Wall Street revenues targets

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

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■ **Diagnostic Deals, from page 1**

- ▶ Svar Life Science, formerly Euro Diagnostica, agreed to transfer its radioimmunoassay portfolio and Neolisa chromogranin A ELISA assay to Diasource ImmunoAssays;
- ▶ Waters acquired the exclusive rights to Prosolia’s desorption electrospray ionization technology for mass spectrometry applications; and
- ▶ Interspace Diagnostics acquired most of the equipment from the Philadelphia laboratory of Rosetta Genomics, which filed for bankruptcy in June.

Strategic Alliances

Exact Sciences and Pfizer agreed to copromote Exact’s Cologuard colorectal cancer screening test Cologuard. Wall Street liked the news as shares of Exact soared on the announcement.

Meanwhile, 23andMe made a four-year deal making GlaxoSmithKline its sole drug discovery collaborator.

The period was also notable for new alliance activity in Asia, including:

- ▶ Oxford BioDynamics’ strategic alliance with GL Capital Group to help it establish a footprint in China;
- ▶ Genetic Technologies’ partnering with Zishan Health Consultancy to facilitate expansion into the Chinese market;
- ▶ Clearbridge Health Limited’s exclusive partnership with Hunan, China-based Agen Medicine Laboratory Technology Company.
- ▶ Qiagen’s non-exclusively collaboration with SRL, the largest clinical testing lab in Japan.

Here’s a summary of key diagnostic deals from mid-July through the third week in August:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Roche	Foundation Medicine	<ul style="list-style-type: none"> ■ Price: \$2.4 billion cash ■ Status: Roche acquires 12.5 million shares it didn't own at \$137 per share at end of July with deal to be consummated by subsequent merger ■ Foundation Medicine to become wholly-owned subsidiary of Roche after merger
Myriad Genetics	Counsyl	<ul style="list-style-type: none"> ■ Price: \$375 million ■ Status: Closing of deal announced in May ■ Counsyl's reproductive health tests to be made part of business unit called Myriad Women's Health targeting Ob/Gyns and reproductive healthcare providers ■ Myriad's women's health sales force to be combined with Counsyl's sales reps
Hologic	Faxitron Bioptics	<ul style="list-style-type: none"> ■ Price: \$85 million ■ Status: Closed ■ Acquisition of specimen radiography firm expands Hologic's portfolio of breast health products
Caprion Biosciences	Primity Bio	<ul style="list-style-type: none"> ■ Price: Undisclosed ■ Status: Closed ■ Acquisition of biomarker and immune monitoring firm expands Caprion's own immunology and molecular profiling business

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Tecan	NuGen	<ul style="list-style-type: none"> Price: \$54.5 million cash Status: To close before end of 2018 Tecan moves into genomics market by acquiring NuGen's sample prep kits for next-generation sequencing and microarrays
Bio-Techne	Exosome Diagnostics	<ul style="list-style-type: none"> Price: Up to \$575 million, \$250 million upfront and \$325 contingent Status: Closed Bio-Techne to leverage Exosome's technology to interpret complex gene expression data and find early predictors of disease progression
Diagenode	Nxt-Dx	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Acquisition of Belgian epigenetics service provider expands Diagenode's epigenomics services platform and epigenetic biomarker discovery efforts
STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Exact Sciences	Pfizer	<ul style="list-style-type: none"> Objective: Co-promote Exact's Cologuard colorectal cancer screening test Dynamic: Exact to retain full responsibility for Cologuard manufacturing and lab Pfizer to participate in marketing, pay part of marketing expenses and get 50% share of gross profits above agreed upon baseline
PerkinElmer	Agena Bioscience	<ul style="list-style-type: none"> Objective: Create low-cost, sample-to-result workflow targeting circulating tumor DNA for liquid biopsy applications that can be completed in one day Dynamic: Combine PerkinElmer's LabChip GX Touch nucleic acid analyzer for DNA quality assessment and quantitation with Agena's MassArray system workflow
Natera	Fox Chase Cancer Center	<ul style="list-style-type: none"> Objective: Evaluate Natera's Signatera circulating tumor DNA assay for kidney cancer recurrence Dynamic: Parties to use the assay and next-generation sequencing to analyze specimens of 49 kidney cancer patients
23andMe	GlaxoSmithKline	<ul style="list-style-type: none"> Objective: New drug discovery Dynamic: Four-year deal + GSK option to extend to fifth year GSK to be 23andMe's exclusive drug discovery collaborator Each side to contribute 50% of initial funding
HTG Molecular Diagnostics	Oncologie	<ul style="list-style-type: none"> Objective: Help Oncologie develop biomarkers for its immuno-oncology drug candidates Dynamic: Oncologie to use HTG's NGS-based molecular profiling instruments, assays and lab services to develop new cancer drugs
Oxford BioDynamics	GL Capital Group	<ul style="list-style-type: none"> Objective: Get Oxford into China market Dynamic: GL Capital to find partners for Oxford's epigenetic biomarkers and technology in mainland China GL Capital also gets 5% equity stake in UK-based Oxford and a seat on its board
Genetic Technologies	Beijing Zishan Health Consultancy	<ul style="list-style-type: none"> Objective: Get Genetic Technologies into China market Dynamic: Create 50/50 joint venture to offer Genetic Technologies' genomic tests in mainland China Zishan to handle sales, account management, marketing and promotion of tests and act as a liaison between the firm and the China FDA
Orig3n	ZhongAn Online P&C Insurance	<ul style="list-style-type: none"> Objective: Sell health tech solutions in China Dynamic: ZhongAn to use Orig3n's genetic tests to supplement its online insurance offerings Sides also to create new lab in Shanghai
Clearbridge Health Limited	Agen Medicine Laboratory Technology Company	<ul style="list-style-type: none"> Objective: Get Clearbridge's into China market Dynamic: Agen to market Clearbridge's ClearCell FX1 System for circulating tumor cell enrichment in China
Qiagen	SRL	<ul style="list-style-type: none"> Objective: Develop companion diagnostic tests for new drugs for Japanese market Dynamic: SRL to use Qiagen workflows in its efforts to seek regulatory approval for new drugs by Japan's Pharmaceutical and Medical Devices Agency

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Qiagen	Hamilton Robotics	<ul style="list-style-type: none"> Objective: Improve processing of Qiagen's QuantiFeron-TB Gold Plus (QFT-Plus) test Dynamic: Integrate Hamilton's Microlab Star automated liquid-handling workstation into QFT-Plus workflow
Qiagen	The Scientific Group (TSG)	<ul style="list-style-type: none"> Objective: Expand Qiagen's presence in African market Dynamic: TSG to be Qiagen's exclusive commercial partner for Africa other than South Africa, Morocco, Algeria, Libya, Tunisia, Egypt, Sudan and Eritrea
Exagen Diagnostics	CareFirst BlueCross BlueShield	<ul style="list-style-type: none"> Objective: Evaluate Exagen's Avise Lupus test for differential diagnosis of systemic lupus erythematosus (SLE) Dynamic: CareFirst to make test available to its members to aid in SLE diagnosis, and collaborate on an exploratory study of how the test's results impact primary care physician practice referral patterns
GeneNews	LifeX	<ul style="list-style-type: none"> Objective: Boost use of GeneNews' biopsy cancer tests by large, multi-entity healthcare systems Dynamic: Parties will also work to further develop and market Aristotle platform
Genedrive	Foundation for Innovative New Diagnostics (FIND)	<ul style="list-style-type: none"> Objective: Evaluate Genedrive's hepatitis C Virus ID Kit Dynamic: FIND to lead evaluation studies on assays in Cameroon and Georgia with Genedrive to provide product in-kind support
Chembio Diagnostics	Foundation for Innovative New Diagnostics (FIND)	<ul style="list-style-type: none"> Objective: Expedite feasibility testing of a rapid diagnostic test for hepatitis C virus (HCV) Dynamic: Chembio to use its DPP technology platform for testing of a rapid HCV core antigen assay
Shivom	eMQT	<ul style="list-style-type: none"> Objective: Sequence the genomes of 1,000 sickle-cell disease patients in sub-Saharan Africa Dynamic: eMQT to collect and store data on 100 patients on Shivom platform If proof-of-concept study is successful, database will be expanded to 1,000 patients
Mapmygenome	Digital DNAtix (DD)	<ul style="list-style-type: none"> Objective: Enhance security and privacy of Mapmygenome's direct-to-consumer genetic tests Dynamic: Leverage DD's blockchain technology allowing researchers to access anonymous data for platform supporting Mapmygenome's genome testing, analysis and related personalized medicine services
Sonic Healthcare USA	ProMedica Health System	<ul style="list-style-type: none"> Objective: Improve laboratory services in Ohio, Michigan and Indiana Dynamic: Create Toledo-based joint venture called ProMedica Pathology Laboratories that combines ProMedica's inpatient and outreach lab testing capabilities with Sonic's esoteric testing capabilities
10X Genomics	BioLegend + Immudex	<ul style="list-style-type: none"> Objective: Use 10X barcoding technology to measure gene and protein expression at single-cell level Dynamic: 10X and BioLegend to co-engineer latter's TotalSeqB and TotalSeq C products to work with 10X's single cell products and Feature Barcoding Technology 10X to combine its barcoding technology with Immudex's Dextramer product
InterSystems	Rhodes Group (subsidiary of TriCore Reference Laboratories)	<ul style="list-style-type: none"> Objective: Support TriCore's Clinical Lab 2.0 initiative to use lab data to improve patient health care Dynamic: Rhodes Group to use InterSystems' HealthShare to create and manage unified views of patient data
Beckman Coulter	US Arkray	<ul style="list-style-type: none"> Objective: Launch iQ Urinalysis Workcell Dynamic: Beckman to exclusively market the product which combines Beckman Coulter's Iris iQ200 Digital Flow Morphology system and the Arkray Aution Max Ax-4030 fully automated analyzer, in US
Lucence Diagnostics	National Cancer Center Singapore (NCCS)	<ul style="list-style-type: none"> Objective: Improve genetic testing for breast and gynecological cancers in Asian women Dynamic: Research study leveraging NCCS database of genomic variants with Lucence's expertise in DNA sequencing and genomic data analysis
Ibex Medical Analytics	University of Pittsburgh Medical Center (UPMC)	<ul style="list-style-type: none"> Objective: Validate Ibex's AI-based prostate cancer diagnostic system Dynamic: Use Ibex's Second Read system, which uses AI and machine learning to identify cell types and features in images of prostate core needle biopsies, on samples collected by UPMC
Biocept	UCSD Moores Cancer Center	<ul style="list-style-type: none"> Objective: Evaluate effectiveness of Biocept's Target Selector liquid biopsy assays in predicting cancer recurrence and treatment response Dynamic: Studies will use Biocept's technology to search for circulating tumor cells and circulating tumor DNA, comparing results with CT or PET scan findings

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	Distributor	Deal Summary
EKF Diagnostics Holdings	McKesson Medical-Surgical	<ul style="list-style-type: none"> Product: EKF's DiaSpect Tm reagent-free hemoglobin analyzer Territories: US Exclusive
Sienna Cancer Diagnostics	Shaanxi GaoYuan	<ul style="list-style-type: none"> Product: Sienna's <i>in vitro</i> diagnostic for detection of the hTERT component of telomerase, a biomarker that aids in diagnosis of bladder cancer Territory: Mainland China Exclusive
Curetis	Future Horizon Scientific	<ul style="list-style-type: none"> Products: Curetis' Unyvero system tests for pneumonia, implant and tissue infections, bloodstream infections, intra-abdominal infections and urinary tract infections Territories: Egypt Exclusive
Curetis	Biko	<ul style="list-style-type: none"> Products: Curetis' Unyvero system tests for pneumonia, implant and tissue infections, bloodstream infections, intra-abdominal infections and urinary tract infections Territories: Uruguay Exclusive
Curetis	Quimica Valaner	<ul style="list-style-type: none"> Products: Curetis' Unyvero system tests for pneumonia, implant and tissue infections, bloodstream infections, intra-abdominal infections and urinary tract infections Territories: Mexico Exclusive
Streck	Cromoion SRL	<ul style="list-style-type: none"> Products: Streck's controls, cell stabilization. and molecular products Territories: Argentina Exclusive three-year deal
HalioDx	Pronto Diagnostics	<ul style="list-style-type: none"> Product: HalioDx's Immunoscore colon cancer assay Territory: Israel
Genetic Technologies	Swisstec Health Analytics	<ul style="list-style-type: none"> Product: Genetic Technologies' genetic screening tests Territory: Asia Genetic Technologies gets 5% equity stake in Swisstec + 5% more if milestones are reached
Namocell	MDxK	<ul style="list-style-type: none"> Product: Namo Single Cell Dispenser tool Territory: South Korea
Namocell	Bioké	<ul style="list-style-type: none"> Product: Namo Single Cell Dispenser tool Territories: Belgium, Netherlands, Luxembourg
Advanced Instruments	Sysmex America	<ul style="list-style-type: none"> Product: Advanced Instruments' GloCyte automated cerebrospinal fluid (CSF) cell counter system Territories: US, Canada, Latin America Exclusive
Lucence Diagnostics	Bangkok Molecular Genetics	<ul style="list-style-type: none"> Products: Lucence's blood-based cancer diagnosis and screening tests Territory: Thailand
LICENSES		
Licensor	Licensee	Deal Summary
MDNA Life Sciences	LabCorp	<ul style="list-style-type: none"> Property: MDNA's noninvasive prostate cancer test LabCorp gets exclusive right in US to use MDNA's technology to develop and commercialize a test measuring prostate cancer risks of patients with an elevated PSA
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Service	Client	Deal Summary
Dynex Technologies	Zeus Scientific	<ul style="list-style-type: none"> Supply agreement under which Dynex's automated ELISA instruments will be sold globally

FDA Watch: Lab Industry Objects to Agency's New LDT Proposal

On Aug. 3, the Food and Drug Administration heated the long simmering controversy over FDA regulation of laboratory developed tests (LDTs) to full boil by submitting a new proposal to Congress, officially known as the [FDA Technical Assistance](#) (TA) on the Diagnostic Accuracy and Innovation Act (DAIA). The American Clinical Laboratory Association (ACLA), immediately responded by sending members of Congress a 26-page letter outlining lab industry concerns.

ACLA Objections

The thrust of the ACLA's letter is that the new TA proposes a “distinctly different framework” from the draft of the DAIA negotiated, in part, by a coalition of diagnostic manufacturers and labs in an attempt to create an industry-led solution to the ADLT regulation controversy. The letter raises six specific objections:

- ▶ FDA lacks the legal authority to regulate LDTs;
- ▶ In vitro clinical tests (IVCTs) should be subject to their own regulatory framework separate from medical devices;
- ▶ The FDA's proposed approach of regulating via guidance rather than specific, binding and definitive regulations is unfair and unacceptable;
- ▶ The transition provision in the TA could potentially subject IVCTs to regulation “immediately after enactment”;
- ▶ The TA's grandfathering provision would allow the agency “to ‘claw back’ grandfathered tests at its discretion without basis in meaningful standards”;
- ▶ The FDA's proposal to eliminate the moderate-risk category for IVCTs will create confusion and may lead to more tests being classified as high risk; and
- ▶ The FDA's definitions of “analytical validity” and “clinical validity” regarding approval standards are problematic and would give the agency “unprecedented discretion in determining whether an IVCT is analytically or clinically valid.”

New FDA Approvals

Here's a look at some of the key FDA approvals announced at the end of July through the third week of August.

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Roche	Approval of Cobas HPV Test as first-line screening test for cervical cancer in women age 25 and older via cervical specimens collected in SurePath preservative fluid
Agilent Technologies	Approval of expanded use of Dako PD-L1 IHC 22C3 pharmDx assay as companion diagnostic test for Merck's anti-PD1 immunotherapy Keytruda for urothelial carcinoma
Techlab	510(k) clearance for H. Pylori Quick Chek rapid detection test for <i>H. pylori</i>
Techlab	510(k) clearance for H. Pylori Chek test for <i>H. pylori</i> on multiple specimens
Grifols	Clearance for Procleix Zika Virus blood screening Zika detection assay

Manufacturer(s)	Product(s)
Inova Diagnostics	Clearance for use of Quanta Flash HMGR marker to diagnose idiopathic inflammatory myopathy
PapGene	Breakthrough Device designation for blood-based cancer diagnostic assay
Siemens Healthineers	Clearance for Atellica IM BRAHMS PCT Assay for ER and ICU use of sepsis assessment, assigning mortality risk and antibiotic therapy decision-making
Siemens Healthineers	Clearance for use of Dimension Hemoglobin A1c turbidimetric inhibition assay for measuring percentage and mmol/mol measurements of HbA1c in venous whole blood
Siemens Healthineers	Clearance of high-sensitivity troponin I assays for use on firm's Atellica IM and Advia Centaur XP/XPT immunoassay analyzers for early diagnosis of heart attacks
Siemens Healthineers	Clearance for use of Advia Centaur CMV IgG quality control material to monitor performance of ADVIA Centaur CMV IgG assay
Hologic	Clearance for Group B <i>Streptococcus</i> (GBS) assay on Panther Fusion system
PerkinElmer	510(k) clearance for NeoLSD MSMS kit for screening common lysosomal storage disorders in newborns
PerkinElmer	510(k) clearance for Euroimmun ANCA IFA assay for qualitative or semi-quantitative determination of ANCA of immunoglobulin class IgG in human serum
BioMérieux	Clearance for ETest received for determination of antimicrobial susceptibility of non-fastidious gram-negative and gram-positive aerobic bacteria
BioMérieux	Clearance for Chromid Carba agar for the detection of carbapenemase-producing <i>Escherichia coli</i> and <i>Klebsiella pneumoniae</i>
Healthy.io	510(k) clearance for Dip.io smartphone-enabled urinalysis kit
Personal Genome Diagnostics	Breakthrough Device Designation for PGDx Elio Plasma Resolve cell-free DNA assay
NeuMoDx Molecular	510(k) clearance for the 288 Molecular System high-throughput molecular diagnostics platform
NeuMoDx Molecular	510(k) clearance for GBS Assay Group B Strep test
Quidel	Clearance for Solana Bordetella Complete Assay for detecting <i>Bordetella pertussis</i> and <i>Bordetella parapertussis</i>
Abbott Laboratories	Clearance for RealTime IDH1 Assay as companion diagnostic to identify patients eligible for Agio Pharmaceuticals' newly approved Tibsovo (ivosidenib) drug for treating patients with relapsed or refractory acute myeloid leukemia with IDH1 mutations

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS IN EUROPE

Manufacturer(s)	Product(s)
ProAxis	CE marking for ProteaseTag Active Proteinase 3 immunoassay
Co-Diagnostics	CE marking for Logix Smart MTB Test for tuberculosis diagnosis
Xiamen Spacegen PCR	CE marking for 6 kits for detecting: i. human thyroid carcinoma RET gene fusions ii. human MGMT gene methylation iii. human EGFR gene T790M mutation iv. human pharmacogenomics SNP v. a human radiotherapeutic side effect-related gene SNP vi. cardiotoxicity prediction of breast cancer
Ortho Clinical Diagnostics	CE marking for Vitros XT 7600 integrated clinical chemistry system

Other international clearances announced in the past month:

Manufacturer(s)	Product(s)	Product(s)
Tianjin Novogene Bioinformatics Technology	China	China FDA approval of NovoFocus NSCLC CDx assay Pathology Solution for use as diagnostic tool

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

After a busy July, the pace and volume of new product launches slowed significantly in August.

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
HTG Molecular Diagnostics	HTG EdgeSeq Precision Immuno-Oncology Panel research-use-only profiling panel of genes involved in host immune response to tumors
IncellDx	BioINk PD-L1 CTC Core Kit for identifying and quantifying PD-L1 expression in circulating tumor cells
Empirical Bioscience	EB Pure Agarose Gel Extraction Kit for rapid isolation of small DNA fragments (70 bp to 20 kb) from agarose gel
Helomics	Precision Oncology Insights personalized oncology platform
Oxford Gene Technology	SureSeq Interpret NGS data analysis software
Enpicom	ImmunoGenomix platform for immunotherapies development, patient stratification and treatment monitoring
Becton Dickinson	Commercial launch of BD AbSeq high-throughput sequencing assay analyzing protein expression at single-cell level
MedTek21	Version 4.0 of MedTek21 medication management platform for precision medicine which includes drug-to-gene monitoring
Asuragen	AmplidEX PCR/CE SMN1 Kit for rapid and scalable determination of functional SMN1 copy number
Biofortuna	ampDRY master mix for PCR applications
SeraCare	AccuSpan HCV RNA Linearity Panel (expansion of AccuPlex line)
Microbiologics	Molecular human papillomavirus control panel
Microbiologics	Molecular human papillomavirus verification panel
Microbiologics	Molecular vaginal control panel
Microbiologics	Molecular vaginal verification panel



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