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Upcoming Events

Conference:

Lab Institute 2017
October 25-27
Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

Dx Earnings Report: Strong Q2 Enables Lab Companies to Consolidate Q1 Gains

The lab industry consolidated its early 2017 gains with an almost equally strong Q2. Although there were some notable declines, most companies posted gains at or above Wall Street expectations. Here's an overview based on firms with at least \$10 million in sales for the quarter.

Gainers

Gainers outnumbered decliners by 26 to 10. And the gains were largely significant with only two gainers missing their Wall Street targets:

- ▶ PerkinElmer which fell \$7 million short of its \$554 million target despite overall 2% growth and 6% gains in diagnostics; and
- ▶ Genomic Health which came in \$600,000 shy of its \$86.1 million target despite an overall 4% gain for the quarter.

Repeating the pattern of Q1, all of the billion-dollar diagnostic companies posted overall and diagnostics segment gains for the quarter, including:

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

It's been a relatively quiet month on the diagnostic front in terms of both deal volume and impact. Here's a rundown of the deals that did come down.

M&A

CRO acquisitions were the M&A headliners for the period. Not surprisingly, LabCorp was at the center of the storm. After acquiring Covance for \$6.1 billion in 2015, LabCorp's contract research business revenue has grown to nearly \$3 billion per year. On July 31, the lab giant doubled down by announcing its

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agreement to buy mid-size UK CRO Chiltern for \$1.2 billion. The deal comes two months after Chiltern moved deeper into Asia by acquiring Japanese biopharm CRO Integrated Development Associates. “Our acquisition of Covance has demonstrated the value of combining diagnostic and CRO capabilities, expertise, data and leadership,” noted LabCorp CEO David King.

A smaller deal was Cancer Genetics’ \$12 million acquisition of oncology biopharm CRO *vivoPharm* announced on Aug. 14. “This accretive acquisition immediately strengthens our market position as the premier partner for oncology therapeutic and diagnostic development,” explained CGI CEO Panna Sharma.

The deals are no aberration. Acquisitions of CROs has been a driving force in diagnostic M&A activity throughout 2017, with Thermo Fisher Scientific’s agreement to acquire Patheon for \$7.2 billion representing the biggest deal of the year so far.

Other notable M&A developments from late July to mid-August:

- ▶ Abbott’s agreement to extend its previously announced \$402 per share cash tender offer for Alere Series B preferred stock in connection with its acquisition of Alere (now priced at \$5.3 billion);
- ▶ Invitae’s twin acquisitions of NGS testing firms Good Start and Combi-Matrix;
- ▶ Roka Bioscience’s \$17.5 million asset sell-off to the Institute for Environmental Health in advance of the company’s liquidation; and
- ▶ Shareholder rejection of a Chinese equity firm’s takeover bid of Epigenomics by shareholders leaving Epigenomics’ CEO to comment that the company now faces “an uncertain situation with respect to its liquidity.”

Strategic Alliances

On July 27, BioMérieux and Sysmex announced that they were dissolving their nearly decade-long joint venture to bring BioMérieux’s IVD products to the Japanese market without explaining why. Sysmex will continue to distribute BioMérieux IVD reagents and medical instruments in Japan until Oct. 31 and provide customer support through March 31, 2018. Meanwhile, BioMérieux will bring its Japanese commercial operations in-house.

On Aug. 17, Helix announced that it had partnered with Illumina Accelerator, the accelerator program launched by Illumina to provide funding, lab space, tech expertise and other support services to startup companies developing consumer DNA products. Under the partnership, Illumina Accelerator will be able to offer its clients access to Helix’s expertise in in NGS, software and product development, marketing, regulatory compliance and other fields.

Other notable alliances:

- ▶ The strategic partnership between Fluidigm and Ascendas Genomics to develop and commercialize the former’s molecular diagnostics products in China; and

- Qiagen and HTG Molecular Diagnostics' new development program—the second under an existing master deal—to use the latter's NGS technology to develop gene expression profiles.

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
LabCorp	Chiltern (UK CRO)	<ul style="list-style-type: none"> Price: \$1.2 billion cash Status: Expected to close in 4Q LabCorp to incorporate Chiltern into its biopharma services unit
Cancer Genetics	vivoPharm (oncology CRO)	<ul style="list-style-type: none"> Price: \$12 million, including \$1.2 million cash and rest in CGI common stock shares Status: Expected to close by end of August Acquisition bolsters CGI's position in oncology discovery, <i>in vivo</i> and <i>in vitro</i> drug development, and early phase clinical trial testing for biotech and pharm companies
Institute for Environmental Health (via (newly formed Rokabio sub)	Roka Bioscience	<ul style="list-style-type: none"> Price: \$17.5 million cash Status: To close by end of 2017 Asset sale as first step in Roka's liquidation Roka shareholders must approve both asset sale and liquidation plan Roka to provide transition services to IEH through end of 2017
Unilabs	Blufstein	<ul style="list-style-type: none"> Price: Undisclosed Status: No closing date given—deal will require foreign regulatory approval Blufstein is an accredited, private lab in Peru with network of 31 collection centers and 4 hospital labs
Veritas Genetics	Curoverse	<ul style="list-style-type: none"> Price: Undisclosed Status: Undisclosed Curoverse, which like Veritas is a Harvard Medical School spinout, is creator of open-source bioinformatics platform
Invitae	CombiMatrix	<ul style="list-style-type: none"> Price: Invitae to offer up to 630,000 shares (value up to \$6.0 million) for CombiMatrix Series F warrants Status: Expected to close in 4Q pending shareholder approval Good Start and CombiMatrix's tests will bolster Invitae's product portfolio (which includes exome sequencing and genetic tests for conditions spanning cardiology, hematology, cancer and metabolic disorders and newborn screening pediatric genetics tests)
Invitae	Good Start Genetics	<ul style="list-style-type: none"> Price: Up to 1.65 million shares of Invitae common stock, \$18.3 million in cash for elimination of outstanding secured debt and payment or assumption of \$6 million of Good Start's liabilities and obligations Status: Expected to close in August Acquisition of Good Start and CombiMatrix (above) enables Invitae to add reproductive health to its genetic testing portfolio and become comprehensive genomic information company
DiaSorin	Siemens Healthineers	<ul style="list-style-type: none"> Price: €47.5 billion (\$55.3 million) on debt- and cash-free basis Status: Expected to close in 2H 2017 DiaSorin acquires Siemens's microtiter-based ELISA immunodiagnosics business and related assets DiaSorin paid \$300 million cash for Quest's Focus Diagnostics' immunoassay and molecular Dx products in March 2016
Agilent Technologies	IP assets of Population Genetics Technologies	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Agilent acquires Genetic Technology's patents for both molecular and sample barcoding technologies which it will apply for improving its NGS detection capabilities
LGC	Link Technologies (supplier of specialty reagents for oligonucleotide synthesis)	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed LGC plans to form new Nucleic Acid Chemistry business unit within its Genomics division combining Link with its existing Biosearch oligo reagent group and Prime Synthesis CPG business
Royal Philips	TomTec Imaging Systems (German software developer)	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Acquisition, coupled with June deal to buy Spectranetics, bolsters Philips' position in cardiac ultrasound and supports its expansion into OBGYN and other clinical areas

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STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Illumina Accelerator	Helix	<ul style="list-style-type: none"> Objective: Provide support to start-ups and new companies developing DNA consumer products Dynamic: Helix to provide expertise to Illumina Accelerator client companies
Cambridge Epigenetix	NuGen Technologies	<ul style="list-style-type: none"> Objective: Development of new epigenetic sequencing products Dynamic: Cambridge to integrate its TrueMethyl technology for oxidative bisulfite sequencing with NuGen's sequencing library preparation kits NuGen will sell new products, the first of which are expected by year's end
Cynvenio Biosystems	Saint Luke's Cancer Institute	<ul style="list-style-type: none"> Objective: Breast cancer research Dynamic: Launch new study evaluating use of liquid biopsy and natural killer cell testing for early detection of recurrent breast cancer in patients at high risk of relapse after neoadjuvant chemotherapy
Alexion	Sema4 (Mount Sinai Health System spinoff)	<ul style="list-style-type: none"> Objective: Speed up diagnosis of rare genetic diseases, which often take years to diagnose Dynamic: Combines Sema4's knowledge in NGS and genome interpretation with Alexion's SmartPanel precision medicine platform
Hemex Health	Tata Elxsi	<ul style="list-style-type: none"> Objective: Development of Hemex's POC lab-in-a-box diagnostic device for integrated diagnosis of malaria and sickle cell Dynamic: Bangalore, India-based Tata Elxsi to serve as Hemex's design and engineering partner Hemex says it plans to sell product for about \$1 per test, including amortized cost of a portable reader
Itus	Wistar Institute	<ul style="list-style-type: none"> Objective: Development of Itus's Cchek platform for early cancer detection Dynamic: Renewal of previous agreement under which Wistar will continue to provide Itus R&D support for developing Cchek
Thermo Fisher Scientific's BRAHMS	Ortho Clinical Diagnostics	<ul style="list-style-type: none"> Objective: Create procalcitonin test for use on Ortho's Vitros systems for small-, mid-, and high-volume clinical labs Dynamic: BRAHMS PCT assay is used in conjunction with other lab findings for managing sepsis
IDbyDNA	ARUP Laboratories	<ul style="list-style-type: none"> Objective: Develop and commercialize NGS infectious disease testing using metagenomics Dynamic: Metagenomics carries potential for testing that's more accurate and comprehensive than conventional testing procedures which may be restricted to specific pathogens and yield a high percentage of negative results
New England Biolabs	TTP	<ul style="list-style-type: none"> Objective: Offer services and reagents to molecular diagnostic technology developers Dynamic: Non-exclusive partnership Results to be added to GenXys' TreatGxPlus software
Qiagen	HTG Molecular Diagnostics	<ul style="list-style-type: none"> Objective: Develop gene expression profiling assays for use with NGS technology Dynamic: Qiagen Manchester and HTG Molecular to use HTG EdgeSeq technology to develop assays to support commercialization of therapeutic products of third (unnamed pharmaceutical) company This is second development program under Qiagen-HTG Molecular's master assay development, commercialization and manufacturing agreement
Bio-Rad Laboratories	Visia Imaging	<ul style="list-style-type: none"> Bio-Rad acquires commercialization rights to Visia Imaging's second-generation immunofluorescence slide processing and reading platform for autoimmune disease evaluation Bio-Rad to offer platform alongside its BioPlex 2200 System
Adaptive Biotechnologies	Cancer Therapy Evaluation Program of National Cancer Institute	<ul style="list-style-type: none"> Objective: Identify immune repertoire dynamics driving cancer immunotherapy responses and expedite development of new immune molecular biomarkers Dynamic: Researchers to use Adaptive's ImmunoSeq platform to sequence T cell and B cell repertoires of patients in NCI clinical trials
Tempus	Rush University Medical Center	<ul style="list-style-type: none"> Objective: Cancer treatment research Dynamic: Parties' second collaboration Tempus also has collaborations with University of Chicago, Duke, University of Pennsylvania, Ohio's University Hospitals Seidman Cancer Center and Mayo Clinic
Pacific Biosciences	Novogene	<ul style="list-style-type: none"> Objective: Co-develop and co-market applications based on PacBio's Sequel precision medicine research system Dynamic: To focus on methods for sample processing, workflow automation, algorithm development and database construction

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	Distributor	Deal Summary
Biocept	VWR	<ul style="list-style-type: none"> Products: Biocept blood collection tubes (validated for preserving ctDNA for up to 96 hours) Territory: All global markets except China Biocept CEO says deal is first step in company's transformation from CLIA lab business to technology and products company
DNASar	SHIPS Bioscience	<ul style="list-style-type: none"> Products: DNASar's Lasergene software suite Territory: Japan Non-exclusive but SHIPS is currently the sole distributor of the DNASar software in Japan
OneOme	ProZed Pharmacy Solutions	<ul style="list-style-type: none"> Products: OneOme's PCR-based RightMed test for measuring effectiveness of certain drugs Territory: Canada Test available exclusively to ProZed customers at Northern Shores Pharmacy in North Bay, Ontario
Streck	Innovative Medical Solutions	<ul style="list-style-type: none"> Products: Streck's cell stabilization and molecular products Territory: Kuwait Streck has inked recent distribution deals in Canada, Austria, Scandinavia, Switzerland, Slovakia, China, Indonesia, the Philippines, Singapore, Malaysia and New Zealand
OncoDNA	Everything Genetic	<ul style="list-style-type: none"> Products: OncoDNA's molecular profiling solutions that combining liquid and solid biopsy assays Territory: UK
OncoDNA	BioHisto Maroc	<ul style="list-style-type: none"> Products: OncoDNA's liquid biopsy and tissue-based genomic tests, including OncoDeep, OncoTrace and OncoSelect Territory: Morocco Expansion of current deal allowing Wallac to distribute Amplidiag in South Africa
Agena Bioscience	HeartGenetics	<ul style="list-style-type: none"> Products: Agena's MassArray Dx system to be marketed with HeartGenetics' HeartDecode genetic testing software and cardiovascular assays Territory: Undisclosed
LICENSES		
Licensor	Licensee	Deal Summary
Christiana Care (via its Gene Editing Institute of the Helen F. Graham Cancer Center & Research Institute)	NovellusDx (Israeli personalized medicine firm)	<ul style="list-style-type: none"> Property: Gene-editing technology Deal part of ongoing research collaboration designed to identify personalized cancer treatments
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier	Client	Deal Summary
Abbott	North West London Pathology	<ul style="list-style-type: none"> \$252 million managed equipment services contract covering UK Partnership expected to result in servicing of 26 million tests per year, 6 percent of UK pathology market

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

A busy month in product launches included a new CE-marked IVD version of Invivoscribe Technologies' LeukoStrat CDx FLT3 Mutation Assay, which the company describes as the first companion diagnostic for acute myeloid leukemia. The assay also secured FDA approval earlier this year.

Helix had a busy month. In addition to partnering with Illumina Accelerator to provide support services to consumer genetics startups (See Diagnostic Deals on page X for the details), the personal genomics firm launched a new online marketplace offering customers DNA sequence interpretations for ancestry, fitness, nutrition and other applications. The new service leverages mobile apps developed by partner companies Admera, Azumio, DNAFit, DotOne, EverlyWell, Exploragen, Genome Medical, Insiteome, Intelliseq, Lose It!, National Geographic, Sema4, Titanovo and Vinome.

Here's a rundown of the other key diagnostic product launches from late July through mid-August.

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
Inivoscribe Technologies	New version of its LeukoStrat CDx FLT3 Mutation Assay, the first companion diagnostic for acute myeloid leukemia
Cynvenio Biosystems	Second-generation PD-L1 expression test.
Color	Genetic test for familial hypercholesterolemia
Lexogen	Small RNA-seq library prep kit compatible with Illumina sequencing instruments
Canon BioMedical	Novallele HRM Analyzer, web-based software for analyzing data from different thermocyclers and well plate formats
DNASTack	Workflows, a new app for its genomics software platform
Advanced Data Systems	Augmented version of MedicsPremier PM for Laboratories to handle added, built-in capabilities for lab practice management
Meridian Bioscience (via its Bionline sub)	JetSeq Clean Kit, a clean-up system for NGS workflows
Asuragen	QuantideX qPCR BCR-ABL minor kit for identifying minor BCR-ABL fusion transcripts in chronic myeloid leukemia patients
Genohm	Version 6.0 of SLIMS, a combination lab information system and electronic lab notebook platform
ArcherDx	Archer VariantPlex Core Myeloid NGS panel that analyzes 37 genes related to myeloid malignancies
Synthego	Modified synthetic single guide RNA libraries for arrayed whole human genome CRISPR screening
Roche	Avenio Millisect System, a tissue dissection instrument
CloudLIMS	New version of its pay-as-you-go LIMS, CloudLIMS Lite software
Thermo Fisher Scientific	Applied Biosystems Precision ID GlobalFiler NGS STR Panel v2 and Converge Software 2.0 for forensic research
Thermo Fisher Scientific	Applied Biosystems Axiom Asia Precision Medicine Research Array containing over 750,000 biomarkers for common and rare diseases
LabCorp	ADAMTS13 test for thrombotic microangiopathy (TMA), a rare life-threatening blood-clotting disorder
Agilent Technologies	AriaDx Real-Time PCR System
Agilent Technologies	Agilent SureSelectXT HS, an updated version of its NGS library prep product
Fluidigm	Advanta Immuno-Oncology Gene Expression Assay, a research-use-only qPCR assay
Empirical Bioscience	2X qPCR Probe Master Mix for probe-based quantitative PCR applications
Exosome Diagnostics	MedOncAlyzer 170, liquid biopsy pan-cancer panel integrating exosomal RNA and circulating tumor DNA into single assay
SeraCare Life Sciences	Reference materials for validating and monitoring Zika virus test methods
SeraCare Life Sciences	ctDNA reference materials for development and validation of liquid biopsy assays

Inside the Lab Industry: The Surge of Do-It-Yourself Test Kits

Consumerism, patient empowerment and affordability are key drivers in the modern medical industry. One of the key manifestations of this within the clinical laboratories sector is the rapid growth of at-home testing products.

The Pros & Cons of At-Home Testing

At-home testing offers significant advantages to consumers, including not just convenience but privacy, which is a major consideration for sensitive testing like sexually transmitted diseases (STDs) assays. At home tests also make diagnostics accessible to the uninsured. Patient-initiated testing is entirely out-of-pocket (although health savings accounts can be used to pay for some tests.)

But at-home testing is also unproven. In addition to wasting treatment resources, some health care professionals worry that at-home testing may generate false results, especially when it's self-initiated, that patients may

rely on in making vital treatment decisions without consulting clinicians, like adjusting medication doses.

Types of At-Home Testing Products

At-home products come in two basic forms:

- ▶ Mail-in tests in which patients collect their own samples (blood, mouth swab, urine or stool) and mail them to a lab for processing; and
- ▶ Instant tests in which sample collection *and* testing are performed at the patients' home with results available in minutes.

Instant tests leverage advancements in lateral flow technology (paper strips, much like easy-to-read pregnancy tests), as well as entirely new forms of testing, including portable analyzers intended for at-home use. Pregnancy tests and blood glucose monitoring may be the best known, do-it-yourself tests, but innovation is expanding the potential for routine home monitoring for both wellness and chronic conditions.

Overview of At-Home Testing Market

Here's a quick profile of key companies offering products that are currently or soon to be commercially available in each product type space.

Mail-In Testing Providers

Notable providers of at-home sample collection and mail-in testing products include:

- ▶ **MyLabBox** (Los Angeles, CA), which offers a nationwide home-based STD testing service that includes panels consisting of 4, 8 or 14 conditions, including HIV, hepatitis C, herpes, syphilis, chlamydia, gonorrhea, trichomoniasis, mycoplasma genitalium, and human papilloma virus. The panels range from \$189 to \$399.
- ▶ **Everlywell** (Austin, TX) which in addition to STD panels offers routine lab tests such as cholesterol and HbA1c, as well as and niche offerings like testosterone, thyroid, and heavy metals testing.
- ▶ **Exact Sciences** (Madison, WI), which offers Cologuard, the first and only FDA-approved stool DNA, noninvasive screening for colorectal cancer. The test assesses for 11 biomarkers, including 7 DNA mutation markers, 2 DNA methylation markers, one hemoglobin marker and Beta actin. But Cologuard is different from most other at-home testing products in 2 important ways: first, it's available by prescription only; it's also more expensive than many at-home tests, listing at \$649 (although some insurance carriers cover some or all of the cost).

Providers of Instant Result Tests

Some of the notable providers of at-home tests that generate instant results include:

- ▶ **Scanadu** (Sunnyvale, CA), whose heavily hyped at-home consumer diagnostics products have yet to make it to the commercial market, including Scanadu Urine, a disposable paddle that consumers dip into a urine sample and use the Scanadu app and camera on their smartphone to read and analyze the results a minute later.

- ▶ **Cor** (San Francisco, CA), which closed its Indiegogo crowdsourcing campaign in May 2016 and is still validating its hardware platform for translating spectral data into quantitative chemistry insights. Users press the single use Cor Cartridge against their arm to get a surface-level blood sample using a fine needle that the company says is completely painless. The cartridge is then placed in the Cor Reader. (Cartridges are available for a \$10-per-month subscription.)
- ▶ **Medical Electronics Systems** (Los Angeles, CA) which has received much attention for its FDA-approved, YO Home Sperm Test, the first home male fertility test kit powered by a smartphone platform and supported by an interactive app experience. The company also manufactures commercial-grade semen analyzers. The at-home test allows users to view and measure the number of motile (moving) sperm in their sample, which the company says is a key measure of assessing male fertility.

Takeaway: There are an expanding number of options for consumers to conduct at-home testing. The commercial market is growing for tests mailed in to CLIA-certified laboratories and is expected to see a number of new entrants for instant tests capable of providing results at home, as well. 

■ Dx Earnings Report: Strong Q2 Enables Lab Companies to Consolidate Q1 Gains, from page 1

- ▶ Danaher which followed up last quarter's 17% Dx growth with 14% increases in Q2 as the Cepheid acquisition continues to pay off;
- ▶ Roche whose total H1 diagnostics revenues were up 5% at \$5.82 billion;
- ▶ LabCorp which posted 8% gains in Dx revenue for the quarter at \$1.80 billion thanks to strong sales in women's health and genetic reproduction products;
- ▶ Abbott which was just able to hit its overall Q2 \$6.64 billion target thanks to 4% growth in core labs revenue (\$1.02 billion);
- ▶ Thermo Fisher which followed Q1's 3% Dx gains with 4% growth in Q2 (\$1.79 billion); and
- ▶ Quest which grew Dx revenues 3% this quarter after posting 2% increases in Q1 (\$1.86 billion).

Decliners

In Q1, being in flu testing was an advantage. This quarter, the tables were turned as the late flu season of 2016 led to aberrant testing revenues not duplicated this year. Quidel (-2% YOY) and GenMark Diagnostics (-1%) were among the companies adversely affected.

It was a tough quarter for NantHealth which had to lay off 300 employees as part of a major business reorganization after seeing revenues decline 17% and fending off negative publicity and shareholder lawsuits for supposedly misrepresenting a key \$12 million deal with the University of Utah.

Things were even rougher for German firm Epigenomics which took an 81% hit in revenues thanks to declining sales of its Epi proColon colorectal cancer test. A bad situation got even worse in August when shareholders rejected

a management-endorsed takeover bid by Chinese equity firms, leading the firm's CEO to issue a statement casting doubt on Epigenomics's liquidity.

Other companies posting year-over-year overall and Dx revenue losses in Q2:

- ▶ Fluidigm fell 15% overall thanks to genomics losses of 35%;
- ▶ Alere suffered 9% losses due to slumping cardiometabolic and infectious disease sales and had to cut its acquisition price tag to keep the Abbott merger alive; and
- ▶ Meridien Biosciences lost 4% in Dx revenues but only 1% overall, enabling the company to meet its Wall Street estimates and maintain its projected EPS of \$.64 to \$.69 for the year.

Diagnostics Earning Reports 2Q 2017 (At least \$10 million in sales)

COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street Estimate	
Abbott Laboratories	\$6.64 billion	+3%	\$6.63 billion	Dx up 4% to \$1.27 billion driven by 4% growth in core lab tests to \$1.02 billion and 9% growth in POC tests to \$139 million, which offset 5% decline in molecular tests to \$114 million
Agilent Technologies	\$1.11 billion	+7%	EPS \$.59 beats est'd \$.52	Dx and genomics post biggest growth at 9% (\$197 million) driven by companion diagnostics
Alere	\$557.7 million	-9%	NA	Declines in infectious and cardiometabolic tests
Becton Dickinson	\$3.04 billion	-5%	\$3.06 billion	Dx revenues grow 3% to \$335 million
BioMérieux	€566.4 million	+11%	NA	Strong growth in microbiology, immunoassays and molecular biology
Bio-Rad	\$504.7 million	-2%	\$515.9 million	Decline due to productivity losses related to European launch of global enterprise resource planning system & lack of anticipated revenues from product
Bruker	\$414.9 million	+12%	\$385.5 million	Driven by MALDI mass spec revenues—extent of gains reflect weakness of 2Q 2016
CareDx	\$12.0 million	+12%	\$11.8 million	Driven by 16% increase in sales of AlloMap heart transplant rejection test
Danaher	\$4.51 billion	+6%	\$4.50 billion	Dx revenues up 14% to \$1.44 billion Cepheid and other acquisitions add 6% to top line
Exact Sciences	\$57.6 million	+149%	\$49.8 million	Company reports 135,000 Cologuard colon cancer tests completed at \$428 per test; raises both Cologuard test volume and revenue guidance for full year
Fluidigm	\$23.9 million	-15%	NA	Genomics revenues down 35% and mass cytometry revenues up 9%
Foundation Medicine	\$35.0 million	+24%	\$34.9 million	Clinical testing up 37% to just under \$13 million and biopharma revenues up 17% to \$22.1 million
GenMark Diagnostics	\$12.4 million	-1%	\$12.4 million	Hurt by comparison to last year in which revenues were driven by unusually late flu season; not so this year
Genomic Health	\$85.5 million	+4%	\$86.1 million	Firm lowers yearly revenue guidance by \$10 million but still projects profitability. Palmetto issues positive coverage determination for Oncotype DX Genomic Prostate Health but hasn't yet finalized
Hologic	\$806.1 million	+12%	\$799.7 million	Total Dx revenues actually fall due to January divestment of Grifols business
Illumina	\$662 million	+10%	\$642.4 million	Growth mostly driven by success of new NovaSeq instruments, service and consumables revenue also up sharply
Invitae	\$14.3 million	+250%	\$13.3 million	30,500 genetic samples tested, up 139% from 2Q 2016
Laboratory Corp. of America	\$2.54 billion	+5%	\$2.47 billion	Dx revenues up 8% to \$1.80 billion with particularly strong growth in women's health and reproductive genetics
Luminex	\$76.5 million	+19%	\$75.5 million	Automated sample-to-answer molecular product sales spike 44% to \$10.7 million

COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street Estimate	
Meridian Bioscience	\$50.1 million	-1%	\$49.2 million	Dx revenues down 4% to \$35.9 million; reaffirms EPS guidance of \$.64-\$.69 for year despite missing EPS for Q by 1 cent
Myriad Genetics	\$200.5 million	+8%	\$193.7 million	Molecular diagnostic testing up 8% to \$187.9 million despite 5% drop in hereditary cancer and 19% drop in Vectra DA rheumatoid arthritis tests
NanoString Technologies	\$34.6 million	+53%	\$32.9 million	Spike due to one-time uptick in collaboration revenue from Lam Research collaboration to develop Hyb & Seq NGS platform; firm also reduces net loss per share guidance for year
NeoGenomics	\$61.7 million	+3%	\$61.4 million	Clinical genetic tests performed up 15% to 155,567 generating 5% increase in testing revenues to \$55.1 million
NantHealth	\$26.2 million	-17%	\$31.3 million	Company lays off nearly 300 employees as part of restructuring
Natera	\$53.6 million	+3%	\$50.6 million	Nearly 126,000 total tests, up 17%, led by Panorama prenatal at 89,400 (+4%)
NeoGenomics	\$66.1 million	+5%	\$63.0 million	Driven by 7% growth in genetic testing; EPS also beat Wall Street estimates
Opko Health	\$314.2 million	-12%	NA	Licensing revenues decline 58%, service revenues down 3% and product revenues up 27%
Pacific Biosciences	\$20.1 million	-3%	\$23.8 million	Consumables up 87%; overall decline attributable to \$3.6 million loss in revenue from Roche that company no longer receives
PerkinElmer	\$547.0 million	+2%	\$554.0 million	Dx revenues up 6% to \$163.8 million
Qiagen	\$349.0 million	+4%	\$346.6 million	Molecular diagnostics up 6% to \$168 million led by QuantiFeron latent TB test which is on track for 25% growth for year; Qiagen ups total year revenue guidance from 6% to 7%
Quest Diagnostics	\$1.94 billion	+2%	\$1.94 billion	Dx revenue up 3% to \$1.86 billion; at \$1.55, EPS crushed Wall Street estimates of \$1.42
Quidel	\$38.3 million	-2%	\$41.8 million	Decline driven by dip in flu testing; immunoassays up 1% \$21.9 million thanks to 21% growth in Sofia which offset 10% decline in QuickVue; molecular up 44% to \$3.2 million
Roche	\$26.34 billion (H1)	+5%	NA	Dx for H1 2017 up 5% to \$5.82 billion, (including 4% growth in Q2); centralized and point of care revenues up 7% for year and molecular up 1%
Thermo Fisher Scientific	\$4.99 billion	+10%	\$4.92 billion	Lab products and services up 4% to \$1.79 billion; company raises both revenues and EPS guidance for full year
Veracyte	\$18.4 million	+25%	\$18.3 million	Afirma Gene Expression Classifier test volume up 11% to 5,834 tests; narrows loss from \$.25 to \$.22 per share
Waters	\$558.3 million	+4%	\$553.1 million	Pharma up 3%, industrial up 5% and academic sales up 7%

FDA Watch: Two More Zika Tests Get Emergency Use Authorization

Zika made the FDA headlines this month, with two more tests receiving emergency use authorization:

- ▶ Thermo Fisher Scientific's TaqPath Zika Virus Kit for the qualitative detection of Zika virus RNA in human serum and urine; and
- ▶ Columbia University's Mailman School of Public Health's CII-ArboViroPlex rRT-PCR test for simultaneous detection of the Zika virus and other similar Flaviviruses.

FDA Steps Up on Serological Zika Testing

In August, the FDA also announced that it's offering a panel of human plasma samples to assist in its evaluation of serological tests detecting recent

Zika virus infection. The panel contains plasma samples from individuals infected with Zika, West Nile or dengue viruses. While the panel is not for research purposes, developers can take use them to determine whether their tests can help identify recent Zika virus infection from fellow viruses.

Currently, there are two primary blood diagnostic tests for Zika: nucleic acid tests that detect infection by confirming presence of a virus' RNA, and serological tests that identify antibodies that the body's immune system produces when it senses harmful organisms like Zika in the blood. Serological tests are crucial given the small window when the virus' genetic material is noticeable in the bloodstream.

Here's a look at key FDA diagnostics approvals in late July through mid-August:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Roche Diagnostics	Approval of Cobas b 101 instrument that uses a single-use reagent disc to measure HbA1c from capillary and venous whole-blood samples
Roche Diagnostics	Approval of Cobas HbA1c test for quantitative measurement of glycated hemoglobin
Thermo Fisher Scientific	Emergency use authorization of TaqPath Zika Virus Kit for qualitative detection of RNA from Zika virus and diagnosis of Zika virus infection in human serum and urine collected alongside patient-matched serum specimen
Columbia University's Mailman School of Public Health	Emergency use authorization of CII-ArboViroPlex rRT-PCR test for simultaneous detection of Zika virus and similar Flaviviruses
iCubate	Approval of iC-System and iC-GPC assay for rapid detection of pathogenic bacteria associated with bloodstream infections—first iCubate product cleared by FDA
ImpediMed	Approval of Sozo bioimpedance spectroscopy platform which uses the ImpediMed L-Dex lateral lymphedema assessment system for measuring and monitoring fluid status and body composition
Abbott Laboratories	Approval of RealTime IDH2 Assay, a companion diagnostic run on Abbott's m2000 RealTime PCR instrument, for identifying acute myeloid leukemia patients with IDH2 gene mutations that may benefit from new Celgene therapy called Idhifa
Bruker	Expanded approval of MALDI Biotyper system to include third version that adds 144 microbial species to database of anaerobes, gram-positive and gram-negative bacteria, and yeasts
BioMérieux	Expanded approval of Vitek MS MALDI-TOF Mass Spectrometry System for rapid pathogen identification to include identification of mycobacteria, Nocardia and molds
Becton Dickinson	Approval of BD FACSLyric flow cytometer system
Immco Diagnostics	Approval of ELISA test for celiac disease performed as a solid phase immunoassay
Luminex	Approval of Aries <i>C. difficile</i> assay for rapid detection of <i>Clostridium difficile</i>
Shenzhen New Industries Biomedical	Approval of Maglumi 2000 automated immunoassay analyzer for running IVD tests on clinical serum samples
Shenzhen New Industries Biomedical	Approval of Maglumi 2000 TSH assay for identifying thyroid disorder via quantitative analysis of thyroid-stimulating hormone in human serum

In addition, DxNA announced that it has applied for 510(k) clearance of GeneSTAT, its real-time PCR system and test for Valley Fever.

New CE Marks & Global Certifications

Here's a summary of notable European CE certifications:

NEW CE CERTIFICATIONS

Manufacturer(s)	Product(s)
Thermo Fisher Scientific	Approval of QuantStudio 5 Dx Real-Time PCR system
Biomatrix	Approval of RNAgard Blood for preserving total nucleic acids in blood for evaluating gene expression and methylation biomarkers
Biomatrix	Approval of SalivaGard HT DNA sample collection tube to provide DNA yield for carrier screening, oncology and other NGS applications
Biomatrix	Approval of LBgard Blood sample collection tube for preserving cfDNA for liquid biopsy and noninvasive prenatal testing.
T2 Biosystems	Approval of T2Bacteria Panel which will be sold as part of T2Sepsis Solution in Europe in 3Q of 2017

On July 21, OraSure Technologies announced that it had secured World Health Organization backing for its OraQuick HIV-Self Test for detecting HIV with an oral swab in 20 minutes. 



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