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Diagnostics Earnings Report: 1Q Marked by Widespread & Substantial Gains

The laboratory industry is off to a strong start in 2017. Although growth rates varied, most firms were up for the quarter. Here's an overview of 1Q 2017 based on the earnings reports we've seen so far.

Gainers

Gainers outnumbered decliners by a staggering 22 to 1. And the gains were largely significant. Only two firms missed their Wall Street revenue estimates for the quarter:

- Becton Dickinson (BD), which came up just $10 million shy of its $3.07 billion target; and
- Veracyte, which grew 21% but still missed its $17.7 million target by $1.3 million.

All of the billion-dollar firms posted increases in diagnostics revenues, in most cases substantial increases:

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

The big story of April wasn't any particular new deal but the apparent resolution of an old one—the Abbott-Alere merger. Deal volume remained brisk, particularly in the alliance arena. But for those who like dramatic, blockbuster stories, April 2017 may have been the cruelest month.

M&A

M&A activity for the year has been fast and furious. But most of the action has centered on the physician side. HealthCareMandA.com reports that there were 48 physician medical group acquisitions in the first quarter of 2017, 78% more than in the pre-

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Diagnostic Deals, *from page 1*

vious quarter and a staggering 109% increase from the first quarter of 2016. Key benchmarks for the year so far:

- **Biggest deal:** The $3.277 billion purchase of Surgical Care Associates by United Health Group subsidiary Optum;
- **Most active purchaser:** MEDNAX with 5 deals closed. Next comes Envision Healthcare with 4, followed by Dermatology Associates and Epiphany Dermatology with 3 each;
- **Target size:** Among the 48 medical groups acquired, 9 had 20 or more physicians.

Things have been far less hectic in the diagnostics sector. After a quiet March, M&A deal volume remained relatively light in April. The headliner was the April 14 announcement that the on-again off-again Abbott and Alere merger was back on again. In addition to dropping their lawsuits, both sides have agreed to new terms essentially giving Abbott a discount to compensate for the erosion in equity value that Alere has incurred since the original deal was announced in February 2016. Specifically, the purchase price has been reduced from $5.8 billion to $5.3 billion, or $51 per common share. The deal still requires regulatory clearance and the approval of Alere's shareholders. If all goes according to plan, closing will take place by the end of the third quarter of 2017.

Other notable M&A deals during the month included:

- The acquisition of Imegen, a firm known for its clinical genetics and genomics products including tests for over 1,500 human genetic diseases, by a pair of private equity firms in Spain for €10 million ($10.8 million);
- Janssen Diagnostics' sale of its Cellsearch test, which the firm claims is the only clinically validated blood test to receive FDA clearance for detecting circulating tumor cells, to Bologna, Italy-based Menarini-Silicon Biosystems; and
- NantOmics' purchase of San Francisco-based consumer genomics firm Genos for an undisclosed amount.

Meanwhile, word came down that Enigma Diagnostics, a UK firm in liquidation, was putting its point-of-care diagnostics platform on the block as part of its liquidation. The platform, known as the Enigma MiniLab, has reportedly attracted £140M million ($174 million) in investment capital to date.

Strategic Alliances

Thermo Fisher, Phillips, Illumina and Invitae were among the diagnostic giants to make significant new strategic collaborations during the month. Thermo Fisher entered into alliances with a pair of foreign partners:

- The Institute of Medical Genetics and Pathology at University Hospital in Basel, Switzerland, to launch a new companion diagnostics development initiative called the Next Generation Companion Diagnostics Center of Excellence Program; and

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- Australia-based SpeeDx designed to secure FDA approval for SpeeDx's ResistancePlus MG assay for antibiotic-resistant *Mycoplasma genitalium*.

HTG Molecular Diagnostics was even busier, concluding three separate alliances with foreign research firms aiming to leverage HTG's proprietary EdgeSeq Oncology biomarker panel to develop new diagnostic products, including:

- A breast cancer recurrence score via a collaboration with the Instituto Valenciano de Oncología in Spain;
- A custom assay to detect nearly 3,000 mRNA targets in collaboration with Daiichi Sankyo; and
- Biomarkers for predicting and diagnosing genetic disorders via partnering with Centre Léon Bérard in France.

On April 20, Grail announced the start of STRIVE, a clinical trial for its next-generation sequencing-based blood test for early-state cancer detection. Grail will collaborate with the Mayo Clinic and Sutter Health to enroll up to 120,000 women who've just received a mammogram in the hopes of validating the test. Other notable alliances from April aimed at diagnostics product development included:

- Royal Phillips's collaboration with PathAI leveraging the latter's deep-learning algorithms and expertise to develop tissue-based early breast cancer detection tests;
- Myriad Genetics' partnership with BeiGene, the latter's latest venture to develop companion diagnostics based on its BRAC Analysis CDx technology—other Myriad partners include AstraZeneca, Medivation, Tesaro and AbbVie; and
- The co-development and cross-licensing arrangement between ArcherDx and HeliTec aimed at developing next-generation sequencing based cancer tests for the Chinese market.

Co-Marketing & Product Integration

April featured an unusually large number of co-marketing deals combining proprietary products to be promoted together as single solutions. Examples:

- Glenalice's agreement to combine its Map technology with BioDiscovery's NxClinical data visualization platform to form a single solution for interpreting next-generation sequencing data;
- The partnership between TTP Labtech and Advanced Analytical Technologies merging the former's AATI Fragment Analyzer with the latter's Mosquito platform to create an integrated next-generation sequencing library preparation solution; and
- The agreement of bioinformatics firm Omicia, which changed its name to Fabric Genomics this month, to incorporate its genome annotation technology into Veritas Genetics' myGenome whole genome sequencing service.

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Here's a graphic rundown of April's key diagnostic deals:

MERGERS & ACQUISITIONS		
Acquiring Company	**Target**	**Deal Summary**
Abbott Laboratories	Alere Inc.	▪ Price: $51 per common share based on equity valuation of $5.3 billion (reduced from original $5.8 billion) ▪ Status: Expected to close by end of Q3 ▪ Both sides agree to drop litigation against other
NantOmics	Genos	▪ Price: Undisclosed ▪ Status: Closed ▪ NantoOmics to absorb Genos's whole-exome sequencing systems into its pan-omic tools
Informatics for Integrating Biology and the Bedside (i2b2) Foundation	TranSmart Foundation	▪ Price: Undisclosed ▪ Merger to form single foundation providing precision medicine open-source biomed software and databases
Menarini-Silicon Biosystems	Janssen Diagnostics	▪ Price: Undisclosed ▪ Status: Closed ▪ Menarini establishes US market presence by acquiring all assets related to Janssen's Cellsearch circulating tumor cell system
Q-Growth Fund and Biolty (Spanish private equity firms)	Imegen	▪ Price: €10 million ($10.8 million) ▪ Status: Closed
STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Thermo Fisher Scientific	Institute of Medical Genetics and Pathology at University Hospital Basel	▪ Objective: Develop TF's NGS-based Oncomine products into tests for use as companion diagnostics ▪ Dynamic: First partnership under Thermo's so called Next Generation Companion Dx Center of Excellence Program
Thermo Fisher Scientific	SpeeDx (Australia)	▪ Objective: Get FDA approval for SpeeDx's ResistancePlus MG assay for antibiotic-resistant *Mycoplasma genitalium* ▪ SpeeDx to submit test to FDA after it's validated for use on the Applied Biosystems 7500 Fast Dx Real-Time-PCR system
HTG Molecular Diagnostics	Instituto Valenciano de Oncología (Spain)	▪ Objective: Develop breast cancer recurrence risk score ▪ Dynamic: Research partnership leveraging HTG's EdgeSeq Oncology biomarker panel
HTG Molecular Diagnostics	Centre Léon Bérard	▪ Objective: Identify biomarkers for predicting and diagnosing genetic disorders ▪ Dynamic: Use HTG EdgeSeq technology to retrospectively characterize immunologic profiles from advanced malignant tumor samples collected in the ProfiLER study
Edico Genome	Congenica	▪ Partnership bundling Congenica's Sapientia genome-analysis software with Edico's field-programmable gate array bioinformatics processor, Dragen, as single product
EpicGenetics	UCLA and University of Illinois College of Medicine Chicago	▪ Objective: Develop new genetic markers for fibromyalgia ▪ Dynamic: University research centers to clinically evaluate EpicGenetics FM/a protein biomarker test for fibromyalgia ▪ Data to be then used identify new markers for disorder
Pfizer	HitGen	▪ Objective: Develop DNA-encoded libraries (DELs) for drug discovery ▪ Dynamic: Partners to use HitGen's technologies to design and screen proprietary DELs for Pfizer to use to discover new small molecule-based drug candidates ▪ HitGen to also screen its own DELs against Pfizer's therapeutic targets
Bristol-Myers Squibb	Nordic Bioscience	▪ Objective: Develop biomarkers to diagnose scar-tissue related to liver diseases ▪ Dynamic: Partnership to evaluate non-alcoholic steatohepatitis in pre-clinical models of fibrotic diseases and clinical settings
Bristol-Myers Squibb	Foundation Medicine	▪ Objective: Use tumor profiling to predict patient response to cancer immunotherapy ▪ Dynamic: BMS to use FM's FoundationOne genomic profiling assay in its cancer drug clinical trials for studying tumor mutational burden and microsatellite instability in subject patients

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Janssen Research and Development	Castleman Disease Collaborative Network	▪ Objective: Improve diagnosis and treatment of idiopathic multicentric Castleman disease (iMCD) ▪ Dynamic: Measure analytes in serum samples from iMCD patients ▪ Janssen to finance venture and contribute serum samples it collected in previous clinical trial
Illumina	Human Vaccines Project	▪ Research partnership to decipher genetic features of human immune system for development of vaccines and immunotherapies
LifeCodexx	Charité–University Medicine Berlin	▪ Objective: Develop test for early detection of preeclampsia ▪ Dynamic: Assay to be based on LifeCodexx's methylation-specific quantitative PCR technology for exploiting different methylation profiles of maternal and fetal DNA in maternal plasma
BGI Genomics	Allen Institute for Brain Science	▪ Objective: Defining brain cell types to promote understanding of neurodegenerative diseases ▪ Dynamic: Organizations discussing collaboration on sequencing technology, bioinformatics and data mining ▪ No actual collaborations yet announced
GATC Biotech	University of Constance (Germany)	▪ Objective: Develop new DNA sequencing methods ▪ Dynamic: Formation of new research partnership called the Alliance for Sequence and Transcript Analysis (ASTRA)
Myriad Genetics	BeiGene	▪ Objective: Develop companion diagnostics ▪ Dynamic: BeiGene, which develops cancer treatments combining immunotherapy and molecularly targeted drugs, to use Myriad's myChoice HRD and BRACAnalysis CDx in clinical development program for its investigational PARP inhibitor BGB-290 ▪ Myriad also has companion diagnostics partnerships for BRACAnalysis CDx with AstraZeneca, Medivation, Tesaro and AbbVie
ArcherDx	HeliTec	▪ Objective: Develop NGS-based cancer diagnostics for Chinese market ▪ Dynamic: Companies to co-develop and cross-license NGS technologies with goal of registering oncology diagnostic kits with the China Food and Drug Administration
Fabric Genomics (previously known as Omicia)	Toma Biosciences	▪ Partnership to co-develop oncology genomic testing and clinical interpretation service for clinical lab clients
Fabric Genomics (previously known as Omicia)	Veritas Genetics	▪ Fabric to incorporate its genome annotation technology into Veritas Genetics' myGenome personal whole-genome sequencing service
Invitae	Alnylam Pharmaceuticals,	▪ Objective: Provide genetic testing for hereditary ATTR (hATTR) amyloidosis, a rare, progressive and life-threatening disease caused by a mutation in the TTR gene ▪ Dynamic: Partners to use Alnylam Act™ program for early genetic testing for prompt genetic diagnosis
Philips	PathAI	▪ Objective: Early breast cancer detection and diagnosis ▪ Dynamic: Leverage PathAI deep-learning algorithms to create applications for automatically spotting cancerous lesions in breast cancer tissue
DNAlytics	VIB (Belgian life sciences research institute)	▪ Objective: Develop blood-based screening test for colorectal cancer ▪ Dynamic: Use VIB's 23-gene expression signature in tumor-educated circulating monocytes to develop test for colorectal screening
BioDiscovery	Genalice	▪ Objective: Co-market and promotion ▪ Dynamic: Combine Genalice's Map technology with BioDiscovery's NxClinical data visualization platform to form single NGS data interpretation solution
Advanced Analytical Technologies	TTP Labtech	▪ Objective: Co-marketing ▪ Dynamic: Partnership to combine TTP's Mosquito and AATI's Fragment Analyzer platforms
DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
Illumina	Lucigen	▪ Products: Epicentre Technologies' genomics kits, enzymes and ancillary reagents (which Illumina acquired in 2011) ▪ Territories: Worldwide ▪ Exclusive
Sygnis	Tanon	▪ Products: InstantBlue stain for protein detection and Ultrafast buffer for western blotting assays ▪ Territory: China ▪ New deal expands Tanon's rights under existing sales agreement

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DISTRIBUTION, SALES & MARKETING AGREEMENTS, *Cont'd.*		
Property Owner	**Distributor**	**Deal Summary**
Kailos Genetics	Illumina	▪ Illumina gets rights to market KG's TargetRich research solutions for pharmacogenetic target enrichment
Infopia	GenDx	▪ Product: Infopia's GeneFinder human leukocyte antigen real-time PCR assay kits ▪ Territory: Europe ▪ Kits to be sold thru GenDx's local distributor network
VHLGenetics	BioBank	▪ Products: Microorganism, animal, and plant genetic testing products ▪ Territory: Norway ▪ Netherlands-based VHL has similar distribution agreements in Spain and Belgium
Dovetail Genomics	Daon BioSciences	▪ Products: Dovetail's genome assembly services ▪ Territory: South Korea ▪ Exclusive ▪ Dovetail named Tomy Digital Biology its distributor in Japan last Dec.
Streck	Anopoli Biomedical Systems (Austrian firm)	▪ Products: Streck's cell stabilization and molecular products ▪ Territory: Not disclosed but presumably Austria
Streck	Ruwag Diagnostics	▪ Products: Streck's cell stabilization and molecular products ▪ Territory: Switzerland
Streck	GenomePrecision Technology	▪ Products: Streck's cell stabilization, molecular, urinalysis and flow cytometry products ▪ Territory: China
Somatex	Hologic	▪ Products: Somatex biopsy products including Tumark Professional X, Q, Vision, and Flex markers and application devices ▪ Territory: US ▪ Exclusive
CellMax Life	Core Diagnostics	▪ Products: CellMax-DNA Genetic Cancer Risk Test and CellMax-LBx Liquid Biopsy assay ▪ Territory: India ▪ Partnership rather than distribution agreement
Mobidiag	AB Analitica	▪ Product: Real-time PCR-based Amplidiag *in vitro* diagnostics ▪ Territory: Italy ▪ 3-year exclusive
Biocept	Oregon Health & Sciences University	▪ Product: Biocept's Target Selector liquid biopsy testing services ▪ Territory: Oregon ▪ Preferred provider collaboration that also includes research and testing services
Acea Biosciences	Bioké	▪ Product: Acea's xCelligence cell analyzer ▪ Territories: Belgium, Netherlands and Luxembourg ▪ Bioké also Benelux distributor of Horizon Discovery Group's reference standards and RainDance's RainDrop Digital PCR systems
MDxHealth	Lab21	▪ Product: SelectMDx prostate cancer test ▪ Territory: UK ▪ Non-exclusive
LICENSES		
Licensor	**Licensee**	**Deal Summary**
Oxford Cancer Biomarkers	My-BioMed Biotechnology	▪ Product: OCB's ColoTox, ColoProg, and ColoPredict tests ▪ Territory: China
1Cellbio	UCB	▪ Product: InDrop single-cell sequencing technology, consumables and training for use in immune cell profiling ▪ Territory: Belgium
Oncgnostics	Changchun Jienuo Medical Technology (subsidiary of Sinopharm Group in China)	▪ Product: Oncgnostics' GynTect cervical cancer test ▪ Territories: China, Hong Kong, Macau ▪ Exclusive
Ghent University	MDxHealth	▪ Product: GU's molecular diagnostic visualization technology for detecting cancer associated epi-genetic changes in tissue and liquid samples ▪ Territory: Global ▪ Exclusive

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Johns Hopkins University	Qiagen	▪ Product: Right to detect AR-V7 biomarker in all sample and cell types using nucleic acid tests ▪ Territory: Global ▪ Exclusive ▪ Q to commercialize its research-use-only AdnaTest Prostate Cancer Panel AR-V7 for detecting androgen receptor splice variant 7 from liquid biopsies to investigate resistance to new advanced prostate cancer drugs
Johns Hopkins and Washington University in St. Louis	Canopy Biosciences	▪ Product: TUNR gene-editing technology ▪ Territory: Undisclosed ▪ Exclusive
Brandeis University	ThermaGenix	▪ Product: BU's technologies to detect and analyze nucleic acids using PCR ▪ Territory: Undisclosed ▪ Exclusive
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier	**Client**	**Deal Summary**
HTG Molecular Diagnostics	Daiichi Sankyo	▪ Objective: Develop custom assay to detect nearly 3,000 mRNA targets using HTG EdgeSeq technology ▪ Dynamic: HTG to provide research services for Daiichi in former's VERI/O lab
Veritas Genetics	Toronto's Women's College Hospital	▪ Veritas to provide BRCA testing for TWCH's The Screen Project for BRCA1 and BRCA2

■ Diagnostics Earnings Report: 1Q Marked by Widespread & Substantial Gains, *from page 1*

- Danaher's diagnostics business grew 17%;
- Roche's diagnostics revenues were up 6% to $2.80 billion;
- LCA's YOY revenues increased from $1.59 billion to $1.72 billion;
- Abbott's revenues grew 4% to $1.16 billion;
- Thermo Fisher's lab products and services sales increased 3% to $1.70 billion; and
- Quest was up 2% with diagnostics revenues of $1.90 billion.

It was a strong quarter for influenza products thanks to the year's harsh and prolonged respiratory disease season which featured circulation of a virulent H3N2 influenza strain. Among the biggest benefactors was Quidel, a leader in influenza products including Sofia, QuickVue and Solana. The company saw flu sales surge 112% to $40.8 million, one factor in the firm's overall 46% YOY increase for the quarter.

Decliners

BD was the only company to report a year-over-year decrease for the quarter, at -3%. But even that figure is misleading since it was largely the result of currency exchange losses and divestiture of DB's respiratory solutions business. BD's revenues for the quarter were actually up 5% on a currency-neutral basis. And diagnostics systems revenues were up a robust 10%, fueled by sales of flu-related products.

Sticking with the earnings-don't-tell-the-whole-story theme, several companies that posted big gains still had to lower their guidance estimates for the year. Examples:

- NeoGenomics, which despite 3% revenue growth, reduced its full-year 2017 revenue and earnings per share guidance resulting in a 12% decline of its shares on Nasdaq; and

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- Pacific Biosciences, which grew 30% but had to reduce its 2017 growth guidance from 40%-60% to 35%-45% due to "U.S. budget uncertainties."

COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street Estimate	
Abbott Laboratories	$1.16 billion Dx revenue	+4%	NA	Dx sales up 5% due to "above-market performance" in core lab and point-of-care
Becton Dickinson	$2.97 billion	-3%	$3.07 billion	Dx growth fueled by flu-and core microbiology products including blood cultures and Kiestra system
BioMérieux	€568 million	+16%	NA	11% growth in microbiology products including BacT/Alert blood culture line
Bruker	$384.9 million	+3%	$372.2 million	Mass spec revenues down but microbiology orders "stabilize"
Danaher	$4.21 billion	+7%	$4.17 billion	Dx revenues up 17% including double-digit core revenue growth from Cepheid
Epigenomics	$4.6 million	+102%	NA	Firm separately announces acceptance of takeover bid Blitz F16-83, subsidiary of Cathay Fortune International
Exact Sciences	$48.4 million	+226%	$37.3 million	Growth driven by 150% increase in Cologuard colon cancer tests
GenMark Diagnostics	$12.5 million	+13%	$12.5 million	Growth driven by strong sales of XT-8 molecular diagnostics system
Illumina	$598.0 million	+5%	$590.8 million	Firm received 135 orders for its new NovaSeq instruments
Laboratory Corp. of America	$2.41 billion net	+5%	$2.41 billion	Dx revenues of $1.72 billion vs. $1.59 billion Q1 2016
Luminex	$77.8 million	+23%	$74.2 million	Nanosphere Verigene molecular product sales up 59% YOY at $10.5 million
Meridian Bioscience	$54.1 million	+6%	$51.2 million	Life science division up 18% to $16.4 million but revenues of newly acquired Magellan Diagnostics flat at $3.6 million
Myriad Genetics	$196.9 million	+3%	$189.1 million	Molecular diagnostic testing up 4% to $185.2 million despite 10% drop in hereditary cancer and 9% drop in Vectra DA rheumatoid arthritis tests
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
OncoCyte (Firm did not report its revenues)	$4.7 million net loss	Net loss up 60%	NA	Company placing its hopes in lung cancer test to be launched in second half of 2017
Pacific Biosciences	$24.9 million	+30%	$24.6 million	Despite increase, PacBio lowers its 2017 growth guidance from 40-60% to 35-45% due to "U.S. budget uncertainties"
Qiagen	$307.7 million	+3%	$306.9 million	Molecular diagnostics up 3% to $142.0 million, or 46% of total sales, despite fall of HPV test sales in U.S.
Quest Diagnostics	$1.90 billion	+2%	$1.87 billion	Growth driven by genetic carrier screening, prescription drug monitoring, hepatitis C and interferon tuberculosis testing
Quidel	$73.7 million	+46%	$62.0 million	Growth driven by molecular, immunoassay, influenza and specialty products

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COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street Estimate	
Roche	$2.80 billion in Dx revenues	+6%	NA	Point-of-care grew 8% and generated the most Dx revenue; immunoassays grew 13%
Thermo Fisher Scientific	$4.77 billion	+11%	$4.68 billion	Laboratory products and services up 3% to $1.70 billion
Veracyte	$16.4 million	+21%	$17.7 million	Afirma Gene Expression Classifier test volume up 9% to 5,834 tests
Waters	$498 million	+5%	$488.6 million	Growth fueled by 9% increase in sales to pharmaceutical industry customers

CORRECTION: Molecular Assays Stave Off Big Cuts in 2017 Clinical Laboratory Fee Schedule

Editor's Note: *The lead story in the November 25, 2016 issue of LIR is about changes to the 2017 Clinical Laboratory Fee Schedule affecting reimbursement for clinical laboratory tests. The first section of the story discusses new molecular tests added to the CLFS in 2017, specifically the seven tests that were in line for major price cuts. The punchline was that the price cuts CMS proposed were never made. The Problem: Although the analysis was correct, the article listed the wrong pricing information for these and other molecular tests contained in the CLFS. Here is a revised version of the affected parts of the article listing the correct prices, including a chart providing a clearer comparison between the CMS proposed and final National Limitation Rate for each test. G2 apologizes for the error and thanks our loyal and attentive users for bringing it to our attention.*

1. Seven Molecular Assays Stave Off Big Cuts

[For many labs, the most significant aspect of the 2017 CLFS is reimbursement for] the 15 CPT codes for molecular tests that CMS added to the CLFS this year. The question: How much should Medicare pay for these esoteric and pricey assays? In June, CMS proposed interim gapfill prices at a discount from their regionalized prices. Led by providers of the assays highlighting the inconsistencies between the proposed gapfill rates and the rates established by the Medicare Administrative Contractors who approved the tests, the industry asked CMS to reconsider the interim rates. "The proposed gapfill rates are inconsistent with rates established by commercial payers and the Protecting Access to Medicare Act of 2014," contended The Coalition for 21st Century Medicine.

CMS apparently took heed, dropping the rate cuts and restored or increasing the regional prices for seven of the tests listed increased by the annual CLFS modifications. Companies benefiting from the change of course included:

- **CareDx**, which instead of a 77 percent cut got its rate restored to the original rate on its AlloMap test to identify heart transplant recipients at low risk of rejection (CPT 81595);
- **Biodesix**, which got the rate restored for its VeriStrat lung cancer aggressiveness test (81538);
- **Genomic Health**, which got the rate restored on its Oncotype DX colon cancer recurrence test (81525);

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- **BioTheranostics**, which got the rate restored for its metastatic tumor origins diagnostic test (81540);
- **Invitae**, which avoided a 33 percent cut on its hereditary breast cancer panel (81432);
- **CardioDx**, which instead of a 28 percent cut had its rate almost completely restored on its coronary artery disease risk test Corus CAD (81493); and
- **Veracyte**,which instead of a 22 percent cut got its rate restored on its thyroid nodule assessment assay Affirma (81545).

2017 Medicare Rate for New Molecular Diagnostic Tests
(**Boldface** tests are those for which discounts were proposed but not adopted)

CPT Code	Test	Proposed National Limitation Rate	Final National Limitation Rate
81412	9-Gene Ashkenazi Jewish Screen	$602.10	$602.10
81432	**Hereditary Breast Cancer Panel, 14 Genes**	**$622.53**	**$931.48**
81433	Hereditary Breast Cancer, Duplications/ Deletions Panel	$602.10	$602.10
81434	Hereditary Retinal Disorder Screen	$602.10	$602.10
81437	Hereditary Neuroendocrine Tumor	$602.10	$602.10
81438	Hereditary Neuroendocrine Tumor, Duplications/ Deletions	$602.10	$602.10
81442	Noonan Gene Screen	$602.10	$602.10
81490	Vectra Screen	$590.61	$590.61
81493	**Corus CAD**	**$741.01**	**$1,042.35**
81525	**Oncotype DX**	**$848.86**	**$3,125.73**
81538	**Veristrat**	**$283.00**	**$2,126.78**
81540	**bioTheranostics**	**$1,522.17**	**$2,920.30**
81545	**Affirma**	**$2,240.16**	**$3,222.40**
81595	**AlloMap**	**$732.00**	**$2,840.75**
0009M	VisibiliT	$602.10	$602.10

FDA Watch: Congress Kills Trump Plan to 'Recalibrate' User Fees

Instead of the budget cuts the President asked for, the newly approved federal government spending plan increases FDA funding by $103 million, $4.665 billion in total. That includes $2.759 billion for FDA discretionary spending, $39 million above FY 2016 outlays. The extra discretionary money will be spent on, among other things:

- Supplemental medical product safety and Precision Medicine initiatives authorized by the *21st Century Cures Act*: $10.9 million;
- Response to Zika, Ebola and other emerging health threats: $10 million; and
- Foreign high-risk inspections: $2.5 million.

From the diagnostic industry perspective, the most significant aspect of the spending plan may be what it does *not* include, namely, the Trump 2018

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budget proposal plan to "recalibrate" medical product user fees by doubling the fees pharmaceutical and medical device companies pay the FDA to review their products. While the concept of making the "industries that benefit from FDA approval pay for their share" rings fair, raising user fees 100 percent threatened to chill new product development especially by biotech and other smaller, entrepreneurial firms operating on tight margins. The proposal also drew criticism for ignoring painstakingly negotiated FDA revenue targets and the consensus that user fees are a supplemental rather than primary funding source of FDA review activities.

Notable New 510(k) Marketing Clearances

As we highlighted in *LIR*'s April issue, the FDA broke new ground by authorizing 23andMe to engage in direct-to-consumer (DTC) marketing of its Personal Genome Service Genetic Health Risk (GHR) tests for 10 diseases or conditions. *Another big development:* Royal Phillips got the green light to market its IntelliSite Pathology Solution, which the company claims to be the first and only digital pathology solution in the U.S. to receive clearance for primary diagnostic use by pathology labs. FDA approval "opens a complete new dimension towards computational pathology which aims to increase accuracies and ultimately enhance patient care," according to a company statement.

The Latest Zika Test

Emergency Use Authorization (EUA) of *in vitro* diagnostics for the Zika virus continues to sizzle with the approval of Nanobiosym's test for qualitative detection of Zika RNA in human serum based on the company's Gene-Radar portable platform. This is the 17th EUA that the FDA has issued for Zika tests since the start of 2016. (See *LIR*, March 2017 for a listing of the previous 16 tests, including subsequent expansions of the scope of approval.)

Here's a rundown of all the notable diagnostic approvals in the past month.

Manufacturer(s)	Product(s)
Royal Philips	Approval to market IntelliSite Pathology Solution, which the company claims is the first and only digital pathology solution in the U.S. to receive clearance for primary diagnostic use
Alere	Approval to market Alere™ Reader, a diagnostic analyzer that can be used in both point-of-care and laboratory settings
Nanobiosym	Emergency Use Authorization for Gene-Radar Zika virus test
23andMe	Approval to market Personal Genome Service Genetic Health Risk (GHR) tests for 10 diseases or conditions
Becton, Dickinson and Company	Approval of BD FACSVia™ system for identifying and counting rWBCs in leucoreduced blood products
Great Basin Scientific	Approval of Bordetella Direct, sample-to-result molecular test to detect *Bordetella pertussis*, the bacteria that causes whooping cough
Qiagen	Approval of ipsogen® JAK2 RGQ PCR Kit (ipsogen JAK2 assay), test detecting the JAK2 V617F/G1849T allele in genomic DNA extracted from EDTA whole blood
Myriad Genetics	Approval of BRACAnalysis CDx for use as complementary diagnostic to identify ovarian cancer patients with germline BRCA mutations likely to benefit from treatment with Zejula
Siemens Healthineers	Pre-market approval Versant HCV Genotype 2.0 assay identifying all 6 hepatitis C virus genotypes

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New CE Marks

BioGx was the most active firm of the month, securing CE approval for four different tests. Here's a listing of notable diagnostic products receiving CE marking for Europe during the month:

Manufacturer(s)	Product(s)
BioGx	BioGx Mycoplasma-Ureaplasma, test using ThinPrep or universal transport media samples to diagnose genital infection
BioGx	BioGx Pneumocystis jirovecii, test using pretreated sputum samples to diagnose pneumonia caused by the eponymous fungus
BioGx	BioGx Mycobacterium tuberculosis Complex, test using pretreated sputum and bronchoalveolar lavage samples to diagnose tuberculosis infection
BioGx	BioGx Bordetella Speciation plus Toxin, test using nasopharyngeal swabs or nasal wash samples to diagnose Bordetella species
GenMark Diagnostics	ePlex Blood Culture Identification fungal pathogen panel
Curetis	Multiplex PCR-based assay for severe intra-abdominal infections
Great Basin Scientific	Stool-based bacterial pathogens detection panel
Vela Diagnostics	Sentosa SA HBV Quantitative PCR Test to detect Hepatitis B virus DNA
Singulex	Sgx Clarity® system, fully-automated *in vitro* diagnostics platform
Roche	Liat System point-of-care platform, which performs real-time PCR in tube-based format, using spatial thermal cycling generating results within 20 minutes
Roche	Assay for *Clostridium difficile*

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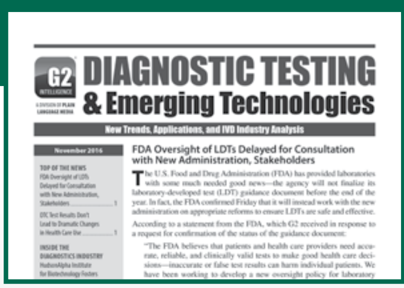

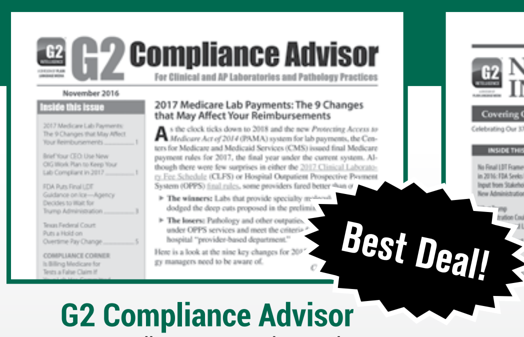

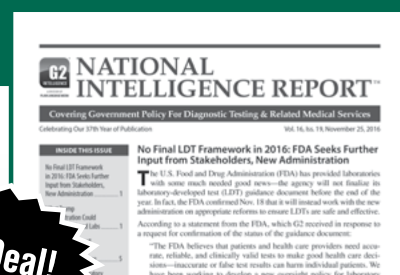

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