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HIGHLIGHTS

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FDA Watch: New Policy Would Allow DTC Marketing of Genetic Tests *without* Premarket Approval

For years, the lab industry has been pressing the FDA to relinquish its rigorous oversight of direct-to-consumer (DTC) genetic health tests. On Nov. 6, the agency finally made a move in that direction proposing to allow precertified manufacturers to bring genetic tests to market without undergoing premarket review.

The present policy dates back to the 2013 warning letter the FDA issued to 23andMe ordering the consumer genomics firm to stop marketing its DNA analysis services. Since then, newfangled DTC genetic tests have required premarket approval.

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Dx Earnings Report: Strong Q3 Adds to Robust 2017 as PAMA Looms for 2018

Big labs continue to post impressive earnings. But the positive Q3 numbers may prove to be the calm before the PAMA storm—at least for major reference labs that generate significant revenues from Medicare. Here's an overview of earnings reports of firms with at least $10 million in sales for the quarter.

Gainers

After enjoying a 26-to-10 margin in the previous quarter, the disparity between gainers and decliners reached an even more impressive 31-to-5 disparity in Q3. Among the gainers, only four failed to make their Wall Street targets, including (by size of miss):

- GenMark Diagnostics which despite 7% year over year growth, missed its $14.6 million target by $3 million;
- NeoGenomics which came up $800,000 short of its $63.9 target as a result of lab closures forced by Hurricanes Harvey and Irma;

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New Policy Would Allow DTC Marketing of Genetic Tests *without* Premarket Approval, *from page 1*

But even before the Trump administration, the FDA has been seeking to modernize its approach to allow room for innovation. According to the agency's notice for public comment, is not necessary for certain class II (moderate risk) devices, including vitamin D mass spectrometry-based test systems and genetic health risk (GHR) assessment test systems. *The catch:* GHR test manufacturers will need first time FDA marketing authorization; after that, though, they will be allowed to commercialize new GHR tests without additional review.

Earlier this year, foreshadowed the new policy in its premarket authorization of 10 GHR tests from 23andMe giving the green light for DTC launches of other tests without premarket review provided that it followed listed controls, which include the requirement that 23andMe publish:

- Labeling outlining test limitations;
- Information about how the test works and its accuracy vis-à-vis a comparative baseline;
- References to applicable clinical guidelines and disease risks; and
- Information on obtaining a genetic counselor.

The Nov. 6 notice, which at this point is a proposal rather than a formal policy, essentially extends the 23andMe approach to all GHR test makers. There's also a limitation: The new approach doesn't apply to diagnostic genetic tests that *inform treatment decisions*, e.g., hereditary cancer tests analyzing BRCA1 and BRCA2 genes to decide if a woman should have a prophylactic mastectomy.

And for now at least, the FDA is maintaining the hard line on DTC companies issuing warning letters to DNA4Life and Interleukin Genetics for marketing tests without premarket approval.

New FDA Approvals

Meanwhile, here's a rundown of key new approvals issued by the FDA in late October through November:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Clinical Genomics +	Approval of Panther Fusion Flu A/B/RSV assay running on Panther Fusion system
Memorial Sloan Kettering Cancer Center	Approval of MSK-IMPACT NGS tumor profiling assay
Abbott	Approval of Alinity c clinical chemistry system
Abbott	Approval of Alinity i immunoassay system
Roche	Approval of Ventana MMR IHC panel for colorectal cancer patients
Roche	Approval of Ventana ALK (D5F3) companion diagnostic to identify ALK-positive non-small cell lung cancer patients who would benefit from treatment with firm's Alecensa (alectinib) drug

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NEW FDA APPROVALS, *Cont'd*

Manufacturer(s)	Product(s)
Luminex	Approval of Aries Group A Strep Assay
Hardy Diagnostics	Approval of Delafloxacin Antimicrobial Susceptibility Disk tests to guide MDs in use of Melinta Therapeutics bacterial skin and skin structure infections treatment drug
Thermo Fisher Scientific	Approval of Sensititre MIC System for assessing patients who may be appropriate for Melinta Therapeutics' Baxdela treatment
Hologic	Approval of Panther Fusion Paraflu multiplexed assay for running on Panther Fusion system
Quidel	Approval of Solana RSV + hMPV assay to detect viral RNA from nasal and nasopharyngeal swabs run on firm's Solana molecular testing instrument
Quidel	Approval of Sofia Lyme FIA Lyme disease test on Quidel Sofia platform
Myriad Genetics	Supplementary premarket approval application of BRACAnalysis CDx to identify metastatic breast cancer patients likely to respond to AstraZeneca's Lynparza (olaparib) drug
Instrumentation Laboratory	Approval of HemosIL AcuStar HIT-IgG(PF4-H) assay

In November, the FDA granted CLIA waivers to the following test kits:

NEW FDA CLIA WAIVERS

Manufacturer(s)	Product(s)
Alere	Alere Technologies AS, Afinion 2 analyzer
Bayer Healthcare	Polymer Technology Systems, Inc., CVS Health At Home A1C Test Kit
Bayer Healthcare	Polymer Technology Systems, Inc., ReliOn Fast A1C Test At-Home A1C System
Bayer Healthcare	Walgreens, Co., Walgreens At Home A1C Test Kit

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS

Manufacturer(s)	Product(s)
Molzym	Approval of Micro-Dx microbial DNA isolation and direct PCR test for routine pathogen diagnosis
Beckman Coulter	Approval of Access hsTnI high-sensitivity troponin assay
SpeeDx	Approval of PlexPCR VHS multiplex qPCR test
Mindray	Approval of HIV and HBV test kits for HBsAg, Anti-HBs, Anti-HBc, HBeAg and Anti-HBe

Other new international approvals included:

- China FDA approval of TBG Biotechnology HLAssure SE SBT portfolio of high-resolution human leukocyte antigen genotyping kits for hematopoietic cell transplantation;
- China FDA approval of Ortho Clinical Diagnostics' Ortho Vision platform; and
- Singapore Health Sciences Authority approval of Vela Diagnostics' Sentosa SQ HIV Genotyping Assay.

Dx Earnings Report, *from page 1*

- NantHealth whose $21.8 million in revenues exceeded Q3 totals from 2016 by 5% but fell $400,000 short of Wall Street estimates; and
- Luminex which missed its target by a heartbreaking $300,000—$74.1 million v. $74.4 million.

For the third straight quarter, almost all of the billion-dollar labs at least met, and in a few cases, smashed their expected gains. The latter included:

- Thermo Fisher which had a monster Q3 featuring not only 14% growth at $5.12 billion, (vs. the Wall Street target of $5.03 billion) but completion of the $7.2 billion Patheon acquisition;
- LabCorp which exceeded its $2.55 billion target by $11 million—while strategic acquisition revenues lifted the figures, the firm also posted a 10% gain in diagnostic sales;
- Danaher which posted 10% overall growth including an eye-popping 20% increase in diagnostic revenues, allowing it to beat its $4.47 target by $6 million.

Abbott and Quest were also able to meet their Q3 Wall Street revenue targets but just barely. Moreover, four labs that posted declines in Q2 reported increases in Q3, including (in order of percentage gain) Fluidigm, GenMark Diagnostics, NantHealth and Quidel.

Decliners

Only five labs posted revenue declines in Q3. Among them was Becton Dickinson, the only 9-figure lab on the bad list. But even that red number came in below what Wall Street was projecting ($3.15 billion actual v. $3.17 billion projected). In addition, CareDx which was down 2% overall, still came in with higher than expected earnings for the quarter ($12.2 million actual v. $12.1 million expected).

Other companies that struggled in terms of revenues:

- OpkoHealth fell nearly 12% to $298 million, well short of its $319.4 million target;
- Pacific Biosciences continues to leak oil with losses of 6% due in large part to falling instrument sales; and
- Veracyte which took a 6% hit, a loss aggravated by accounting considerations and the conversion of its Affirma test sales from a cash to accrual basis.

Perhaps surprising by its absence from the decliners list is NantHealth, a firm in the process of restructuring that managed to post positive growth of 2%—albeit nearly $1 million shy of its $29.2 million Wall Street target.

Diagnostics Earning Reports 3Q 2017 (At least $10 million in sales)

COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street Estimate	
Abbott Laboratories	$6.83 billion	+6%	$6.72 billion	Dx up to $1.28 billion driven by 6% growth in core lab tests to $1.03 billion, 6% growth in POC tests to $131 million and 3% growth in molecular tests to $115 million
Becton Dickinson	$3.17 billion	-2%	$3.15 billion	Loss, which is less than Wall Street projected, driven by divestiture of respiratory solutions business; Dx revenues grow 5% to $359 million
BioMérieux	€540 million	+6%	NA	23% in molecular bio driven by BioFire FilmArray line
Bio-Rad	$535 million	+5%	$508 million	Newly acquired RainDance Technologies generates $75 million in sales
Bruker	$435.6 million	+11%	$414.6 million	Organic growth of 3% net of 5% in acquisition boosts and 2% in positive currency effects
CareDx	$12.2 million	-2%	$12.1 million	AlloMap sales down $400K but projected to jump $3.24 million in 2018 due to PAMA Medicare rate hikes
Danaher	$4.53 billion	+10%	$4.47 billion	Dx revenues up 20% to $1.45 billion driven by strong immunoassay sales
Enzo Biochem	$28.2	+6%	NA	Molecular Dx drives 13% growth in clinical labs segment
Exact Sciences	$72.6 million	+158%	$65.0 million	136% increase in Cologuard colon cancer tests completed to 161,000 (vs expected 150,000). EPS decline narrows from -.30 to .23 cents per share
Fluidigm	$24.7 million	+12%	NA	Genomics revenues down 20% to $10.3 million; EPS loss narrows from -.68 to .46 cents per share
Foundation Medicine	$42.7 million	+45%	$38.0 million	Clinical testing up 37% to just under $13 million and biopharma revenues up 17% to $22.1 million
GenMark Diagnostics	$11.6 million	+7%	$14.6 million	Strong sales of newly FDA approved ePlex and eSensor XT-8 molecular Dx systems but not enough to meet Wall Street target
Hologic	$802 million	+11%	$792.5 million	Total Dx revenues fall 7% to $291.7 million despite strength of Aptima women's health line in molecular segment
Illumina	$714 million	+18%	$692.8 million	NovaSeq instruments continue to drive growth with non-GAAP income of $1.11 per share v. .99 cents expected
Invitae	$18.1 million	nearly +300%	$13.3 million	Driven by revenues from newly acquired Good Start Genetics; 10% PAMA cut in Invitae's hereditary cancer panel (CPT 81432) expected to hurt 2018 revenues
Laboratory Corp. of America	$2.66 billion	+10%	$2.55 billion	Acquisitions revenues spike totals though DX revenues up 10% to $1.84 billion; PAMA cuts expected to reduce 2018 revenues
Luminex	$74.1 million	+4%	$74.4 million	Misses Wall Street target despite 17% increase in assay revenues and driven by strong automated sample-to-answer molecular product sales
MDxHealth	$30.5 million	+38%	NA	Numbers inflated by $12.1 million in patent sales to Exact Sciences; total sales up 3% to $18.4 million
Meridian Bioscience	$49.7 million	+2%	$48.1 million	Dx revenues up 4% to $36 million
Myriad Genetics	$190.2 million	+7%	$183.4 million	8% increase in molecular tests offsets 9% decline in hereditary cancer sales
NanoString Technologies	$27 million	+13%	$27 million	Prosigna IVD kit sales up nearly 50% to $17 million; big news for Q3 was setback in Merck companion diagnostic collaboration
NeoGenomics	$63.1 million	+4%	$63.9 million	Hurricanes Irma and Harvey kept clinical testing revenues growth to just 1%; meanwhile Medicare continues to refuse coverage of firm's molecular tests
NantHealth	$21.8 million	+5%	$29.2 million	Firm in process of restructuring gets $1 million boost from GPS sales in Asian market
Natera	$56.7 million	+5%	$56.0 million	Testing volume up 15% at 130,400 tests processed led by Panorama prenatal at 87,400 (+4%)

COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total	YOY	Wall Street Estimate	
NeoGenomics	$66.1 million	+5%	$63.0 million	Driven by 7% growth in genetic testing; EPS also beat Wall Street estimates
Opko Health	$263.5 million	-12%	$319.4 million	Product revenues up 10% to $22.8 million but DX products not broken out; CEO notes that BioReference Labs business fell short but projects improvement in 2018
OraSure Technologies	$42.3 million	+31%	$40.8 million	Driven by 186% growth in hepatitis C testing revenues to $8 million
Oxford Immunotec	$30.4 million (YTD)	+17%	$30.1 million	Growth driven by tuberculosis and tick-borne disease testing
Pacific Biosciences	$23.5 million	-6%	$28.6 million	Consumables up 62% to $10.6 million; YOY net loss grows from $17.5 million to $22.0 million
PerkinElmer	$554.3 million	+8%	$552.4 million	Dx revenues up 13% to $168.9 million
Qiagen	$364 million	+7%	$363.3 million	Molecular DX up 9% to $180 million, over 50% firm's total sales, 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	$1.93 billion	+2%	$1.92 billion	DX revenue up 3% to $1.865billion; anticipated 2018 losses from PAMA cuts expected to be offset by revenues from acquisitions; firm now projecting total 2017 revenues of 7.71 billion, in range of forecasts from earlier in year
Quidel	$50.9 million	+3%	$50.3 million	Immunoassays drive 12% growth in DX sales; FDA approval of Solana RSV + hMPV expected to increase molecular revenues in 2018
Roche	$40.61 billion (YTD)	+5%	NA	DX up to $8.37 billion—centralized and point of care revenues up 7%, molecular up 3%, tissue up 13% but diabetes care down 1%; look to Asia Pacific and global market to offset PAMA losses in 2018
Thermo Fisher Scientific	$5.12 billion	+14%	$5.03 billion	Labs up 16% to $1.93 billion and specialty DX up 6% to $843.7 million—Asia Pacific sales continue growing at low double digits rate
Veracyte	$18.6 million	-6%	$19.6 million	Higher collection costs absorb gains in test revenues accrued due in part to conversion of Afirma Gene Expression Classifier test from cash to accrual basis; YOY net loss grows to $7.0 million or 21 cents per share, which at least falls below Wall Street estimates of 23 cents
Waters	$565.6 million	+7%	$553.2 million	Balanced growth with especially strong sales in mass spec business

* **Bold face:** Companies that met or exceeded Q3 Wall Street revenues target

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

The pattern of high volume and relatively low impact continued with strategic alliances outnumbering acquisitions at rate of roughly 3:1.

M&A

Following the trio of mega-deal closings, Abbott/Alere, ThermoFisher/Patheon and LabCorp/Chiltern, mid-October to November was a bit of an anti-climax in the M&A realm. Most of the action featured the closing of previous deals rather than the initiation of new ones. Quest was the most active player acquiring Cleveland HeartLab from the Cleveland Clinic and a Los Angeles area lab network from the California Laboratory Association. Other notable deals included closings of acquisitions announced in July:

- Siemens Healthineers' acquisition of Epocal from Abbott as part of its sell-off to clear way for the Alere merger;

- Konica Minolta's intriguing purchase of California genetics testing firm Ambry Genetics for $1 billion; and
- Invitae's $35 million acquisition of CombiMatrix, which paired with the recent acquisition of Good Start Genetics, positions Invitae to add reproductive health testing to product line and become comprehensive genomic information company.

Strategic Alliances

Skyline Medical was among the most active firms on the alliance front announcing a pair of joint ventures enabling it to expand its contract research organization services, including deals gaining access to Helomics' D-Chip platform to create new approaches for personalized cancer diagnosis and care and CytoBiosciences' personalized research services.

LabCorp also announced multiple deals including a partnership allowing its Covance Drug Development business to leverage MC10's wearable sensor technology for clinical trials and patient testing and monitoring and giving LabCorp an equity stake in the tech firm. Some of the other noteworthy alliances from the period include:

- The collaboration between Roche Diagnostics and Inotrem to develop a companion diagnostic test for septic shock treatment for clinical trials to run on Roche's Elecsys immunochemistry platform;
- Myriad Genetics' collaboration with CareFirst BlueCross BlueShield on an 18-month study to evaluate the effectiveness of the Vectra DA test for detecting and treating rheumatoid arthritis; and
- The new China joint venture between Sciex and Hangzhou-based Zhejiang Dian Diagnostics Objective: aimed at commercializing Class I, II and III reagents for the SCIEX Triple Quad 4500MD LC-MS/MS system.

Here's a graphic summary of the key diagnostic deals from mid-October through November:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Invitae	Alere	▪ Price: Total deal value of approximately $34.9 million, including Invitae's issuance of 2.7 million common shares to former CombiMatrix shareholders ▪ Status: Closing of deal announced in July
Siemens Healthineers	Epocal (from Abbott)	▪ Price: Undisclosed ▪ Status: Close of deal announced in July ▪ Abbott had to sell off Epocal to get regulatory approval for Alere merger ▪ Acquisition enables Siemens to complete its own blood-gas portfolio
Quest Diagnostics	California Laboratory Associates (CLA)	▪ Price: Undisclosed ▪ Status: Closed ▪ Quest acquires Los Angeles area clinical lab network
Quest Diagnostics	Cleveland HeartLab (from Cleveland Clinic)	▪ Price: $94 million all-cash deal ▪ Status: Expected to close by end of year ▪ Quest to create its first national center of excellence in cardiometabolic disorders at lab
Konica Minolta	Ambry Genetics	▪ Price: Up to $1 billion cash, including $800 million upfront and up to $200 million over 3 years ▪ Status: Closing of deal announced in July ▪ Ambry to become subsidiary of Konica Minolta and keep its name and continue its genetic testing operation from its current California HQ

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Angle	Axela (University of Toronto microarray spinout)	▪ Price: £3.7 million ($4.9 million) to be financed by placement of new shares ▪ Status: Closed ▪ Angle acquires intellectual property, fixed assets, inventory, employees and interest in leased property from Axela
Almac	BioClin Laboratories	▪ Price: Undisclosed ▪ Status: Closed ▪ BioClin is Ireland-based firm that provides GMP microbiology testing and GLP bioanalysis
Aurora Diagnostics	CytoPath	▪ Price: Undisclosed ▪ Status: Closed ▪ Aurora now has 30 affiliated local pathology practices
GenExosome Technologies (newly formed subsidiary of Avalon GloboCare)	Beijing Jieteng	▪ Price: Undisclosed ▪ Status: Closed ▪ GenExosome acquires 100% of Chinese exosome technology company's the outstanding stock ▪ GenExosome also closed separate asset purchase agreement with target firm's CEO to acquire patents and patent applications for research and development of exosome technologies
Exact Sciences	SampleMinded	▪ Price: Undisclosed ▪ Status: Closed ▪ Acquisition Salt Lake City-based software development firm enables Exact to bolster its IT systems

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Guardant Health	Bristol-Myers Squibb	▪ Objective: Develop GuardantOMNI assay liquid biopsy panel for accelerating clinical trials and targeted cancer therapy research ▪ Dynamic: Similar to Guardant's existing pharma collaborations with AstraZeneca, Merck, Merck KGaA, and Pfizer
Roche Diagnostics	Inotrem	▪ Objective: Develop companion diagnostic test for septic shock treatment for clinical trials ▪ Dynamic: Work to create prototype assay for quantitative measurement of soluble plasma circulating protein (sTREM-1) in septic shock patient samples to run on Roche's Elecsys immunochemistry platform
Clearbridge Biomedics	Leica Biosystems	▪ Objective: Comarketing in support of circulating tumor cell research ▪ Products covered include Clearbridge's ClearCell CTC enrichment system and LBS' Bond Rx staining platform with aims of creating integrated and automated workflow for CTC enrichment and immunostaining
Varian Medical Systems	DNAmito	▪ Objective: Software product integration ▪ Dynamic: OEM(original equipment mfg.) agreement integrating DNAmito's Prodecis into Varian's 360 Oncology care management software
Ymir Genomics	Knight Cancer Institute at Oregon Health and Science University	▪ Objective: Develop urinary biomarkers to detect hepatocellular carcinoma ▪ Dynamic: Ymir to isolate extracellular vesicles and study miRNA profiles of urine samples from liver cancer patients ▪ OHSU will then use vesicle preps to determine specific protein profiles
Laboratory Corporation of America	Capital Health	▪ Objective: Care delivery ▪ Dynamic: LabCorp to serve as reference lab for hospital group hospitals, cancer center and outpatient clinics ▪ LabCorp to also provide other lab support services
Laboratory Corporation of America	MC10	▪ Objective: Product development and research ▪ Dynamic: Partnership in which LabCorp's Covance Drug Development business will use MC10's wearable sensor technology for clinical trials, research studies, and patient testing and monitoring ▪ LabCorp also invests undisclosed amount in MC10
Thermo Fisher Scientific	Blueprint Medicines	▪ Objective: Develop and commercialize Thermo Fisher's Oncomine Dx Target Test as companion diagnostic for Blueprint's BLU-667 ▪ Dynamic: Thermo Fisher to retain test's global commercialization rights ▪ In June, FDA approved test as companion diagnostic for three NSCLC treatments, from AstraZeneca, Pfizer, and Novartis and under deal, Thermo Fisher will seek clearance from other regulatory authorities
Hummingbird Diagnostics	Saarland University	▪ Objective: Validate blood-based microRNAs as biomarkers for early detection of pulmonary diseases ▪ Dynamic: Analysis of 5,000 samples from lung cancer, COPD, Alzheimer's and Parkinson's patients with resulting IP rights to be allocated in accordance with framework agreement
Sciex	Zhejiang Dian Diagnostics	▪ Objective: Develop and commercialize Class I, II and III *in vitro* diagnostic reagents for the SCIEX Triple Quad 4500MD LC-MS/MS system ▪ Dynamic: Newly formed joint venture based in Hangzhou, China

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Sygnis (under Innova Biosciences brand name)	Abingdon Health	■ Objective: Provide full lateral flow assay development services to Innova customers ■ Dynamic: Sygnis to have access to Abingdon's ADXLR5 reader systems ■ Deal also makes Innova preferred colloidal gold supplier to Abingdon
ReadCoor	Joint Pathology Center	■ Objective: Develop diagnostic tools for determining pathogenic cause of mortality using ■ Dynamic: Use ReadCoor's Florescent In-Situ Sequencing technology to analyze inflamed tissue samples from JPC's tissue repository
Skyline Medical	Helomics	■ Objective: Develop contract research organization services ■ Dynamic: New joint venture to leverage Helomics D-Chip platform to create new approaches for personalized cancer diagnosis and care
Skyline Medical	CytoBiosciences	■ Objective: Develop contract research organization services ■ Dynamic: New joint venture in which Skyline will provide access to CytoBioscience's personalized research services to expand its client base and expertise
Myriad Genetics	CareFirst BlueCross BlueShield	■ Objective: Research to develop Myriad's Vectra DA rheumatoid arthritis test ■ Dynamic: Conduct 18-month clinical utility study aims to determine if Vectra DA enables rheumatologists to provide better treatment at lower costs than do conventional approaches
FDNA	Asia-Pacific Society of Human Genetics (APSHG) + University of Hong Kong	■ Objective: Improve FDNA's NGS phenotyping technology in Asia-Pacific populations ■ Dynamic: FDNA to train APSHG on use of its Face2Gene technology to recognize phenotypes for all Asia-Pacific ethnicities
Labcyte	University of Helsinki's Institute for Molecular Medicine Finland	■ Objective: Expand existing personalized medicine partnership to new applications based on Labcyte's liquid handling and automation platforms ■ Dynamic: Partners to cooperate on cell-based assay development and screening, developing advanced cell models ■ Labcyte's Echo liquid handler to be integrated into FIMM's genomics program
Cota	Memorial Sloan Kettering Cancer Center	■ Objective: Build clinical and genomic data sets ■ Dynamic: Cota to run MSK's anonymized clinical records through its Cota Nodal Address classification system
PathoQuest	Memorial Sloan Kettering Cancer Center	■ Objective: Establish PathoQuest's iDtect blood test within MSK's microbiology lab ■ Dynamic: PathoQuest to compare iDtect with standard testing methods for identifying microbes responsible for infections in febrile neutropenia patients
ArcherDx	Celgene	■ Objective: Develop and commercialize NGS-based companion diagnostic for Celgene's investigational drug CC-122 for diffuse large B cell lymphoma ■ Dynamic: ArcherDx to use its Anchored Multiplex PCR technology in combination with Illumina MiSeqDx sequencer and Archer Analysis bioinformatics software to develop diagnostic
Amgen	Adaptive Biotechnologies	■ Objective: Clinical research ■ Dynamic: Adaptive to use its NGS-based immune repertoire profiling assay ClonoSeq to measure minimal residual disease in patients with multiple myeloma as part of phase 3 clinical trial sponsored by Amgen
Natera	Aarhus University	■ Objective: Clinical research for early detection of colorectal cancer recurrence ■ Dynamic: Study evaluating circulating tumor DNA as a biomarker to detect residual disease, treatment response, and disease recurrence in colorectal cancer patients
Natera.	Imperial College London + University of Leicester	■ Objective: Evaluate Natera's Signatera circulating tumor DNA technology for detecting breast cancer recurrence ■ Dynamic: New study to identify optimal biomarkers for predicting disease progression in women with breast cancer after surgery and adjuvant therapy
CureOne	Washington University School of Medicine	■ Objective: Link cancer genomic data with treatment information ■ Dynamic: CureOne to work with Wash U's GPS lab to share data through latter's N1 Registry open-access database linking NGS data with treatment and clinical outcome information
Berg	Sanofi	■ Objective: Identify biomarkers of influenza vaccine performance ■ Dynamic: Berg to use its Interrogative Biology platform to assess potential biomarkers of seasonal influenza vaccination outcomes
Pillar Biosciences	Illumicare	■ Objective: Develop NGS-based *in vitro* diagnostics ■ Dynamic: Pillar to use its stem loop inhibition-mediated amplification (SLIMamp) technology to develop diagnostics that run on Illumina's MiSeqDx instrument

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
NanoString Technologies	NSABP Foundation	▪ Objective: Characterize immunophenotypes in colorectal cancer ▪ Dynamic: Study using NanoString's PanCancer IO 360 gene expression panel to test samples from NSABP tumor tissue specimen biobank to identify targetable pathways
Immunovia	Linköping University	▪ Objective: Find autoimmine disease diagnostic biomarkers ▪ Dynamic: Use Immunovia's Immray antibody array platform to identify biomarkers for tests targeting rheumatoid arthritis, primary Sjögren's syndrome, systemic lupus erythematosus, and vasculitis.
Fabric Genomics	Rady Children's Institute for Genomic Medicine	▪ Objective: Provide fast and accurate identification of pediatric disease-causing variants to improve clinical care for children
Fabric Genomics	Utah Genome Project	▪ Objective: Provide fast and accurate identification of pediatric disease-causing variants to improve clinical care for children
Fabric Genomics	Genomics England's 100,000 Genomes Project	▪ Objective: Provide fast and accurate identification of pediatric disease-causing variants to improve clinical care for children
Fabric Genomics	Edico Genome	▪ Objective: Bundle secondary and tertiary NGS analysis data technologies ▪ Dynamic: Fabric's Opal Clinical interpretation software to be combined with Edico's Dragen platform
BC Platforms	UK Clinical Research Collaboration Tissue Directory and Coordination Centre	▪ Objective: Develop unique biobank research platform ▪ Dynamic: Platform to be based on BC's BC|Rquest system for analyzing and viewing aggregated genomic and clinical data from multiple biobanks
DuPont Pioneer	Broad Institute	▪ Objective: License CRISPR-Cas9 intellectual property for commercial agricultural research and product development ▪ Dynamic: Entities to provide joint non-exclusive licenses covering the CRISPR-Cas9 technology each entity respectively controls
Amgen	Boston Children's Hospital	▪ Objective: Identify novel genes underlying anomalies of pain sensitivity and validate genetic findings as potential targets for therapeutics ▪ Dynamic: Combine Amgen's expertise in genetic target identification and validation with access to Boston Children's Division of Pain Medicine to identify patients with abnormal pain conditions

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
LGC	Diagenode	▪ Products: LGC's DNA fragmentation sonication systems ▪ Territories: Clinical and agricultural biotechnology markets in Europe, Middle East, Africa, South America, and Canada, and agbio market in US ▪ Exclusive
Fluxion Biosciences	Harvard Bioscience	▪ Products: Fluxion's BioFlux and IonFlux cellular analysis platforms ▪ Territories: North America
Contextual Genomics	Idengene	▪ Product: Contextual's Find-It solid tumor test ▪ Territory: Brazil
Genedrive	Sysmex Europe	▪ Products: Genedrive HCV ID kit and Genedrive PCR platform ▪ Territories: Europe, Middle East and Africa
Genedrive	Sysmex Asia Pacific	▪ Products: Genedrive HCV ID kit and Genedrive PCR platform ▪ Territory: Asia Pacific region ▪ Genedrive responsible for product development, quality management, and manufacturing ▪ Sysmex responsible for sales, marketing, customer support, and distribution ▪ Genedrive retains Indian market rights
Genedrive	Xcelris Labs	▪ Termination of distribution deal for Genedrive's tuberculosis and antibiotic-resistance test in India
Zymo Research	VWR	▪ Products: Zymo's DNA purification, RNA extraction, microbiomic analysis, and epigenetics products ▪ Territory: North America
MdxHealth	Unilabs	▪ Products: MDx Health's SelectMDx urine test for prostate cancer ▪ Territories: France, Portugal, Sweden, Norway, Denmark, Finland, UK, Italy, and Switzerland ▪ Agency service agreement under which Unilabs' medical lab in Geneva will perform SelectMDx service testing using SelecMDx CE-market IVD kits it purchases from MDxHealth

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
OncoDNA	CyberKnife Sigulda	▪ Products: OncoDNA's tumor profiling solutions ▪ Territory: Latvia
University of Zurich	Fluidigm	▪ Products: University's histoCAT cytometry imaging software alongside Fluidigm's own new Hyperion Imaging System ▪ Territory: Global
Genomic Vision	AmCare Genomics Laboratory	▪ Products: Genomic's facioscapulohumeral muscular dystrophy diagnostic assay ▪ Territory: China ▪ Exclusive
IncellDx	GIMDx	▪ Products: IncellDx's single-cell immune-oncology and oncology diagnostic products ▪ Territory: China ▪ Exclusive ▪ GIMDx to supply its China-based parent company Guangzhou Improve Medical Instruments with IncellDx component products, to be kitted and co-labeled for Chinese market
Oncimmune	SmartGene	▪ Product: Oncimmune's EarlyCDT-Lung test ▪ Territory: Poland ▪ Exclusive ▪ SmartGene to offer test for 3 years and must meet minimum sales commitments of £900,000 ($1.2 million) over term of contract to keep the deal
GenePeeks	Core Diagnostics	▪ Products: GenePeeks' preconception screen and advanced analytics platform ▪ Territory: India ▪ Exclusive
LICENSES		
Licensor	**Licensee**	**Deal Summary**
Oxford Genetics	Twist Bioscience	▪ Property: Oxford Genetics' SnapFast technology platform ▪ Access to SnapFast gives Twist application-specific genetic expression vectors for cloning synthesized DNA
ERS Genomics	Cellecta	▪ Property: ERS Genomics' CRISPR-Cas9 intellectual property ▪ Scope: Global ▪ Non-exclusive
Stanford University	ClearLight Diagnostics	▪ Property 1: IP covering inventions that can be applied to Clarity-processed tissues for visualization and quantification of immunolabeled long process structures ▪ Property 2: Flow-assisted tissue-clearing device ▪ Property 3: Computational pipeline for automated image registration
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Servicer	**Client**	**Deal Summary**
Theradiag	Biogen	▪ Theradiag to provide its Lisa Tracker kits for monitoring Biogen's Flixabi (infliximab) biosimilar ▪ Biogen gets right to supply Lisa Tracker monitoring kits in competitive tenders in in France
Personalis	US Department of Veterans Affairs	▪ Personalis to sequence over 34,000 additional whole human genomes for VA's Million Veteran Program

Report: Outreach Labs Remain Profitable Despite Antiquated Systems & Lack of Exec Respect

Hidden within the basement of your average hospital is a $24 million business, one that provides a top quality, must-have service and operates at a margin of around 25% to 30%. That business is the hospital lab. The so-called outreach model seeks to leverage this potential by positioning the hospital lab as a business and profit center. And if you're into (or thinking about getting into) outreach, you should check out the new report from a firm that's been tracking the sector for 16 years.

The Chi Study

The report, entitled "*16th Annual National Hospital/Health System Laboratory and Outreach Survey Findings*," comes from national consulting firm Accumen Inc. and its subsidiary Chi Solutions Inc. and is based on a proprietary survey system that tracks key metrics of outreach performance and business trends. *The goal:* Help hospital and health system execs leverage their own labs.

The Positive Findings

The upshot of this year's report: Outreach labs are continuing to perform well despite the difficult business environment and fierce competition from national labs. This year's survey respondents also report that:

- They have the capacity to take on additional testing;
- Operating margins remain at or above historic levels as a result of aggressive cost cutting and synergies from consolidation; and
- They have the opportunity to cut costs and improve strategic performance by reducing blood and/or test utilization.

The Negative Findings

The report also finds that outreach labs face significant challenges not just from the outside but within their own hospitals and health systems. One is the lingering perception of executives of the lab as "cost center" rather than "profit center." Another is the lack of adequate systems for billing, connectivity, incentive compensation and monitoring profitability.

Future Growth Opportunities

The key strategic takeaway from the report is the finding that the physician office business is the most profitable market segment for outreach and its most promising opportunity for future growth.

Medicare Reimbursement:
CMS Finalizes Controversial PAMA Fee Schedule

It's official. CMS is going forward with its controversial 2018 PAMA Clinical Laboratory Fee Schedule (CLFS). Regrettably, the final version closely tracks the preliminary one (See *GCA*, Oct. 24, 2017, for the details) with just a few minor adjustments:

1. Phase-In Reduction Cap of Cuts Over 10%

Situation: The National Limitation Amount (NLA) for a lab test HCPCS code is based on a percentage of the median of all local fee schedule amounts, including $0. Medicare pays whichever is lowest among the billed amount, local fee schedule amount or NLA.

Preliminary CLFS: The 23 HCPCS codes with a $0 NLA and a local fee schedule amount of over $0 in 2017 were slated for the full NLA treatment rather than the 10% reduction cap.

Final CLFS: The $0 local fee schedule amount test rates have been re calculated. *Result:* 16 of the 23 tests will qualify for the phase-in reduction cap.

2. Payment Floor for Diagnostic or Screening Pap Smear Lab Tests

Situation: The national minimum payment amount for a diagnostic or screening pap smear lab test is $14.60 for tests furnished in 2000. The national minimum payment amount for later years is then annually adjusted. The CY 2017 floor for these tests was $14.49. The CY 2018 update factor is 1.1%, which yields a CY 2018 floor of $14.65.

Preliminary CLFS: CMS didn't apply the national minimum payment amount floor to the 24 diagnostic or screening pap smear laboratory HCPCS codes for CY 2018.

Final CLFS: The minimum applies for eight of these codes; the remaining 16 will be paid the higher private payor rate-based payments, with the phase-in reduction cap where applicable.

3. Payment for Home Use Hemoglobin A1c (HbA1c) Kits

Situation: The payment rate for a diagnostic test for HbA1c labeled for home use by the FDA must equal the payment rate for HCPCS Code 83036 glycated hemoglobin test (and subsequent codes).

Preliminary CLFS: The CMS proposed rate of $22.50 for HCPCS code 83037 didn't apply the private payor rate-based payment for code 83036 of $11.99 even though 83037 is a home use test.

Final CLFS: The CY 2018 payment rate for HCPCS 83037 has been reduced from $22.50 to $11.99.

4. Removal of General Health Panel Code (HCPCS 80050)

Situation: HCPCS 80050, a bundled code that includes a comprehensive metabolic panel (HCPCS code 80053), thyroid stimulating hormone test (HCPCS code 84443) and a complete blood count (HCPCS code 85025), is not payable under Medicare.

Preliminary CLFS: CMS listed 80050 as a payable code.

Final CLFS: HCPCS 80050 has been removed from the list of payable codes.

PAMA: CMS Ignores Flawed Processes, Finalizes 2018 PAMA Pricing; Labs Need to Take Immediate Action to Offset Impending Lean Times

By Kyle Fetter, *VP & General Manager of Diagnostic Services, XIFIN, Inc.*

The final 2018 clinical laboratory fee schedule (CLFS) is out, and it is evident that the argument that the Centers for Medicare & Medicaid Services (CMS) PAMA process was fundamentally flawed fell on deaf ears within CMS. Despite a groundswell urging delay, CMS issued a final clinical lab fee schedule for 2018 that is, with a few exceptions, in line with draft pricing.

While stakeholders like ACLA, AHA, and Quest Diagnostics continue to appeal to government entities for a halt to implementation, it's time for laboratories to face facts: The deep cuts that have resulted from the PAMA exercise mean troubled times are ahead and labs will not be able to cost-cut

their way into the black. More than ever, diagnostic providers need to focus on ensuring their lab operations maximize revenue, reimbursement, and cash flow, in an efficient, scalable, and automated manner.

"CMS did not address some of the anomalies of clearly faulty reporting by tossing out clear outliers where prices were reported at a penny, or an unusually low rate. Disappointing, but consistent with a lack of consideration for legitimate comments from the industry.."

—Lale White, CEO, XIFIN

Changes from the Draft Schedule to Final

While it is disappointing that CMS did not give most of the lab industry's comments on preliminary schedule enough consideration, there are a few instances where they did adjust according to the commentary. Even so, the general trends seen with draft rates still hold. Sole-source lab tests came out on top based on this market-based pricing scheme, while the broader impact on the molecular diagnostics market was more varied.

While the preliminary 2018 CLFS release did not cap codes that did not have a national limitation amount at the 10 percent cut, as required by PAMA, CMS applied this cap in final pricing.

CMS also agreed that the general health panel—including complete blood count tests, the comprehensive metabolic panel, and thyroid tests—is not a payable Medicare benefit and was therefore deleted from the 2018 CLFS. The agency also corrected payment rates for 23 codes where the phase-in reduction cap for 2019 and 2020 were wrongly listed due to transcription errors.

In addition to final PAMA rates, CMS released final crosswalk and gapfill determinations for new CPT codes for 2018. The agency also said that it is working on an application that labs can use to classify their tests as advanced laboratory diagnostic tests, which are priced every year under PAMA, as opposed to every three years for clinical diagnostic lab tests.

Flawed Methodology Delivers Severe Impact

Quest Diagnostics went on the record stating, "The final fee schedule remains deeply flawed because it is plagued by a distorted market data collection process that excluded key components of the lab market. As an example, less than 1 percent of all laboratories submitted data, and over 99 percent of hospital and physician office laboratories were prohibited from reporting their rates. Also, based on the data submitted to CMS, Quest alone represented nearly 40 percent of all the market data CMS collected despite accounting for less than 15 percent of Medicare claims under CLFS." XIFIN has performed its own extensive analysis and agrees the exclusion policies have led to a fundamentally flawed data set.

Furthermore, as XIFIN CEO Lale White explained in a genomeweb interview, "CMS did not address some of the anomalies of clearly faulty reporting by tossing out clear outliers where prices were reported at a penny, or an unusually low rate. Disappointing, but consistent with a lack of consideration for legitimate comments from the industry."

CMS' preliminary prices for clinical lab tests issued under the Protecting Access to Medicare Act (PAMA) raised concerns with many labs. Although the agency had initially estimated that PAMA pricing would save the government

$390 million, current estimates hover closer to $670 million in cuts, a 10 percent reduction in the $7 billion that CMS pays annually for lab tests.

Quest Diagnostics CEO Steve Rusckowski states, "These cuts will hurt the industry and our company." ACLA calls the final schedule "detrimental to patient care."

How Outreach Labs Can Overcome the PAMA Reimbursement Squeeze

If implementation of the 2018 PAMA-based CLFS is not delayed, many laboratories, including hospital outreach labs, will face severe consequences. In fact, one hospital CEO has stated, "In certain instances, this will cause rural hospitals to significantly scale back—if not completely eliminate—their outreach laboratory programs simply because they can no longer afford the cost to provide those services."

At Lab Reimbursement Summit on Dec. 8, 2017, I'll discuss the challenges facing outreach laboratories and addresses how RCM systems can become the backbone to ensuring financial health for outreach labs.

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

Here's a rundown of the key diagnostic product launches from mid-October through November.

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
Ilumina	NextSeq 550Dx NGS sequencer
Ilumina	Expansion of existing MiSeq Dx platform to include formalin-fixed paraffin-embedded tissues
Illumina	S4 flow cell and reagent kit for its NovaSeq 6000 NGS instrument
Qiagen	New consulting business to help life sciences and molecular diagnostics companies build and commercialize their products
Thermo Fisher Scientific	MagMax DNA Multi-Sample Ultra 2.0 reagents for DNA extraction from blood, saliva, buffy coat and buccal swabs
Thermo Fisher Scientific	Commercial launch of Applied Biosystems Axiom Africa Arrray for medical and population genomics for global health and population research
TwistDx kits	TwistAmp Liquid liquid format recombinase polymerase amplification kits
BioDiscovery	NxClinical 4.0, software for interrogation of copy number, sequence variants and allelic changes from single NGS assay
MedReleaf	Canadian launch of ReleafDx genetic test to help physicians prescribe cannabis
3dbiosurfaces +	DNAnexus CloudSeq suite of cloud-based tools supporting informatics infrastructure needs of customers using Illumina's NovaSeq systems
Stratec Consumables	3D NS-NC slide, a microarray substrate
New England Biolabs	NEBNext Ultra II FS Library Prep Kit for NGS enzyme-based DNA fragmentation and library preparation
SeraCare Life Sciences	Seraseq Myeloid Mutation DNA Mix and Myeloid RNA Fusion Mix NGS reference material for hematologic malignancies
Invivoscribe	Research use-only version of LymphoTrack TRB Assay for Illumina MiSeq sequencing platform
Dolomite Bio	Nadia single-cell platform for single-cell RNA sequencing
Definiens	Now offering Immuno-Oncology Panel (IO-Panel) as part of its "Insights" services portfolio
MGI Tech (subsidiary of BGI)	MGISEQ-2000 and MGISEQ-200 NGS platforms
MGI Tech (subsidiary of BGI)	MGIFLP modular NGS workstation
MGI Tech (subsidiary of BGI)	MGIUS-R3 robotic ultrasound system
Admera Health	PGxOnco test for cancer supportive care
Admera Health	LiquidGx lineof liquid biopsy-based tests for tumor profiling and drug resistance monitoring
PerkinElmer	Chemagic Prime automated nucleic acid isolation and assay setup instrument
Cancer Genetics	AntigenID neoantigen service to identify neoantigens and neoantigen signatures
MNG Laboratories	Diagnostic RNA sequencing services for patients with neurogenetic disorders
TTP +	Primer pairs, group C and group G Streptococcus for use in molecular LDTs
Sphere Fluidics	Cyto-Mine Single-Cell Analysis System platform for automating single-cell analysis, sorting, imaging and dispensing in biopharm discovery
Agilent Technologies	First expansion of its SureGuide pooled CRISPR libraries for functional genomics
Tempus	Tempus xT genome sequencing panel for diagnosis, prognosis and therapeutic targeting of cancer
Phosphorus	Elements diagnostic genetic testing software platform
Desktop Genetics	DESKGEN Series CRISPR Libraries to support gene editing in academics and biopharma
Genomenon	Offering free version of its Mastermind genomic search engine for clinical, research and academic institutions

SPECIAL BONUS ARTICLE FROM G2 NEWSLETTER *DIAGNOSTIC TESTS AND EMERGING TECHNOLOGIES*

G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

DIAGNOSTIC TESTING & Emerging Technologies

New Trends, Applications, and IVD Industry Analysis

Malpractice Lawsuit Calls Out Lack of Genetic Counseling

A 36-year-old Oregon woman filed a $1.8 million medical malpractice lawsuit against her doctors and a southwest Oregon medical center for "negligent diagnosis and treatment" resulting from misinterpretation of genetic test results by a nurse practitioner, gynecologist, and a surgeon. Additionally, the lawsuit cites a failure of providers to refer to a genetic counselor.

Elisha Cooke-Moore was erroneously told her she had the MLH1 gene mutation associated with Lynch syndrome. Cooke-Moore underwent genetic testing for hereditary cancer risk (Myriad's MyRisk test) due to family history—her mother and grandmother's cancers.

While the test report stated, "no clinically significant mutation has been identified," it also flagged a variant of unknown significance (VUS) in the MLH1 gene (MLH1 c.191A>G). Based on a misinterpretation of the results by her physicians, Cooke-Moore was diagnosed with Lynch Syndrome and underwent a preventive double mastectomy and hysterectomy in 2016. It was only after her surgeries, when seeking consultation for complications, that another doctor caught the misdiagnosis.

The American College of Medical Genetics and Genomics states in its 2015 guidelines for the interpretation of sequence variants that a VUS should not be used in clinical decision making. The guideline goes on to say that while efforts to reclassify the variant are underway, additional patient monitoring may be wise.

The complaint states the "plaintiff was not sufficiently informed about Lynch Syndrome or the meaning of genetic testing results." Additionally, the lawsuit specially states that the plaintiffs did not refer to a genetic counselor "before or after undergoing testing, as recommended by the National Cancer Institute."

This case highlights the importance of appropriately counseling patients about genetic risk factors particularly when non-genetic experts are ordering tests and in settings, like southern Oregon, where there are shortages of genetic counselors.

Takeaway: While this lawsuit does represent an individual case, clinical laboratories can play an important role in assisting providers regarding variant interpretation and patient counseling.

● ● ● SPECIAL BONUS ARTICLE FROM G2 NEWSLETTER *NATIONAL INTELLIGENCE REPORT* ● ● ●

G2 INTELLIGENCE
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NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Opioid Subscribing Doctor Convicted in Lab Referral Kickback Scam

Case: Two doctors at a Maryland pain management clinic that prescribed pain relief medications to patients accepted kickbacks to refer all urine tests to a New Jersey lab. Six defendants were charged in the scheme: four of them pled guilty; one of the doctors committed suicide and the other doctor decided to take his chances with a jury. It turned out to be a bad decision. The doctor was convicted of 26 felony charges and now faces the possibility of up to 99 years in prison.

Significance: This case is the most recent example of how the current opioid drug epidemic is influencing the direction of federal health care fraud enforcement. This summer, the Department of Justice unleashed a potent nationwide crackdown on opioid drug abuse, both illegal and prescription. While labs and physicians are not necessarily the primary target, they are well within the range of potential suspects to the extent that urine testing plays a key role in detecting prescription opioid abuse.

Maine Hospital Pays $1.51 Million to Settle False Claims Charges

Case: The feds charged Mercy Hospital with overbilling Medicare and MaineCare for urinalysis tests. Rather than risk a trial, Mercy has agreed to shell out $1.514 million to settle the claims.

Significance: The takeaway is how the supposed scam worked. Mercy allegedly made false use of a billing modifier code to receive payment for multiple same-day urinalysis drug screening tests performed at its affiliate, Mercy Recovery Center that did not arise from separate, medically necessary encounters with the same patients on the same days. *Result:* Mercy separately billed for the urinalysis drug screening tests on a per-test basis instead of bundling and billing the tests as one claim per single patient encounter.

Luminex Settles Trademark Suit against Curiox BioSystems

Case: In late August, Luminex filed a federal trademark-infringement lawsuit against Curiox BioSystems for implementing "a wide-ranging scheme to confuse the market" about its affiliation with Luminex and "trick customers into engrafting Curiox's non-validated parts into the Luminex system. The complaint accuses Curiox of trying "to cobble together an unvalidated Frankenstein-ish system that fails at the very thing assay testing is designed to accomplish —producing accurate test results." Now comes word that the parties have agreed to settle the case.

Significance: The settlement bars Curiox from stating or implying in its advertising that:

- Its Curiox DA-Bead Plate enables equivalent or better sensitivity, reproducibility or detectability than the Luminex system; and
- The DA-Bead Plate is validated for use with the Luminex system.

SPECIAL BONUS ARTICLE FROM G2 NEWSLETTER *G2 COMPLIANCE INSIDER*

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For Clinical and AP Laboratories and Pathology Practices

OIG Work Plan Monthly Review: November 2017

The OIG added four new items to its Work Plan this month, all of which have potential indirect effects on clinical labs involved in providing the targeted services.

1. Opioids in Medicaid: Concerns about Extreme Use and Questionable Prescribing

Concern: Medicaid beneficiaries are particularly vulnerable to opioid abuse and overdose deaths because they are more likely to have chronic conditions and comorbidities requiring pain relief, especially if they qualify for Medicaid due to a disability.

The OIG notes that there has been a "significant increase" in Medicaid claims for telemedicine, telehealth and telemonitoring services.

What OIG Will Investigate: The OIG will identify cases in which beneficiaries may have gotten extreme amounts of opioids through Medicaid as a result of shopping for doctors, pharmacies or other prescribers. The agency will use the results as baseline data for identifying both beneficiaries who receive extreme amounts of opioids and providers with questionable opioid prescribing patterns.

2. Medicaid Services Delivered Using Telecommunication Systems

Concern: The OIG notes that there has been a "significant increase" in Medicaid claims for telemedicine, telehealth and telemonitoring services.

What OIG Will Investigate: The OIG will review selected States' Medicaid payments for tele-services to ensure that they are on the level. Items the agency is likely to check:

- Qualifications and use of facility site codes by the originating site;
- Whether all services billed were covered;
- Use of POS codes and modifiers by the distant site;
- Whether the rendering provider was an eligible distant site provider;
- Compliance with geographic location requirements for tele-services; and
- Whether the technology used met the applicable audio and visual requirements.

3. Medicare Claims on Which Hospitals Billed for Severe Malnutrition

Concern: There are three Diagnosis Related Groups (DRGs) for hospital

Managed care accounted for over 40% of total Medicaid payments in 2015 and that rate continues to grow.

inpatient treatment of malnutrition based on the severity of the condition—mild, moderate or severe. Severe malnutrition is classified as a major complication or comorbidity (MCC). And adding an MCC to a Medicare claim can result in a higher Medicare payment because the claim is coded at a higher DRG.

What OIG Will Investigate: The OIG will review whether providers are using the proper DRG codes for severe malnutrition to ensure that no upcoding is taking place.

4. Use of Funds by Medicaid Managed Care Organizations

Concern: Managed care accounted for over 40% of total Medicaid payments in 2015 and that rate continues to grow. Capitation in which Managed Care Organizations (MCOs) receive a pre-determined rate for each enrollee regardless of actual services rendered is one of the methods Medicaid uses to control Medicaid costs.

What OIG Will Investigate: The OIG will review whether Medicaid MCOs are spending their capitation payments to provide quality medical services, including lab tests, to enrollees.