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FDA Watch: Gottlieb Resignation Costs Lab Industry a Valuable Frenemy

Scott Gottlieb, M.D., is resigning as FDA commissioner, the position he's held since 2017.

Although his reign lasted just two years, Gottlieb has been a long time friend and foe of the lab industry having served as deputy commissioner during the George W. Bush administration. The key question: Will the initiatives and policies he championed during his tenure continue after he's gone?

Why Gottlieb Is Leaving

The first clue to answering that question is that Gottlieb isn't being

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Inside the Lab: Communication, Leadership & Managing Amid Change

Greek philosopher Heraclitus said the only thing constant is change. Although he never managed a diagnostic lab, his words certainly apply to the lab environment.

The Case for Transparency

Change is a constant for the lab industry. Mergers, acquisitions, facility closings, new technologies and methods, management turnover—it's hard enough just to keep up let alone keep your staff apprised. Regrettably, failure to provide this information breeds uncertainty, rumor, fear and negativity that affects morale and productivity. That's why it's so important to take the trouble to communicate at least some information to those affected by events, even in situations calling for confidentiality. Here's how to handle common scenarios:

Merger or acquisition: Once M&A talks begin, word gets out fast and fuels speculation. While you can't disclose the details, you can make a point to ensure staff gets the news from you rather than the media,

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■ FDA Watch, from page 1

forced out. He's resigning for personal rather than political reasons, namely his desire to be closer to his wife and three young daughters in Westport, CT.

His Legacy & Impact on Labs

Gottlieb will be remembered for his commitment to making one of the federal government's most opaque agencies more transparent and his energy in advocating reforms designed to simplify and speed up the cumbersome FDA approval process and ending the "shenanigans" that thwart competition.

Historically, becoming FDA commissioner has proven a less than effective way of winning friends in the lab industry. But Gottlieb was different. What the industry really appreciated (and may sorely miss when he's gone) was Gottlieb's willingness to tackle the controversial lab-developed tests (LDTs) issue. "The agency helped support major legislative efforts to secure a more modern framework for the efficient regulation of diagnostic tests," Gottlieb said in his resignation letter.

Under Gottlieb, the agency has made several proposals to make it easier to bring new tests to market. Specifically, it has worked with industry and Congress to generate support for the VALID Act, a bill aimed at resolving the longstanding controversy around FDA regulation of LDTs that would bring all diagnostics under a single regulatory pathway using more modern and technologically realistic approval criteria.

Meanwhile, the volume of test approvals has increased markedly during Gottlieb's tenure, including:

- ▶ Two new flu [tests](#);
- ▶ First NGS residual cancer detection [test](#) to gain FDA approval;
- ▶ New point-of-care [tests](#) for Ebola; and
- ▶ First approved objective blood [test](#) for concussion evaluation.

Under Gottlieb, the FDA also softened its previous resistance to genetic tests, most notably in allowing 23andMe to engage in direct to consumer marketing of its products. So, it's not that biotechnology stocks fell on the day he announced his resignation.

Of course, lab tests are just part of the story. Gottlieb has also won praise for his determination to speed approval of new generic drugs and the agency's handling of the opioid crisis. Of course, he's not without critics. One problem area is his support for e-cigarettes, which the anti-tobacco groups contend has contributed to the growth of vaping among teens. Gottlieb has also managed to tick off the other side by pushing to regulate the amount of nicotine in cigarettes and proposing a ban on menthol cigarettes.

His Successor

Norman Sharpless, M.D., director of the National Cancer Institute has been named acting commissioner. He will oversee the agency until President Trump nominates and the Senate confirms a permanent successor.

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New FDA Approvals

Here's a look at the key FDA approvals announced from late February to late March:

NEW FDA APPROVALS	
Manufacturer(s)	Product(s)
Roche Diagnostics	Clearance for Ventana PD-L1 Assay as first companion diagnostic to identify triple-negative breast cancer patients for the Tecentriq-Abraxane combination
Roche Diagnostics	Clearance for Ammonia II assay, enzymatic test measuring ammonia in human plasma run on Roche's Cobas c systems
Euroimmun (now owned by PerkinElmer)	Clearance for Anti-tissue Transglutaminase ELISA (IgA) test kit to detect IgA class antibodies against tissue transglutaminase in human serum and ethylenediaminetetraacetic acid (EDTA) plasma
Euroimmun (now owned by PerkinElmer)	Clearance for Anti-tissue Transglutaminase ELISA (IgG) test kit for qualitative determination of IgG class antibodies against tissue transglutaminase in human serum and EDTA plasma to diagnose celiac disease
BioMérieux	Clearance for two culture bottle products for recovery and detection of bacteria and yeast from blood: * BacT/Alert FA Plus Culture Bottles * BacT/Alert PF Plus Culture
BioMérieux	Clearance for Vitek 2 Gram-negative Susceptibility Card for use with Vitek 2 Systems to determine susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents
T2 Biosystems	Breakthrough device designation for T2Resistance Panel
Hitachi Chemical Diagnostics	Clearance for Optigen AP 3600 high capacity allergy testing system
GenePOC	Clearance for rapid molecular assay to detect group A Streptococcus run on firm's Revogene instrument
Instrumentation Laboratory	510(k) clearance for Gem Premier ChemStat in vitro diagnostic analyzer incorporating IL's Intelligent Quality Management module
Beckman Coulter	Clearance for MicroScan Dried Gram-Negative MIC/Combo Panels and Dried Gram-Negative Break-point Combo panels to determine antimicrobial agent susceptibility to and/or identify species level of aerobic and facultatively anaerobic gram-negative bacilli
CoaguSense	Clearance for Prothrombin Time /INR Monitoring System to measure INR units and provide prothrombin time results expressed in seconds
EKF Diagnostics	Clearance for use of its Quo-Test A1c System for detecting glycated hemoglobin levels in venous whole-blood samples
Sekisui Diagnostics	Clearance for Sekure Acetaminophen L3K Assay to measure acetaminophen in serum, lithium heparin plasma and sodium heparin plasma, and for diagnosis and treatment of acetaminophen overdose toxicity
U&U Medical Technology	Clearance for use of its Blood Collection Sets in routine venipuncture procedures
Abbott	CLIA waiver for use of its reformulated rapid influenza diagnostic test, BinaxNOW Influenza A & B Card 2, with firm's Digival diagnostic reader for rapid detection of influenza virus

New CE Marks & Global Certifications

Notable European CE certifications during the period:

NEW CE MARKINGS IN EUROPE	
Manufacturer(s)	Product(s)
Bruker	CE-IVD marking for FluoroCycler XT PCR system and FluoroType MTBDR 2.0 Liquid Array assay for detecting tuberculosis and antibiotic resistance
Roche	CE marking for newly launched Navify Mutation Profiler clinical software
Abbott	CE marking for Alinity m molecular diagnostics system and assays

Continued on page 4

■ FDA Watch, from page 3

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Omega Diagnostics Group	CE marking for Visitect CD4 Advanced Disease test for monitoring people living with HIV
Personal Genome Diagnostics	CE marking for PGDx Elio Plasma Resolve liquid biopsy
Ortho Clinical Diagnostics	CE marking for Vitros XT MicroSlide technology enabling labs to run two tests at the same time
Co-Diagnostics	CE-IVD marking for Logix Smart ZDC PCR-based multiplex test for diagnosing Zika virus, dengue fever and chikungunya infection
Oncgnostics	Extended CE-IVD marking for GynTect cervical cancer assay to run on Roche's Cobas z 480 quantitative PCR-based analyzer

Other international clearances announced during the period:

OTHER INTERNATIONAL CLEARANCES

Manufacturer(s)	Country(ies)	Product(s)
Amoy Diagnostics	China	National Medical Products Administration (NMPA) approval for BRCA1 and BRCA2 gene mutation detection kit
Thermo Fisher Scientific	Japan	Ministry of Health, Labour and Welfare expanded approval for Oncomine Dx Target Test CDx System

• • • DIAGNOSTIC DEALS • • •

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

Spring has sprung with the announcement of a king-size deal: Danaher's \$21.4 billion cash acquisition of GE Life Sciences, known as GE Biopharma, from General Electric Company (GE). Here's a quick overview of the transaction and the rest of the past month's activity (from late February to late March).

M&A

Danaher's binding agreement to acquire GE Biopharma is the biggest M&A deal in the diagnostics space in over a year. The acquired business will operate as a standalone company within Danaher's \$6.5 billion Life Sciences segment. Other companies in the unit include Pall, Beckman Coulter Life Sciences, SCIEX, Leica Microsystems, Molecular Devices, and Phenomenex, along with IDT businesses. According to Danaher CEO Thomas P. Joyce, Jr., "GE Biopharma is renowned for providing best-in-class bioprocessing technologies and solutions. This acquisition will bring a talented and passionate team as well as a highly innovative, industry-leading product suite to our Life Sciences portfolio, providing an excellent complement to our current biologics workflow solutions."

Unloading GE Biopharma is part of a larger, ongoing restructuring plan by GE that has it exiting several sectors in order to focus on three core segments: aviation, power, and renewable energy.

Assuming regulatory approval, the transaction is expected to close in the fourth quarter.

Other noteworthy M&A deals during the period include cancer fighting firm Oncimmune's acquisition of Protagen Diagnostics, a leader in personalized immune-profiling, for up to \$5.5 million and Grifols' acquisition of a 26.2% stake in Shanghai RAAS as part of a strategic alliance to manufacture, market, and develop plasma products and transfusion diagnostic solutions in the Chinese market.

Strategic Alliances

Among new alliances are several involving companies based in China. Natera, a genetic-testing company in San Carlos, Calif., has entered into a 10-year partnership agreement with China's BGI Group, known as BGI Genomics, which operates a genomic sequencing center. The agreement will commercialize Natera's circulating tumor DNA Signatera minimal residual disease (MRD) test in China. Details about this and other agreements are provided in the chart below.

In addition to these alliances is one of note not included in the chart, because it is about the end of an agreement. Epigenomics, a molecular diagnostic company headquartered in Germany, has terminated its collaboration with China's BioChain for the licensing of the Septin9 marker and exclusive Chinese distribution rights for Epi proColon, Epigenomics' blood test for colorectal cancer. The companies entered into the licensing deal in March 2016. Epigenomics is exercising its right to terminate the agreement, based on the fact that BioChain has not paid more than the agreed minimum royalties over a three-year period.

Here's a summary of key diagnostic deals from late February through late March:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Danaher	General Electric's Biopharma business	Price: \$21.4 billion cash Status: Definitive agreement expected to close Q4 2019 Danaher financing the deal with \$3 billion from equity offering, cash on hand + proceeds of debt and/or new credit facilities issuance GE business to operate as a standalone company within Danaher's \$6.5 billion Life Sciences segment
Oncimmune	Protagen Diagnostics	Price: Up to \$5.5 million—62% in Oncimmune common shares (at \$2.07 per) + balance contingent on milestones Status: Closed Qiagen, currently an investor in Protagen to become an investor in Oncimmune and get up to 862,179 shares to settle a convertible loan and accrued interest of \$3.0 million made to Protagen
Constellation Alpha Capital	DermTech	Price: \$15 million cash + enough Constellation common shares to make DermTech majority owner of combined company's shares Status: Expected to close in Q2 DermTech, which provides skin and skin cancer diagnostics, to become wholly-owned sub of Constellation
Bruker	Arxspan	Price: Undisclosed Status: Closed Acquiring cloud software provider enables Bruker to boost its own software products
Summa Equity	Olink Proteomics	Price: Undisclosed Status: Closed Acquisition of Swedish life sciences firm known for its proximity extension assay (PEA) technology

Continued on page 6

■ Diagnostic Deals, from page 5

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Grifols	Shanghai RAAS	Price: \$1.9 million value in form of 45% of economic rights + 40% of voting rights in Grifols US sub, Grifols Diagnostic Solutions Status: Expected to close 2H 2019 Grifols acquires 26.2% stake in Shanghai RAAS as part of strategic alliance agreement to manufacture market, and develop plasma products and transfusion diagnostic solutions for China market
Precision for Medicine	SimplicityBio	Price: Undisclosed Status: Closed Acquisition of AI tech firm enables Precision for Medicine to add AI to its QuartzBio bioinformatics and multiomics data integration platform for biomarker-guided drug development
BioMérieux	Baxter International	Objective: Develop biomarkers for acute kidney injury detection Dynamic: BioMérieux to utilize expertise from its newly acquired Astute Medical business, including Nephrocheck assay for guiding sepsis treatment

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Qiagen	Tecan Group	Objective: Improve processing of Qiagen's QuantiFeron-TB Gold Plus (QFT-Plus) diagnostic test Dynamic: Non-exclusive partnership to standardize and automate manual steps in liquid handling for aliquoting of QFT-Plus samples using Tecan's Fluent lab automation workstation and Lithium Heparin single-tube workflow Tecan's life sciences business to directly supply Fluent systems to labs that want to implement the workflow
Genomics England	Cambridge Cancer Genomics (CCG.ai)	Objective: Improve patient access to monitor treatment effectiveness of immunotherapies Dynamic: Partnership in which AI startup CCG.ai will join Discovery Forum, a Genomics England-led collaboration platform for genomics researchers in UK CCG.ai also to contribute its liquid biopsy technology and a sequencing panel for measuring tumor mutational burden to assess treatment resistance to immunotherapy drugs
Microba	Macrogen	Objective: Develop microbiome research services for international markets Dynamic: Initial collaboration on shotgun metagenomic sequencing-based service for South Korea and other nations outside Australia Parties also plan to build library of high-resolution gut microbiome data for use in developing microbiome-based diagnostics and therapeutics
My Gene Counsel	Ambry Genetics	Objective: Offer medical-grade testing to verify direct-to-consumer (DTC) genetic test results Dynamic: Alliance to also provide DTC genetic counseling to individuals found to be at high risk for cancer
BeaconLBS	MagnaCare	Objective: Offer BeaconLBS' point-of-care physician decision support platform to MagnaCare's physician and lab providers network Dynamic: BeaconLBS platform leverages EHR and lab ordering systems to provide physicians access to evidence-based guidelines and pricing information to guide choice of test and testing lab
Advanced Biological Laboratories	Mayo Clinic Laboratories	Objective: Develop NGS test to detect mutations associated with antiviral resistance in human cytomegalovirus Dynamic: Test to sequence PCR amplicons of UL54 and UL97 genes in which drug resistance with CMV has been associated Use ABL's DeepChek-CMV software to analyze the data and interpret possible drug resistance in virus Mayo Clinic gets financial interest in new technology with revenues going to support non-profit interests
Sona Nanotech	Olm Diagnostics	Objective: Develop point-of-care diagnostic tests for infectious diseases Dynamic: Sona manufactures gold nanorods producing different colors when integrated into a test strip, making them ideal for multiplexing Olm Diagnostics wants to develop rapid, multiplexed lateral flow assays to detect infectious diseases in humans to help doctors perform primary diagnoses

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner 2	Deal Summary
Biocartis	Bristol-Myers Squibb	Objective: Develop a companion diagnostic for Bristol-Myers Squibb cancer immunotherapies initially focusing on colorectal cancer (CRC) Dynamic: Jointly develop, register and get FDA approval for Biocartis' Idylla MSI test, which provides information on microsatellite instability status of a CRC tumor from a single slice of FFPE tumor tissue without need for a reference sample
Lucence Diagnostics	Stanford University School of Medicine	Objective: Develop AI algorithms to improve diagnosis and treatment of liver cancer by analyzing both imaging and molecular data Dynamic: Lucence to process dataset of 5,000+ liver cancer patients to identify changes and patterns in imaging and mutations that could predict effectiveness of a therapy Use data from Lucence's LiquidHallMark blood test analyzing DNA of cancer-related mutations and viral targets
Natera	BGI Genomics	Objective: Commercialize Natera's circulating tumor DNA Signatera minimal residual disease (MRD) test in China Dynamic: 10-year partnership under which BGI Genomics will pay Natera \$50 million, including upfront licensing fees, prepaid royalties and future milestone payments—plus ongoing royalties Natera will prepay BGI Genomics \$6 million for sequencing services Natera and BGI Genomics to initially offer Signatera test through specialty hospital networks in China and then across the entire country after gaining regulatory approval for test on BGI's DNBseq sequencing technology platform Sides also plan to develop reproductive health tests run on DNBseq in other "select markets"
Ortho Clinical Diagnostics	Beijing Leadman Biochemistry	Objective: Launch 4 assays for China market Dynamic: Tests (cystatin C for early diagnosis of chronic kidney disease; -hydroxybutyrate dehydrogenase for diagnosing heart attack; homocysteine for assessing risk factors for coronary atherosclerosis, Alzheimer's disease, venous embolism, neonatal defects and habitual abortion; and total bile acids for early detection of liver injury) approved for use in China on Ortho's Vitros 4600 chemistry system and Vitros 5600 integrated system Leadman to offer tests as reagents in prefilled packages for use specifically with the Vitros systems
Illumina	Boai NKY Medical Holdings	Objective: Develop NGS-based hereditary disease tests in China Dynamic: Create an NGS system based on Illumina's MiniSeq system and NKY's library prep kits and analysis software and get regulatory approval for use in China
Atgenomix	Yourgene Bioscience Taiwan	Objective: Create unified system for advanced whole-genome sequencing and whole-exome sequencing variant analysis Dynamic: Combine Atgenomix's high-speed data analytics platform with Yourgene's hereditary and cancer mutation analysis workflows
Admera Health	MedCDx	Objective: Co-develop companion diagnostics Dynamic: Non-exclusive collaboration agreement giving each side access to the other's existing portfolios for the purpose of CDX co-development
Bio-Techne	Lisen Imprinting Diagnostics Wuxi	Objective: Accelerate development of molecular diagnostics in Chinese market Dynamic: Strategic partnership with no financial or other terms announced
Centogene	Sarepta Therapeutics	Objective: Identify patients with Duchenne muscular dystrophy (DMD) in Middle East and North Africa Dynamic: 12-month strategic collaboration under which Centogene will conduct molecular testing using deletion/duplication analysis and full-length sequencing of DMD gene diagnostic services to help physicians treating patients with DMD symptoms
Biocept	Providence St. Joseph Health, Southern California + Saint John's Health Center + John Wayne Cancer Institute	Objective: Evaluate usage of cerebral spinal fluid (CSF) in liquid biopsy testing for metastatic cancer Dynamic: Biocept to use its Target Selector liquid biopsy platform to test CSF samples from patients diagnosed breast, lung and other cancers and melanoma to determine if leptomeningeal metastases (LM) has occurred Researchers to then compare results to standard testing methods to confirm diagnosis

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■ Diagnostic Deals, *from page 7*

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner 2	Deal Summary
Boehringer Ingelheim	GNA Biosolutions	Objective: Develop emergency veterinary diagnostics Dynamic: Research collaboration to create rapid diagnostic test for African swine fever to be used on GNA portable molecular diagnostic platform
Invitae	BioMarin + Stoke Therapeutics + Xenon Pharmaceuticals	Objective: Expand Invitae's free genetic testing program for children with epilepsy Dynamic: Behind the Seizure testing to be offered to kids 0 to 5-years-old
Oova (Mount Sinai Health System spinout)	Thorne Research	Objective: Make Oova's fertility monitoring tool available to over 3 million consumers and 35,000 clinicians Dynamic: Partnership under which Oova's at-home test will be sold bundled with Thorne supplements
Illumina + Baylor Genetics + Broad Institute + HudsonAlpha Institute for Biotechnology	Mayo Clinic + Rady Children's Institute for Genomic Medicine + Hospital for Sick Children + Stanford Medicine	Objective: Expand access to clinical whole-genome sequencing (WGS) for diagnosis of genetic diseases Dynamic: Launch new consortium called Medical Genome Initiative to focus on publishing lab and clinical best practices for applying WGS required for clinical WGS to be implemented at scale

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Property Owner	Distributor	Deal Summary
Sienna Cancer Diagnostics	Inside Diagnósticos	Products: Sienna's telomerase reverse transcriptase (hTERT) test Territory: Brazil Exclusive
EliTechGroup	Hardy Diagnostics	Products: EliTechGroup's Mycofast US Territory: Undisclosed Hardy Diagnostics made authorized distributor
SpeeDx	Al Zahrawi Medical Supplies	Products: SpeeDx Resistance Plus and PlexPCR products Territory: Kuwait, Bahrain, Qatar, Yemen, Oman, UAE, Saudi Arabia, Bahrain, Qatar, Oman
Luxia Scientific	Life Genomics	Products: Luxia's microbiome test Territory: Norway, Denmark, Iceland, Finland Exclusive distribution agreement
AusDiagnostics	Custom Science	Products: AusDiagnostics' PlexWell technology and products for multiplexed NGS applications Territory: Australia Exclusive
AusDiagnostics	Beijing Pukairui Biotech	Products: AusDiagnostics' PlexWell technology and products for multiplexed NGS applications Territory: China Exclusive
AusDiagnostics	Thunder Bioscience	Products: AusDiagnostics' PlexWell technology and products for multiplexed NGS applications Territory: Korea Exclusive
AusDiagnostics	Custom Science Auckland	Products: AusDiagnostics' PlexWell technology and products for multiplexed NGS applications Territory: New Zealand Exclusive
AusDiagnostics	Sciencewerke	Products: AusDiagnostics' PlexWell technology and products for multiplexed NGS applications Territory: Singapore, Malaysia, Indonesia Exclusive
AusDiagnostics	Sopachem	Products: AusDiagnostics' PlexWell technology and products for multiplexed NGS applications Territory: Belgium, Netherlands, Denmark Exclusive

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Property Owner	Distributor	Deal Summary
AusDiagnostics	Zotal	Products: AusDiagnostics' PlexWell technology and products for multiplexed NGS applications Territory: Israel Exclusive
AusDiagnostics	Labtech International	Products: AusDiagnostics' PlexWell technology and products for multiplexed NGS applications Territory: UK, Ireland Exclusive
AusDiagnostics	Nippon Genetics Europe	Products: AusDiagnostics' PlexWell technology and products for multiplexed NGS applications Territory: in Germany, Austria Exclusive
Mobidiag	Ibn Rushd Medical & Scientific Equipment	Products: Mobidiag's Novodiag antibiotic resistance testing products Territory: Kuwait Exclusive, 2-year deal
Mobidiag	Interlab Interautomatika UAB	Products: Mobidiag's Amplidiag and Novodiag infectious disease and antibiotic resistance testing products Territory: Latvia, Lithuania 2-year deal
Mobidiag	Helix2	Products: Mobidiag's Amplidiag and Novodiag infectious disease and antibiotic resistance testing products Territory: Greece 2-year deal

LICENSES

Licensor	Licensee	Deal Summary
Translational Genomics Research Institute	Advanced Biological Laboratories	Property: NGS-based DeepCheck-TB test for tuberculosis Advanced to distribute test which is available for research only
Washington University in St. Louis	Q BioMed	Property: Biomarker, growth differentiation factor 15 (GDF15) for determining severity of glaucoma Exclusive
Zymo Research	Pangea Laboratory	Property: Urine-based laboratory-developed test for bladder cancer detection Test, called Bladder Care, uses qPCR to measure methylation level of three bladder cancer-specific biomarkers in urine samples

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/Service	Client/User	Deal Summary
GE Healthcare Bio-Sciences	T2 Biosystems	GE Healthcare Bio-Sciences to manufacture and supply proprietary superparamagnetic particles for use with T2 Bio's products

NEW CLINICAL STUDIES

DX Partner	Other Partner	Description of Study
Quest Diagnostics	Regional Medical Center (Orangeburg, SC)	Quest to provide full lab management services, including lab equipment, supplies and procurement processes
Helomics	Viome	Partnership to investigate associations between ovarian cancer and the gut microbiome
uBiome	University of Louisville	Study whether the microbiome can be used to predict patient responses to certain inflammatory bowel disease therapies
Geisinger Health	Johns Hopkins University	Study whether a liquid biopsy test that combines targeted circulating tumor DNA analysis with different protein markers can detect cancer early in healthy individuals
Oxford Biodynamics	Wellcome Trust + Urology Foundation + British Medical Assoc.	OBd's EpiSwitch test for blood-based diagnosis of prostate cancer to be evaluated as part of ongoing PROSTAGRAM trial assessing methods for early-stage prostate cancer detection

■ Inside the Lab, from page 1

social networks and water cooler crowd. It doesn't have to be a formal, detailed announcement. *Example: "We're having preliminary conversations about merging with another company. We're in the very early stages and no decisions have been made. I wanted you to know because there are bound to be rumors. If you have any questions, please feel free to ask. I also promise to let you know as soon as any decisions are made."*

Continue to provide updates. At some point, information about redundancy and possible layoffs may become available. Don't avoid discussing these matters. Employees will appreciate that you are forthcoming, even when the news may create personal hardship.

Facility closing: You should let staff know as soon as possible if your facility is closing. Your approach will depend on how the closing impacts staff members and their jobs.

Facility relocation: Relocations aren't as traumatic when they're local—although seemingly minor moves can be dislocating when they affect employees' commutes. Moves involving geographical distance are a different animal. In either case, consider the situation in the context of what you would want to know if you were in staffers' shoes. Make an effort to share news and answer questions. Get answers to any open questions, and then share the news.

Legal Implications When Layoffs Are Involved

It's important to note that when a facility closing, merger or acquisition leads to mass layoffs, it may trigger legal obligations under the Worker Adjustment and Retraining Notification (WARN) Act, which mandates transparency under certain circumstances.

The federal law requires that companies with more than 100 employees provide 60 calendar day written advance notice when 50 or more employees at a single location are affected. There are exceptions to the rule, such as when a closing is related to unforeseeable business circumstances, along with other stipulations. More information about WARN is available at the U.S. Department of Labor website.

WARN is a federal law. Some states have their own layoff notice laws. The California law, for example, applies to employers with 75 or more employees where 50 or more employees are to be laid off. If you haven't already, familiarize yourself with the requirements of the states in which you conduct business.

Dealing with Internal Changes

Although not as dislocating as mergers, acquisitions, closings, etc., introduction of new technologies, processes and leadership can also be extremely stressful. Recognize that these changes aren't just business as usual and that communication is essential to help employees cope.

New technologies and/or processes: Explain why the new technology or process is necessary.

At the same time, focus on the benefits of the change and the ways it will:

- ▶ Make your lab more efficient;
- ▶ Enable the lab to make a more positive impact on patients and even save lives;
- ▶ Increase profitability.

New leadership: Gallup research finds that one in two employees have left a job to get away from a manager. If a change in leadership is planned at your lab, help everyone get off on the right foot by briefing staff members, ideally before the new leader starts.

Takeaway: Effective, timely communication during times of change won't address every issue related to a transition. It will, however, make it easier for your lab to move forward.

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

March was the most intense month of the year so far for new diagnostic products highlighted by 23andMe's launch of a new genetic Health Predisposition report assessing a consumer's risks of developing type 2 diabetes. Here's a rundown of all the key launches from late February to late March:

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)/Service(s)
23andMe	Health Predisposition report assessing customer's genetic risks of developing type 2 diabetes
Akoya Biosciences	Codex tissue analysis and biomarker discovery system
Akoya Biosciences	PhenoOptics 2.0 NGS-based biomarker multiplexing platform
Roche Diagnostics	Navify Mutational Profiler and Navify Therapy Matcher to support NGS-based cancer genomic profiling tests
SeqOnce Biosciences	RhinoSeq DNA Library Preparation Kit for NGS sample preparation
Mission Bio	Tapestri Designer cloud-based tool for designing and ordering single-cell DNA panels
Strata Oncology	Version 3.0 of StrataNGS pan-cancer assay for solid tumors
Asuragen	AmplideX PCR/CE SMN1/2 kit
Diagenode	New version of its DNA shearing instrument called Megaruptor 3
Shield Diagnostics	Target-NG rapid molecular test for antibiotic susceptibility in <i>Neisseria gonorrhoeae</i>
Aldevron + Integrated DNA Technologies	GMP SpyFi Cas9 Nuclease
Oxford Nanopore Technologies	Flongle (portmanteau for "flow cell dongle") adapter for the Minlon and Gridlon X5 sequencing platforms that takes single-use flow cells
DNAexus	New cohort browser for its DNAexus Apollo platform for clinico-genomic data science analysis
LGC, Biosearch Technologies	RapidDxFire Thermostable RT thermostable reverse transcriptase for diagnostic kit developers
Integrated DNA Technologies	rhAmpSeq targeted sequencing system

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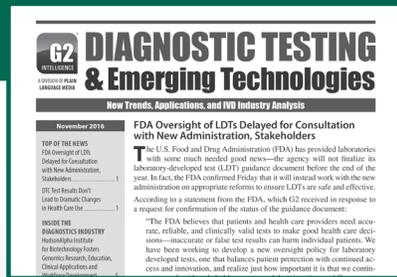
The DX Pipeline, from page 11

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)/Service(s)
BioIVT	Xpressway Profile Safety Package compendium of 46 expression profiles for genes used in drug safety assessments
Beckman Coulter + Apostle	Apostle MiniMax High Efficiency Cell-Free DNA Isolation Kit
Loop Genomics	Kit and service for mRNA transcript counting and phasing using its synthetic long-read technology that works in conjunction with NGS on Illumina instruments
Twist Biosciences	New products for Twist Human Core Exome Kit and Twist Custom Panels NGS target enrichment workflows, including: *Twist Fast Hybridization and Wash Kit *Twist Universal Blockers *Twist Universal Adapter System *Twist Mechanical Fragmentation Library Prep Kit for highly-degraded samples
Lexogen	Corall Total RNA-Seq Library Prep Kit
Furukawa Electric	Single Cell Hunter microchip-based automated live cell high-throughput screening system
Bionano Genomics	New products related to Saphyr platform for structural variation detection in genome analysis, including: *Saphyr Chip with three independent flowcells *Bionano Prep SP kit for DNA isolation from blood and cells
Agilent	Magnis NGS Prep System fully automated NGS library prep system
Dolomite Bio	scRNA-Seq Reagent Kit for generation of PCR-amplified cDNA libraries on firm's Nadia instrument

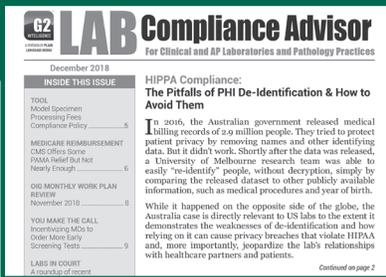


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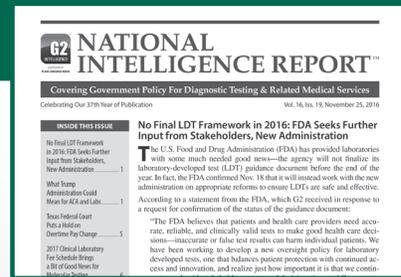
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