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LABORATORY INDUSTRY REPORT™

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HIGHLIGHTS

The COVID-19 pandemic is a rapidly-developing story.

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Emerging Tests: Lab Industry Mobilizes to Develop Coronavirus Detection Test

The global coronavirus (COVID-19) outbreak came without warning and is having a seismic impact on laboratories and the diagnostics business. The imperative for the industry right now is to develop a safe and rapid method of reliably detecting the virus, preferably at the point of care. Here's a rundown of the progress being made in achieving that objective.

The Central Role of RT-PCR Test Technology

Although much remains to be learned about COVID-19, researchers have noted its similarity to coronaviruses found

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Diagnostic Deals: Urgent Need for Coronavirus Diagnostics Fuels Strategic Collaboration

Not surprisingly, teaming up for development and commercialization of coronavirus (COVID-19) detection and vaccination products was a major theme of strategic alliance making during the period. Notable deals included:

The collaboration between Curetis Group company Ares Genetics and China-based BGI Group to bring the latter's newly CE-marked COVID-19 molecular test to the European market via an NGS testing service launched by Ares using BGI reagents;

The pairing of LGC Biosearch Technologies with diagnostics software developer UgenTec on a research-use-only AI-based coronavirus detection workflow;

Expansion of the current joint development agreement between Takis Biotech and DNA Sciences subsidiary LineaRx

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in bats, including the severe acute respiratory syndrome (SARS) virus. Accordingly, test developers have based tests to detect and confirm the virus on currently existing rapid real-time reverse transcription polymerase chain reaction (RT-PCR) technology. Companies that have previously developed RT-PCR assays for detection of multiple viruses have a head start in bringing a COVID-19 test to market.

RT-PCR is also the technological basis of the lone test currently approved in the U.S. for emergency use to detect COVID-19, the 2019 Real Time RT-PCR Diagnostic Test Panel developed by the U.S. Centers for Disease Control and Prevention (CDC).

Private Sector Initiatives in Asia

Not surprisingly, the most progress has been made in China, Hong Kong, and Southeast Asia where the outbreak began and continues to pose the greatest threat.

The BGI Group Assay

Few private diagnostic companies have played a more direct and active role in COIVD-19 response on the ground in Asia than Chinese genome sequencing company, the BGI Group. BGI and its MGI Tech subsidiary were the first to sequence the 2019-nCoV genome and subsequently developed a real-time fluorescence PCR kit for detecting coronavirus in a few hours. The kit received emergency clearance from China's National Medical Products Administration (NMPA). In addition to scaling up production of the assay, BGI donated 230,000 kits and opened a medical test laboratory to support COVID-19 response efforts in Wuhan and Hubei Province.

Other private firms that are seeking or have received regulatory approval for COVID-19 detection assays in Asia include:

- Luminex, which is seeking NMPA approval in China for its NxTag Respiratory Pathogen Panel, but only for ruling out COVID-19 infection;
- Kogene Biotech, which received emergency clearance for its 2019 Novel Coronavirus Real-time PCR Kit in Korea; and
- Seegene, which also received emergency clearance in Korea for its Allplex 2019-nCoV Assay.

The Hong Kong Assays

On Jan. 31, the journal *Clinical Chemistry* published the results of a study by investigators from China and Hong Kong claiming to have developed a pair of assays for rapid identification and confirmation of 2019-nCoV. Using publicly available sequencing information about the virus, the researchers focused on viruses in the sarbecovirus subgroup of

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betacoronaviruses and developed one-step RT-PCR tests targeting two regions of the viral genome—ORF1b and N. They then evaluated the tests in a panel of negative and positive control samples, including respiratory specimens from patients suspected of having COVID-19 during different stages after the onset of the illness. Each RT-PCR took about an hour and 15 minutes to run.

The researchers found that the assays were sensitive only to sarbecoviruses, with both suspected patients testing positive. They also determined that the N gene assay was 10 times more sensitive than the ORF1b assay in detecting positive samples. Based on these findings, the researchers recommended:

- Using the N gene assay for initial COVID-19 testing;
- Using the ORF1b assay if the patient tests positive to confirm the result; and
- Follow up testing by a World Health Organization (WHO) reference laboratory if the first test is positive and the second test is negative.

The PolyU Multiplex Respiratory Screening Panel

Less than a week after publication of the *Clinical Chemistry* RT-PCR tests study, scientists from The Hong Kong Polytechnic University (PolyU) announced that they have developed a comprehensive panel capable of detecting 30 to 40 respiratory infectious disease pathogens, including COVID-19, in less than an hour via a single test. Incorporating polymerase chain reaction technology into the diagnostic system allows the device to be fully automated from sample nucleic acid extraction and amplification to signal detection and analysis to achieve point-of-care capability. The system does not require manual interaction across the testing process.

Chips and Apps

Response has also extended to mobile point-of-care test lab-on-chip solutions that can diagnose pathogens via an end user's cell phone. One of the first applications of this technology to COVID-19 came on Jan. 24 when Singapore biotech firm Veredus Laboratories announced plans for a February 1 commercial launch of a kit capable of detecting the coronavirus with "high specificity and sensitivity." The VereCoV kit is based on lab-on-chip technology which integrates two molecular biological applications, polymerase chain reaction and microarray. This is the same application that Veredus, which is currently owned by Japanese plastics giant Sekisui Chemicals, has used to create kits for detecting the Mers, Zika, Dengue and H1N1 viruses. The company claims the new kit can detect, differentiate and identify all three coronaviruses in a single test in about two hours.

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The Private Sector Response in Europe

Although East and Southeast Asia have been the center of activity, scientists, public health laboratories and commercial test makers in the U.S., Europe and other regions affected by the outbreak are also working furiously to develop and secure expedited emergency regulatory approval for new experimental COVID-19 detection tests.

The first private sector company to gain approval for a COVID-19 to gain test in Europe is Primerdesign, the molecular division of Novacyt. On February 17, just two weeks after launching a research-use-only coronavirus test, Novacyt announced that it had received CE marking for a commercial molecular COVID-19 test. The Paris-based firm is also seeking FDA EUA authorization in the U.S.

On February 24, U.S. firm Co-Diagnostics announced that it has received CE-IVD marking for its Logix Smart Coronavirus COVID-19 test. The reverse-transcriptase quantitative PCR assay uses proprietary Co-Primer technology that the company claims can improve test specificity, reducing the likelihood of a false positive. "We look forward to scaling up production to meet global demand with this regulatory clearance in place, and to obtaining approvals from other bodies that will allow us to further increase the reach of this invaluable diagnostic tool," noted **Dwight Egan**, CEO of the Utah-based company, whose stock shout up nearly 30% to $3.93 on the day CE-IVD approval was announced.

Meanwhile, the pioneering BGI Group has teamed with Curetis Group company Ares Genetics to make its COVID-19 molecular tests available in Europe. Under the deal, Ares will launch a next-generation sequencing testing service for the virus using BGI reagents and collaborate in the distribution of NGS and PCR testing kits.

The Private Sector Response in the U.S.

In the U.S., the FDA is following the same playbook it used in responding to previous virus outbreaks like SARS and Zika, by calling on diagnostic test sponsors interested in potential EUA for coronavirus detection tests to contact the agency's Center for Devices and Radiological Health (CDRH) (CDRH-EUA-Templates@fda.hhs.gov) for information and templates. Several firms have announced plans to seek EUA for new coronavirus tests but, as of February 26, the CDC assay remains the only product approved for COVID-19 detection in the U.S.

Private Sector Companies Working on Coronavirus Detection Tests for FDA Emergency Use Authorization

Cepheid is developing an automated molecular test for use on its GeneXpert Systems to detect the 2019-nCoV strain in around 30 minutes

Qiagen is developing an expanded version of its QiaStat-Dx Respiratory Panel to include molecular assays for detecting COVID-19 from nasal swabs of symptomatic patients, which it hopes to submit for FDA approval before the end of February

Finnish company **Mobidiag** is working on a Novodiag molecular diagnostic test to identify novel coronavirus and other influenza viruses in 30 minutes via its joint venture with Chinese company Autobio Diagnostics

Hibergene, a Dublin-based medtech company specializing in developing tests for infectious diseases has fast-tracked a new, rapid test for coronavirus that it hopes will be on the market "in months"

FDA WATCH

Agency Finalizes CLIA Waiver Guidance for New IV Devices

On Feb. 25, the FDA issued a pair of final guidances to help manufacturers seeking clearance for new for new in vitro diagnostic devices. Here are the highlights.

CLIA Waivers

The first guidance document, "Recommendations for CLIA Waiver Applications for Manufacturers of In Vitro Diagnostic Devices," explains how sponsors can demonstrate accuracy, i.e., "insignificant risk of erroneous result," of in vitro diagnostic tests for purposes of obtaining a CLIA waiver. Among other things, it recommends that sponsors use a two-tier approach to demonstrate that their device is robust and has appropriate and effective risk control measures to ensure insignificant risk of an erroneous result:

- Tier 1: Risk Analysis and Flex Studies. Sponsors should conduct a systematic and comprehensive risk analysis identifying all potential sources of error, including test system failures and operator errors, and which of these errors can lead to a risk of a hazardous situation; and
- Tier 2: Fail-Safe and Failure Alert Mechanisms. Sponsors should also identify the control measures, including fail-safe and failure alert

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FDA Watch: Agency Finalizes CLIA Waiver Guidance for New IV Devices, *from page 5*

mechanisms that will reduce risks for each of the sources of error they identify. Then, once the control measures have been implemented, they should (1) verify that each control measure has been properly implemented, and (2) verify and/or validate the effectiveness of each control measure.

Dual 510(k) and CLIA Waiver Submissions

The second guidance document, "Recommendations for Dual 510(k) and CLIA Waiver by Application Studies," aims to make the dual CLIA waiver and Section 510(k) clearance pathway for certain Class I and Class II IVD devices created as part of the Medical Device Use Fee Amendment of 2012 less burdensome. For dual submission, the guidance recommends that sponsors include:

- A device description;
- A determination that a device is simple to use;
- Results of a risk analysis with potential sources of error identified;
- Failure-alert and fail-safe mechanisms that have been verified to mitigate risk of errors;
- Flex studies demonstrating insensitivity of the test to environmental and usage variations under stress conditions;
- Descriptions of the design;
- Results of analytical studies testing sensitivity, measuring interval, specificity, linearity, precision, carry-over, reagent stability and sample stability;
- Comparison studies and reproducibility studies;
- Clinical performance studies, if necessary; and
- Proposed device labeling.

New FDA Approvals

Key new product approvals announced from late-January through late February 2020:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
US Centers for Disease Control and Prevention	Emergency Use Authorization for 2019-nCoV Real-Time RT-PCR Diagnostic Panel to detect coronavirus
Asuragen	Clearance to market AmplideX Fragile X Dx and Carrier Screen Kit, first genetic test for fragile X syndrome (FXS).
Lucid Diagnostics	Breakthrough device designation for EsoGuard Esophageal DNA Test to detect esophageal dysplasia and potential cancer risk run on EsoCheck Cell Collection Device

Manufacturer(s)	Product(s)
Siemens Healthineers	510(k) clearance for Advia Centaur Total IgE assay to detect total IgE in serum + plasma run on Advia Centaur, Advia Centaur XP + Advia Centaur XPT systems
DiaSorin	Clearance for Liaison Lyme Total Antibody Plus assay and Liaison Lyme Total Antibody Plus Control Set to detect lgG and IgM antibodies to Borrelia burgdorferi in serum and plasma samples
Thermo Fisher Scientific	Clearance for Sensititre 20- to 24-hour Haemophilus influenzae/Streptococcus pneumoniae minimum inhibitory concentration or breakpoint susceptibility system with lefamulin (Nabriva's Xenleta), in 0.008 to 16 µg/mL dilution range
Shenzhen Bioeasy Biotechnology	Clearance for Bioeasy Multi-Drug Test Cup assays to detect drugs in human urine at specified cutoff concentrations
Beckman Coulter	510(k) clearance for Access PCT assay

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Primerdesign (division of Novacyt)	CE marking for molecular test to detect COVID-19 virus
Quotient Limited	CE marking for serological disease screening (SDS) microarray run on firm's Mosaiq system for blood grouping and transfusion-transmitted infection screening
Bioneer	CE-IVD marking for AccuPower hepatitis B virus quantitative PCR kit
DrawBridge Health	CE marking for OneDraw test system for collecting blood samples from upper arm for hemoglobin A1C testing without a needle
Qiagen	CE marking for Therascreen PIK3CA RGQ PCR kit for identifying breast cancer patients with PIK3CA mutation
NeuMoDx Molecular	CE-IVD marking for assay to detect and differentiate Trichomonas vaginalis and/or Mycoplasma genitalium in urine samples

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
BGI + MGI Tech subsidiary	China	National Medical Products Administration (NMPA) emergency use approval for: * metagenomic sequencing kit for coronaviruses *2019 novel coronavirus reverse transcription PCR kit *ultra-high-throughput sequencer DNBSEQ-T7
Genetron Health	China	NMPA emergency use approval for Genetron S2000 NGS system + a kit for an eight-gene lung cancer panel
Seegene	Korea	Ministry of Food and Drug Safety emergency use approval for Allplex 2019-nCoV coronavirus detection assay

Inside the Lab Industry: Reimbursement Cuts & Payor Denials Belie Industry's Steady Growth

The worldwide market for clinical laboratory services has grown 2.9% per year since 2010 with an estimated value of $121.5 billion in 2019. And over the next five years that growth is expected to increase at a compound annual growth rate (CAGR) of 3.8%, reaching a market value of $146.4 billion by 2024. That's the headline of a new report from healthcare market research firm Kalorama Information.

What's Driving Growth

PAMA and reimbursement cuts, increasing payment denials and overall economic uncertainty belie the long-term growth of the lab services industry. Thus, while times are tough for individual labs and lab entities, the industry is on an almost inevitable path to growth. Most medical treatment decisions run through the lab. According to Kalorama, 70% to 80% of physicians' diagnoses are based on lab test results. Drivers for continued growth include:

- The aging population;
- The growing incidence of chronic diseases and management;
- Increasing utilization of diagnosis for disease monitoring; and
- Advances in lab testing technologies and practices.
- Growth by Lab Market Segment

According to Kalorama, clinical chemistry (routine and essential testing) represents the largest market segment by far, followed by immunology and microbiology.

Market Segments Ranked by Global Worth

- Clinical chemistry (routine and essential testing)
- Immunology and microbiology
- Cytology and histology
- Genetic testing
- Toxicology testing

Source: Kalorama Information.

Growth by Market Segment

According to Kalorama, clinical chemistry (routine and essential testing) represents the largest market segment by far, followed by immunology and microbiology. The U.S. is the world's largest market for clinical lab services, accounting for 53% of all global revenues. And while the U.S. market is mature, growth in testing volume is expected to continue over the next five years driven by test orders for preventative health care. Kalorama also lists the U.S. and China as the two most attractive markets for growth and new opportunities.

Diagnostic Deals: Urgent Need for Coronavirus Diagnostics Fuels Strategic Collaboration, *from page 1*

to preclinical development of a linear DNA vaccine for COVID-19; and Johnson & Johnson's new partnership with the U.S. Biomedical Advanced Research and Development Authority (BARDA) for accelerated development of a coronavirus vaccine.

The Month in M&A

M&A activity was sluggish in February, in terms of both deal volume and value. The deals that did take place were largely modest in scope and at undisclosed prices. Among the transactions for which purchase price was reported, Meridian Bioscience's acquisition of Israeli GI and liver diagnostics firm Exalenz Bioscience was the most expensive at 6.10 shekels per share and 169 million shekels in total ($49 million). The deal, which is expected to close in the second quarter, will enable Meridian to bolster its stool antigen product line via addition of Exalenz' BreathID Breath Test Systems, a, a point-of-care urea breath test platform for H. pylori detection.

In releasing its 2019 fourth quarter earnings, Exact Sciences disclosed that it had made a strategic move in the cancer diagnostics space via a pair of acquisitions:

- NGS-based cancer diagnostic test maker for therapy selection Paradigm Diagnostics; and
- Viomics, a molecular firm specializing in biomarker selection for cancer diagnostics.

• • •

Here's a summary of the key M&A and other strategic diagnostic deals announced from late January through February:

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Meridian Bioscience	Exalenz Bioscience	• Price: $49 million (6.10 Israeli shekels per share) • Status: Expected to close by end of Q2 • Meridian to add Exalenz's BreathID Breath Test Systems, a point-of-care urea breath test platform for H. pylori detection
P4 Diagnostix	Strand Diagnostics	• Price: Undisclosed • Status: Closed • Assets acquired include Strand's Know Error system for forensic DNA testing + UroSeq test panel for advanced prostate cancer • Sale enables Hologic to concentrate breast health and molecular diagnostics core businesses

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Diagnostic Deals, *from page 9*

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Quest Diagnostics	Memorial Hermann Health System	• Price: Undisclosed (all cash) • Status: Expected to close in Q2 • Quest acquires outreach lab division of about 30 patient service centers + 60 in-office lab service sites • Quest to also provide management services for all 21of Memorial Hermann's hospital labs + become sole preferred provider of lab services for Memorial Hermann Health Plan
Exact Sciences	Paradigm Diagnostics	• Price: Undisclosed • Status: Closed • Exact acquires seller of NGS-based cancer diagnostic test used for therapy selection
Exact Sciences	Viomics	• Price: Undisclosed • Status: Closed • Exact acquires molecular diagnostics company specializing in biomarker selection for cancer diagnostics
OncoCyte	Insight Genetics	• Price: $7 million cash + $5 million OncoCyte common shares + 10-year revenue share of up to 10% net collected revenues for current IG pharma service offerings + tiered revenue share percentage of net collected revenues through end of lifecycle of new cancer tests developed using IG's technology + contingent consideration of up to $6 million cash and/or common shares • Status: Closed • OncoCyte acquires IG lung cancer immunotherapy test in development + access to IG's existing pharma services infrastructure, including a CLIA-certified + CAP-accredited lab + menu of single-gene tests for various biomarkers
Abcam	Applied StemCell	• Price: Undisclosed • Status: Closed • Abcam acquires Applied's gene editing platform and oncology research products, including AccuRef reference materials
Sysmex	Astrego Diagnostics	• Price: Undisclosed • Status: No closing date announced • Sysmex to acquire 24.9% stake in company that makes Captiver system for rapid detection of bacterial infection and antibiotic susceptibility in biofluid
Predictive Oncology	Quantitative Medicine	• Price: Undisclosed • Status: Expected to close by end of H1 • Predictive to couple QM's Core predictive modeling platform with its own tumor profiling expertise and data to develop precision therapies
BGI Group	Ares Genetics (part of Curetis Group)	• Objective: Make BGI's COIVD-19 coronavirus detection tests and kits available in Europe • Dynamic: Ares to launch NGS testing service for virus using BGI reagents

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
UgenTec	LGC Biosearch Technologies	• Objective: Launch AI-based workflow for COIVD-19 detection • Dynamic: Research-use-only workflow to be based on UgenTec's FastFinder PCR diagnostics software platform and Biosearch's reagents
Thermo Fisher Scientific	NanoPin Technologies	• Objective: Develop liquid chromatography mass spectrometry (LC-MS) workflows for blood-based infectious disease detection • Dynamic: Leverage use NanoPin's diagnostic platform and Thermo Fisher's LC-MS technology to develop sensitive and fast clinical infectious disease assays to determine infection stage and monitor patient treatment response
Thermo Fisher Scientific	Q-linea	• Objective: Commercialize Q-linea's ASTar automated antibiotic susceptibility testing instrument • Dynamic: TF gets exclusive rights to offer ASTar instrument in all markets except Sweden • TF Thermo already offers the Sensititre Complete Automated AST System for determining minimal inhibitory concentration (MIC)
Becton Dickinson	Babson Diagnostics	• Objective: Support small volume blood collection at retail pharmacies • Dynamic: Combine BD's capillary blood collection device and Babson's automated sample handling + analytical technologies to help retail pharmacies offer lab-quality diagnostic testing
Lucid Diagnostics	Fred Hutchinson Cancer Research Center	• Objective: Use Lucid's EsoCheck Esophageal Cell Collection Device to evaluate Center's Barrett's Esophagus (BE) progression biomarkers • Dynamic: Lucid gets exclusive option to license Center's BE progression biomarkers for one year after completion of a Phase II study demonstrating their accuracy
Namocell	HepaTx + Takara Bio	• Objective: Use Namocell's Single-Cell Dispenser to perform single-cell isolation on HepaTx's hepatocyte-like cells (iHeps) • Dynamic: Will also use Takara's SMART-seq technology to characterize iHeps
Euformatics	Bio.logis	• Objective: Provide pharmacogenomic information for patients undergoing NGS-based genetic testing • Dynamic: Integrate Bio.logis' Genetic Information Management Suite (GIMS) for analyzing genetic test data into Euformatics' OmnomicsNGS annotation and variant interpretation platform
Advaxis	Personalis	• Objective: Use Personalis' ImmunoID NeXT Platform for biomarker discovery • Dynamic: Extension of current collaboration supporting Advaxis' ongoing Phase I/II program to advance its investigational ADXS-503 antigen delivery construct platform alone and in combination with pembrolizumab for non-small cell lung cancer patients

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Diagnostic Deals, *from page 11*

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
CosmosID	Bioeostasis	• Objective: Provide standardized, end-to-end services for preclinical development of next-generation microbiome-based health products • Dynamic: Integrate preclinical development studies from Biomeostasis' rodent facility with CosmosID's standardized GLP workflows and strain-level microbiome analysis
ProSciento	Nordic Bioscience	• Objective: Identify translational biomarkers for nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) • Dynamic: Use ProSciento's Nash Pass patient registry and Nordic's Protein FingerPrint biomarker technology to validate minimally invasive biomarkers for NAFLD and NASH

To read the rest of this story go to: https://www.g2intelligence.com/diagnostic-deals-urgent-need-for-coronavirus-diagnostics-fuels-strategic-collaboration/

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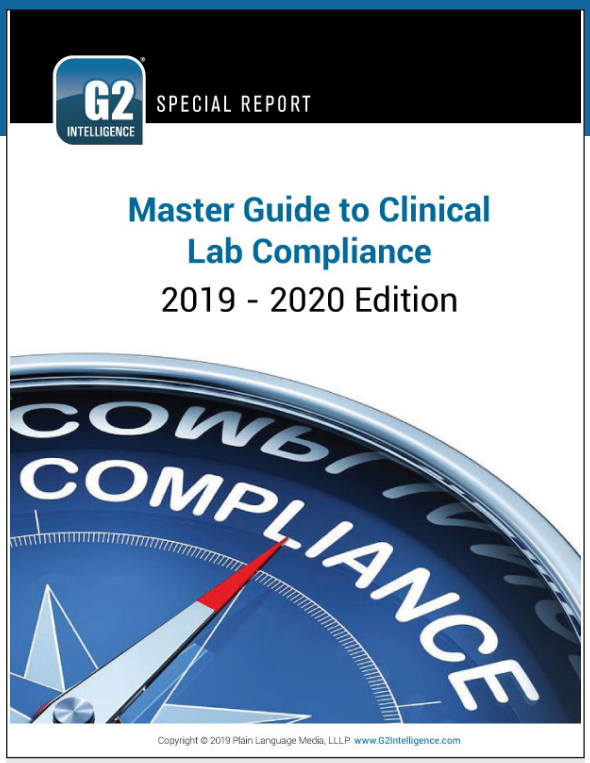

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