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HIGHLIGHTS

Industry Buzz: Qiagen and the Terrible, Horrible, No Good, Very Bad Day

Qiagen has been leaking oil for a while now. But after months of disappointing sales and dashed expectations, things came to a dramatic head over the less than 24 hour period between Oct. 7 and 8, 2019.

Poor Earnings

It started with news of disappointing earnings. On Oct. 7, the company announced that net earnings for Q3 2019 would come in at "about 3%," instead of the between 4% and 5% previously

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

After a brief summer lull, strategic deal making ramped up in September, especially in alliance making where volume nearly doubled last month's levels. Here's an overview of the long-term trends and key deals from late August through the third week of September.

Mergers & Acquisitions and Asset Sales

The M&A highlight of the month was the closing of Agilent's acquisition of privately held life science instrumentation manufacturer BioTek for $1.7 billion. The deal, which was announced in July, boosts Agilent's position in the immune-oncology and immunotherapy markets, albeit at a higher valuation than what the firm had previously pursued. Meanwhile, the other Dx blockbuster announced in July, the $2.8 billion acquisition of Genomic Health by rival genetic

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Industry Buzz: Qiagen and the Terrible, Horrible, No Good, Very Bad Day, *from page 1*

expected. Qiagen attributed the disappointing results to "significantly weaker-than-expected developments in China," and reaffirmed its faith in strong growth in the long-term. But investors didn't want to hear it, sending Qiagen stock plunging 20% ahead of the next day's market opening.

A Crucial Leadership Loss

But while disappointing growth had been anticipated, the Oct. 8 announcement that Qiagen CEO **Peer Schatz** was stepping down after 27 years to "pursue new opportunities" came as a body blow. Schatz was one of Qiagen's first employees and a driving force in building the company, which since 1993:

- Has gone from $2 million to $1.6 billion in annual sales;
- Increased its market capitalization by over 300 times; and
- Has grown from 25 to over 5,200 employees in 35 different countries.

Senior VP **Thierry Bernard**, head of Qiagen's molecular diagnostics business, serves as interim CEO while the company searches for a permanent successor.

A Surprising New Strategic Direction

On Oct. 8, the same day it announced the loss of Schatz, Qiagen announced a strategic pivot: Rather than trying to develop its own instruments, Qiagen had opted to enter into a long-term partnership with previous rival Illumina to develop next-generation sequencing (NGS) kits and companion diagnostics for Illumina's hardware. Qiagen also said it plans to reprioritize and reallocate in order to "free up resources" to better focus on its new partnership, including suspending its in-house work on developing NGS-related hardware, though it will continue supporting customers of its GeneReader next-gen system. (See Diagnostic Deals on page 1 for details about the Illumina deal).

Market Reaction

It was a lot for the market to absorb. "Following yet another disappointing quarter, we remain uncertain of QGEN's ability to execute on its long-term revenue outlook," wrote J.P. Morgan analyst **Tycho W. Peterson**. "The CEO's departure adds more uncertainty to the near- and medium-term outlook," noted Patterson in downgrading Qiagen's stock from Neutral to Underweight.

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FDA Watch: New Process for Simultaneous Review IVD Tests Used in Cancer Drug Trials

Typically, *in vitro* diagnostic (IVDs) tests used in investigational cancer drug trials require two submissions: one for the IVD test and another for the drug. But on Oct. 9, the FDA issued final guidance allowing companies to submit for simultaneous review for the clinical trial.

The New Streamlined Process

The new streamlined process is optional but the FDA "encourages sponsors to use it. . . when possible to reduce administrative burden on sponsors and FDA and to maintain the current level of regulatory approval." the agency said in its final guidance. Sponsors submit to the Center for Devices and Radiological Health (CDER) or Center for Biologics Evaluation and Research (CBER) all information about the oncology codevelopment program (including information about the investigational IVD) in the trial protocol for the investigational new drug application (IND).

One sponsor should take the lead in communicating with FDA about the IND. To indicate its intent to use the streamlined process, the sponsor should include the text "Streamlined IVD SRD" in either:

- In Section 11 (under "Other") of the Form FDA 1571, Investigational New Drug Application; or
- The cover letter it submits with the IND (along with a reference to which section(s) of the electronic common technical document contains relevant information).

The final guidance also lists the additional information about the IVD and how it will be used in the trial that the sponsor should list in the protocol it submits for the IND, including:

- A description of the device;
- How the results from the investigational IVD will be applied in the clinical trial;
- A description of the population and information regarding what is known about the prevalence of the biomarker (evaluated by the investigational IVD) in the patient population;
- The specimen type that will be collected for investigational IVD testing (including the anatomical site) and whether any biopsy conducted exclusively for investigational IVD testing could present a potential for serious risk to the health, safety or welfare of the subject.

By signing Form FDA 1571 (section 17) sponsors provide assurance of an institutional review board review of the complete clinical trial protocol and

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activities for the investigational IVD and the investigational drug, the final guidance specifies.

The CBER or CDER will then use the information to determine as part of the IND review and within the 30-day review period whether use of the IVD is significant risk (SR), nonsignificant risk (NSR) or exempt from investigational device exemption (IDE) requirements.

Determination	Consequence
NSR	CBER or CDER confirms determination in appendix to Study May Proceed Letter + reminds sponsor to follow NSR procedures in obtaining biopsies for testing + submit unanticipated adverse device effect reports to IND
SR	CBER or CDER confirms determination in appendix to Study May Proceed Letter + asks sponsor to submit IDE application to CBER or Center for Devices and Radiological Health (CDRH) + not start trial until after IDE is approved
Exempt	CBER or CDER confirms determination in appendix to Study May Proceed Letter

New FDA Approvals

Here's a look at other new product approvals announced from late September through late October:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Ortho Clinical Diagnostics	Clearance for Ortho Sera suite of reagents that enabling extended antigen phenotyping for use with the Ortho Vision analyzer
Cleveland Diagnostics	Breakthrough device designation for blood-based prostate cancer test that evaluates structural changes to prostate-specific antigen (PSA) rather than just measuring the level of the biomarker a la traditional PSA tests
OraSure Technologies	Clearance for OraQuick Ebola Rapid Antigen Test, first US-approved rapid detection test for Ebola virus
BioMérieux	Clearance for ETest Eravacycline assay for determining antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria
Philips Electronics	received 510(k) clearance for Philips IntelliSite Pathology Solution (PIPS) with a modified display
Binding Site Group	Clearance for Human IgA liquid reagent kit for use on firm's Spaplus turbidimetric analyzer
Qingdao Hightop Biotech	Clearance for Pregnancy Rapid Test to measure human chorionic gonadotropin (hCG) in early pregnancy detection
Bioeasy Biotechnology	Clearance for Bioeasy Marijuana Test Dip Card and Bioeasy Marijuana Test Strip lateral flow immunochromatographic assays for preliminary detection of marijuana in urine
Beckman Coulter	Clearance for FC 500 MPL and MCL flow cytometers to measure biological and physical properties of cells and other particles as they pass through laser beams in a single file

Manufacturer(s)	Product(s)
Beckman Coulter	510(k) clearance for DxA 5000 total laboratory automation solution
Sekisui Diagnostics	510(k) clearance for Acucy Influenza A&B test + CLIA waiver for use on the Acucy Reader
Exact Sciences	Expanded clearance for Cologuard DNA-based colorectal cancer screening test in average-risk people age 45 and older (as opposed to previous clearance for people age 50 and over)
Cepheid	Clearance for Xpert BCR-ABL Ultra test for monitoring disease burden in patients with chronic myeloid leukemia
Luminex	510(k) clearance for real-time PCR-based Aries MRSA Assay running on firm's Aries sample-to-answer system
Abbott	Clearance for Architect Stat highly sensitive troponin blood test for more rapid detection of heart attacks
Bühlmann Laboratories	510(k) clearance for Calex Cap fecal extraction device for use with firm's fecal calprotectin test

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
HemoSonics	CE marking for QStat Cartridge, allowing Quantra Hemostasis System to be used in hospital trauma surgery and liver transplants
LumaCyte	CE marking for Radiance label-free, single-cell analysis instrument
SpeeDx	CE-IVD marking for ResistancePlus MG Flexible cartridge to test for sexually transmitted infection Mycoplasma genitalium and antibacterial resistance determination on Cepheid FleXible cartridge
Saladax Biomedical	CE marking for use of MyCare Insite Clozapine Test to treat and monitor patients with schizophrenia
Sphingotec	CE-IVD marking for IB10 Sphingotec DPP3 test for dipeptidyl peptidase 3
Roche	CE marking for atezolizumab (Roche's Tecentriq) in combination with chemotherapy for patients with PD-L1-positive, unresectable, locally advanced triple-negative breast cancer
Roche	CE marking for Ventana PD-L1 (SP142) Assay for patients with PD-L1-positive, unresectable, locally advanced triple-negative breast cancer
Systaaq Diagnostic Products	CE-IVD marking for SuperExtract 32, and viral nucleic acid extraction kit

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Cytek Biosciences	China	National Medical Products Administration approval for Cytek Northern Lights flow cytometer
Biomerica	Colombia	Ministry of Health and Social Protection Institute National Surveillance of Drugs and Food approval for EZ Detect colorectal screening test

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

With 10 days still left to run, October was shaping up to be the busiest month of 2019 for new product launches. Here's a summary of the key diagnostic products unveiled so far:

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)/Service(s)
Sophia Genetics	Updated version of Sophia Whole Exome Solution
Illumina	Infinium Global Diversity Array, a commercial version of the array designed for the National Institutes of Health All of Us research program
Integrated DNA Technologies	NGS Discovery Pools, individually synthesized, 5'-biotinylated oligo pools enabling researchers to build custom panels
Living DNA	Two new genealogy + wellbeing consumer information kits: *$49 or £49 Starter DNA Kit *$129 or £129 Wellbeing Kit providing advice on vitamins, metabolism, fitness and exercise
Thermo Fisher Scientific	Acrometrix BCR-ABL Panel for use as an external control for analytical validation of BCR-ABL test methods
iGenomX	Next Generation Genotyping (NGG) application for population-scale research, including Riptide High-Throughput Rapid Library Preparation (HT-RLP) system
Nonacus	ExomeCG exome capture kit
TriLink Biotechnologies	Ion Torrent Convert barcode primer set for small RNA library preparation on Thermo Fisher Scientific's sequencing platform
Gencove	Low-pass sequencing platform
New England Biolabs	NEBNext Direct Genotyping Solution
HTG Molecular	HTG EdgeSeq Autoimmune Panel
Magbio Genomics	HighPrep Total RNA Plus Kit, RNA purification chemistry for Mawi DNA Technologies' iSwab-RNA-V2 collection tool
Paragon Genomics	CleanPlex Hereditary Cancer Panel V2
Qiagen	QIAseq FastSelect -rRNA and -Globin HMR Kits for removing ribosomal RNA + globin messenger RNA
Loop Genomics	Targeted, long-read, single-cell transcriptomics service that couples Illumina sequencing instruments with probe capture and cDNA from single cells to generate long-read data
PercayAI	CompBio to help identify relationships within multi-omic datasets to inform drug discovery
Claret Bioscience	SRSLY (Single Reaction Single-stranded LibrarY) directional NGS library preparation kit called
Predictive Laboratories	FertilityDX genetic testing service enabling physicians to tailor fertility treatments
Predictive Laboratories	ARTguide DNA-based blood test evaluating risk of endometriosis and other genetic causes of infertility in women
PerkinElmer	PG-Seq Rapid Non-Invasive Preimplantation Genetic Testing for Anueploidy kit for testing spent embryo culture media for chromosomal abnormalities during in vitro treatment

Company(ies)	Product(s)/Service(s)
Sema4	Expanded Carrier Screen for family planning with personalized residual risk
Dante Labs	Whole Genome and WholeGenomeZ sequencing test services
Co-Diagnostics	Vector Smart ZDC test to identify presence of Zika, dengue and chikungunya in mosquito populations
PerkinElmer	PG-Seq Rapid Non-Invasive Preimplantation Genetic Testing for Anueploidy kit for testing spent embryo culture media for chromosomal abnormalities during in vitro treatment
NanoString Technologies	nCounter Human Organ Transplant gene expression panel for evaluating immune response following organ transplantation
Ambry Genetics	+RNAinsight, combined DNA and RNA genetic test for hereditary cancer syndromes
ATCC	ATCC Genome Portal, a publicly available database of reference-quality genome sequences
T2 Biosystems	T2Resistance Panel for genotypic antibiotic resistance marker testing for research use only
nRichDx	High-yield sample prep Revolution System
Sysmex Inostics	SafeSeq Breast Cancer and Head and Neck Cancer Panels, which both run on firm's NGS SafeSeq platform
Fluidigm	New Maxpar cadmium metal labeling kits for use with mass cytometry: 106Cd, 110Cd, 111Cd, 112Cd, 113Cd, and 116Cd
Era7	V4V6 taxonomic profiling service for amplicon analysis
Streck	has commercially launched its RNA Complete Blood Collection Tube (BCT)

Diagnostic Deals, *from page 1*

cancer testing firm Exact Sciences, remains on track for a late 2019 closing.

But perhaps the most noteworthy M&A theme was role reversal, with big lab companies acting as sellers rather than buyers. Thus, two different firms made strategic divestments during the period, including:

- Natera, which sold off its Evercord cord blood and tissue banking business to California Life Sciences Company CBR (Cord Blood Registry) to focus on its core genetic reproductive health, oncology and organ transplant testing operations; and
- OraSure Technologies which sold its cryosurgical systems operations to CryoConcepts so it could give full attention to its core infectious disease and molecular solutions businesses.

In addition to the deals listed below, Illumina announced that it had received an unsolicited "mini-tender offer" from investment firm TRC Capital for up to 500,000 shares of Illumina common stock at a cash price

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of $268.60 per share. Illumina recommended that shareholders decline the offer, which remains open until midnight Oct. 2. TRC has made similar offers for other companies seeking to acquire just enough of an equity stake to stay below the SEC tender offer disclosure requirement threshold, the Illumina board noted.

The other notable M&A deal not listed in the table is the newly announced merger of Cardea Bio and Nanosens Innovations, the companies that teamed up to create a CRISPR-Cas9-based biosensor diagnostic device using a CRISPR-Chip transistor. The plan is for Nanosens to become a Cardea subsidiary with the new firm selling CRISPR-Chip-based products under the Nanosens brand name.

Strategic Alliances

Volume-wise, September was the year's most active month of strategic alliance deal making. Among the most intriguing collaborations was the pairing of Quest Diagnostics with data analysis firm hc1 to launch a new service called the Quest Lab Stewardship to help health systems avoid over- and under-ordering of lab tests. By turning the lemons of intense payor scrutiny over test ordering into the lemonade of utilization management based on testing results, this deal highlights the needs of labs to leverage their testing data to evolve their businesses.

Here's a summary of key diagnostic deals announced from late August through the third week of September:

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Exact Sciences	Genomic Health	• Price: $2.8 billion in cash and stock • Status: Expected to close by end of 2019 • Genomic Health common shareholders to get per share price of $27.50 in cash and $44.50 in shares of Exact stock, subject to 10% collar based on Exact's volume-weighted average price for 45 trading days ending July 26 • Create cancer DX megafirm that unites Exact's Cologuard with Genomic Health's Oncotype DX

Acquiring Company	Target(s)	Deal Summary
OpGen	Curetis GMbH	• Price: Curetis to receive 2,662,564 new common shares of OpGen (73% stake) based on $24 million valuation of combined business with current OpGen holders keeping remaining 27% equity share • Status: Expected to close in early 2020 • Curetis to become wholly owned subsidiary of OpGen to create transatlantic, US-based, Nasdaq-listed company with a commercial-stage molecular diagnostics and bioinformatics franchise and pipeline focusing on infectious diseases and antimicrobial resistance
Agilent Technologies	BioTek Instruments	• Price: $1.17 billion • Status: Closed • Acquisition of privately held life science instrumentation manufacturer expands Agilent's presence in cell analysis, immuno-oncology and immunotherapy • Agilent expects BioTek to contribute $20 million to $25 million to 4Q revenues with no material impact on EPS for quarter
CBR (Cord Blood Registry)	Natera	• Price: Undisclosed • Status: No closing date announced • Natera sells its Evercord cord blood and tissue banking business to focus on core genetic testing business in reproductive health, oncology and organ transplantation
OncoCyte	Razor Genomics	• Price: $10 million in cash upfront for 25% of Razor's outstanding equity + $1 million milestone associated with recent positive CMS coverage decision for Razor test assessing risk in early-stage lung cancer patients after surgery • Status: Initial closing expected in Sept. • Razor to use $4 million from initial $10 million payment to support supplemental clinical trial of test • Razor shareholders eligible for additional $10 million in cash and/or $5 million in OncoCyte common stock upon achievement of clinical trial milestones • OncoCyte to use Razor test as predicate in seeking Medicare coverage for its own DetermaVu assay
MyHeritage	River Road Bio	• Price: Undisclosed • Status: Closed • Israeli consumer genomics firm acquires owner of Promethease + SNPedia • MyHeritage to offer Promethease free of charge through end of this year + maintain SNPedia as a free resource for academic + non-profit users

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Diagnostic Deals, *from page 9*

Acquiring Company	Target(s)	Deal Summary
CellaVision	RAL Diagnostics	• Price: $27.7 million • Status: Expected to close in fall 2019 • Acquisition of sample preparation firm to bolster CellaVision's sample prep services for hematology, pathology, cytology + microbiology
ViVitro Labs	ProtomedLabs SASU	• Price: Undisclosed • Status: Closed • Cardiovascular test equipment + medical device testing lab merge operations under ViVitro Labs name
CareDx		• Price: Undisclosed • Status: Closed • CareDx acquires provider of software to simplify transplant quality tracking + waitlist management
PreCheck Health Services	LD Technology + Medical Screening	• Price: $5 million in cash upfront + deferred payment of $7 million in cash + $3 million in stock within 12 months • Status: No closing date announced • Acquisition of medical device firms boosts PreCheck's point-of-care screening capabilities
CryoConcepts	OraSure Technologies	• Price: $12 million cash • Status: Closed • OraSure sells off its cryosurgical systems business to focus on its core molecular solutions + infectious disease businesses
Inex Innovations and Exchange	Nova Satra Dx	• Price: Deal valued at $72 million • Status: Closed • Merger to form new company, called Inex Innovate, aiming to introduce new tests for ovarian cancer and breast cancer in Asian women by 2020
Progenity	Medimetrics	• Price: Undisclosed • Status: Closed • Progenity acquires Medimetrics' portfolio of patents for ingestible device technologies

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Thermo Fisher Scientific (TF)	Eli Lilly and Company	• Objective: Develop companion diagnostic test for Lilly's RET kinase inhibitor, LOXO-292 • Dynamic: Use TF's Oncomine Dx Target test to identify non-small cell lung cancer + thyroid cancer patients with RET alterations who might benefit from LOXO-292 • TF to seek FDA supplemental premarket approval broadening clinical claims of Oncomine Dx Target • TF to get global commercial rights to new CDx test

Partner 1	Partner(s) 2+	Deal Summary
Thermo Fisher Scientific	Cedars-Sinai	• Objective: Develop liquid chromatography mass spectrometry workflows for clinical research • Dynamic: Create data acquisition strategies for global plasma protein profiling + peptide selective reaction monitoring (SRM) assays for analyzing plasma with or without enrichment • Use TF's new triple quadrupole mass spectrometers for large quantitation assays to assess targeted protein workflows in a CLIA environment
Illumina	Adaptive	• Objective: Develop test kits for Adaptive's ClonoSeq + ImmunoSeq Dx NGS tests to run on Illumina's NextSeq 550Dx system • Dynamic: Under 5-year non-exclusive partnership, Adaptive to seek regulatory approval for + commercialize kits • Illumina to develop custom software for using kits on NextSeq instruments + exclusively license software to Adaptive Combine NeuroFlow's IntegrateHealth platform with Genomind's Professional PGx Express genetic testing service so that physicians can use former to administer latter + provide test results to patients • Adaptive to give Illumina 2 technology access milestone payments for software development + tiered revenue share payments ranging from a low to mid-single digit percentage of kits' net sales
Foundation Medicine	Natera	• Objective: Develop + commercialize personalized circulating tumor DNA monitoring assays for biopharma + clinical customers who order FoundationOne CDx • Dynamic: Use FoundationOne CDx test as baseline to define unique variants that codeveloped liquid biopsy assays will monitor • Foundation holds option to expand partnership to its FoundationOne Liquid or FoundationOne Heme tests as baseline for monitoring assays • Foundation gets exclusive right to commercialize assays • Foundation to pay Natera roughly $13 million in upfront licensing fees + prepaid revenues, as well as roughly $32 million in future minimum annual + milestone payments • Revenues to be shared

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Diagnostic Deals, *from page 11*

Partner 1	Partner(s) 2+	Deal Summary
CareDx	NanoString Technologies	• Objective: Develop gene expression profiling test called HistoMap to identify allograft rejection in transplant biopsy tissue • Dynamic: Combine CareDx's transplant registries + expertise with NanoString's nCounter platform + newly launched Human Organ Transplant panel
Quest Diagnostics	hc1	• Objective: Provide new Quest Lab Stewardship service to help health systems avoid ordering too many or too few tests • Dynamic: Service integrates with electronic medical record to guide doctors as they order tests, creates a systemwide set of tests + analyzes utilization trends
Coriell Life Sciences (CLS)	KPMG	• Objective: Provide pharmacogenomics data to clinicians at the point of care • Dynamic: Thermo Fisher Scientific to contribute genetic analysis technology + clinical decision support content • CLS to offer its Enterprise PGx platform system, backed by TF data + team of pharmacists, to assess genetic risks related to specific patients' prescribed medications + link that information to an institution's EHR system • KPMG's clinical intelligence platform to analyze information to help clinicians develop treatment plans for patients

See more Diagnostic Deals at https://www.g2intelligence.com/diagnostic-deals-a-roundup-of-the-key-mergers-acquisitions-alliances-licenses-and-other-strategic-transactions-from-the-past-month-30/

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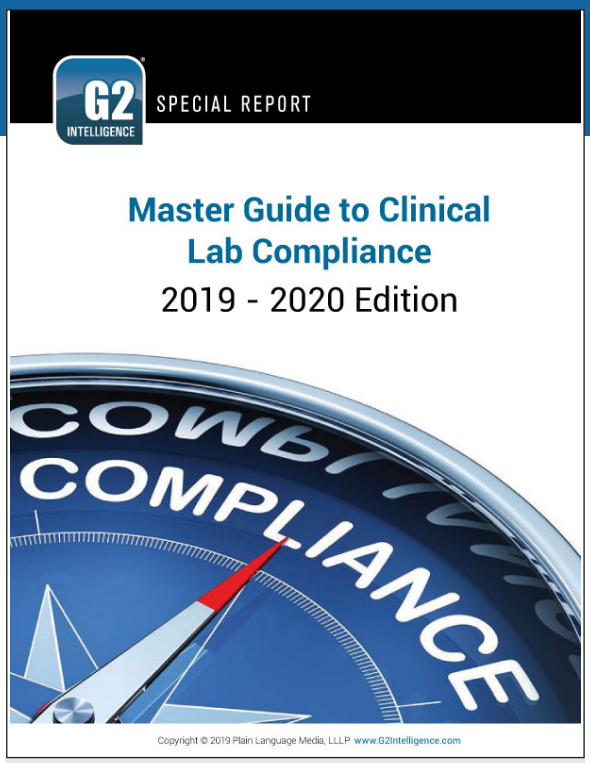

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