G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

July 2020

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Compliance Perspectives: Use Contact Logging to Ensure Lab Employees Practice Social Distancing

Managing a lab compliance program in the age of COVID-19 poses new and unprecedented challenges. One of the biggest and most important is ensuring that lab employees and the persons they interact with on the job follow social distancing requirements. To succeed in this effort, you must have the capability to track actual encounters. One possibility is digital technology, the use of apps, wearables and other so called "contact tracing" solutions that monitor encounters in real time. But in addition to being highly privacy-invasive, these solutions may be too costly and cumbersome for many labs. So, you may want to consider using this cheaper, easier and less intrusive manual method instead.

What's At Stake

Without a vaccine or treatment, social distancing, i.e., keeping at least six feet away from other people, has been the primary defense against COVID-19. Even though the shutdown phase of the pandemic is ending, labs and other businesses will have

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GAO Report: Federal COVID-19 Testing Data Collection Effort Has Been Ineffective

The federal government has done a poor job of collecting and reporting COVID-19 testing data to the CDC since the pandemic began. That's the conclusion of a U.S. Government and Accountability Office (GAO) report published on June 24, citing issues of accuracy, reliability and consistency resulting "in limited information on the spread of COVID-19 in communities."

Under the current model, the CDC gets testing data from state and local public health authorities that collect the information from testing labs. But labs didn't start reporting that data

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to keep following social distancing requirements or risk shutdown and penalties, not to mention infections to staff.

The Role of Contact Logging

"Contact tracing" is the generic term for a system of gathering data about individuals' physical encounters with other people. In the COVID-19 context, this data plays a crucial role in social distancing compliance monitoring by enabling your lab to:

- Analyze the number, duration and nature of potentially dangerous encounters, i.e., those closer than six feet, involving lab employees; and
- Identify the individuals involved in those encounters in case it becomes necessary to notify them of potential exposure, e.g., a physician who spent a lot of time working in close contact with one of your lab's phlebotomists who tested positive for COVID-19 24 hours later.

How Contact Logging Works

Contact logging is a method of contact tracing in which employers gather the data manually by requiring each person who comes to their facilities complete a form logging the contacts they had while they were at the premises. As with any other system, contact logging requires clearly defined metrics. For purposes of social distancing, the key metric is contact closer than six feet.

But you also need to maintain a sense of proportionality and accept the fact that some close contact is bound to occur at some point during the day with the understanding that COVID-19 infection risk is a function of not only distance but also duration of exposure. So, rather than every close encounter, the better metric would be close encounters lasting longer than a prescribed time period, such as 10 seconds. Two other key metrics:

- "Dangerous contacts" that pose immediate hazard of infection regardless of distance and duration, e.g., somebody sneezes or coughs on another person; and
- "Prolonged close contact," a cumulative close contact exposure threshold (e.g., 15 minutes in a single shift) triggering the need for the lab to initiate discipline, notification or other organizational response.

The Mechanics of Contact Logging

For as long as the social distancing mandate remains in effect, you should require all persons who come to your facilities—not just lab employees but also vendors, clients, patients and visitors—to complete a log of close or dangerous contacts they had during their shift or visit, including the name of the person and approximate duration of close contacts in minutes and seconds and submit it to a supervisor. (You can adapt the Model Encounter Log on page 3 for your own use).

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Lab Compliance Advisor (ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

Designate a lab supervisor to process the logs to confirm that each employee and visitor present during the shift submitted one, flag any dangerous contacts and total the cumulative minutes and seconds of each close contact time to determine whether there was any prolonged close contact.

Organizational Response Action

Require supervisors to immediately notify you of any dangerous or prolonged close contact so you can decide what, if anything, your lab should do in response. For example, should the employee be barred from entry and ordered to go into self-isolation? Do visitors involved in prolonged close contact need to be notified of their potential exposure? The supervisor should also follow up with any employee subject to prolonged close contact during the very next shift to go over the social distancing rules, get the employee's explanation and determine whether to impose discipline in accordance with the lab's progressive discipline policies.

Takeaway

If, like many compliance managers, you've been made the COVID-19 coordinator for your lab (if not, you might want to forward this analysis to whoever at your lab is performing that function), you face the daunting responsibility of enforcing social distancing. Contact logging is a relatively simple and inexpensive method for gathering the encounter data you need to ensure your own employees are following the rules.

TOOL MODEL COVID-19 CONTACT LOG SHEET

Maintaining social distancing will be the price that labs and other businesses will have to pay to reopen and remain open until the COVID-19 threat goes away. But for social distancing to work, there must be a way to track and analyze actual encounters between people at your facility. One simple way to gather the essential data is to have employees and visitors complete a contact log sheet. Here's a model your lab can adapt for its own use.

XYZ Laboratory Contact Log

INSTRUCTIONS: ALL employees, contract workers, couriers, clients, patients, guests, visitors and other persons who come to XYZ Laboratory facilities must complete this form logging information about any encounter they had with another individual that is closer than the required social distancing boundary of six feet for 10 or more seconds in duration while at the facility. Please enter each encounter in a single line; if you had more than five reportable encounters, please list a cumulative minute/second total and include the approximate number of encounters in parentheses.

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Model Tool: COVID-19 Contact Log Sheet, *from page 3*

Note that dangerous contacts in which another person sneezes or coughs on you must be reported immediately regardless of how far the other person was from you and how long the encounter lasted.

Name: _____ Date: _____

Relationship to XYZ Laboratory, if not an employee, e.g., visitor, patient, etc.:_____
_____

XYZ Laboratory Employees You Contacted			
First & Last Name	Location	Minutes	Seconds
Contract Workers, Couriers, Clients, Customers, Visitors, Others You Contacted			
First & Last Name	Location	Minutes	Seconds
Dangerous Contacts			
List the name, location and details of any encounters you had in which another person sneezed or coughed on you, regardless of how close the person was and how long the encounter lasted:			

NOTE THAT DANGEROUS CONTACTS MUST ALSO BE REPORTED *IMMEDIATELY* TO YOUR SUPERVISOR OR XYZ LABORATORY SECURITY PERSONNEL

Labs IN COURT

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

Arizona Lab's 20-Year Quest to Regain CLIA Certification Comes Up Empty

Case: CMS revoked an Arizona lab's CLIA certification in 2000. Three unsuccessful appeals and one failed petition to the U.S. Supreme Court later—eight years in total—the seven CLIA deficiencies, which the lab owner continued to insist were invalid, remained unremedied and the $30,000 fine unpaid. In 2013, the owner sought new CLIA certification for the lab but the state refused to process the application unless and until the owner paid the fine and resolved the previous sanctions. A new round of appeals ensued and the case landed in an Arizona federal district court which ruled against the owner.

Analysis: The CLIA law establishes a specific process for appealing the denial of certification under which a lab must first go to an Administrative Law Judge (ALJ) before it can go to federal court. But I'm not asking for new CLIA certification, the owner argued, just reinstatement of the old one. The court didn't buy it. CMS didn't temporarily suspend the lab's CLIA certification back in 2000, it permanently revoked it. As a result, this was a new application and the owner had to follow the CLIA appeals process and take its case to the ALJ.

[*Ali v. United States HHS*, 2020 U.S. Dist. LEXIS 110998]

Failure to Redo "Error" Message A1c Test on Diabetic Patient ≠ No-Brainer Medical Malpractice

Case: A patient with Type 2 diabetes presented to a federal health clinic with normal heart function, clear lungs and no swelling. And since he didn't complaint about light-headedness or dizziness, the examining doctor ordered relatively simple bloodwork, namely, a basic metabolic panel and A1c test, which measures average glucose level over a three-month period. The A1c test returned an "error" result, indicating that there was something wrong with the way the test was performed, e.g., air bubbles in or too small a blood sample or a bad cartridge. But the doctor saw no reason to keep the patient and discharged him without repeating the test. Right after being discharged, the patient wrapped his car around a telephone pole wrecking the vehicle and his back. He claimed he blacked out and sued the clinic for medical malpractice in botching the test. The clinic moved to dismiss the case without a trial and the New York federal district court granted the motion.

Significance: Rule: To prove medical malpractice, the plaintiff needs at least one expert witness. Exception: Expert testimony isn't required if the medical malpractice is so obvious that a layperson can tell it occurred, e.g., a doctor amputates the wrong leg. Since the patient apparently couldn't find an expert witness to testify on his behalf, he contended that

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Labs in Court *from page 5*

discharging him without redoing the A1c test after an "error" message qualified as the obvious kind of malpractice that you don't need a doctor to recognize. But the court disagreed:

- The A1c test was irrelevant to a discharge decision because it doesn't measure current glucose levels;
- The "error" result just meant the test went wrong and said nothing about the patient's glucose levels;
- Since the patient wasn't in any distress, the doctor's decision not to repeat it was reasonable.

[*Moore v. United States*, 2020 U.S. Dist. LEXIS 92729]

Billing & Coding: AMA Creates New CPT Code 87426 for COVID-19 Antigen Testing

On June 24, the AMA Current Procedural Terminology (CPT) approved new CPT code 87426 to report COVID-19 antigen tests, which use immunofluorescent or immunochromatographic techniques to detect the SARS-CoV-2 virus at the point of care. As of June 26, only one such test has received Emergency Use Authorization (EUA) from the FDA, the Sofia 2 SARS Antigen FIA rapid point-of-care test from Quidel, which received EUA on May 8. On the same day it unveiled the new CPT 87426 code, the AMA also issued new Proprietary Laboratory Analyses (PLA) Codes 0223U and 0224U for SARS-CoV-2 detection.

New CPT & PLA Codes for SARS-CoV-2 Tests

The new 87426 antigen testing code is the latest in a series of CPT codes created by the AMA in response to the pandemic. Here's the entire list of the SARS-CoV-2 related CPT and PLA codes that have been approved or revised and published for the 2021 CPT code set, listed in chronological order:

- **CPT Code 87635** (effective March 13, 2020) for infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique; Effective March 13, 2020;
- **CPT Code 86318** (effective April 10, 2020) revised for use to report immunoassay for infectious agent antibody(ies) and be a parent to 86328;
- **CPT Code 86328** (effective April 10, 2020) for single step antibody testing for severe acute respiratory syndrome coronavirus 2;

- **Child Code 86769** (effective April 10, 2020) for multiple-step antibody testing for severe acute respiratory syndrome coronavirus 2;
- **PLA Code 0202U** (effective May 20, 2020) for the BioFire® Respiratory Panel 2.1 (RP2.1) test;
- **CPT Code 87426** (effective June 24, 2020) for infectious agent antigen detection by immunoassay technique of SARS-CoV and SARS-CoV-2;
- **PLA Codes 0223U and 0224U** for detection of SARS-CoV-2.

Case of the Month: Feds Launch First COVID-19 Testing Fraud Prosecution

Stop me if you've heard this one before. The DOJ has charged a publicly traded Silicon Valley med tech firm and its CEO with touting a sham finger stick blood test to defraud payors and rip off investors. No, the company is not Theranos, and the executive is not Elizabeth Holmes. But while the dimensions and scope of this scam are much smaller, there are some eerie resemblances. And to top it all off, the product at its center is a COVID-19 test.

Feds Sound the Warning on COVID-19 Ripoffs

From almost the moment the pandemic began, there has been a wave of bogus COVID-19 testing products and marketing claims. The federal government certainly noticed this and warned consumers about fraudulent coronavirus testing almost from the moment. (See, for example, "OIG Warns of COVID-19 Testing Scams," LCA, March 30, 2020.) But it's taken until June for the prosecutions to begin.

The defendant in this first DOJ criminal action for COVID-19 testing fraud is Mark Schena, president of Sunnyvale, California-based Arrayit. The demand for COVID-19 testing is astronomical but the reimbursement rates relatively modest. But what if a COVID-19 test could be somehow bundled with a much higher-reimbursing product? According to the DOJ criminal complaint, that was the strategy Arrayit used by coupling its finger prick technology, blood-based novel coronavirus rapid detection with its more costly allergies tests kit.

To give things more oomph, Schena and colleagues pumped up its capabilities. In March, they began distributing marketing emails claiming the test was capable of rapid COVID-19 detection when used in combination with the allergies test kit.

But according to the DOJ, the test wasn't only unproven and unapproved, it didn't even exist at the time. It was only on the day that the emails were

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Case of the Month: Feds Launch First COVID-19 Testing Fraud Prosecution, *from page 7*

sent that Schena actually ordered the COVID-19 antigens. The company later developed and self-validated the test and submitted it the FDA for emergency use authorization (EUA). But the agency denied EUA clearance after finding the test's performance was wanting.

The Market Falls for the Pitch

But, of course, none of this was known to investors. Nor did they know that Arrayit was actually broke. All they heard were the company's claims that it was generating millions of dollars in billings for a rapid COVID-19 detection test. Thinking they had spotted a pearl in the midst of a pandemic, investors caused Arrayit's stock price to double—albeit it remained a low-priced penny stock. The federal Securities and Exchange Commission (SEC) suspended trading for the stock for two weeks in April.

The DOJ Lowers the Boom

On June 9, the DOJ charged Schena with criminal securities fraud and conspiracy to commit healthcare fraud by transmitting email communications and marketing materials that misrepresented Arrayit's ability to provide accurate, fast, reliable and cheap COVID-19 tests in compliance with applicable regulations and instructing its patient recruiters and medical clinics to add on or bundle Arrayit's much more lucrative allergy test with its COVID-19 test regardless of medical necessity.

But there was more. The complaint also alleges that, as part of the scheme, Arrayit paid doctors kickbacks to use their provider numbers to charge insurance companies for patients the doctors had never seen. For example, one doctor told investigators that Arrayit used his provider identifier number to receive insurance reimbursement for allergy tests from patients the doctor had never treated. An Arrayit executive paid the doctor illegal kickbacks from the reimbursement in exchange. Investigators said Medicare paid Arrayit $290,000 and private insurance companies another $2 million for medically unnecessary tests generated as the result of kickbacks.

In a separate action, the SEC charged a penny stock trader with falsely claiming Arrayit had an approved COVID-19 test. SEC said the claim was made to drive up the share price of Arrayit, without disclosing his stake in the company. The trader allegedly made $137,000 in six weeks.

Takeaway

In terms of the dollar amounts and lives impacted, the Arrayit case is of far less significance than Theranos. However, it's a harbinger of things to come. You can bet your house that there will be many more enforcement actions against test makers and labs for false billing and marketing of COVID-19 tests in the months ahead.

Billing & Coding: CMS Issues Reminders for Billing COVID-19 Specimen Collection & Symptom/Exposure Assessment

On June 18, CMS offered up some guidance on billing Medicare for COVID-19 symptom and exposure assessment and specimen collection performed on and after March 1, 2020:

- Use CPT code 99211 to bill for assessment and collection provided by clinical staff (such as pharmacists) incident to your services, unless you're reporting another Evaluation and Management (E/M) code for concurrent services;
- The above guidance on code 99211 applies to all patients, not just established ones;
- Submit the CS modifier with code 99211 (or other E/M code for assessment and collection) to waive cost sharing;
- If you didn't include the CS modifier when you submitted 99211, contact your Medicare Administrative Contractor so it can reopen and reprocess the claim;
- CMS will automatically reprocess claims billed for code 99211 that it denied due to place of service editing.

GAO Report: Federal COVID-19 Testing Data Collection Effort Has Been Ineffective, *from page 1*

until the end of March. And the data they did report was limited to testing results, not counting testing done at the point of care.

The GAO also says that the data which has been reported is inconsistent. Reasons:

- Labs haven't been counting tests the same way.
- When states didn't report data for a specific day, the CDC has been collecting and reporting the testing data from websites aggregating the data. **Problem:** Some state websites count the number of people tested and others count the number of samples tested, which could be different.
- The CDC reported states' testing data as viral load testing without recognizing that some states also include antibody tests in their data in their report.

These issues have "made it more difficult to track and know the infection rate, mitigate the effect of infections, and inform decisions on reopening communities," according to the report.

Takeaway

*The new HHS rules requiring labs to report COVID-19 testing data by August 1 (see the story on **page 10**) are an attempt to fix the problems cited by the GAO and ensure the steady flow of comprehensive and consistent data for use in infection monitoring, prevention and reopening.*

Compliance Briefing: How to Comply with the New HHS COVID-19 Test Data Reporting Rules

The U.S. Department of Health and Human Services (HHS) has ordered labs that perform COVID-19 testing to report test data to state and local public health agencies by August 1, 2020. What makes the task so challenging isn't just the immediacy of the deadline but the data labs are being asked to report, including not just testing results but also extensive personal and demographic data about the patients being tested. Because labs generally don't have direct contact with patients—particularly in the COVID-19 context—they're simply not set up to collect and process this data. Here's a look at the new reporting rules and what your lab must do to comply with them.

Why Labs Are Being Asked to Report Data

It's kinda' flattering that the U.S. government has come to understand the crucial role lab test data plays in the direction of public health. This is particularly so during a global pandemic. According to the guidance HHS issued on June 4, "complete and comprehensive laboratory testing data, including standardized test results, relevant demographic details and additional information" is essential to furthering understanding of COVID-19 incidence and trends thereby enabling public health officials to:

- Determine when to initiate epidemiologic case investigations;
- Assist with contact tracing;
- Assess the availability and use of testing resources;
- Identify supply chain issues for reagents and other materials; and
- Provide vital guidance for COVID-19 and SARS-CoV-2 mitigation and control activities.

This isn't the first time the administration has called on labs to report test data. On March 29, Vice President Mike Pence sent a letter requesting that hospitals with in-house labs submit daily COVID-19 testing data reports to HHS to help the U.S. Centers for Disease Control and Prevention (CDC) "support states and localities in addressing and responding to the virus."

The difference is that the new request is so much broader, not only in terms of the labs it covers but especially the scope of data that must be reported. (See the related item on page 1.)

HOW TO COMPLY: 8 FAQs

Here are some FAQs breaking down the key details lab managers need to understand to ensure compliance by the August 1 deadline.

Q1. Is Your Lab Required to Report?

A: The new HHS lab data reporting requirements cover all labs, including commercial and hospital labs, testing locations operating as temporary overflow or remote locations for a lab and other facilities or locations

performing testing at point of care or with at-home specimen collection related to SARS-CoV-2.

Q2. When Must Your Lab Report?

A: Labs must complete daily reports for all testing they complete and for each individual they test within 24 hours of knowing or determining the results. All data must be made available by August 1.

Q3. To Whom Must Your Lab Report?

A: Labs must report the data on a daily basis to the appropriate state or local public health department based on the individual's residence.

Q4. How Must Labs Report the Data?

A: The guidance lists three methods labs can use to submit lab testing data to state or local public health departments for subsequent transmission to the CDC:

- Direct submission, as required by state and/or local law or policy. These entities will then submit deidentified data to the CDC on a daily basis using either Health Level 7 (HL7) messaging;
- Submission via a centralized platform (such as the Association of Public Health Laboratories' AIMS platform) which will then route the data to the appropriate state and local authorities and, eventually to the CDC after the data is properly de-identified; or
- Submission through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department and thence to the CDC, as directed by the state.

Q5. What Data Must Your Lab Report?

A: The trickiest aspect of the new guidance is the unprecedented scope of the data it requires labs to collect and report, including:

- Personal demographic information about patients' age, ethnicity, race and sex;
- Test ordered (using harmonized LOINC codes provided by the CDC);
- Device Identifier
- Test result (using appropriate LOINC and SNOMED codes, as defined by the Laboratory) In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC);
- Test Result date (date format);
- Accession #/Specimen ID;
- Patient residence zip code and county;
- Ordering provider's name and NPI (as applicable) and zip code;
- Performing facility's name and/or CLIA number (if known), and zip code;
- Specimen Source (using appropriate LOINC, SNOMED-CT or SPM4, or equivalently detailed alternative codes);

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- Date test ordered (date format); and
- Date specimen collected (date format).

As if this weren't challenging enough, the guidance also says labs should collect and report even more detailed personal demographic information that public health officials will not pass along to the CDC, including the ordering provider's address and phone number as well as the patient's:

- Name (Last name, First name, Middle initial);
- Street address;
- Phone number with area code; and
- Date of birth.

Q6. How Will Your Lab Get the Data?

A: The first task, of course, will be figuring out how to get personal and demographic data from patients with whom your lab doesn't directly interact. As the guidance acknowledges, the data elements required "go above and beyond what has been historically requested" of labs. Consequently, labs will have to gather the information from the test orderer.

Of course, the difficulty of relying on ordering providers for reportable data is something labs understand all too well. Can you say "medically necessary." The good news, sort of, is that HHS attempts to address this bottleneck by saying that persons or entities that order a diagnostic or serologic test, collect a specimen or perform a test "should make every reasonable effort to collect complete demographic information and include the data" when ordering a lab test to enable the test provider to collect and report the data to state and local public health departments (emphasis added).

If information isn't available, the guidance says that ordering providers or their designees, labs and State Public Health departments "should consider leveraging resources like state or regional HIEs and National Health Information Networks (HIN) to obtain missing, required information" (once again, our emphasis).

Q7. How Will Your Lab Get the Data When Patients Collect Samples at Home?

A: According to the guidance, the sample collection process should address submission to the testing lab of not only the specimen but also the required data elements. For point of care testing, the lab (including a facility or setting with a certificate of waiver) must ensure the test is set up and operational to deliver timely and complete electronic results (with identifiers) in accordance with the methods of submission.

Q8. How Will Your Lab Get the Data When Testing Is Done at Home?

A: What about the COVID-19 tests where not only sample collection but also actual testing is done at home via a testing device that displays test results? Although the FDA has yet to issue Emergency Use Authorization (EUA) for one, COVID-19 home test products are in the pipeline and likely to reach the market soon. HHS "encourages" developers of such tests "to consider ways in which" the data elements and information required by the guidance "could be collected and reported, such as "through applications on a personal smartphone or tablet, a patient portal, direct transmission from the test platform itself or other innovative technologies."

Takeaway

Labs can look to downstream ordering physicians and even upstream public health departments for help gathering the necessary data in time for the August 1 deadline. Ultimately, though, while the collection and reporting obligations of the latter are all "should," the core reporting obligations of labs, i.e., the obligation to report the data elements to be passed along to the CDC, are a "must."

*Moreover, HHS officials, including Admiral **Brett Giroir**, M.D., assistant secretary for health and lead for COVID-19 testing efforts, have reported that labs would be the ones targeted for penalties if the data aren't reported. Specifically, those penalties would be dished out by the FDA in the form of fines, warning letters or even imprisonment, in extreme cases.*

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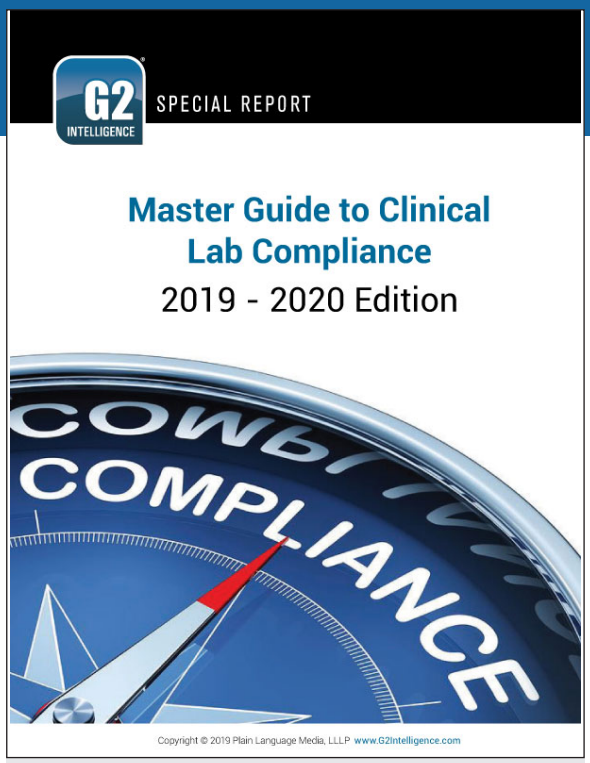

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