G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 41st Year of Publication

Vol. 20, Iss. 7, July 2020

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New Laws: HHS Requires Labs to Report Extensive & Unprecedented COVID-19 Testing Data by August 1

Three months into the pandemic, HHS has decided that it would be a good idea for labs that perform COVID-19 testing to report not only test results but other real-time data that labs generally don't report but which public health officials need to coordinate with each other and make sounder decisions in responding to COVID-19, including personal demographic information about patients being tested. Here's what labs need to know about the new data reporting rules to ensure compliance by the August 1, 2020 deadline.

The Crucial Role of Lab Testing Data

According to the guidance, which HHS issued on June 4, "complete and comprehensive laboratory testing data, including standardized test results, relevant demographic details and additional

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New Laws: Federal Legislation Would Give Labs Grants to Expand COVID-19 Testing Capacity

We all hope the worst of the pandemic is over and that life can get back to something like normal. But even as America reopens, the disturbing truth remains that the virus is still out there and that the nation's labs still lack anything close to the SARS-CoV-2 testing capacity that would be required if another outbreak were to occur. At the end of May, the U.S. House of Representatives introduced two new bills to remedy that situation via providing labs access to grants to enhance their COVID-19 testing capacity.

The Diagnostic Testing for Public Health Labs Act

The first bill, The Diagnostic Testing for Public Health Labs Act, would require the U.S. Centers for Disease Control and Prevention (CDC) to offer grants, capped at $2 million per lab, to

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information" plays a key role in 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.

Of course, the value of lab data in responding to COVID-19 is beyond dispute. That's why Vice President **Mike Pence** sent a letter on March 29 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 New HHS Data Reporting Guidance

However, the original Pence request was limited to data about test results. The new HHS guidance is far broader not only in terms of the labs it covers but especially the kind of data it asks for. Here's a rundown of the crucial details.

Which Labs Must Report

The new 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.

When Labs Must Report

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.

To Whom Labs Must Report

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

How Labs Must Report

The guidance lists three methods labs can use to submit lab testing data to state or local public health departments:

- 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

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National Intelligence Report (ISSN 2332-1466) 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.

- Submission through 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

What Labs Must Report

The real headline of the new guidance is the unprecedented scope of the data that labs must collect and report to state and local public health officials for subsequent transmission to the CDC, including personal demographic information about patients' age, ethnicity, race and sex, as well as:

- 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);
- Date test ordered (date format); and
- Date specimen collected (date format).
- Name (Last name, First name, Middle Initial);
- Street address;
- Phone number with area code; and
- Date of birth.

In addition to the above information, the guidance 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:

How Labs Are Supposed to Get the Data

As the guidance acknowledges, the data elements required "go above and beyond what has been historically requested" of labs. And there's a good

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reason for this, namely, that clinical labs don't usually interact directly with patients. Consequently, labs will have to gather the information from the test order.

The good news is that the guidance 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).

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.*

In the News: Feds Charge Silicon Valley Med Tech Executive with Massive COVID-19 Stockholder Swindle

The executive of a publicly traded Silicon Valley medical tech firm has been charged with swindling investors and insurers by misrepresenting the diagnostic capabilities of a test using finger stick blood collection. Hmmm. That sounds vaguely familiar. But while you've probably heard that plot line before, this case isn't about Elizabeth Holmes and Theranos. It's a brand new case, one that involves COVID-19 testing.

Theranos Meets COVID-19

The federal government has been sounding the warning on fraudulent coronavirus testing almost from the moment the pandemic started. (See, for example, "OIG Warns of COVID-19 Testing Scams," *LCA*, March 30, 2020.) But while investigations and prosecutions were all but inevitable, the nature of this new federal case is somewhat surprising.

The defendant is Mark Schena, president of Sunnyvale, California-based Arrayit. According to a criminal complaint filed by the DOJ, Arrayit sought to cash in on the COVID-19 pandemic to sell more of its high-reimbursing allergy tests. Starting in March, the Schena and colleagues distributed marketing emails claiming that the company's unapproved blood test based on finger prick technology, was capable of rapid novel coronavirus detection when used in combination with the allergies test kit.

But according to the DOJ, the test didn't exist. It was only on the day that the emails were 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, investors didn't know any of this. 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 Files Criminal Charges

On June 9, the DOJ dropped the hammer charging 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

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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

COVID-19 detection tests don't command very high reimbursement rates. That makes it tempting to bundle them with higher-paying assays. The fact that there's also a global pandemic and crying need for tests capable of rapid and accurate COVID-19 detection creates the opportunity to take an otherwise "pedestrian" healthcare fraud scam to the level of Wall Street swindle and massive securities fraud a la Theranos.

Former Illumina Accountant Settles Insider Trading Claims with SEC

Speaking of alleged securities fraud committed by insiders at publicly traded lab companies, on June 5, the U.S. Securities and Exchange Commission (SEC) agreed to settle with a former Illumina accountant accused of insider trading. The SEC claimed that Jana Kiena shorted Illumina stock after receiving information from an accounting manager that the firm would post disappointing revenues in the second quarter of 2019. But because Ms. Kiena self-reported her trading within a month, she was able to cut a pretty good settlement deal, including disgorgement of the $249,228 she earned in profits from the trading but a relatively low civil penalty of $124,613.

Congress to HHS: Give Labs the Money They Need to Develop COVID-19 Testing Capacity

This is a bad time to be a clinical lab in the U.S. Although a recovery seems to be in the works, the pandemic has drastically reduced testing for just about anything and everything other than COVID-19 over the past three months. And while COVID-19 testing volume is unprecedented,

the modest reimbursements it generates aren't nearly enough to offset the losses in other testing segments. Meanwhile, even as COVID-19 relief dollars flow freely, the labs aren't getting anything close to what they need to meet COVID-19 testing demand or even stay in business.

A Congressional Call for Help

The good news is that at least some of the people in positions of power get it, including the 30 members of the U.S. House of Representatives from both parties that sent a letter urging HHS Secretary **Alex Azar** to direct federal funds to support clinical labs during the pandemic. The June 1 letter calls on Azar to "distribute a portion of the Public Health and Social Services Emergency Fund (PHSSEF) funding appropriated by Congress for testing that has not otherwise been allocated directly to clinical laboratories" to enable them to expand their SARS-CoV-2 testing capacity and meet the unprecedented demand for COVID-19 testing.

The "allocated" and "appropriated" references are Congress-speak for the $25 billion directed to the PHSSEF as part of the Paycheck Protection Program and Health Care Enhancement Act (PPPHCE Act). That money includes $11 billion for states, localities, territories and tribes to enhance COVID-19 testing capacity. And those dollars are in addition to the funds already appropriated to the PHSSEF under the CARES Act.

The good news is that labs are eligible for these funds; the bad news is that the federal government hasn't specifically designated for labs. Rather than the recognition and support for their heroic role in stepping up during the public health emergency, the testing labs have been left to compete for federal assistance with other recipients.

What the Letter Recommends

The bipartisan group of representatives is urging HHS to direct a portion of the funding not already allocated to labs so that they can work to maintain their investments in critical resources for testing platforms, reagents, swabs and PPE, as well as for hiring, training and providing overtime pay to lab staffers. "These funds will ensure that labs can continue to rapidly scale up diagnostic and antibody testing, particularly for healthcare workers, first responders, and other Americans on the frontlines of this pandemic – and ultimately for all citizens to be able to return to school, work, and the activities they enjoy," the letter notes.

Takeaway

This isn't the first time Secretary Azar has found a letter like this in his inbox. On April 29, American Clinical Laboratory Association President ***Julie Khani*** *sent Azar a letter asking HHS to allocate $10 billion from the PHSSEF to support expanded testing capacity for both diagnostic and serologic tests.*

OIG Watch: Agency to Review First Two Years of PAMA-Based Medicare Reimbursements for Lab Tests

As we pass the midpoint of the third year of the PAMA experiment—if that's what it is—the OIG announced plans to review what happened in years one and two. One of the new items on the agency's Work Plan for May is to analyze Part B lab test payments made under the 2018 Clinical Laboratory Fee Schedule (CLFS), the first year of PAMA-based Medicare reimbursement for lab tests. Specifically, the OIG will publish an analysis of the top 25 lab tests by expenditure for 2018. The June OIG Work plan provides for doing a similar analysis for 2019. So, stay tuned.

The Next Round of COVID-19 Legislation: What It Will Take to Prevent a Second Outbreak

The next wave of federal COVID-19 relief legislation is in the works and the lab industry is doing its level best to ensure that it includes the necessary support for lab testing that the previously laws failed to deliver.

HEROES & Villains

On May 15, the U.S. House of Representatives narrowly passed the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act, a new $3 trillion COVID-19 stimulus bill. In addition to $75 billion to support diagnostic testing and contact tracing activities to monitor and suppress the COVID-19 virus, the HEROES Act would:

- Eliminate deductibles, copayments and other cost sharing for COVID-19 treatment (the way previous legislation did for COVID-19 testing);
- Provide $1 trillion to state and local governments;
- Expand family and medical leave and unemployment compensation;
- Establish a fund to give essential workers hazard pay; and
- Provide additional direct payments up to $1,200 per person.

But the HEROES Act faces an uncertain future in the Republican-controlled Senate, at least according to Senate Majority Leader **Mitch McConnell** who has described the bill as a "big laundry list of pet priorities" that has "no chance of becoming law." The latter phrase is backed up by the fact that President Trump has promised to veto it in the highly unlikely prospect that it squeaks through the Senate and reaches his desk.

The AACC's 5 Recommendations

On May 26, the American Association for Clinical Chemistry (AACC), a

global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare, sent a letter to Senate leadership expressing the urgency that any new COVID-19 legislation include measures to improve SARS-CoV-2 testing capacity. AACC president **Carmen Wiley** presented five recommendations the organization contends are necessary to prevent a second wave of the pandemic.

1. Integrated Testing Strategy

According to the AACC, HHS should take the lead in working together with Congress and other government stakeholders to develop an integrated COVID-19 testing strategy that:

- Establishes a common terminology;
- Identifies current challenges and necessary resources to overcome them;
- Lays out a plan for acquiring and distributing needed materials; and
- Creates benchmarks and timelines for measuring progress.

2. Improve Supply Chain Coordination

AACC recommends that the federal government get involved to eliminate persisting testing supply shortages by creating a mechanism for labs and healthcare facilities to regularly report current inventory levels. The government would then use that data to identify need and allocate resources to facilities accordingly.

3. Strengthen Public Health Infrastructure

AACC believes that Congress should provide funding enabling the Centers for Disease Control and Prevention to rebuild the public health infrastructure and oversee COVID-19 state and federal surveillance activities, including testing capacity, the rate of transmission, where the virus is spiking and falling, and contact tracing.

4. Expansion of COVID-19 Serological Testing

The AACC says the federal government should take steps to facilitate widespread patient access to accurate antibody testing by not only certifying the quality of serological SARS-CoV-2 antibody tests but also ensuring that labs that provide them are fairly reimbursed.

5. Safeguard Financial Solvency of Healthcare Providers

Finally, the AACC calls on the federal government to continue to provide financial assistance enabling commercial labs, hospitals and other healthcare facilities to survive the massive financial losses they're experiencing as a result of declining demands for medical services during the pandemic. The $100 billion in assistance provided by the first round of COVID-19 relief legislation, specifically the Coronavirus Aid, Relief,

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and Economic Security (CARES) Act, while helpful, wasn't enough to help hospitals and labs avoid layoffs, furloughs and hours reductions of lab technologists and other skilled testing personnel.

Takeaway

The CARES Act and other federal COVID-19 relief legislation was a good start. And since the pandemic began, the labs and the rest of the healthcare industry has made significant progress in expanding testing capacity, reducing the time to obtain results and improving test accuracy. However, as the AACC notes, "there is still much to do." The U.S. still remains a long way from achieving the capacity to perform the widespread testing that would be necessary to prevent a new wave of COVID-19 cases. And as states begin to gradually peel back their social distancing restrictions, the lack of testing capacity is of serious concern and will be resolved only if the federal government implements fundamental and systematic change.

New Products: First SARS-CoV-2 Antigen Test Gets EUA Clearance from the FDA

First came the molecular and then the serologic assays. And last month, the FDA granted emergency use authorization (EUA) for a COVID-19 assay based on a third kind of testing methodology: antigen detection.

The 3 Basic Types of Coronavirus Tests

Molecular: Most of the COVID-19 that have gained EUA, including the initial test from the U.S. Centers for Disease Control and Prevention (CDC), are molecular tests that use reverse transcription-polymerase chain reaction (PCR) that use tissue nasopharyngeal samples collected by a swab to detect RNA material from the SARS-CoV-2 virus. These tests are accurate but also slow to the extent that they must be performed at an offsite lab.

Serologic: In addition to being much faster, blood-based serology tests detecting antibodies produced by the body to fight the SARS-CoV-2 virus offer the potential to differentiate between active and previous infection. But serology tests lack the specificity and sensitivity of PCR assays making them prone to false positives and negatives.

Antigen: Like antibody testing, antigen tests detect viruses indirectly. But there are some important differences. For one thing, while antibody tests are blood based, antigen tests analyze nasopharyngeal samples from swabs the way PCR tests do. And instead of antibodies, antigen tests detect

the presence of antigens or toxins a virus produces that cause the body to produce those antibodies.

The downside is that antigen tests are less sensitive than PCR assays, which makes them prone to false negatives. Accordingly, patients who test negative may need to have confirmatory PCR tests. However, antigen testing may still be appropriate for many applications like screening health care workers and other high-risk groups and triaging patients during peak outbreak periods.

Advantages of Antigen Testing

Antigen tests offer significant advantages over the other available methods, including how relatively inexpensive they are to produce. They also generate results rapidly at the point of care. This combination of scalability and speed makes antigen testing the potential solution to the urgent need for high throughput testing essential to contain the spread of COVID-19 and ensure the safe re-emergence of the economy.

"Antigen tests are important in the overall response against COVID-19 as they can generally be produced at a lower cost than PCR tests," noted US Food and Drug Administration (FDA) Commissioner **Stephen Hahn**. "And once multiple manufacturers enter the market, antigen tests can potentially scale to test millions of Americans per day due to their simpler design, helping our country better identify infection rates closer to real time."

FDA Approves First Antigen Test for SARS-CoV-2

On May 8, the Quidel Sofia 2 SARS Antigen FIA assay became the first antigen assay to receive EUA for SARS-CoV-2 use. The product is a point of care test designed for use with the firm's Sofia 2 fluorescent immunoassay analyzer to detect SARS-CoV-2 protein fragments in nasal or nasopharyngeal samples. Its reported sensitivity of 85 percent definitely puts false negatives into play. The agency reportedly cleared the test within 24 hours of receiving Quidel's application.

It's not surprising that Quidel is the first to bring a SARS-CoV-2 antigen test to the US market. The firm also produces immunoassays for its Sofia platform including tests for influenza A and B, respiratory syncytial virus (RSV), group A Streptococcus and other infectious diseases. Quidel claims that the new Sofia 2 SARS Antigen FIA test, which the EUA authorizes moderate- and high-complexity CLIA laboratories and facilities that have a CLIA waiver to perform, delivers results in 15 minutes and costs only $5 per test to produce.

Takeaway

More SARS-CoV-2 tests are in the pipeline. The FDA said that it's expecting to clear more SARS-CoV-2 antigen tests and that it intends to create a new streamlined and expedited EUA pathway for antigen tests.

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help public health labs purchase testing platforms and supplies to boost testing capacity. Eligible labs would include state, local, and tribal public health labs, public health labs coordinated by the CDC, and other labs that provide "population-based testing for the prevention and control of infectious, communicable, genetic, or chronic diseases."

The Rapid Testing for Communities Act

The second bill, the Rapid Testing for Communities Act, would require the CDC to award grants to healthcare providers to support SARS-CoV-2 diagnostic testing outside of a lab, prioritizing underserved and rural areas. The grants would be used to purchase equipment and supplies to perform same-day diagnostic testing at the point of care. Grants would be capped at $20,000.

Takeaway

Both bills were introduced by U.S. Reps. ***Diana DeGette*** *(D-Colorado) and* ***Larry Bucshon*** *(R-Indiana). Thus, while the recent federal COVID-19 relief legislation didn't provide anywhere near the support labs require to develop the capacity they need to meet the historic demands for SARS-CoV-2 testing, it's comforting to know that there's an active bipartisan group in the House working hard to right the situation. (See the related story on* ***page 6****) on the letter written by 30 members of Congress calling on HHS Secretary* ***Alex Azar*** *to allocate more federal relief money to labs for developing diagnostic and serologic testing capacity.)*

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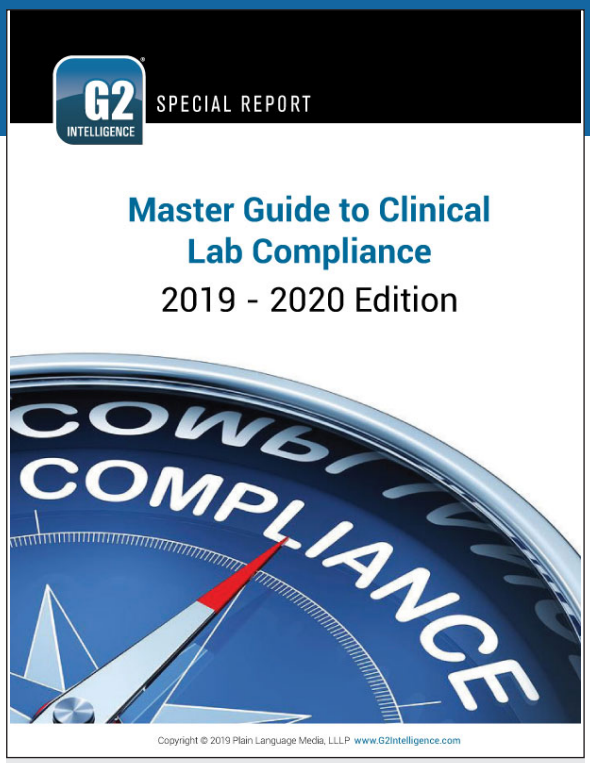

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