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New Trends, Applications, and IVD Industry Analysis

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COVID-19: Surging COVID-19 Cases Are Pushing Laboratories to the Breaking Point

Long lines for testing. Shortages of critical testing supplies. Case backlogs and long reporting delays.

Laboratories across the country and the patients they serve are reliving the nightmares of March and April as COVID-19 cases surge across the country. Things could get even worse this time around as holiday season get-togethers, winter weather and flu season all converge. The key question: Do laboratories have the capacity to keep up with testing demands?

The Bleak Outlook

Regrettably, the answer at this point seems to be no. U.S. laboratories are currently testing 1.5 million people per day, which is more than double the rate in July. But as case volume

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LDTs: HHS Orders FDA to Resume EUA Review of Laboratory Developed Tests for COVID-19

Oh no you don't! A month after the U.S. Food and Drug Administration (FDA) announced its decision to discontinue review of applications for Emergency Use Authorization (EUA) submitted by test makers for laboratory developed tests (LDTs) to diagnose COVID-19, the Department of Health and Human Services (HHS) has ordered the agency to resume LDT EUA applications and to do so in a "timely manner." The new HHS mandate is the latest and perhaps most decisive twist in what has become a somewhat bizarre battle within the administration over regulation of LDTs.

The COVID-19 EUA Regulatory Roller Coaster

One of the unforeseen results of the public health emergency has been to accelerate the long-running debate over FDA regulation of

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COVID-19: Surging COVID-19 Cases Are Pushing Laboratories to the Breaking Point, *from page 1*

increases and patients rush to get tested before traveling to be with family for Thanksgiving, this is not nearly enough. A Nov. 12 statement by American Clinical Lab Association (ACLA) president **Julie Khani** warns that at this rate, some ACLA members are likely to reach or exceed their current testing capacities in the coming days.

The Continuing Supplies Shortage

Trump administration officials estimate that the U.S. has enough tests to screen between 4 million and 5 million per day in November. The problem with those numbers is that they are based on the premise that laboratories will have ample supplies to perform those tests. And that is simply not the case.

The supplies shortages that bedeviled testing efforts back in the spring have continued. Clinical laboratories are facing delays or cancellations on orders for critical supplies, such as pipette tips, Khani notes. Recent Food and Drug Administration authorization of specimen pooling, that is, testing a pool of samples rather than its constituent individuals, allows for more efficient use of testing supplies, *provided that* the pool tests negative. But if the pool comes back positive, all pool members must be tested individually, which necessitates utilization of supplies. Accordingly, pooling works best for use in populations at low risk, or with a low prevalence of infection. However, positivity rates across the country are currently on the rise, meaning that individual testing is becoming increasingly necessary.

Shrinking Reimbursement for Tests

Meanwhile, laboratories are finding it increasingly difficult to get reimbursed for the COVID-19 tests they do perform. When the public health emergency first began, Medicare paid laboratories $51 per test for high throughput COVID-19 diagnostic tests. Recognizing that the rate was inadequate, the Centers for Medicare and Medicaid Services (CMS) subsequently raised it to $100 per test. However, in October, CMS announced a new payment policy for 2021 under which laboratories will only qualify for the $100 payment rate if:

- They complete the billed test in two calendar days or less; AND
- They complete the majority of high throughput COVID-19 tests in two calendar days or less for **all** of their patients (not just their Medicare patients) in the previous month.

Laboratories that take longer than two days will receive only $75 per test. In essence, CMS is disguising a reimbursement cut as a reimbursement increase.

DTET

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Laboratories are also facing reimbursement challenges from private payors. The *Families First Coronavirus Response Act* (FFCRA) and *Coronavirus Aid, Relief, and Economic Security Act* (CARES) require insurers to cover COVID-19 tests without seek copayments or other out-of-pocket costs. However, regulatory guidance issued by the U.S. Department of Health and Human Services (HHS) in June suggests that the rule does not apply to "testing conducted to screen for general workplace health and safety (such as employee "return to work" programs), for public surveillance or any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19."

The laboratory industry contends that health plans and insurers are exploiting this loophole to evade their FFCRA and CARES reimbursement obligations. Health insurance groups have responded by accusing laboratories of price gouging for COVID-19 tests. And, of course, patients are caught in the middle.

Takeaway

Even though more people are being tested than ever before, it is becoming increasingly clear that the U.S. has not resolved its COVID-19 testing problems. Supplies remain scarce. Case numbers continue to grow. And laboratories are being stretched to their breaking point. With the onset of the holidays and flu seasons, things are likely to get much worse before they get better.

FDA WATCH

Agency Authorizes First Fully At-Home COVID-19 Testing Kit

With COVID-19 cases surging, the U.S. Food and Drug Administration (FDA) made history on Nov. 17 by granting Emergency Use Authorization (EUA) to an all-in-one COVID-19 diagnostic that allows people to test themselves in their own home. Although the agency has previously authorized COVID-19 diagnostic tests for at-home sample collection, this is the first time it has given the green light to a full at-home testing kit for the virus. "A test that can be fully administered entirely outside of a lab or healthcare setting has always been a major priority for the FDA to address the pandemic," noted **Jeff Shuren**, director of FDA's Center for Devices and Radiological Health, said in a statement.

The At-Home Test

The product making the milestone is the Lucira COVID-19 All-in-One Test Kit from Emeryville, California-based Lucira Health.

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FDA Watch, *from page 3*

The single use test is based not on PCR technology but real-time loop-mediated isothermal amplification (LAMP) that operates at ambient temperatures to detect SARS-CoV-2 RNA from self-collected swab samples. Physicians prescribe the test for patients age 14 or above that they suspect have the virus. The assay runs on a handheld battery-powered device that looks like a thermometer and which provides a result via LED readout in 30 minutes or less. The EUA also allows for use of the test at the point of care in doctor's offices, hospitals, urgent care and other CLIA-waived settings on samples collected by a healthcare provider.

According to the FDA, the Lucira test achieved 94 percent sensitivity and 98 percent specificity in a community testing study comparing the assay to an FDA-authorized SARS-CoV-2 test with known high sensitivity. Lucira adapted the test from a prototype it originally created for use as a flu test before pivoting in response to the COVID-19 pandemic.

Lucira says that it expects the test, which costs $50, to be available nationwide by the early spring. Lucira also plans to file for FDA approval for allowing the test to be prescribed through a telehealth visit, with the kit to be delivered by mail. "This new testing option is an important diagnostic advancement to address the pandemic and reduce the public burden of disease transmission," noted FDA Commissioner **Stephen Hahn** in a statement.

LabCorp May Be Next

Meanwhile, testing giant LabCorp may soon up the ante by launching an at-home diagnostic of its own capable of detecting not only COVID-19 but also influenza and respiratory syncytial virus from a single sample making it perfectly suited for flu season. The new product, which will be offered through LabCorp's Pixel service, will be an at-home version of the combined test currently provided in doctors' offices, hospitals and other point of care settings.

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Here are the other key new FDA EUAs and clearances announced from late October through late November:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Foundation Medicine	Clearance for FoundationOne Liquid CDx test as companion diagnostic with olaparib (AstraZeneca and Merck's Lynparza)
Quansys Biosciences	EUA for Q-Plex SARS-CoV-2 Human IgG (4 Plex) immunoassay
DNA Genotek	EUA for ORAcollect RNA ORE-100 and ORAcollect RNA OR-100 saliva collection devices for SARS-CoV-2 testing

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Manufacturer(s)	Product
LabCorp	Reissued EUA for COVID-19 RT-PCR Test changing type of samples that can be used for pooled testing
Color	Reissued EUA for loop-mediated isothermal amplification-based SARS-CoV-2 test allowing use on self-collected samples
PerkinElmer	Reissued EUA for New Coronavirus Nucleic Acid Detection Kit allowing use for pooled samples
Roche	Clearance for Cobas EGFR Mutation Test v2 as companion diagnostic for non-small cell lung cancer therapies
Agena Bioscience	EUA for MassArray SARS-CoV-2 Panel
Merck	Accelerated clearance for pembrolizumab (Keytruda) plus chemotherapy as treatment for locally recurrent, unresectable, or metastatic triple-negative breast cancer patients with high PD-L1-expressing tumors
Celltrion	EUA for Sampinute COVID-19 Antigen MIA magnetic force-assisted electrochemical sandwich immunoassay
Foundation Medicine	Clearance for FoundationOne Liquid CDx test as companion diagnostic for three new targeted cancer therapies, including alpelisib (Novartis' Piqray) in advanced or metastatic breast cancer, rucaparib (Clovis Oncology's Rubraca) in advanced ovarian cancer, and alectinib (Genentech's Alecensa) in metastatic non-small cell lung cancer
Foundation Medicine	Clearance for FoundationOne CDx test as companion diagnostic for use with larotrectinib (Bayer's Vitrakvi) to identify cancer patients with neurotrophic receptor tyrosine kinase fusions

Innovation: New Artificial Intelligence-Based Risk Score May Help Avoid Unnecessary COVID-19 Hospitalizations

Researchers at Massachusetts General Hospital (MGH) have developed a diagnostic tool that uses artificial intelligence to generate a score to assess the prognosis of individual patients diagnosed with COVID-19 at the point of care in outpatient settings. The tool may enable urgent care centers and emergency departments to make rapid and automatic determinations about which patients are most likely to develop complications and need to be hospitalized.

The Diagnostic Challenge

The primary objective of most current COVID-19 diagnostics is to determine whether a person does or does not have the virus. However,

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Innovation: New Artificial Intelligence-Based Risk Score May Help Avoid Unnecessary COVID-19 Hospitalizations, *from page 5*

once a patient tests positive, providers must make crucial decisions about hospitalization and treatment based on the patient's individual risks and likelihood to develop complications. In addition to promoting sound care decisions, having a tool to assess the prognosis of COVID-19 patients would also help physicians avoid overburdening already extended hospitals by hospitalizing only patients at greatest risk of negative outcomes.

The Study

When the COVID-19 pandemic first began, infectious disease physician **Gregory Robbins**, MD, enlisted the help of his colleagues on the MGH Biothreats to develop a sophisticated method of assessing the risk of outpatients diagnosed with COVID-19. Dr. Robbins and a team of experts in neurology, infectious disease, critical care, radiology, pathology, emergency medicine and machine learning came up with a potential solution: the so-called COVID-19 Acuity Score (CoVA) based on data input from 9,381 adult outpatients seen in MGH's respiratory illness clinics and emergency department from March 7 to May 2, 2020. "The large sample size helped ensure that the machine learning model was able to learn which of the many different pieces of data available allow reliable predictions about the course of COVID-19 infection," noted one of the authors of the study, which was published in *The Journal of Infectious Diseases*.

CoVA is based on 30 different predictors, including demographics like age and gender, COVID-19 testing status, vital signs, medical history and chest X-ray results (when available). After developing it, the team tested CoVA in another 2,205 patients seen between May 3 and 14 to ensure it would actually work on new patients "in the real world." And it did. Thus, within the prospective validation group:

- 26.1 percent of patients experienced hospitalization within seven days;
- 6.3 percent of patients experienced critical illness within seven days; and
- 0.5 percent of patients died within seven days.

The key point is that CoVA demonstrated excellence in predicting which patients would fall into each of these categories. Among CoVA's 30 predictors, the top five most reliable proved to be the patient's:

- Age;
- Diastolic blood pressure;
- Blood oxygen saturation;
- COVID-19 testing status; and
- Respiratory rate.

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Takeaway

CoVA is not the first risk score developed for predicting COVID-19 complications. However, as noted by one of the study authors, what makes it unique is that it is based on a very large patient sample and specifically designed for use in the outpatient setting, rather than for patients who are already in the hospital. It is also the only score that has been prospectively validated. Consequently, CoVA may prove to be an extremely valuable diagnostic tool, particularly at a time when U.S. COVID-19 cases and hospitalizations are once more surging.

Top of the News: CDC Knowingly Sent Flawed COVID-19 Test Kits to Public Laboratories in Early Days of Crisis

Early missteps characterized the federal government's initial efforts to ensure a supply of reliable COVID-19 diagnostic tests in response to the public health emergency. And now a new National Public Radio (NPR) report contends that the U.S. Centers for Disease Control and Prevention (CDC) deliberately sent test kits to public labs despite knowing that they were apt to fail to 33 percent of the time.

The CDC's Decision

The Nov. 6 report's conclusion is based on a "root-cause analysis" internal review that the CDC conducted to understand why its early real-time reverse transcription polymerase chain reaction RT PCR coronavirus test did not function properly, costing scientists and public health officials precious weeks in the early days of a pandemic.

The CDC test, the first to receive Food and Drug Administration emergency use authorization for COVID-19, was designed and built in record time. According to NPR, the tests were all boxed up and ready to go on Feb. 6 when a scientist in an infectious disease laboratory on the CDC's Atlanta campus discovered the high failure rate while putting the test kit through its final paces.

A failure rate of that magnitude would have normally precluded releasing the test. But the CDC apparently caved in to the intense pressure and proceeded to distribute the test to about 100 public laboratories across the country, including the New York City Public Health Laboratory.

Problems with the CDC Laboratory

The CDC's deliberate decision to release a flawed test kit was not the only troubling finding of the root-cause analysis. The reviewers also determined that the CDC's Respiratory Viruses Diagnostic Laboratory was beset with

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Top of the News: CDC Knowingly Sent Flawed COVID-19 Test Kits to Public Laboratories in Early Days of Crisis, *from page 7*

problems, including "process failures, a lack of appropriate recognized laboratory quality standards, and organizational problems related to the support and management of a laboratory supporting an outbreak response."

The problems with the Respiratory Viruses Diagnostic Laboratory were reported last month by ProPublica. NPR's story is the first time the CDC internal review's findings have been made public. The CDC declined to discuss the review with NPR.

Takeaway

The decision of the CDC to rush an unproven if not faulty COVID-19 test kit to public laboratories in response to enormous public pressure is a cautionary tale that the agency and other scientific authorities will have to bear in mind when releasing a vaccine for the virus.

DTC: Research Supports Viability of Using Health Data from Consumer Wearables to Diagnose COVID-19

That Fitbit, smartwatch or other device that many of us wear around our wrist to count our steps, calories burned and other fitness metrics on a daily basis may prove to be an ideal tool for transmitting other significant diagnostic information about our health. And a new study by Scripps Research Translational Institute published in *Nature* suggests that such information may include whether we have COVID-19. Specifically, the study finds that a smartphone application (or "app") in combination with passively collected physiologic data from wearable devices, such as fitness trackers, is capable of determining whether a person reporting symptoms is positive or negative for COVID-19.

The Diagnostic Challenge

When it comes to preventing the spread of COVID-19, widespread testing and time are of the essence. Cases must be rapidly and reliably diagnosed so that persons who have or have had recent exposure to somebody has the virus know this information and can go into immediate self-isolation before they expose other people. However, current COVID-19 testing technology lacks the necessary scalability, rapidity and reliability to make this possible.

In addition, current COVID-19 screening at the point of care relies on survey questions about symptoms, recent exposure and travel history (and

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in some cases body temperature measurements). These screening methods are primarily based on identifying COVID-19 by its symptoms. However, approximately 40 percent to 45 percent of SARS-CoV-2 infection cases are pre-symptomatic or asymptomatic cases.

Wearables and COVID-19 Diagnosis

The idea of using Fitbit and other wearable devices for diagnostic purposes is nothing new. The Nature study authors claim that Smartwatches and activity trackers can improve the ability to objectively characterize each individual's unique baseline for resting heart rate, sleep and activity and can therefore be used to identify subtle changes in that user's data that may indicate that they are coming down with a viral illness. Previous research indicates that this "method, when aggregated at the population level, can significantly improve real-time predictions for influenza-like illness."

The *Nature* study conducted by researchers from the Digital Engagement and Tracking for Early Control and Treatment (DETECT) is one of the first to consider wearables for COVID-19 diagnosis. The aim was to investigate whether the addition of individual changes in sensor data to symptom data can be used to improve our capability to identify COVID-19-positive versus COVID-19-negative cases among participants who self-reported symptoms.

The Study's Findings

After analyzing data from more than 30,000 participants from March 25 to June 7, 2020, the researchers concluded that adding individual changes in sensor data improves models based on symptoms alone for differentiating symptomatic persons who are COVID-19-positive and symptomatic persons who are COVID-19-negative.

Of the 30,529 participants enrolled, 78.4 percent connected their Fitbit devices to the study app, 31.2 percent connected the data from the Apple HealthKit, while 8.1 percent connected data from Google Fit (as the percentage numbers suggest, some individuals connected to multiple platforms). Among the 3,811 participants who reported that they were experiencing symptoms, 54 reported testing positive and 279 reported testing negative for COVID-19.

The researchers found that individual changes in physiological measures captured by most smartwatches and activity trackers are, in fact, capable of significantly improving the distinction between symptomatic individuals with and without a diagnosis of COVID-19 beyond symptoms alone.

The *Nature* study affirms an earlier study cited by the researchers finding that symptom data in over 18,000 SARS-CoV-2-tested individuals captured via a smartphone-based app was helpful in distinguishing

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DTC: Research Supports Viability of Using Health Data from Consumer Wearables to Diagnose COVID-19, *from page 9*

between individuals with and without COVID-19. Although the *Nature* study results are encouraging, the authors were careful to note that they are based on a relatively small sample of participants.

The Fitbit Study

Wearable makers have also been active in exploring the diagnostic potentials of their products. Before the pandemic, San Francisco-based Fitbit applied its own tracking health and wellness metrics technology to develop an algorithm to detect breathing rate, resting heart rate and other factors. The original intention was to alert users to signs of flu infection. But when the public health crisis began, Fitbit pivoted and adapted the concept for COVID-19.

The algorithm was studied only in a retrospective setting, and there was a need for a prospective study to validate it in a real-world setting. Accordingly, Fitbit recently announced that it is collaborating with Northwell Health's Feinstein Institutes for Medical Research on a study to validate the Fitbit COVID-19 early detection algorithm. The Fitbit study is supported by a $2.5 million award from the U.S. Department of Defense through the medical technology enterprise consortium. The award is part of the consortium's efforts to keep military personnel healthy by detecting the virus before symptoms emerge.

Several thousand frontline and custodial Northwell staffers are expected to participate in the study. Once the study is initiated, enrolled Northwell employees will be given a Fitbit smartwatch. Upon notification of signs of potential illness, they will be given COVID-19 tests for verification.

Takeaway

Momentum for applying wearables health and wellness measuring technology for purposes of widespread, consumer-based COVID-19 diagnostics is building rapidly, as is the scientific evidence to support the validity of the concept. Were it to succeed, the approach of wedding consumer wearables to COVID-19 detection and differentiation could go a long way in resolving the current rapid testing challenge. Moreover, the early research suggests that using data generated by wearables may help identify infection clusters before wider community spread occurs.

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Emerging Tests: Qiagen Launches Portable COVID-19 Antigen Digital Testing Hub

The rapid evolution of COVID-19 testing in response to the need for speed and mobility continues. One notable development on the antigen testing front is Qiagen's U.S. rollout of a portable digital test called QIAreachSARS-CoV-2 Antigen Test that laboratories can use to detect SARS-CoV-2 antigens in people with active infections in two to15 minutes. The company announced its intention to launch the test back in September.

The Qiagen Test

Qiagen, which had been targeted for acquisition by Thermo Fisher Scientific before the pandemic and massive spike in demand for Qiagen's COVID-19 testing products intervened, developed the new antigen in partnership with Australian digital-diagnostics company, Ellume based on the hub-and-stick system the companies originally developed for use in rapid tuberculosis diagnostics. The QIAreach Antigen test contains a rechargeable battery for eight hours of remote use and can connect to laboratory software to record results.

The digital device automates and standardizes analysis of the results, without requiring laboratory staff to manually inspect and record the outcome of each sample. Previous tests of clinical samples have shown a false-negative rate of 10 percent, while delivering zero false positives. The hub can also process antigen and antibody tests side-by-side.

According to Qiagen, the QIAreach Antigen test's capacity to provide digital results for more than 30 swab samples per hour while processing antibody tests in parallel, establishes a new standard for scalability and flexibility. The company believes this to be an important step toward decentralized mass screening by processing samples in a short period.

Takeaway

Qiagen has begun to market and distribute this latest test in the U.S. after filing for Food and Drug Administration emergency use authorization (EUA) for symptomatic patients. CE-IVD registration for the European Union and other markets is expected by the end of the year. The company plans to have the authorization amended before the end of this year to enable its use at the point of care, and it is also pursuing an in vitro diagnostic CE marking in Europe.

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LDTs: HHS Orders FDA to Resume EUA Review of Laboratory Developed Tests for COVID-19, *from page 1*

LDTs. Some of the most innovative and important new COVID-19 tests to receive EUA in the early days of the pandemic were LDTs created by testing companies, universities and medical centers. The demonstrated ability of laboratories to create new COVID-19 tests at a time of desperate need seemed to vindicate the case for relaxing FDA regulation in the interest of innovation and public health.

The other impetus to rapid change was the current administration's policy to cut regulatory red tape for business. Historically protective of its regulatory authority over LDTs, the FDA needed a little prodding to loosen the reins. That prodding came on Aug. 19 when the HHS announced that the FDA would no longer require premarket review for LDTs but that laboratories could still seek EUA voluntarily. In addition, the FDA would now have to use the notice and rulemaking process to create new rules and could no longer regulate LDTs via website notices and other informal methods.

On Oct. 7, the FDA fired back by announcing that it was bowing out of EUA review for any LDTs to "make the best use" of its review resources. The decision applied not just to new submissions but also to LDT EUA applications already in the pipeline.

While supportive of the initial HHS policy, the laboratory industry criticized the FDA response. In a statement, American Clinical Laboratories Association (ACLA) president **Julie Khani** called on the FDA to continue to let laboratories continue to voluntarily seek EUA for COVID-19 LDTs, noting that many of the tests that had already received EUA are precisely the kinds of "innovative, high-throughput [tests] that have reduced reliance on supplies and been integral to expanding testing capacity" that the new FDA policy is purportedly designed to promote.

The New HHS Back to Work Order

The most recent twist came on Nov. 16 when HHS Assistant Secretary for Health and White House coronavirus testing czar **Brett Giroir** ordered the FDA to resume EUA review of COVID-19 LDTs and do it fast. The agency's orders are to clear the backlog of submissions created by its decision to cease review within 14 days. If, as is highly likely to prove the case, the FDA is unable to meet that deadline, the National Cancer Institute (NCI) will step in to help.

"We recognize the FDA has a huge workload," Giroir noted. "That's why we're trying to provide additional resources. I don't think anybody can question the scientific integrity of the NCI."

What Is At Stake

The reason the HHS has chosen to intervene is the fear that laboratories will not create new LDTs for COVID-19 unless they can secure EUA because of potential liability exposure if the product does not work as

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planned. **Explanation:** Normally, new diagnostics and medical products must undergo long and extensive clinical review before they can reach the market. But in times of public health emergency, it becomes necessary to accelerate the standard review protocols. The upside with abbreviated vetting is that products become available faster; the downside is that they carry greater than normal risks to users. Accordingly, producers are at higher risk of being sued for products liability.

To ensure that fear of liability does not chill innovation, a federal law called the *Public Readiness and Emergency Preparedness Act* (PREP) provides immunity to test makers and other producers that create medical products in response to a public health emergency. Thus, the FDA decision not to perform EUA review of LDTs for COVID-19 strips test makers of their PREP immunity and makes them a sitting duck for trial lawyers and products liability lawsuits if something goes wrong with the test.

Giroir acknowledged that this was behind the order for FDA to resume EUA review of COVID-19 LDTs, noting on a media call that "without an EUA, although the tests can be used, they cannot receive liability protection under the PREP Act." Giroir added that the goal is to ensure that universities and other LDT makers are "given the same liability protection as major corporate developers and manufacturers."

Takeaway

Although not cited by HHS, there is another factor that makes the new policy so important and beneficial to makers of COVID-19 LDTs, namely, reimbursement. The Families First Coronavirus Response Act (FFCRA) requires commercial payors to cover medically necessary SARS-CoV-2 testing without cost sharing, but only if those tests have EUA from the FDA. Consequently, laboratories developing new SARS-CoV-2 LDTs without securing EUA status face the prospect of not being reimbursed for their tests.

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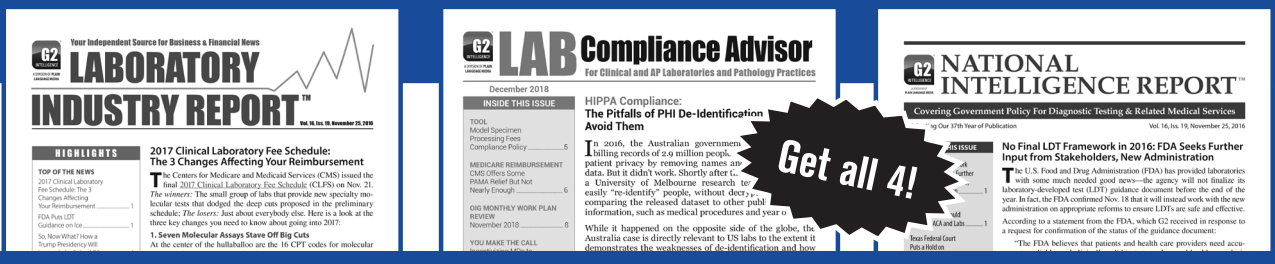

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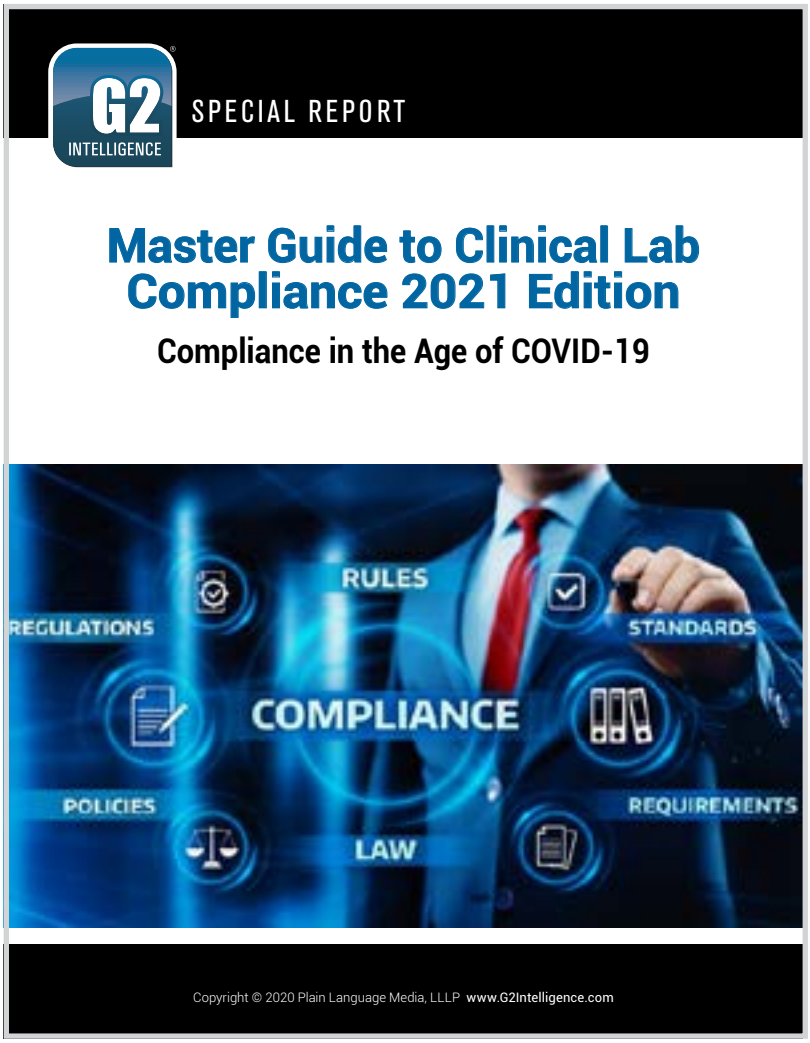

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