G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

# DIAGNOSTIC TESTING & Emerging Technologies

New Trends, Applications, and IVD Industry Analysis

APRIL 2020

## IN THIS ISSUE



G2Intelligence.com

## Emerging Tests: How Laboratories Are Developing New Coronavirus Diagnostic Tests at Record Speed

The criticism leveled at the Food and Drug Administration (FDA) over the lack of diagnostic tests for COVID-19 in the U.S. belies the unprecedented speed with which new coronavirus tests are reaching the market. Admittedly, the agency was slow out of the gate, waiting until early February to put a coronavirus diagnostics strategy into action. But in the roughly six weeks since then, progress has been unprecedented. Here is a look at the FDA's regulatory response and where things stand right now.

### The Historical Context

This is the fifth time the U.S. has declared a public health emergency for an infectious disease. The previous emergencies were for H7N9 influenza, Middle East Respiratory Syndrome

*Continued on page 2*

## The Coronavirus Crisis: Is CT More Effective than Laboratory Testing in Detecting COVID-19?

Could it be that we are barking up the wrong tree in terms of how best to diagnose 2019 novel coronavirus COVID-19? Current U.S. guidelines prioritize laboratory testing over computed tomography (CT) and other types of chest scans to detect COVID-19. However, a recent study from Wuhan, China, ground zero for the pandemic, concludes that CT scans are better at diagnosing COVID-19 and should supplant laboratory testing as the primary method of COVID-19 screening.

### The Diagnostic Challenge

Current laboratory tests for diagnosis of COVID-19 are based on reverse-transcription polymerase chain reaction (RT-PCR) technology involving the application of gene sequencing for

*Continued on page 11*

Emerging Tests: How Laboratories Are Developing New Coronavirus Diagnostic Tests at Record Speed, *from page 1*

(MERS), Ebola, EV-D68 and Zika virus. In each case, the FDA has relied on its EUA pathway to bring new tests to market on a rapid basis. And in each case, the initial EUA went to either the U.S. Centers for Disease Control and Prevention (CDC) or Department of Defense, typically within a week of the emergency's being declared.

The government tests were designed as a stopgap measure offering immediate relief until commercial laboratories could get EUA clearance for their own tests. But that took at least two months, as illustrated by the table below.

**Time Lag between Emergency Declaration & Approval of Commercial Laboratory Test**

| Infectious Disease | Emergency Declared | First Commercial Test EUA |
|---|---|---|
| Ebola | Aug. 5, 2014 | Oct. 10, 2014 (BioFire Diagnostics) |
| Zika | Feb. 26, 2016 | April 28, 2016 (Quest) |
| MERS | May 29, 2013 | July 17, 2015 (Altona Diagnostics) |

## The Initial FDA COVID-19 Response

Initially, the FDA response to COVID-19 followed the same path as the previous outbreaks. Thus, on Feb. 4, within days after the emergency was declared on Jan. 31, the agency issued its first approval for a coronavirus test to the CDC's reverse transcriptase real-time PCR (rRT-PCR) assay. The so called 2019 Real Time RT-PCR Diagnostic Test Panel was approved for use only by CDC-designated laboratories certified to perform high-complexity testing in accordance with agency protocol.

As before, the strategy was for the CDC assay to hold down the fort until commercial tests arrived. The CDC distributed test kits to state health departments and public health laboratories around the country. But reagent, instrumentation and laboratory staff shortages, coupled with questions about the test's reliability in ruling out infection, made the pace of commercial test development frustratingly slow. Adding to the problem was the fact that unlike in previous outbreaks in which the pathogen was familiar to laboratory scientists, SARS-CoV-2 was something totally novel.

## The New Pathway

Facing these obstacles and an acceleration of the COVID-19 crisis, the FDA made a crucial and unprecedented pivot in strategy. After initially rejecting the idea, the agency announced on Feb. 29 that it would allow high-complexity CLIA laboratories to develop and start using validated coronavirus tests before it even completes review of their EUA applications. High-complexity laboratories would be required to strictly follow CDC testing protocols, notify the FDA of test validation and submit a complete EUA request within 15 days after validation.

DTET

Glenn S. Demby, Executive Editor

Barbara Manning Grimm, Managing Editor

Jim Pearmain, General Manager

Andrea Stowe, Business Development

Pete Stowe, Managing Partner

Mark T. Ziebarth, Publisher



***Diagnostic Testing and Emerging Technologies*** (ISSN 2330-5177) 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.

The new strategy of test-now-get-approval-later effectively mobilized the 300 to 400 high-complexity laboratories across the country in the campaign to deliver immediate testing relief, including LabCorp, which launched its LabCorp 2019 Novel Coronavirus (COVID-19) NAA test on March 6. Like the EUA tests, the LabCorp assay uses PCR technology to qualitatively detect the SARS-CoV-2 virus from respiratory samples collected at the point of care. Other major high-complexity laboratories that have or are in the process of gaining EUA clearance through this novel pathway include Quest Diagnostics, BioReference Laboratories (part of Opko Health) and Enzo Biochem.

## Expansion of the New Pathway

On March 16, the FDA extended the strategy of allowing laboratories to rapidly offer validated tests while simultaneously pursuing EUA clearance beyond high-complexity laboratories to commercial manufacturers, such as Roche and Hologic (both of which have received EUAs for coronavirus test kits). As with high-complexity laboratories, manufacturers are required to notify the FDA of assay validation and submit an EUA within 15 days.

## Takeaway

*While not without risk, the new FDA strategy of loosening up the pre-approval rules in the interest of deliver rapid testing is clearly working. As of March 20, 10 SARS-CoV-2 detection tests have gained EUA clearance, including six in the previous week. And that number is literally increasing by the hour with many more assays in the pipeline.*

**CORONAVIRUS TESTS WITH FDA EMERGENCY USE AUTHORIZATION** (as of March 20) (in chronological order of EUA approval date)

- **US Centers for Disease Control and Prevention:** 2019-nCoV Real-Time RT-PCR Diagnostic Panel to detect coronavirus
- **New York State Department of Public Health:** New York SARS-CoV-2 RT-PCR Diagnostic Panel for emergency use by public laboratories in the state
- **Roche:** Cobas SARS-CoV-2 Test for qualitative detection in nasopharyngeal and oropharyngeal swab samples
- **Thermo Fisher Scientific:** TaqPath COVID-19 Combo Kit for qualitative detection of SARS-CoV-2 nucleic acid in nasopharyngeal swab, nasopharyngeal aspirate and bronchoalveolar lavage specimens
- **Hologic:** Panther Fusion SARS-CoV-2 assay for use on firm's Panther Fusion, which can provide results in less than three hours and process up to 1,150 coronavirus tests in 24 hours

*Continued on page 4*

Emerging Tests: How Laboratories Are Developing New Coronavirus Diagnostic Tests at Record Speed, *from page 3*

- **Quidel:** Lyra SARS-CoV-2, RT-qPCR assay for qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal or oropharyngeal swab specimens
- **Abbott:** Abbott RealTime SARS-CoV-2 EUA run on firm's PCR-based m2000 RealTime System
- **Quest Diagnostics:** SARS-CoV-2 rRT PCR test
- **GenMark Diagnostics:** ePlex SARS-CoV-2 Test for qualitative detection in nasopharyngeal swab samples used on firm's sample-to-answer ePlex system
- **DiaSorin Molecular:** Simplexa COVID-19 Direct assay run on firm's sample-to-answer Liason MDX real-time PCR instrument

# FDA WATCH

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

## SARS-CoV-2 Detection Assays Highlight List of Key New Product Approvals

Key new U.S. Food and Drug Administration product approvals announced from mid-February 2020 through March 20, 2020 include emergency use authorization (EUA) for eight different commercial tests for qualitative detection of the SARS-CoV-2 virus in patients showing symptoms of or suspected of having coronavirus.

## FDA Finalizes CLIA Waiver Guidance for Approval of New In Vitro Diagnostic Devices

On Feb. 25, the FDA issued a pair of final guidances to help manufacturers seeking clearance for new in vitro diagnostic devices. Here is a summary of the key points from each guidance.

### CLIA Waivers

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

- **Tier 1: Risk Analysis and Flex Studies.** Sponsors should conduct a systematic and comprehensive risk analysis identifying all potential

sources of error, including test system failures and operator errors, and which of these errors can lead to a risk of a hazardous situation; and

- **Tier 2: Fail-Safe and Failure Alert Mechanisms.** Sponsors should also identify the control measures, including fail-safe and failure alert mechanisms that will reduce risks for each of the sources of error they identify. Then, once the control measures have been implemented, they should (1) verify that each control measure has been properly implemented, and (2) verify and/or validate the effectiveness of each control measure.

## Dual 510(k) and CLIA Waiver Submissions

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

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

## New FDA Approvals

Key new product approvals announced from mid-February 2020 through March 20, 2020 include emergency use authorization (EUA) for eight different commercial tests for qualitative detection of the SARS-CoV-2 virus in patients showing symptoms or suspected of having coronavirus:

| Manufacturer(s) | Product(s) |
|---|---|
| Roche | EUA for Cobas SARS-CoV-2 Test for qualitative detection |
| Thermo Fisher Scientific | EUA for TaqPath COVID-19 Combo Kit for qualitative detection of SARS-CoV-2 nucleic acid |
| Hologic | EUA for Panther Fusion SARS-CoV-2 assay for use on firm's Panther Fusion system |

*Continued on page 6*

FDA WATCH: A roundup of recent cases, enforcement actions and stories involving the diagnostics industry, *from page 5*

| Manufacturer(s) | Product(s) |
|---|---|
| Quidel | EUA for Lyra SARS-CoV-2, RT-qPCR assay for qualitative detection of nucleic acid from SARS-CoV-2 |
| Abbott | EUA for Abbott RealTime SARS-CoV-2 EUA run on firm's PCR-based m2000 RealTime System |
| Quest Diagnostics | EUA for SARS-CoV-2 rRT PCR test |
| GenMark Diagnostics | EUA for ePlex SARS-CoV-2 Test run on firm's sample-to-answer ePlex system |
| DiaSorin Molecular | EUA for Simplexa COVID-19 Direct assay run on firm's sample-to-answer Liason MDX real-time PCR instrument |
| Meridian Bioscience | Clearance for Curian analyzer and Curian HpSA assay using immunofluorescent technology to detect Helicobacter pylori antigens in stool samples |
| Roche | Clearance for CINtec Plus Cytology test to assess risk of cervical cancer in women with HPV infections |
| Roche | Breakthrough device designation for Elecsys Galad score to diagnose early-stage hepatocellular carcinoma |
| Roche | Clearance for Cobas Influenza A/B and RSV nucleic acid test running on firm's Cobas Liat |
| Roche | Clearance for Tina-quant C-Reactive Protein IV test for measuring C-reactive protein in serum and plasma on firm's Cobas c systems |
| MFB Fertility | Clearance for Proov at-home progesterone ovulation test |
| Abbott | Clearances for i-Stat Chem8+ cartridge running on iStat 1 system for measuring:<br>*Glucose and creatinine<br>*Hematocrit (for determining total red cell volumes)<br>*Sodium, potassium, chloride and blood urea nitrogen |
| Siemens Healthineers | Clearance for Advia Centaur BR assay to measure cancer antigen CA 27.29 using the Advia Centaur systems |
| BioMérieux | Clearance for marketing Vitek 2 AST-GN Polymyxin B quantitative assay for antimicrobial susceptibility testing of Gram-negative bacilli |
| ARK Diagnostics | Clearance for ARK Fentanyl II immunoassay to measure fentanyl in human urine at a cutoff concentration of 1.0 ng/mL on automated clinical chemistry lab analyzers |
| Ortho Clinical Diagnostics | 510(k) clearance for Vitros BRAHMS procalcitonin assay to identify bacterial infections |
| Kurin | Clearance for novel push-button needle |

# Testing Trends: USPSTF Recommends Hepatitis C Virus Infection Screening for All Adults

In response to a spike in hepatitis C virus (HCV) infection cases among young adults, the U.S. Preventive Services Task Force (USPSTF) revised its guidance and is now recommending that *all* adults, not just older ones get HCV screening.

## HCV Testing Trends

The last time the USPSTF issued HCV screening guidance was back in 2013 when adults born between 1945 and 1965 accounted for an estimated three-fourths of HCV infections. Accordingly, the guidance recommended screening only for adults in that high-risk group. However, the incidence of HCV infection has grown roughly 3.8-fold between 2010 and 2017. Growth in the infection rate has particularly affected younger people, especially intravenous drug users in the age range of 20 to 39. Other the that have been hit hard include American Indian/Alaskan Native and non-Hispanic white populations, according to the USPSTF.

The other significant development that prompted the organization to revisit its 2013 guidance is the availability of highly effective direct-acting antiviral (DAA) treatments that produce higher rates of sustained virologic response with fewer serious side effects than previous interferon-containing therapies.

## The USPSTF Evidence Review

In response to these post-2013 developments, the USPSTF commissioned a systematic evidence review to address, among other issues:

- Whether HCV screening of adolescent and adults without abnormal liver enzyme levels reduces disease-related mortality;
- The effectiveness of different risk- or prevalence-based methods for screening on clinical outcomes;
- The yield of one-time versus alternative screening strategies for HCV infection;
- The potential harms of screening and antiviral treatments;
- The effects of interventions during childbirth;
- The effectiveness of currently recommended antiviral treatments in improving patient outcomes and achieving a sustained virologic response; and
- The association between a sustained virologic response following antiviral treatment and a reduction in the risk of HCV-related adverse health outcomes.

In addition to being wider ranging than the evidence review preceding the 2013 HCV screening guidance, the latest review also included adolescents.

*Continued on page 8*

Testing Trends: USPSTF Recommends Hepatitis C Virus Infection Screening for All Adults, *from page 7*

The review found that all-oral DAA regimens were associated with sustained virologic response rates greater than 95 percent with few short-term harms compared with older therapies, and that such a response was associated with improved clinical outcomes compared with no response.

The review also found that screening remains highly accurate and that there were no observable differences in yield between repeat versus one-time screening or alternative screening strategies such as ones based on risk.

Also critical to the review were modeling studies indicating that expanded screening strategies would be beneficial, including one hypothetical cohort showing that screening all people in the U.S. ages 18 and older would identify approximately 256,000 additional HCV cases and result in an estimated 280,000 additional individuals achieving sustained virologic responses.

### The New USPSTF Screening Guidance

The revised guidance, which were published in the March 16 issue of the *Journal of the American Medical Association*, broaden previous guidelines by recommending one-time screening in asymptomatic individuals ages 18 to 79, along with periodic screening for individuals at continued risk for HCV infection. More precisely, the USPSTF issued a B grade recommendation for HCV screening for all individuals 18 years and older. The grading indicates a high certainty of a moderate net benefit or a moderate certainty that the net benefit is moderate to substantial.

### Takeaway

*Keep in mind that the USPSTF guidelines and specifically the B grade for broader HCV screening, carry significant weight with not only providers but also payors. One big reason for that the Affordable Care Act requires private insurers and Medicaid to cover preventive services with no cost sharing if they are recommended by the USPSTF with a grade of A or B.*

## Genetic Tests: New NCCN Recommends Biomarker Prostate Cancer Testing for Intermediate & High-Risk Men

With all the COVID-19 hullabaloo, a potentially significant development in genetic prostate cancer testing has flown under the radar. It happened on March 16, when the National Comprehensive Cancer Network (NCCN) revised its prostate cancer guidelines by recommending molecular testing for patients with unfavorable intermediate or high risk for aggressive disease.

### The New NCCN Guidelines

Previously, the NCCN has "not routinely recommended" molecular testing for intermediate- and high-risk patients. However, the revised guidelines say that men with unfavorable intermediate-risk and high-risk disease with a life expectancy of 10 years or longer should consider the use of biomarker tests that gauge the aggressiveness of a patient's cancer. The NCCN specifically names two commercial tests for patients to consider:

- The Prolaris test from Myriad Genetics; and
- The Decipher test from GenomeDx Biosciences.

Prolaris and Decipher were also on the list of tests that might also be worthy of consideration for men who have low-risk or favorable intermediate-risk disease and life expectancy of 10 years or longer. Others included:

- The Oncotype DX Prostate Test from Exact Sciences/Genomic Health; and
- ProMark from Dianon Pathology.

### Takeaway

*What prompted the NCCN to change its mind? Part of the answer might be suggested by the statement Myriad issued after the announcement of the guidelines update noting that recently presented data from a study involving more than 700 men demonstrated that Prolaris could predict whether a man would benefit from multi-modality therapy or if he could avoid aggressive treatment.*

## PAMA: COVID-19 Relief Bill Defers 2021 Medicare Part B Lab Test Price Cuts for One Year

The $2 trillion COVID-19 relief bill, CARES (Coronavirus Aid, Relief and Economic Security Act), provides for free coronavirus testing without adequately compensating the labs who perform the tests. But it's also not totally devoid of financial relief, including a badly needed—albeit temporary—respite from the next round of PAMA Part B lab test price cuts.

### Labs Shortshrifted on Immediate, Direct Relief . . .

Under CARES, insurers must pay for COVID-19 tests without imposing cost sharing charges. And with patients out of the picture, payors will seek to alleviate their costs out by reducing reimbursement to testing labs. This leaves labs in what the American Clinical Laboratory Association describes as "an untenable situation, absorbing growing, uncompensated costs for

*Continued on page 10*

PAMA: COVID-19 Relief Bill Defers 2021 Medicare Part B Lab Test Price Cuts for One Year, *from page 9*

testing specimens with no assurance that they will be appropriately or fairly reimbursed for all the tests they are performing."

Regrettably, CARES doesn't do much to alleviate this situation. Instead of the $5 billion the industry requested for direct support, testing labs will have to get what they can from the allocated $100 billion for hospitals, $11 billion for diagnostics, treatments and vaccines and $16 billion for the Strategic National Stockpile via the Public Health and Social Services Emergency Fund.

### . . . But Get a Bit of Relief from PAMA

To make up for the relative lack of direct financial support, CARES provides labs a bit of relief on the PAMA front. In 2021, the reduction cap, i.e., maximum amount by which CMS could reimbursement for Medicare Part B lab tests was scheduled to rise to 15% in 2021. But CARES puts the cap rise and resulting reimbursement cuts on hold for one year. And given how the political tide had been turning in the lab industry's favor before the COVID-19 crisis, that extra year may prove extremely valuable down the road.

The Coronavirus Crisis: Is CT More Effective than Laboratory Testing in Detecting COVID-19?, *from page 1*

qualitative detection of the SARS-CoV-2 virus that causes the disease from nasopharyngeal and oropharyngeal swab samples of patients showing symptoms or suspected of having coronavirus.

However, there are a number of problems with RT-PCR technology, including its low sensitivity which impairs its effectiveness in detecting the virus. As a result, while a positive test is a reliable indication of infection, a negative test is not a conclusive indication that a patient does not have it. Accordingly, the CDC and US Food and Drug Administration (FDA) are advising physicians not to rule out COVID-19 infection on the basis of a negative test alone but to do so only after evaluating other factors, including clinical observations, the patient's medical history and epidemiological information.

CT scans, by contrast, are not subject to these same limitations. A CT scan allows doctors to see inside the body. Using a combination of X-rays and a computer to create pictures of organs, bones, and other tissues, it provides much more detail than a regular X-ray. This, coupled with the fact it is fast and relatively easy to perform, make chest CT, a routine imaging tool for pneumonia diagnosis.

The question then becomes: Do these same qualities make chest CT a better method for diagnosing COVID-19?

## The Wuhan Study

With this question in mind, researchers at Tongji Hospital in Wuhan, China, set out to investigate the diagnostic value and consistency of chest CT imaging in comparison to RT-PCR assay in COVID-19 detection. They evaluated 1,014 patients who underwent both chest CT and RT-PCR tests between January 6 and February 6, 2020.

The study, which was published in the journal *Radiology*, found that the sensitivity of CT for COVID-19 infection was 98%, compared to 71% sensitivity of RT-PCR. Specifically, the study results showed that:

- 601 patients (59%) had positive RT-PCR results;
- 888 patients (88%) had positive chest CT scans;
- The sensitivity of chest CT in suggesting COVID-19 was 97%, based on positive RT-PCR results;
- Among patients with negative RT-PCR results, 75% (308 of 413 patients) had positive chest CT findings; and
- Of the patients with negative RT-PCR results that had positive CT chest findings, 48% were considered as highly likely cases and 33% as probable cases.

After conducting analysis serial RT-PCR assays and CT scans, the researchers found that the interval between the initial negative to positive RT-PCR results was four to eight days. And of course, 96 hours of not being in isolation or quarantine despite having the virus would be ample time to infect other people.

**Bottom Line:** Based on these findings, the researchers concluded that CT rather RT-PCR laboratory tests should be used as the primary screening tool for COVID-19. "Early diagnosis of COVID-19 is crucial for disease treatment and control," the researchers wrote. "Compared to RT-PCR, chest CT imaging may be a more reliable, practical and rapid method to diagnose and assess COVID-19, especially in the epidemic area."

## Conflict with COVID Diagnostic Recommendations in the US

As of March 19, 2020, some medical practices are actually using chest CT to inform decisions on whether to test a patient for COVID-19; but they are doing so only as an interim measure until more widespread COVID-19 laboratory testing becomes available. The Wuhan study's conclusion that CT be the primary method of COVID-19 detection conflicts directly with current U.S. medical guidelines, including those from the Centers for Disease Control and Prevention (CDC) and the American College of Radiology (ACR), neither of which recommends that CT scan be used as the primary screening or detection method for COVID-19.

Both organizations question the reliability of CT. According to the CDC, a normal chest CT does not mean a person does not have COVID-19 infection and should not dissuade a patient from being quarantined;

*Continued on page 12*

The Coronavirus Crisis: Is CT More Effective than Laboratory Testing in Detecting COVID-19?, *from page 11*

similarly, an abnormal CT is not specific for diagnosis. Another problem with use of CT scans for COVID-19 detection is that it exposes testers and subsequent patients who get scans in the same location or via use of the same equipment to infection risk.

Accordingly, the CDC has declined to endorse CT or chest radiographs (CXR) to diagnose COVID-19, and maintains that viral laboratory testing remains the only specific method of diagnosis. Even when radiologic findings are suggestive of COVID-19, the CDC requires that they be confirmed via viral testing.

The ACR also recommends not using CT to screen for or as a first-line test to diagnose COVID-19. Specifically, the organization says that:

- CT should be used sparingly and reserved for hospitalized, symptomatic patients with specific clinical indications for CT and that appropriate infection control procedures be followed before scanning subsequent patients;
- Facilities may consider deploying portable radiography units in ambulatory care facilities for use when CXRs are considered medically necessary to the extent the surfaces of these machines can be easily cleaned, avoiding the need to bring patients into radiography rooms; and
- Radiologists should familiarize themselves with the CT appearance of COVID-19 infection so as to be capable of identifying findings consistent with infection in patients imaged for other reasons.

## Takeaway

*The clinical basis of the U.S. COVID-19 response is that laboratory testing, while flawed, remains the safest and most reliable method of detecting the disease. However, it is food for thought that empirical experience from Wuhan, China, directly challenges that premise and suggests that another diagnostic method, namely CT and chest scans, may be much more effective in determining whether a patient has or does not have COVID-19.*

G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

# DIAGNOSTIC TESTING & Emerging Technologies

New Trends, Applications, and IVD Industry Analysis

## Important Notice: G2 Intelligence Moves to Digital-Only Publishing Format

As you know, American business is being hit hard by the COVID-19 pandemic.

The impact upon the publishing and media industry, and our critical suppliers and vendors, is growing increasingly severe. We are uncertain of our ability to continue to produce and deliver print versions of our publications, and we see no clear timeframe for resolution.

Therefore, G2 Intelligence has made a decision to move to a Digital-Only publishing format for the immediate future. All G2 newsletters, reports, and other information services will continue to be available in digital format to help support the lab industry during this crisis, but print versions will be discontinued.

Accessing your G2 products digitally (email, pdf, website, and other electronic formats) has many advantages, including more rapid distribution of important content, access to archives, and a content-rich website that offers many additional special features and benefits for our Members.

### Additional improvements will be phased in over the coming months.

Fortunately, most of our Members already receive their G2 publications digitally. If you are already a digital Member, there will be no visible impact upon your service. But if you receive your publications print only, we need your email address to convert you to digital distribution. If you receive multiple copies, we need the email addresses of all those in your organization who are members so they continue to receive their product. A G2 representative will be in touch with all our print only Members to help you make an easy transition and answer any questions.

If you have any questions,or you wish to update your email information, please contact **Andrea** at **888-729-2315, ext 316**.