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HIGHLIGHTS

Emerging Tests: Inside the FDA's Four-Armed COVID-19 Test Response Strategy

What started as the traditional Emergency Use Authorization (EUA) response deployed by the FDA for previous infectious illness outbreaks has rapidly evolved into something altogether different and unprecedented featuring four different and parallel pathways. Until now, those pathways were revealed one at a time on a piecemeal basis. But on March 25, the agency assembled all of the pieces into a single framework while providing new guidance on how each of them works. The clarification came during a webinar provided by CDRH associate director **Elizabeth Hillebrenner**. Here's the lowdown.

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Diagnostic Deals: Labs, Universities and Even Computer Companies Target Point-of-Care COVID-19 Test Development

The imperative to create and provide tests capable of detecting the SARS-CoV-2 virus that causes COVID-19 coronavirus continues to fuel strategic deal making. SARS-CoV-2 point-of-care tests was the objective of three of the key strategic collaborations during the period, including the creation of Corona Diagnostics, a new joint venture between Todos Medical and Emerald Organic Products that will seek FDA approval for a rapid point-of-care kit called Colloidal Gold. A week earlier, Todos announced that it had entered into an exclusive agreement to distribute Colloidal Gold in the US and Israel.

Most of the point-of-care SARS-CoV-2 tests in the pipeline are based on technology that detects the antibodies the body creates to fight off the virus. But one of the new ventures

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Policy A

The pathway the agency calls "Policy A" is for high-complexity CLIA labs seeking to launch validated SARS-CoV-2 laboratory-developed tests, including molecular tests, or antigen or antibody tests. Breaking from previous practice, the FDA is letting labs perform those tests immediately after internal validation without an EUA as long as they notify the agency and apply for an EUA within 15 days. Hillebrenner says the agency had received 98 notifications from labs running LDTs to date.

Policy B

First unveiled on March 16, "Policy B" allows states to authorize tests to be performed in high-complexity CLIA labs within their jurisdictions. Again, the tests can be run immediately after internal validation and notification to the FDA with no EUA. But unlike Policy A tests, Policy B tests don't require a subsequent EUA. According to Hillebrenner, four states—New York, Washington, Nevada and Maryland—have notified the FDA of their intent to follow the Policy B pathway.

Policy C

Policy C is the Policy A counterpart for commercial manufacturers of COVID-19 tests, allowing test makers to launch tests upon validation with an EUA, provided that they notify the FDA immediately and submit an EUA application within 15 business days. Policy C covers molecular, antigen and antibody tests that can be used in clinical labs and at the point-of-care, but not tests intended to be used at home. Hillebrenner says that four manufacturers have notified the FDA that they're distributing kits under the Policy C path so far: Becton Dickinson, Qiagen, BGI and Co-Diagnostics.

Policy D

Policy D covers antibody-based serology tests, whether the source is a commercial manufacturer or a high-complexity lab. These tests can be used on patients immediately after validation without the need to apply for an EUA. Over a dozen test developers are pursuing the Policy D pathway.

EUA Updates

As of March 27, the FDA had granted 15 EUAs for COVID-19 tests.

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COVID-19 TESTS WITH FDA EMERGENCY USE AUTHORIZATION
(as of March 27) (in chronological order of 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
- **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
- **Cepheid:** Xpert Xpress SARS-CoV-2 (first point-of-care COVID-19 test receiving EUA)
- **Primerdesign:** COVID-19 Genesig Real-Time PCR assay
- **Mesa Biotech:** Accula SARS-CoV-2 test
- **BioMérieux:** BioFire COVID-19 test
- **PerkinElmer:** New Coronavirus Nucleic Acid Detection Kit

(See "FDA Watch" on page 4 for a list of all new tests receiving FDA approval this month)

FDA WATCH

The Month in Global New Diagnostic Test Approvals

In addition to Emergency Use Authorization clearances for 15 COVID-19 tests (see page 2 for a list of the tests), the FDA cleared a number of other non-coronavirus tests via its standard pathways. Here's the rundown of key new approvals announced during March 2020.

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Life Technologies (Thermo Fisher Scientific)	Clearance for Applied Biosystems 3500 Dx Genetic Analyzer and Applied Biosystems 3500xL Dx Genetic Analyzer
Magnolia Medical Technologies	Clearance for expanded Steripath Gen2 Initial Specimen Diversion Device line of blood contamination reduction products
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: *Glucose and creatinine *Hematocrit (for determining total red cell volumes) *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

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Euroimmun (part of PerkinElmer)	CE marking for Anti-SARS-CoV-2 ELISA tests for immunoglobulin classes A and G
Thermo Fisher Scientific	CE marking for COVID-19 diagnostic test
DiaCarta	CE marking for QuantiVirus SARS-CoV-2 test
AusDiagnostics	CE marking for multiplex PCR assay for SARS-CoV2, influenza and respiratory syncytial virus (RSV)
Vision Medicals	CE-IVD marking for SARS-CoV-2 Clinical Sequencing assay
3D Medicine Science & Technology	CE marking for SARS-CoV-2 and Influenza A&B RT-qPCR detection kit
Qiagen	CE marking for QiaStat-Dx Respiratory SARS-CoV-2 Panel to detect and differentiate SARS-CoV-2 and 21 other respiratory pathogens
Credo Diagnostics Biomedical	CE marking for assay to detect SARS-CoV-2
Genematrix	CE-IVD certification for Neoflex COVID-19 kit
CerTest BioTec	CE marking for ViaSure SARS-CoV-2 Real Time PCR Detection Kit
Genomica	CE marking for COVID-19 (SARS-CoV2) diagnostic kits
BGI	CE-IVD marking Real-Time Fluorescent RT-PCR kit for detecting SARS-CoV-2
EliTech Group	CE marking for GeneFinder COVID-19 RealAmp kit
Snibe Diagnostic	CE marking for Maglumi 2019-nCoV (SARS-CoV-2) IgM/IgG kits
Co-Diagnostics	CE-IVD marking for Logix Smart Coronavirus COVID-19
GenoScreen	CE-IVD marking for Deeplex Myc-TB kit for tuberculosis antibiotic susceptibility and resistance
DxTerity Diagnostics	CE marking for DxCollect at-home fingerstick blood collection device for RNA and DNA testing

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Fosun Pharmaceutical	China	National Medical Products Administration emergency approval for SARS-CoV-2 detection kit
A*STAR and Tan Tock Seng Hospital	Singapore	Health Sciences Authority provisional approval for SARS-CoV-2 test

M&A Report: Thermo Fisher $11.5 Billion Qiagen Blockbuster Highlights Huge Strategic Month

Deals weren't plentiful in March and, not surprisingly tailed off as the COVID-19 crisis deepened. But the deals that did occur were massive in significance, highlighted by what in normal times would have been the diagnostics business story of the month. It happened on March 3, 2020, when Thermo Fisher Scientific announced plans to acquire molecular

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M&A Report: Thermo Fisher $11.5 Billion Qiagen Blockbuster, *from page 5*

diagnostics and pharmaceutical research powerhouse Qiagen for $11.5 billion. Although it came on the heals of Qiagen's public determination to spurn would-be acquisition partners and go it alone, rumors of a takeover had been swirling since last October when long-time Qiagen CEO **Peer Schatz** tendered his resignation.

Terms of the Deal

Under the deal, which is slated to close in 2021 subject to regulatory approval and the usual closing conditions, Thermo Fisher will pay $43.35 per share of Qiagen common stock, a premium of roughly 23% above the closing price on the Frankfurt Prime Standard on March 2, the trading day before the deal was announced. Thermo Fisher will also assume approximately $1.4 billion of net debt from Qiagen.

Thermo Fisher also provided additional details about the terms regarding what happens if the deal falls through, which assume critical importance in light of the COVID-19 situation. Each side is on the hook to the other for termination payments depending on why the deal is terminated. Under one set of scenarios, Qiagen would have to pay Thermo Fisher $367 million in cash; another set of scenarios would obligate Thermo Fisher to give Qiagen a reverse termination cash payment of $575 million.

The Business Strategy

"This acquisition provides us with the opportunity to leverage our industry-leading capabilities and R&D expertise to accelerate innovation and address emerging healthcare needs," noted Thermo Fisher Chairman, President and CEO **Marc Casper** in a statement. In addition to its $1.53 billion in 2019 revenues, Qiagen's principal allure are its infectious disease and other molecular test products, which will significantly expand Thermo Fisher's own specialty diagnostics portfolio. In his statement, Casper cited specific Qiagen products, including its:

Quantiferon-TB Gold Plus latent tuberculosis detection test, which will bolster Thermo Fisher's own allergy, autoimmunity and transplant diagnostics tests; and

QiaSymphony platform for molecular infectious disease testing, and QiaStat-Dx syndromic testing system, which will complement Thermo Fisher's gene analysis technologies.

Qiagen's sample prep technologies, assays and bioinformatics solutions will fit nicely within the Thermo Fisher life sciences suite.

Exact Sciences Makes a Move

Coming off its recent merger with Genomic Health, Exact Sciences was also active with a pair of acquisitions designed to expand its genetic cancer testing footprint beyond its signature Cologuard test, including of:

- Paradigm Diagnostics, the producer of a solid tumor sequencing test that recently received a Medicare local coverage determination from Medicare Administrative Contractor Palmetto; and
- Viomics, a molecular diagnostics company specializing in biomarker selection for cancer diagnostics.

xact didn't disclose the price of either acquisition but did indicate that it paid stock for Paradigm and will pay a combination of cash and stock for Viomics.

Invitae Takes Aim at Myriad Genetics

The other big M&A story of the month was Invitae's shopping spree consisting of three strategic purchases, the most significant of which was the $95 million acquisition of Diploid, a Belgian firm that manufactures Moon, AI software for diagnosing genetic disorders from gene sequencing. Invitae's addition of Diploid's pharmacogenetic assets throws down the gauntlet to Myriad Genetics, which has strong new direct competition in the hereditary cancer risk and non-invasive prenatal testing market.

Here's a summary of the key M&A diagnostic deals announced from late February through March:

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Thermo Fisher Scientific	Qiagen	• Price: $11.5 billion • Status: Expected to close in 2021 • Qiagen molecular test products expand TF's specialty diagnostics • Qiagen with sample prep technologies, assays and bioinformatics solutions complement TF's life sciences products
Invitae	YouScript	• Price: $79.3 million, including $25 million cash + balance in Invitae common stock • Status: No closing date announced • Acquisition of provider of support platform that helps physicians manage patients' medications in accordance with genetic test results
Invitae	Genelex	• Price: $20.7 million in Invitae common stock • Status: No closing date announced • Acquisition of pharmacogenetic testing firm
Invitae	Diploid	• Price: $95 million, including $32 million cash + $63 million in Invitae common stock • Status: Closed • Invitae gains new pharmacogenetic capabilities via acquisition of Belgian maker of AI software for diagnosing genetic disorders from gene sequencing

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M&A Report: Thermo Fisher $11.5 Billion Qiagen Blockbuster, *from page 7*

Acquiring Company	Target(s)	Deal Summary
Exact Sciences	Paradigm Diagnostics	• Price: Undisclosed (at least partially stock) • Status: Closed • Acquisition of producer of solid tumor sequencing test that recently received a Medicare local coverage determination from Palmetto
Exact Sciences	Viomics	• Price: Undisclosed (cash + stock) • Status: Closed • Exact acquires molecular diagnostics company specializing in biomarker selection for cancer diagnostics
Yourgene Health	AGX-DPNI	• Price: €2.4 million ($2.7 million) cash + up to €1.7 million ($1.87 million) in cash earn-out payments based on sales growth performance • Status: No closing date announced • Yourgene acquires its current distribution partner for Iona noninvasive prenatal test in France
Abcam	Marker Gene Technologies	• Price: Undisclosed • Status: No closing date announced • Abcam acquires Oregon-based life sciences research tools firm
Fluidigm	InstruNor	• Price: $7.2 million, including $5.2 million cash + $2 million in stock • Status: Closed • Norwegian provider of integrated sample preparation systems for flow and mass cytometry to become part of Fluidigm's mass cytometry business

Industry Buzz: COVID-19 Relief Bill Leaves Labs Out in the Cold

Labs who have answered the call to mobilize beyond capacity so that people can be tested for COVID-19 can be forgiven for thinking nobody in Washington "CARES" about them. What else are they supposed to feel when the new $2 trillion COVID-19 relief bill, CARES (Coronavirus Aid, Relief and Economic Security Act), doesn't include the financial support they need to answer the public call. But while CARES is a massive disappointment, it does toss labs a few crumbs.

First, the Bad News

The CARES Act requires private insurers to cover all COVID-19 testing, including tests still awaiting emergency use authorization from the FDA (see the related story on page 4), without patient cost sharing. While laudable, Congress' desire to make COVID-19 tests available to Americans free of charge is devoid of reality. After all, making businesses give away their goods and services is hardly the formula for sustainable success, let alone survival. So, it's hardly a surprise that American Clinical Laboratory Association (ACLA) President **Julie Khani** issued a statement noting that labs "remain in an untenable situation, absorbing growing,

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

But the lawmakers didn't heed the warning. The ban on patient cost sharing remains and the offsetting CARES emergency funding relief for labs is well short of the $5 billion the ACLA requested, leaving labs to get what they can from:

- $11 billion for diagnostics, treatments and vaccines and $16 billion for the Strategic National Stockpile via the Public Health and Social Services Emergency Fund; and
- $80 million to the FDA for treatments, vaccines and diagnostics.

The other big pile of CARES relief money on the table is the $100 billion slated for hospitals. Presumably, at least some of that will go for testing.

Next, the Good News

What the lab industry does get from CARES is 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.

Diagnostic Deals: Urgent Need for Coronavirus Diagnostics Fuels Strategic Collaboration, *from page 1*

unveiled this month pairs North Carolina vaccine maker Heat Biologics with the University of Miami that uses isothermal amplification technology to detect viral nucleic acids. According to test codeveloper **Sylvia Daunert**, chair of biochemistry and molecular biology at the University of Miami Miller School of Medicine, "unlike tests that detect antibodies (IgG and IgM method), which can take weeks to manifest, our test is being developed to utilize molecular recognition and amplification of the target virus. This should allow for much earlier detection—within a couple days of exposure—providing critical and time-sensitive information to help curb the spread of the disease."

One of the more unusual new COVID-19 collaborations is the alliance among BGI Genomics, part of the Guangdong, China-based BGI Group that has played a leading role in coronavirus test development, and computer technology firms Intel and Lenovo. The strategy is to leverage the latters' computational and genomic analysis expertise and technologies, including a high-performance computing cluster to process

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Diagnostic Deals: Urgent Need for Coronavirus Diagnostics Fuels Strategic Collaboration, *from page 9*

reads from BGI's BGI DNBSeq-T7 sequencer, to advance BGI's research into COVID-19 virulence, transmission patterns and host-pathogen interactions in the interest of accelerating development of COVID-19 diagnostics and the identification of potential drug targets.

Here's a summary of the key strategic diagnostic deals announced from late February through March 2020:

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Todos Medical	Emerald Organic Products	• Objective: Provide rapid point-of-care COVID-19 test in US • Dynamic: Create joint venture to seek FDA approval for and distribute Colloidal Gold assay detecting antibodies to SARS-CoV-2
Heat Biologics	University of Miami	• Objective: Develop point-of-care COVID-19 test • Dynamic: Assay to detect SARS-CoV-2 via isothermal amplification technology detecting viral nucleic acids rather than by detecting antibodies
Chembio Diagnostics	LumiraDx	• Objective: Develop point-of-care diagnostic tests for SARS-CoV-2 and IgM and IgG antibodies to the coronavirus on both firms' platforms • Dynamic: Expand on existing collaboration to develop point-of-care diagnostic tests for infectious diseases to address significant global health threats
BGI Genomics (BGI Group)	Intel + Lenovo	• Objective: Research COVID-19 genome • Dynamic: BGI to leverage the two computer companies' computational and genomic analysis technologies to advance its studies of COVID-19 virulence
Cepheid	Sherlock Biosciences	• Objective: Develop new molecular diagnostic tests for infectious diseases, starting with test to detect SARS-CoV-2 virus • Dynamic: Use Sherlock Biosciences' CRISPR-based SHERLOCK platform to design tests to run on Cepheid's GeneXpert systems
Illumina	IDbyDNA	• Objective: Provide streamlined workflow solution for NGS detection of infectious diseases • Dynamic: Comarket IDbyDNA's Explify platform for use with Illumina's NGS instruments + library preparation kits
Biocartis	Immunexpress	• Objective: Co-commercialize Immunexpress' SeptiCyte Rapid test on Biocartis' Idylla platform • Dynamic: Under expansion of existing agreement, Biocartis to lead European commercialization as exclusive distributor of SeptiCyte Rapid test • Immunexpress to lead commercialization of test in US

Partner 1	Partner(s) 2+	Deal Summary
Biocartis	Bristol-Myers Squibb	• Objective: Register Biocartis Idylla MSI test as companion diagnostic in China • Dynamic: Firms have companies have an existing collaboration to register the assay in US as a companion diagnostic for immunotherapies in metastatic colorectal cancer
Qiagen	NuProbe	• Objective: Develop NGS-based cancer liquid biopsy tests • Dynamic: Firms to explore integration of their respective amplicon-based target enrichment technologies to analyze DNA mutations with low variant allele fractions starting with a research-use only clinical oncology product
Thermo Fisher Scientific	Janssen Biotech	• Objective: Develop companion diagnostic test to support enrollment of cancer patients for clinical trials • Dynamic: Scientists from each firm to initially validate biomarkers for use with Thermo Fisher Oncomine Dx Target Test to identify non-small cell lung cancer (NSCLC) patients for clinical trials
AmoyDx	Janssen Research and Development	• Objective: Develop NGS-based companion diagnostic for Chinese market • Dynamic: AmoyDx to develop + seek Chinese regulatory approval for its LC10 Essential NGS panel as companion diagnostic to undisclosed cancer therapy
Prevencio	Microsoft	• Objective: Use Microsoft's Azure AI-based computing cloud platform to sell Prevencio's AI-based HART cardiac blood tests • Dynamic: Microsoft Healthcare's salesforce to sell tests to its customer base, including hospitals, life science companies + CROs
PMI Biopharma Solutions	Nashville Biosciences	• Objective: Provide drug discovery + development services • Dynamic: Offer Nashville Biosciences genomic data + in silico technologies with PMI's lab + research services as combined package for drug target identification + validation
Diagenode	MGI	• Objective: Comarket Diagenode's NGS library preparation products in US, Europe + Asia Pacific • Dynamic: Non-exclusive deal, the companies have made Diagenode D-Plex library preparation products available on MGI sequencing platforms
Inspirata	Mikroscan	• Objective: Market + distribute oncology informatics products to US labs + hospitals • Dynamic: Bundle Mikroscan SL5 Dual-Mode Real Time Telemicroscopy and Digital Pathway systems and L5 Real-Time Telemicroscopy systems with Inspirata Dynamyx case management software

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Diagnostic Deals, *from page 11*

Partner 1	Partner(s) 2+	Deal Summary
Fluidigm	Next Gen Diagnostics (NGD)	• Objective: Develop + sell sample preparation products for sequencing-based pathogen surveillance • Dynamic: Exclusive partnership to integrate Fluidigm Juno microfluidic sample prep system into NGD's workflow for pathogen whole-genome sequencing • Fluidigm to get milestone payments starting this year + additional revenue over five years
LabCorp	ZPredicta	• Objective: Develop + commercialize tumor-specific preclinical models based on ZPredicta's 3D cell culture platform • Dynamic: ZPredicta's platform integrates organ-specific cellular and extracellular elements into 3D culture models for in vitro cancer drug testing
LabCorp	Resolution Biosciences (RB)	• Objective: Commercialize RB's Resolution ctDx Lung test • Dynamic: LabCorp to launch test in the first half of 2020 + act as exclusive provider with RB performing assay as a laboratory-developed test out of its CLIA facility

To read the rest of this story go to: https://www.g2intelligence.com/fda-watch-the-month-in-global-new-diagnostic-test-approvals/

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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.

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