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The Coronavirus Crisis: Test-Now, Regulate-Later Strategy Generates Robust Dx Test Pipeline in Record Time

Historically, the lag between Public Health Emergency (PHE) declaration and FDA approval of a lab test to diagnose the pathogen has been a minimum of eight weeks. Eight weeks into the coronavirus PHE, 18 different COVID-19 tests have received FDA Emergency Use Authorization (EUA)—tests from not only the CDC but also high-complexity CLIA and commercial labs. And that number grows literally every day. It's an unprecedented achievement and here's how it happened and continues to happen:

The Historical Context

This is the fifth time the US has declared a PHE in response to the outbreak of an infectious disease. The previous emergencies were for H7N9 influenza, Middle East Respiratory Syndrome (MERS), Ebola, EV-D68 and Zika virus. In each case, the FDA has relied on

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LDTs: VITAL Act Would Eliminate FDA Regulation of New Tests During Health Emergencies

In standing aside and allowing test makers to validate and perform COVID-19 laboratory developed tests (LDTs) and not wait for Emergency Use Authorization (EUA) (see the related story on this page), the FDA has actually acknowledged what the diagnostics industry has been arguing for years, namely, that agency overregulation of LDTs is an obstacle to test development and innovation. But the irony of the situation isn't lost on one US Senator who introduced a bill that would make the accelerated pathways approach being taken for COVID-19 test development a permanent part of public health emergency response. Here's the lowdown.

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its EUA pathway to bring new tests to market on a rapid basis. And in each case, the initial EUA went to either the CDC or US 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 PHE Declaration & FDA Approval of Commercial Lab 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)

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The Initial FDA COVID-19 Response

Initially, the FDA response to COVID-19 followed the same path as the previous outbreaks. Thus, on February 4, within days after the emergency was declared on January 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 labs around the country. But reagent, instrumentation and lab 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 lab scientists, SARS-CoV-2 was something totally novel.

So, the FDA began to improvise utilizing a totally new tactic: Allow labs to validate and deploy tests first and seek EUA later. And not only that. The agency fashioned a different application of the approach for different kinds of labs, eventually creating four separate pathways for approval. It wasn't until March 25, that the agency sought to conceptualize all 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**.

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. Policy A tests can be performed only by the lab that develops them. Nearly 100 labs are currently running LDTs, according to Hillebrenner, including those at Yale, Northwestern and Massachusetts General Hospital.

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 labs to seek 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 without 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 EUA. Over a dozen test developers are pursuing the Policy D pathway. On April 1, North Carolina-based Cellex's qSARS-CoV-2 IgG/IgM Rapid Test became the first coronavirus serology test to receive FDA EUA clearance.

Takeaway

While significant reagent, instrumentation and staffing bottlenecks remain, the speed and extent of the diagnostic response to COVID-19 has been extraordinary and beyond all historical precedent. But then again, so is the urgency of the situation. Of course, the test-first-and-worry-about-regulatory-approval strategy is not without risk; and it may still not be enough to meet the urgent demand for COVID-19 testing (see related story about continuing test shortages on ***page 7****). But the creativity and energy of both the regulators and test makers in developing tests for detecting a totally novel pathogen in such a small window of time should not go unrecognized.*

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COVID-19 LAB TESTS RECEIVING FDA EMERGENCY USE AUTHORIZATION

(As of April 10, 2020)

Date	Manufacturer(s)	Test Receiving EUA
Feb 4	CDC	2019 Real Time RT-PCR Diagnostic Test Panel
March 2	New York State	Wadsworth Center, New York State Department of Public Health's New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel
March 13	Roche	Cobas SARS-CoV-2 Test
March 15	Thermo Fisher Scientific	TaqPath COVID-19 Combo Kit for qualitative detection of SARS-CoV-2 nucleic acid
March 16	LabCorp	COVID-19 RT-PCR test
March 16	Hologic	Panther Fusion SARS-CoV-2 assay for use on firm's Panther Fusion system
March 17	Quidel	Lyra SARS-CoV-2, RT-qPCR assay for qualitative detection of nucleic acid from SARS-CoV-2
March 18	Abbott	Abbott RealTime SARS-CoV-2 EUA run on firm's PCR-based m2000 RealTime System
March 19	Quest Diagnostics	SARS-CoV-2 rRT PCR test
March 19	GenMark Diagnostics	ePlex SARS-CoV-2 Test run on firm's ePlex system
March 20	DiaSorin Molecular	Simplexa COVID-19 Direct assay run on firm's Liason MDX real-time PCR instrument
March 21	Cepheid	Xpert Xpress SARS-CoV-2 point-of-care test
March 23	Primerdesign	COVID-19 Genesig Real-Time PCR assay
March 24	Mesa Biotech	Accula SARS-CoV-2 test
March 24	BioMérieux	BioFire COVID-19 test run on firm's BioFire FilmArray system
March 24	PerkinElmer	New Coronavirus Nucleic Acid Detection Kit
March 25	Quidel	Expanded EUA for Lyra SARS-CoV-2 assay
March 27	BGI Americas (BGI Genomics US sub)	BGI Real-Time Fluorescent RT-PCR Kit
March 27	Luminex	NxTag CoV Extended Panel
March 27	Abbott	SARS-CoV-2 point-of-care test
March 30	Qiagen	QiaStat-Dx Respiratory SARS-CoV-2 Panel, first "syndromic" testing product to be deployed in US
March 30	NeuMoDx	NeuMoDx SARS-CoV-2 Test Strip for use on NeuMoDx 288 Molecular + NeuMoDx 96 Molecular systems

Date	Manufacturer(s)	Test Receiving EUA
April 1	Yale New Haven Hospital Clinical Virology Laboratory	SARS-CoV-2 RT-PCR test
April 2	Cellex	qSARS-CoV-2 IgG/IgM Rapid Test, first coronavirus serology test to get EUA clearance
April 2	Ipsum Diagnostics	COV-19 IDx, an RT-PCR-based SARS-CoV-2 test
April 3	Becton Dickinson + BioGX	Sample-Ready hospital SARS-CoV-2 assay for use on BD Max system
April 6	ScienCell Research Laboratories	ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR Detection Kit
April 6	Co-Diagnostics	Logix Smart Coronavirus COVID-19 Test
April 6	Luminex	Aries SARS-CoV-2 Assay
April 6	Massachusetts General Hospital	MGH SARS-CoV-2 assay
April 6	Infectious Disease Diagnostics Laboratory at Children's Hospital of Philadelphia	SARS-CoV-2 RT-PCR Test
April 6	Diagnostic Molecular Laboratory at Northwestern Medicine	SARS-CoV-2 Assay
April 7	Gnomegen	COVID-19 RT-Digital PCR Detection kit for diagnosing SARS-CoV-2
April 8	Viracor Eurofins Clinical Diagnostics	Viracor SARS-CoV-2 molecular assay
April 8	Becton Dickinson	BD MAX ExK TNA-3 kit run on the BD Max system
April 9	Stanford Health Care Clinical Virology Laboratory	SARS-CoV-2 assay
April 9	DiaCarta	QuantiVirus PCR diagnostic (Dx) test for COVID-19

Cybersecurity: OCR Temporarily Eases HIPAA Privacy Restrictions for Telehealth Practice

In furtherance of its social distancing strategy, the federal government is temporarily allowing labs and other health care providers to use communication technologies like Facetime or Skype for any telehealth treatment or diagnostic purpose, even if not directly related to COVID-19. And now the HHS Office of Civil Rights (OCR) has announced that,

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Cybersecurity: OCR Temporarily Eases HIPAA Privacy Restrictions for Telehealth Practice, *from page 5*

effective immediately, it will waive potential HIPAA penalties against providers that, acting in good faith, use everyday communications technologies to serve patients during the COVID-19 public health emergency, even though some of these technologies and the manner in which they're used, may not fully comply with normal HIPAA Privacy Rules.

Telehealth HIPAA Relief

During public health emergencies (PHEs), restrictions that impair care delivery may get aside and providers get license to do things they're not allowed to do during times of normalcy. Using communications technology to practice telehealth is a striking example. But to make it work, the government must temporarily waive not only care quality and practice restrictions but also HIPAA requirements limiting the collection, use and disclosure of protected health information (PHI). And as the principal enforcer of federal HIPAA privacy requirements, it falls to the OCR to temporarily rewrite the rules.

Permissible & Impermissible Technologies

HIPAA relief isn't new but, like the COVID-19 pandemic itself, the scope of the new latitude is wider than it's ever been. Thus, for as long as the PHE remains in effect, a lab or other covered health care provider can provide telehealth services for any reason related to the good faith diagnosis and treatment of patients, not just for the diagnosis and treatment of health conditions related to COVID-19. Just as empowering is that providers may use any available non-public facing remote video communication product to communicate with patients, including, among others:

- Apple FaceTime;
- Facebook Messenger video chat;
- Google Hangouts video; and
- Skype.

What remains off-limit for telehealth services use, however, are public facing video communications technologies, such as Facebook Live, Twitch and TikTok.

Recommended Privacy Precautions for Telehealth

OCR recommends that providers recognize and take measures to minimize the privacy risks associated with telehealth practice, including:

Notifying patients that these third-party communications applications carry potential privacy risks;

Enabling all available encryption and privacy modes when using such applications;

Use technology vendors that are HIPAA compliant and willing to enter into HIPAA business associate agreements (BAAs) in connection with the provision of their video communication products. (See the box below.)

HIPAA-Compliant Vendors

The following are vendors that represent that they provide HIPAA-compliant video communication products and that they will enter into a HIPAA BAA:

- Skype for Business
- Updox
- VSee
- Zoom for Healthcare
- Doxy.me
- Google G Suite Hangouts Meet

However, OCR has indicated that it will not impose penalties against providers for not having a BAA with video communication vendors.

Coronavirus: Nearly 3 in 4 Physicians Say They Can't Provide Easy & Rapid COVID-19 Testing

Development of new lab tests to detect the SARS-CoV-2 virus that causes COVID-19 coronavirus has been faster and more prolific than anybody could dare expect for a pathogen that was unknown just a few months ago. But it still may not be enough to satisfy the urgent demand for COVID-19 testing—at least not yet. That's the depressing conclusion of a new survey from Harvard Medical School, the Rand Corporation and Doximity, a professional medical network of which 70% of US physicians are members

Quick and Easy Testing Remains Elusive

Conducted between March 21-24, the survey "Physicians Views on the Coronavirus Pandemic Response," included 2,600 physicians. Half of the respondents said they've treated at least one patient with potential COVID-19 symptoms. When asked whether they were "currently able to test their patients for COVID-19 quickly and easily," 73.3% of those physicians who reported treating at least one potential COVID-19 case answered "no."

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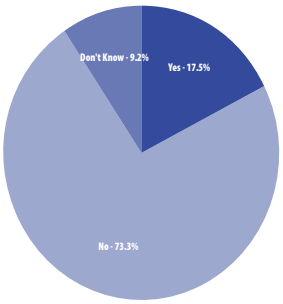
Coronavirus: Nearly 3 in 4 Physicians Say They Can't Provide Easy & Rapid COVID-19 Testing, *from page 7*

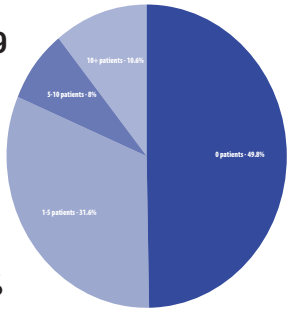
Are you currently able to test your patients for COVID-19 quickly and easily?

- **Yes - 17.5%**
- **No - 73.3%**
- **Don't Know - 9.2%**



How many patients have you treated with possible COVID-19 symptoms, but have not been able to test for COVID-19

- **0 patients - 49.8%**
- **1-5 patients - 31.6%**
- **5-10 patients - 8%**
- **10+ patients - 10.6%**

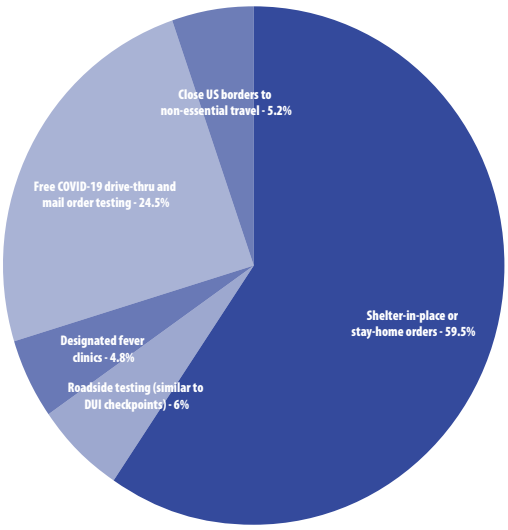


Some of the other noteworthy survey findings:

- Close to 50% of the physicians surveyed said they believed patients are avoiding testing due to financial and health insurance concerns;
- Over 77% reported that they don't believe their hospital/clinic has adequate medical supplies and equipment if the pandemic worsens;
- Close to 70% believe that the government hasn't taken appropriate measures to support the medical supply chain and ensure that their hospital/clinic has the medical supplies it needs to address the pandemic;
- Close to 60% did not believe that there were enough precautions in place in their clinic to protect them from infection while treating COVID-19 patients;
- 70% did not believe the government is responding adequately to the pandemic;
- Nearly 60% believed social distancing, closing schools and travel restrictions were an appropriate reaction to the potential risks of COVID-19;
- Nearly 60% believe the stay-at-home or shelter-in-place orders would do the most to "flatten the curve," while nearly 25% believed free COVID-19 drive through and mail in testing would do the most; and

From observing your patient habits, which of the following US policy actions would "flatten the curve" the most?

- **Shelter-in-place or stay-home orders - 59.5%**
- **Roadside testing (similar to DUI checkpoints) - 6%**
- **Designated fever clinics - 4.8%**
- **Free COVID-19 drive-thru and mail order testing - 24.5%**
- **Close US borders to non-essential travel - 5.2%**



- Over 50% reported increasing their use of telemedicine in response to the pandemic.

Takeaway

"The findings highlight the difficult road ahead for healthcare providers confronting the coronavirus pandemic," said Chris Whaley, Ph.D., lead author and Policy Researcher at the RAND Corporation in a ***press release****. "We hope this insight on physician experiences and concerns surrounding the pandemic will help design appropriate and immediate policy response." It's also worth noting that much has happened since the survey, including the adoption of the CARES Act and the COVID-19 acceleration of the testing pipeline. Regrettably, the physician outlook from an anecdotal basis seems to remain less than optimistic.*

OIG Update: OIG Temporarily Waives Anti-Kickback Restrictions for Certain COVID-19 Physician Arrangements

As it previously did with the Stark Law (See *National Intelligence Report, NIR*, March 25, 2020), the OIG is temporarily loosening Antikickback Statute (AKS) restrictions to clear the way for health care arrangements during the COVID-19 emergency that would be problematic in times of normalcy. Here's what's going on and what it may mean for your lab.

Public Health Emergency (PHE) Waiver Rules

During a PHE, the OIG has discretion not to impose penalties on remuneration arrangements that violate the AKS. On March 30, 2020, the OIG announced it was exercising that discretion by issuing what's called Blanket Waivers for such arrangements. **The message:** Right now, delivering COVID-19 diagnosis and treatment is more important than the need to avoid arrangements offering remuneration in exchange for Medicare and other federal referrals. Things that labs may be allowed to offer, pay or provide referring physicians (and/or their immediate family members) during the emergency include, among other things:

- Remuneration for services or items at above or below fair market value;
- Free or below fair market value rent for leased office space or equipment, e.g., giving a physician free telehealth communications equipment;
- Hospital medical staff incidental benefits above the usual limits;
- Nonmonetary compensation above the usual limits;
- Loans at below fair market value interest or at terms not offered to non-referral sources; and
- Referral by a physician in a group practice for medically necessary designated health services furnished by the group practice in a location that doesn't qualify as a "same building" or "centralized building."

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OIG Temporarily Waives Anti-Kickback Restrictions for Certain COVID-19 Physician Arrangements, *from page 9*

Eligibility Criteria

To qualify for the Blanket Waiver, providers must act in good faith and the arrangement must be purely for COVID-19 purposes, which include:

- Diagnosis or medically necessary treatment of COVID-19 for any patient or individual, whether or not the patient or individual is diagnosed with a confirmed case of COVID19;
- Securing the services of physicians and other health care practitioners and professionals to furnish medically necessary patient care services, including services not related to diagnosis and treatment of COVID-19, in response to COVID-19 outbreak in the US;
- Ensuring the ability of health care providers to address patient and community needs due to COVID-19 outbreak in the US;
- Expanding the capacity of health care providers to address patient and community needs due to COVID-19 outbreak in the US;
- Shifting the diagnosis and care of patients to appropriate alternative settings due to COVID-19 outbreak in the US; or
- Addressing medical practice or business interruption due to COVID-19 outbreak in the US to maintain the availability of medical care and related services for patients and the community.

Takeaway: Should You or Shouldn't You

The Blanket Waivers apply automatically if the arrangement meets the criteria and you don't have to get pre-review and clearance from the OIG. However, the OIG reserves the right to review any arrangement and impose penalties if it determines that it doesn't satisfy the requirements. The OIG is also willing to issue an Advisory Opinion if parties do want a green light before entering into the arrangement.

Billing & Coding: New HCPCS Codes for COVID-19 Specimen Collection

CMS has established two new Level II HCPCS codes for COVID-19 specimen collection:

- **G2023** - Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source; and
- **G2024** - Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency, any specimen source.

These codes are billable by clinical diagnostic labs, effective with line item date of service on or after March 1, 2020.

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 that 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 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.

LDTs: VITAL Act Would Eliminate FDA Regulation of New Tests During Health Emergencies, *from page 1*

FDA Regulation of LDTs during Health Emergencies

LDTs developed, validated and performed inside the same lab are normally regulated under CLIA. *The Federal Food, Drug and Cosmetic Act*, by contrast, doesn't expressly give the FDA authority to regulate lab tests. However, while largely leaving lab regulation to CMS under CLIA, the agency has long argued that its regulatory oversight of medical devices extends to LDTs, including broad authority to stipulate requirements for test providers (or exempt them from requirements) during Public Health Emergencies (PHEs).

Accordingly, as part of its initial response after declaring a PHE for COVID-19 on January 31, the federal government set aside CLIA and required that all tests for the novel coronavirus obtain an EUA from the FDA before they could be used on patients, largely the same pattern followed in previous PHEs. The FDA also stuck with its usual strategy of issuing EUA for a federal government test within a week of the declaration, in this case, a reverse transcriptase real-time PCR developed by the CDC, authorizing only public health labs and the Department of Defense labs to use the test. But problems with the initial CDC kit led to a weeks-long delay until the CDC issued a new one, with labs having to spend that critical time wrestling with bureaucratic approval in the EUA process to use their own tests, depleting needed resources.

The good news is that the FDA responded by loosening the strings and allowed labs to validate and perform LDTs for COVID-19 without first securing agency EUA. (See the related story on **page 1**). But precious time had been lost.

A New FDA-Less Pathway for LDTs

Against this backdrop, Senator **Rand Paul** (R-KY) introduced the *Verified Innovative Testing in American Laboratories (VITAL) Act of 2020* on March 17, 2020, to establish a new pathway to make tests quickly and widely available during PHEs. Specifically, the bill would let labs develop and use tests within days, providing a better opportunity to isolate, contain and understand viruses.

Paul and supporters of the bill believe that VITAL is necessary to update CLIA by removing LDTs from FDA oversight in light of the slow federal response to expand access to SARS-CoV-2 virus tests during the present pandemic. The FDA has been criticized for requiring test developers

and manufacturers to get EUA from the agency prior to launching testing. "When we face a health emergency, government should trust academic, community and public health labs to do what they are already trained and certified to do," noted Senator Paul in a press release. "With all of the debates about how government should respond, here's one thing it can stop doing: piling counter-productive bureaucratic hurdles in the way of our medical professionals."

The 4 Things the VITAL Act Does

Dr./Senator Paul's plan would institute a legislative fix that allows labs to follow the CLIA process even during public emergencies, helping prevent delays and waste of time and money. Specifically, VITAL:

1. Clarifies that the *Public Health Service Act* governs all aspects of laboratory-developed testing procedures—including during a PHE;
2. Requires CMS to hold a public meeting to solicit recommendations on updating the CLIA regulations within 90 days of enactment;
3. Requires the Secretary of HHS to report to Congress, within 180 days of enactment, recommendations to update the CLIA and their associated regulations, and about the availability and utilization of LDT procedures during the 2020 COVID-19 pandemic. The COVID-19 assessment would have to include information about:
   - The average length of time from validation to achieving EUA before and after February 29, 2020;
   - The number of patients and samples tested by labs using these procedures; and,
   - Recommendations to ensure that in future outbreaks, the public health system and clinical laboratories don't encounter delays to testing.
4. Expresses the Sense of Congress that labs using LDTs should adhere to personnel requirements under §353 of the *Public Health Service Act*, and the federal government should work to:
   - Ensure that patients receive the most appropriate tests for medical evaluation and treatment;
   - Ensure that lab-developed testing is accurate, precise, clinically-relevant and monitored for quality performance;
   - Enable lab professionals to provide their services without undue restrictions;
   - Ensure that oversight of LDTs doesn't limit patient access, impede innovation, constrain flexibility or limit the sustainability of tests;
   - Preserve the ability of the lab community to provide surge capacity in PHEs, including biological, chemical, radiological and nuclear threats, infectious disease outbreaks or other emergent situations; and

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LDTs: VITAL Act Would Eliminate FDA Regulation of New Tests During Health Emergencies, *from page 13*

- Safeguard, strengthen and expand the existing Laboratory Response Network.

VITAL vs VALID

The VITAL Act strikes a counterpoint to another bipartisan-backed bill introduced earlier this month in the Senate and House of Representatives called the Verifying Accurate, Leading-edge IVCT Development (VALID) Act (See *National Intelligence Report, NIR*, March 18, 2020, for details about VALID.) While VITAL updates existing federal lab standards under CLIA, VALID would create an entirely new risk-based oversight framework for in vitro clinical tests, a category comprising LDTs and test kits, and bring them all under the FDA's aegis.

VALID sponsors in the House (Reps. Larry Bucshon (R-Indiana) and Diana DeGette (D-Colorado)), and in the Senate (Richard Burr (R-North Carolina) and Michael Bennet (D-Colorado)), have made the case that VALID is needed in light of the present public health situations. When VALID was introduced on March 5, Bucshon argued that during a public health crisis the government must act quickly to ensure hospitals and labs can develop tests to identify those infected and stop the spread of the virus. He added that VALID "will overhaul the federal government's outdated system that is slowing down our ability to respond to these threats."

VALID would effectively end the longstanding disagreements between the FDA and the lab industry about whether the agency has the statutory authority to regulate LDTs. It would also end the agency's historic practice of "enforcement discretion" over LDTs, and instead, implement a new framework that brings all clinical tests under its oversight.

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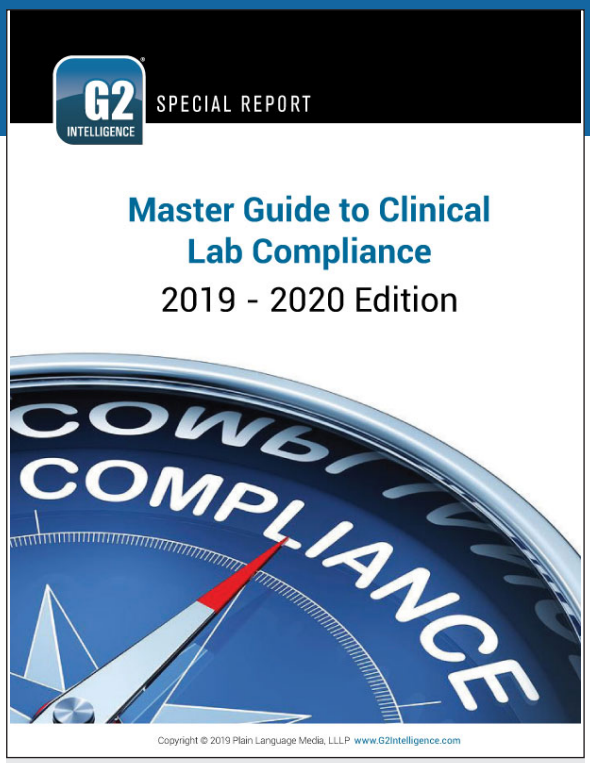

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A Practical, Plain-Language Guide to Protecting Your Lab against Costly False-Claims, Anti-Kickback, and Stark Law Violations

For over two decades, clinical labs have been the target of a relentless stream of **investigations, audits, reviews, lawsuits**—and even **criminal prosecutions**—by the Centers for Medicare and Medicaid Services, and other Federal and State agencies.

Without a doubt, enforcement actions for **False-Claims violations** top the list. But the government has also systematically and aggressively grown the number of investigations into **Anti-Kickback** and **Stark Law violations.**

And that's just the tip of the iceberg. Investigations and **enforcement actions by state governments** have become increasingly aggressive... **whistleblower lawsuits** continue to grow sharply... and the ACA has earmarked **over $350 Million in funds for stepped up enforcement though 2020**, so you can be sure that labs like yours will come under increasing legal scrutiny.

Lab Compliance Essentials gives you the **practical, plain-language help** you need to understand the laws, and take **proven steps to protect your lab** from costly False-Claims, Anti-Kickback, Stark Law, and other legal and compliance violations.

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