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Emerging Tests: SARS-CoV-2 Antigen Testing Is Here but Is It Really a 'Game Changer'

First came the molecular and then the serological assays. And now a third kind of coronavirus testing methodology has made its official US debut: antigen tests. Some have hailed this development as a "game changer" in the effort to meet the current unprecedented demand for testing. But are they right?

The Diagnostic Challenge

Molecular tests using reverse transcription-polymerase chain reaction (PCR) to detect RNA material from the virus is accurate but slow to the extent it must be performed at an offsite laboratory. In addition to being much faster, blood-based serology tests detecting antibodies produced by the body to fight the SARS-CoV-2 virus offer the potential to differentiate between active and previous

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Emerging Tests: FDA Pulls in the Reins on Makers of Unproven Coronavirus Serology Assays

The U.S. Food and Drug Administration continues to struggle in its quest for a regulatory policy to unlock the potential of blood-based COVID-19 serology testing while reining in fraudulent marketing and accuracy challenges. Here is a look at the latest developments.

The Diagnostic Challenge

As the curve flattens and society turns to the business of reopening, a new kind of coronavirus diagnostic testing is needed, one that is capable of not only detecting SARS-CoV-2 antibodies in a person's system but also determining whether they are due to a current or previous COVID-19 infection. In addition to enabling governments, employers and other decision makers to figure out if a person is "safe" for public activity or needs to be in quarantine, such data is crucial to tracking COVID-19 among specific populations.

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Emerging Tests: SARS-CoV-2 Antigen Testing Is Here but Is It Really a 'Game Changer', *from page 1*

infection. But serology tests lack the specificity and sensitivity of PCR assays making them prone to generate false positives and negatives.

Like antibody testing, antigen tests detect viruses indirectly. But there are some important differences. For one thing, while antibody tests are blood based, antigen tests analyze tissue nasopharyngeal samples collected by a swab the way PCR tests do. And instead of antibodies, antigen tests detect the presence of antigens or toxins a virus produces that cause the body to produce those antibodies.

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

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The Promise of SARS-CoV-2 Antigen Testing

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

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

FDA Approves First Antigen Test for SARS-CoV-2

Perhaps it is significant that on May 8, the 65th anniversary of VE Day commemorating victory in Europe after World War 2, the FDA for the first time granted Emergency Use Authorization (EUA) to an antigen coronavirus test. The Quidel Sofia 2 SARS Antigen FIA assay is a point of care test designed for use with the firm's Sofia 2 fluorescent immunoassay analyzer to detect SARS-CoV-2 protein fragments in nasal or nasopharyngeal samples. It has a reported sensitivity of 85 percent, a rate that definitely puts false negatives into play. The agency reportedly cleared the test within 24 hours of receiving Quidel's application.

It is not surprising that Quidel is the first to bring a SARS-CoV-2 antigen test to the US market. The firm also produces immunoassays for its Sofia

platform including tests for influenza A and B, respiratory syncytial virus (RSV), group A Streptococcus and other infectious diseases. Quidel claims that the new Sofia 2 SARS Antigen FIA test, which the EUA authorizes moderate- and high-complexity CLIA laboratories and facilities that have a CLIA waiver to perform, delivers results in 15 minutes and costs only $5 per test to produce.

Potential Impact

The headline is not just that a SARS-CoV-2 antigen test has reached the market but the potential impact of the test to help close the current gap between COVID-19 testing demand and supply. Quidel says that it is ramping up production from 200,000 to 1.5 million tests per week and expects in the next few weeks to have the capacity to make 9 million tests per months. And because 40,000 doctors' offices across the country already have a Sofia analyzer installed in their office, the test should be more readily accessible than most of the other assays that have secured EUA status.

And more may be on the way. The FDA said that it is expecting to clear more SARS-CoV-2 antigen tests and that it intends to create a new streamlined and expedited EUA pathway for antigen tests.

Takeaway

PCR testing is the gold standard for COVID-19 testing accuracy but it is not a high-throughput modality and thus not enough to meet the current unprecedented test volume demands. Antigen testing is scalable but lacks the sensitivity necessary to make negative test results completely reliable. It is for this reason that several models of rapid influenza diagnostic tests (RIDTs) had to be pulled off the market. Even so, just the way RIDTs are in demand during a bad flu season, SARS-CoV-2 antigen tests may represent an acceptable better-than-nothing alternative in a market facing the dire need for COVID-19 testing supply. Thus, while not yet a "game changer," the introduction of antigen testing should help satisfy the desperate demand for coronavirus testing.

COVID-19 Serology Testing: Now Even the "Good" Tests Are Coming Under Fire

The inaccuracy of serology tests that detect antibodies to the SARS-CoV-2 virus has become an issue of mounting concern. Even though the lack of sensitivity and specificity of these tests is well documented, the vast majority of the more than 150 SARS-CoV-2 serology tests currently provided in the U.S. reached the market through a pathway that did not require Food and Drug Administration (FDA) review.

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COVID-19 Serology Testing: Now Even the "Good" Tests Are Coming Under Fire, *from page 3*

The supposed silver lining is the group of 11 tests that did actually receive Emergency Use Authorization (EUA) clearance and are thus deemed the most reliable. However, a new study casts suggests that one of the fastest and most widely used of these gold standard tests has major sensitivity problems, missing as many as half of the cases that another test found to be positive.

The NYU Study

Researchers from New York University (NYU) set out to evaluate one of the newly approved SARS-CoV-2 serology tests used in their laboratories. While those tests also included the Cepheid Xpert Xpress and Roche Cobas assay, Abbott Laboratories' ID Now point of care test was an attractive target for study because of its fast turnaround—the Abbott test produced results in as little as five minutes, as compared to 45 minutes for the Cepheid test and 3.5 hours for the Roche assay. Of course, these are the very same qualities that make ID Now the go-to test for so many end users, including the White House which uses the assay to test officials and screen visitors.

The researchers assessed 101 dry nasal swabs and 101 nasopharyngeal swabs from the same patients to compare the ability of the ID Now and Cepheid Xpert Xpress tests to detect SARS-CoV-2 viral nucleic acids. They found that the ID Now test performed well at first but generated more false negatives as the viral load decreased. According to the study, which was published on the BioRxiv preprint platform and which has not undergone peer review, the Abbott test missed one-third of the samples detected positive by the Cepheid test when using nasopharyngeal swabs, and 48 percent of the samples detected when using dry nasal swabs.

Based on these results, the researchers found that those who used ID Now for first-step screening, would have to confirm over 80 percent of the tested samples "to be confident that the negative results are truly negative." On the bright side, they concluded that the test had high specificity and positive predictive value, meaning that "a positive result can be interpreted as a true positive."

The Reaction

Abbott and the FDA reacted swiftly by questioning the researchers' testing methods and noting that the findings were not consistent with other studies and accounts of the ID Now test's accuracy. "Abbott has distributed more than 1.8 million ID Now tests and the reported rate of false negatives to Abbott is at .02 percent, which we've previously shared with the FDA," according to a company spokesperson.

The NYU study provides excellent ammunition for those who have criticized the White House and FDA for relaxing regulatory scrutiny and

allowing unproven serology tests to reach the market. At the same time, it is not the first study to call the Abbott test's accuracy into question. The NYU researchers cited a separate study by the Cleveland Clinic finding that ID Now COVID-19 had a false negative rate of 14.8 percent—although that might have been influenced by the fact that study samples were stored in viral transport media instead of being directly inserted into the ID Now platform.

In response to the Cleveland Clinic study, Abbott recommended using dry swabs for best results. But the NYU researchers found that sensitivity of ID Now using dry swabs was actually lower than when using viral transport media—51.6 percent vs. 66.7 percent.

Study Finds Abbott Serology Test More Accurate than Euroimmun Serology Test

Two days after the NYU study came out, researchers from Washington University in St. Louis and Barnes Jewish Hospital published a study in Clinical Chemistry finding Abbott's SARS-CoV-2 IgG assay more accurate than another EUA-cleared serology test, the Anti-SARS-CoV-2 ELISA assay produced by PerkinElmer's Euroimmun business. Testing samples from 103 patients found by polymerase testing to have COVID-19 and 153 patients without the disease, the study found that 14 days after the onset of symptoms:

- The Abbott test had a specificity of 99.4 percent and a sensitivity of 93.8 percent; and
- The Euroimmun assay had a specificity of 94.8 percent and a sensitivity of 85.4 percent.

However, the researchers characterized the differences in sensitivity and specificity between the tests "statistically insignificant" and said more studies would be necessary to confirm that the Abbott test had higher sensitivity and specificity than the Euroimmun test.

Takeaway

Even the FDA has admitted that it was a mistake to allow SARS-CoV-2 serology antibody tests to market without agency review and is now requiring all test makers to submit their products for independent validation by federal laboratories. (See the story on ***page 1****.) What makes the NYU report so disconcerting is that the test it questions is one that is not only so widely used but also among the small group of assays that came through the more rigorous pipeline requiring agency review and EUA clearance. And if even that test is not reliable, can any of the COVID-19 serology trusts currently being provided be trusted?*

FDA WATCH

After Initial Resistance, Agency Warms to Home COVID-19 Testing

Back in March, the US Food and Drug Administration (FDA) stated that the newly liberalized clearance scheme it was deploying to expedite the COVID-19 diagnostic testing pipeline did not apply to at-home testing due to concerns about the marketing of fraudulent test kits. However, the agency seems to have reversed that policy and recently broke new ground by authorizing coronavirus testing by multiple laboratories in nasal samples collected by consumers using an at-home kit.

The Rutgers and LabCorp Assays

At-home sample collection of COVID-19 test samples also some obvious advantages over the standard method in which a qualified health care professional armed to the teeth in personal protective equipment inserts a swab into the nostrils to access and perform a tissue scrape of the nasopharynx at the back of the nasal cavity. On April 13, the FDA granted Emergency Use Authorization (EUA) to the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay, version of the Thermo Fisher Scientific Applied Biosystems TaqPath COVID-19 Combo Kit modified to allow for testing on saliva samples that can be collected at home. Just over a week later, the agency gave LabCorp the go-ahead for at-home sample collection.

However, these approvals of at-home sample collection had only marginal impact on overall COVID-19 testing capacity since in each case, the EUA was limited to testing at each approvee's respective laboratory. As a result, neither Rutgers nor LabCorp are authorized to ship the at-home samples collected using their kits to third party laboratories for analysis.

The Everlywell At-Home Collection Kit

On May 15, the FDA took things to the next level by granting EUA clearance to a kit created by Austin, Texas-based Everlywell for COVID-19 testing by separate CLIA-certified laboratories using assays that also received EUA clearance that same day. Specifically, the Everlywell COVID-19 Test Home Collection Kit has now been cleared for self-collection of nasal samples and subsequent analysis by Fulgent Therapeutics using the Fulgent COVID-19 by RT-PCR Test and by Assurance Scientific Laboratories using the Assurance SARS-CoV-2 Panel.

Takeaway: More to Come?

The Everlywell EUA also includes language leaving open the possibility of authorizing other high complexity-certified CLIA laboratories to perform testing using the Everlywell kit, "provided that the data are submitted in an EUA request that demonstrate the accuracy of each test." according to the agency.

Here are some of the other key new FDA clearances announced in May:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Color	EUA for Color SARS-CoV-2 LAMP Diagnostic Assay using loop-mediated isothermal amplification (LAMP) technology
Myriad Genetics	Clearance for BRACAnalysis CDx as companion diagnostic to identify patients with germline BRCA1/2 mutations who can benefit from newly approved AstraZeneca and Merck's olaparib (Lynparza) drug
Foundation Medicine	Clearance for FoundationOne CDx as companion diagnostic to identify patients with to identify patients with HRR-mutated genes who can benefit from newly approved AstraZeneca and Merck's olaparib (Lynparza) drug
Ventana Medical Systems	Clearance for VENTANA PD-L1 SP142 Assay as companion diagnostic device for identifying metastatic non-small cell lung cancer (NSCLC) patients who can benefit from Genentech's newly approved atezolizumab (Tecentriq) drug
Agilent Technologies	Clearance for expanded use of PD-L1 IHC 28-8 pharmDx as companion diagnostic to identify NSCLC patients who can benefit Bristol Myers Squib's Opdivo and Yervoy's from NSCLC who are appropriate for treatment with nivolumab and ipilimumab drug
Bio-Rad	Clearance for CFX96 Dx real-time PCR instrument for in vitro diagnostic testing
Quidel	Expanded EUA for Lyra SARS-CoV-2 assay to detect virus without an upfront nucleic acid extraction step
Quidel	EUA for Sofia 2 SARS Antigen FIA assay
Everlywell	EUA for COVID-19 Test Home Collection kit
Fulgent Therapeutics	EUA for Fulgent COVID-19 by RT-PCR Test
Assurance Scientific Laboratories	EUA for SARS-CoV-2 Panel
GeneMatrix	EUA for NeoPlex COVID-19 Detection Kit
Hologic	EUA for Aptima SARS-CoV-2 assay
Cedars-Sinai Medical Center	EUA for SARS-CoV-2 RT-PCR assay
One Health Laboratories	EUA for SARS-CoV-2 Real-Time RT-PCR Test
Applied DNA Sciences	EUA for Linea COVID-19 RT-PCR test
Columbia University	EUA for Triplex CII-SARS-CoV-2 rRT-PCR test
Thermo Fisher Scientific	Expanded EUA for Applied Biosystems TaqPath COVID-19 Combo Kit

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FDA Watch, *from page 7*

Manufacturer(s)	Product
Abbott	EUA for Alinity m SARS-CoV-2 assay
Abbott	EUA for SARS-CoV-2 IgG serology blood test
1drop	EUA for 1copy COVID-19 qPCR Multi Kit
BioMérieux	EUA for SARS-CoV-2 R-Gene test kit
Opti Medical Systems	EUA for Opti SARS-CoV-2 RT-PCR kit
Sherlock Biosciences	EUA for Sherlock CRISPR SARS-CoV-2 kit
Grifols Diagnostic Solutions	Clearance for Procelix Panther System featuring Automation Ready Technology (ART)
Siemens Healthineers	EUA for Fast Track Diagnostics SARS-CoV-2 test
Euroimmun (owned by PerkinElmer)	EUA for Anti-SARS-CoV-2 ELISA serology test
Roche	EUA for Elecsys Anti-SARS-CoV-2 antibody serology test
Bio-Rad Laboratories	EUA for 2019-nCoV CDC ddPCR Triplex Probe Assay for use on firm's QX200 and QXDx Droplet Digital PCR systems
BioFire Diagnostics	EUA for Respiratory Panel 2.1

Test Utilization: COVID-19 Test Shortage Is Real & Likely to Last through 2020

Sadly, the question of whether there is enough COVID-19 testing in the U.S. to meet demand has become a political football. Here is a look at the findings of one group that set out to answer this question objectively and without political bias.

The Need for COVID Testing Data

One of the problems with evaluating the current state of COVID-19 testing in the U.S. is the lack of data. According to The COVID Tracking Project (the Project), a volunteer organization dedicated to collecting and publishing COVID-19 data, there is no complete account of COVID-19 testing data anywhere in the U.S.

Since the U.S. government is not tracking and reporting COVID-19 testing data on a national level, the Project sought to collect this data from the public health authority in each state, territory and the District of Columbia—56 jurisdictions in all. Each of these authorities reports its data in its own way, including via online dashboards, data tables, PDFs, press conferences, tweets and Facebook posts. And while many states and territories have slowly moved toward more standard methods of reporting, the actual taxonomies and categories of information remain in flux.

The Findings

Based on the COVID-19 testing data it was able to collect, the Project published a report that includes these findings, as of May 12, 2020:

- 9,637,930 COVID-19 tests have been performed in the U.S.;
- 1,360,705 of those tests were positive; and
- 8,277,225 of those tests were negative.

The Project also reports that daily test volumes are growing dramatically. Thus, the number of new COVID-19 tests performed on the day of May 12 was 289,472, as compared to the 140,562 new tests performed on April 12, and the 5,137 new tests performed on March 12.

What the Test Numbers Mean

According to the Project, as of May 12, 1,360,930 people in the U.S. have tested positive for COVID-19; among those who tested positive, 76,617 have died. And those numbers include only individuals who were tested. Things become even scarier and more sobering when you consider that countless others have contracted and died from the virus but were never tested at all.

In addition to testing for clinical treatment, the reopening of the U.S. economy will precipitate a vast new demand for COVID-19 screening tests from employers seeking to identify and prevent carriers from infecting others at the workplace. When you factor in workplace screening, experts estimate that some 100 million to 200 million tests will be needed for the rest of the year. However, tests remain in short supply, as do testing personnel, reagents, swabs and other materials. And while the diagnostic testing manufacture pipeline is operating at a frantic pace, doubt remains about whether industry will be able to satisfy these soaring COVID-19 testing demands in the near future.

Takeaway

Based on the limited data available, it appears that COVID-19 testing in the U.S. continues to lag behind and that the gap between demand and supply is not likely to close any time soon. Mass testing and screening is likely to remain an elusive objective as the tests that are available remain reserved for the sick and symptomatic.

Genetic Testing: Despite Recommendations, Autism Patients Are Not Fragile X, Karyotype or CMA Testing

Whether due to lack of insurance coverage, personal preference or other reasons, patients with autism spectrum disorder (ASD) are not getting recommended genetic testing. That is the conclusion of a new study published in *Jama Psychology* documenting a disturbing disconnect between professional recommendations and clinical practice.

The Diagnostic Challenge

ASD is among the most strongly genetic neuropsychiatric conditions, with an increased frequency of rare, deleterious copy number variants and single-nucleotide variants. Several medical professional societies recommend Chromosomal Microarray Analysis (CMA) and fragile X testing for people with ASD, and there is growing support for exome sequencing upfront. In addition, as noted in the autism section of the U.S Centers for disease Control's (CDC) website, clinical practice recommendations from the Academy of Neurology and the Child Neurology Society call for genetic testing in children with autism.

The Study

The study, which was approved by the institutional review board at Lifespan and conducted by Dr. Eric Morrow, PhD, head of the Developmental Disorders Genetics Research Program at Brown University and colleagues, evaluated self-reported data on testing in 1,280 people with ASD. Diagnosis of ASD had been confirmed, based on assessment with the Autism Diagnostic Observation Schedule. Participants were between the ages of 1.75 and 68 years, with the following breakdown:

- 0-4 years: 172 participants;
- 5-9 years: 360;
- 10-14 years: 408;
- 15-19 years: 208; and
- 20+ years:132.

Among participants with confirmed ASD diagnosis, only 16.5 percent reported having received some genetic testing. The breakdown:

- Fragile X:13.2 percent (169 participants);
- Karyotype: 7.2 percent (92); and
- CMA: 4.5 percent (57).

Only three percent of participants reported having received both Fragile X and CMA testing. Another 9.4 percent reported that they were unsure whether they had received any testing, and 21.4 percent did not answer the survey.

Takeaway

The study authors suggested multiple reasons for the discrepancy between recommendations and actual testing including:

- *Participant preferences;*
- *Insurance coverage constraints—there was no difference in CMA testing in participants with and without private insurance but there was a strong increase in testing in participants with public insurance;*
- *Limits in clinician knowledge and comfort with genetic testing, with the data showing a lower frequency of genetic testing in people diagnosed with ASD by psychiatrists and psychologists; and*
- *Changes in genetic testing practices over time and a reduced likelihood of adults with ASD being offered testing.*

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Emerging Tests: FDA Pulls Back the Reins on Makers of Unproven Coronavirus Serology Assays, *from page 1*

Because serology testing offers that potential, the U.S. Food and Drug Administration (FDA), the agency that has maintained air-tight control over unproven laboratory developed tests for over a decade, has relaxed its regulatory standards to an unprecedented degree, allowing tests beset with accuracy problems to reach the market without regulatory review. At the same time, it created a more rigorous pathway requiring Emergency Use Authorization (EUA) for higher quality serology tests.

Serology tests tend to be lacking in specificity resulting in false positives causing people who are still susceptible to COVID-19 into falsely believing they are immune; the other issue is lack of sensitivity resulting in false negatives. And in the COVID-19 planning context where sample sizes are limited, small errors in either direction have a disproportionate magnifying effect that can lead to dangerously wrong conclusions.

However, the FDA decided to roll the dice. The good news is that more than 150 serology tests reached the market as a result of the strategy. The bad news is that only 11 of those tests used pathway requiring EUA clearance.

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Emerging Tests: FDA Pulls Back the Reins on Makers of Unproven Coronavirus Serology Assays, *from page 11*

SARS-CoV-2 Serology Tests with FDA EUA Clearance, as of May 18

Date	Manufacturer(s)	Serology Test Receiving EUA
April 2	Cellex	qSARS-CoV-2 IgG/IgM Rapid Test
April 15	Chembio Diagnostics	DPP COVID-19 point-of-care test and analyzer for IgM and IgG antibodies
April 16	Mount Sinai Laboratory	COVID-19 ELISA IgG Antibody Test
April 24	Autobio Diagnostics	Anti-SARS-CoV-2 Rapid Test immunoassay
April 24	Ortho Clinical Diagnostics	SARS-CoV-2 immunoassay
April 24	DiaSorin	Liaison SARS-CoV-2 S1/S2 IgG serology assay detecting IgG antibodies)
April 26	Abbott Laboratories	SARS-CoV-2 IgG antibody test
April 29	Bio-Rad Laboratories	Platelia Total Ab immunoassay for SARS-CoV-2
April 30	NY State Department of Health's Wadsworth Center	New York SARS-CoV Microsphere Immunoassay for Antibody Detection
May 2	Roche	Elecsys Anti-SARS-CoV-2 antibody test
May 4	Euroimmun	Anti-SARS-CoV-2 ELISA test

To make matters worse, companies that took the easy route misrepresented their tests as having FDA approval and made unsubstantiated claims about their products' capabilities. Rather than take the enforcement action, FDA encouraged test makers to use the EUA pathway in the future and submit tests already on the market to independent validation. Predictably, the response was "thanks but no thanks."

FDA Creates New Umbrella Pathway

After coming under enormous criticism, the FDA backed down. Well, sort of backed down. On April 29, the FDA announced creation of a new "umbrella" pathway requiring test makers to submit tests for independent evaluation.

Under the new process, an interagency testing group at the National Cancer Institute would assess the approximate specificity, sensitivity and overall predictive value of submitted tests against a panel of samples confirmed positive for anti-SARS CoV-2 IgM and IgG antibodies. Tests would also be run against confirmed antibody negative samples or pre-COVID-19 samples, with 10 of these 80 negative samples being HIV positive. To receive clearance:

- Tests reporting on both IgM and IgG must perform with overall sensitivity of 90 percent and specificity of 95 percent;

- Tests reporting the immunoglobulins separately must have sensitivity of at least 70 percent for IgM and 90 percent for IgG; and
- Tests must show no cross-reactivity with HIV.

The first batch of tests to undergo evaluation were the assays that received EUA clearance.

Takeaway

The agency continues to walk back its previously ill-advised leniency with serology test makers. On May 22, the agency named 28 assays that it says should be taken off the market. Not surprisingly, all of those tests were products that came through the pathway not requiring EUA clearance, mostly manufactured overseas. The list also includes he list includes tests made by:

- Beverly Hills, California-based Vita Testing;
- Diazyme Laboratories, a subsidiary of defense contracting giant General Atomics;
- Pharmatech, which was acquired by Caris Life Sciences last year; and
- BioMedomics, which developed a rapid fingerstick test formerly sold by Becton Dickinson.

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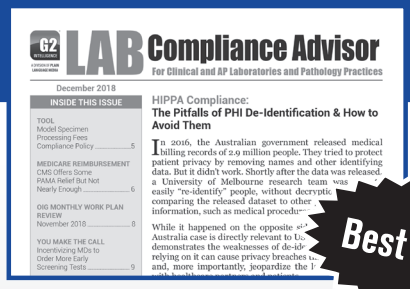
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