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New Trends, Applications, and IVD Industry Analysis

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IN THIS ISSUE

Emerging Tests: FDA Clears the Way for Serial Use At-Home and Point-of-Care Asymptomatic Screening Tests

At-home and point-of-care (POC) serial testing for purposes of screening the asymptomatic is, arguably, the most promising, long-term market for new SARS-CoV-2 diagnostics. On March 16, 2021, the U.S. Food and Drug Administration (FDA) issued new guidance to help developers of these tests bring their products to market faster. Here is a rundown of the new "Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing" (Template) and what it portends for the laboratory test development business.

The Diagnostic Challenge

Notwithstanding the slight uptick in early March, COVID-19 case, hospitalization and death rates across the U.S. are falling and,

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FDA to SARS-CoV-2 Test Developers: Evaluate Impact of Genetic Mutations on Test Performance

Evolution and mutation of SARS-CoV-2 virus has made COVID-19 diagnosis a moving target. On Feb. 22, 2021, the U.S. Food and Drug Administration issued new guidance telling developers of SARS-CoV-2 tests how to evaluate the impact of viral mutations on test performance. The guidance covers all three types of SARS-CoV-2 tests—molecular, serology and antigen—including both tests seeking and that have already received Emergency Use Authorization (EUA).

The Diagnostic Challenge

Like other living organisms, viruses evolve over time. And they evolve quickly. Virus evolution often outpaces diagnostics

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Emerging Tests: FDA Clears the Way for Serial Use At-Home and Point-of-Care Asymptomatic Screening Tests, *from page 1*

knock on wood, will continue to do so in the coming months. Regrettably, though, COVID-19 is not going away; nor is the need for SARS-CoV-2 testing. However, what will change are testing demands and utilization patterns. As the virus retreats, the emphasis is bound to shift from testing the symptomatic for the purposes of providing medical treatment to testing the asymptomatic for screening.

Of course, these products will have to get past the FDA goalie and secure Emergency Use Authorization (EUA) to reach the market. And therein lies the problem. Previously, all of the templates that the agency had created to help developers get EUA were for products designed to test patients with COVID-19 symptoms, recent exposure and other risk factors. Although the agency had signaled its interest in authorizing such tests, it had not developed a template for tests to be performed on asymptomatic individuals on a serial basis as part of a screening program. And without guidance, many developers have been understandably reluctant to invest in serial tests. The Template may allay these fears and drive development of SARS-CoV-2 serial tests for use in screening.

The SARS-CoV-2 Screening Test Template

The Template is more than just guidance and advice. It opens a streamlined and expedited path for EUA of serial tests, specifically POC or at-home tests with demonstrated strong performance in symptomatic persons. For the first time, the FDA has indicated that it will grant EUA for such tests for over-the-counter (OTC) use without first requiring them to be validated in asymptomatic individuals. In a statement, the FDA expressed its belief "that evidence of a test's strong performance in symptomatic patients combined with serial testing can mitigate the risk of false results when testing asymptomatic individuals."

The Template's target audience is developers of molecular and antigen tests for serial use by asymptomatic individuals at home as part of a testing program, such as by health care workers under an employer screening program designed to prevent workplace infection. The FDA suggests that individuals in such programs be tested twice over two to three days with a minimum of 24 hours and maximum of 36 hours between tests. However, developers can still seek clearance for less frequent testing regimens, such as twice a week. **Exception:** Only "higher sensitivity molecular tests" will be considered for tests of once or week or wider frequencies.

The Template explains what developers must do to demonstrate the effectiveness of a test's performance in symptomatic individuals to qualify for expedited EUA. Specifically, developers may generate validation data by testing symptomatic individuals serially according to the guidelines. According to the Template, the FDA will consider authorizing serial tests for OTC use at-home and POC tests if they have a positive percent

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agreement of 80 percent or greater (compared to PCR) with 70 percent at the lower bound of the two-sided 95 percent confidence interval.

Serial tests with sensitivity in symptomatic individuals below 80 percent could still receive EUA; but the Template says that "clinical evaluation in an asymptomatic population would generally be expected prior to authorization of a screening claim, including for OTC use" for tests below the 80 percent mark.

Tests authorized for screening based on symptomatic data will also have to be validated in asymptomatic individuals within a certain timeframe. The FDA also says that it may revise or revoke the EUA of tests that are not validated and that do not show adequate performance in asymptomatic individuals.

Takeaway

Generating data to demonstrate the performance on asymptomatic individuals has been a major bottleneck to development of serial SARS-CoV-2 tests designed for asymptomatic screening. But under the Template, developers may no longer need that data to secure EUA for their products. Companies in a strong position to benefit from this new regime include Quidel, which is currently developing an OTC version of its QuickVue SARS test, as well as those who have products already cleared for at-home use (see the box below). To date, only three companies have gotten EUA for OTC COVID-19 diagnostic products:

- *Ellume for its all-in-one Ellume COVID-19 Home Test*; and*
- *Cue Health for its Cue COVID-19 Test*; and*
- *LabCorp for the Pixel by LabCorp COVID-19 Test Home Collection Kit.*

COVID-19 Products with EUA Clearance for At-Home Testing

- TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific)
- BinaxNow COVID-19 Ag Card (Abbott Laboratories)
- EmpowerDX At-Home COVID-19 PCR Test Kit (Clinical Enterprise, Inc.)

Inside the Diagnostics Industry: Guardant Health Takes Aim at Exact Sciences' Leadership of Colorectal Cancer Market

Colorectal cancer is a key segment of the U.S. and world diagnostics market that generates billions of dollars in test revenues per year and is projected to grow at an annual rate of nearly 6 percent. Although the space is crowded, Exact Sciences is one of if not the leading firms in the market,

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Inside the Diagnostics Industry: Guardant Health Takes Aim at Exact Sciences' Leadership of Colorectal Cancer Market, *from page 3*

particularly the colorectal minimal residual disease segment (MRD). However, in recent months, one firm has made particularly aggressive moves to challenge Exact Sciences for share of the MRD market: Guardant Health.

Exact Sciences' Acquisition of Ashion Analytics

On Feb. 17, 2021, Exact Sciences announced that it has reached an agreement to acquire Ashion Analytics from the Translational Genomics Research Institute (TGen) for an undisclosed price. Ashion is a CLIA-certified and CAP-accredited sequencing laboratory whose genomic testing assets will bolster Exact's efforts to enhance its Cologuard product and develop new precision oncology diagnostics for MRD and other cancers. Those Ashion assets include the GEM ExTra comprehensive cancer test, as well as whole-exome, matched germline and transcriptome sequencing capabilities.

The Ashion acquisition, which is scheduled to close in the second quarter, is just one element of Exact's larger strategic collaboration with TGen. A month earlier, the Wisconsin-based molecular diagnostics firm announced that it had signed a worldwide exclusive license to TGen's Targeted Digital Sequencing (TARDIS) technology, which will now be incorporated into Cologuard. The collaboration also includes 10-year research agreement for development of patents and clinical evidence to support the scientific reliability of MRD testing necessary to secure coverage from payors.

Guardant Health Takes on Cologuard

Guarant Health seems to be emerging as Exact's principle rival in the MRD market. Last year at this time (February 2020), Guardant, which produces its own Guardant360 liquid biopsy assay for MRD, unveiled plans to invest heavily in new products to take on Cologuard and cash in on "significant market opportunities" in the colorectal and MRD space. In 2019, the Redwood, CA-based precision oncology firm launched its Lunar assay, but only for research and drug development use. Meanwhile, stronger than expected Guardant360 sales helped minimize net losses generated by the firm's stepped-up research and development efforts.

On the very same day that Exact announced that it was acquiring Ashion, its rival launched Guardant Reveal, a commercial version of the Lunar assay. Guardant claims that the new test is the first blood-only liquid biopsy test for detection of residual and recurrent disease from a simple blood draw. According to the firm, the new test improves management of early-stage colorectal cancer patients by detecting circulating tumor DNA in blood after surgery to identify patients with MRD who may benefit most from adjuvant therapy and by detecting recurrence months earlier

than current standard of care methods like imaging or carcinoembryonic antigen (CAE) tests.

Takeaway

At this point, Exact Sciences and Guardant Health are not so much competing for as sharing the colorectal and MRD market. Cologuard still reins supreme in screening. But Guardant is spending big bucks to develop a rival screening product to compete with Cologuard. Meanwhile, dual residual and recurrence capabilities of the new Guardant Reveal product move the company deeper into the cancer care pathway. But just as Guardant is working to close the gap with Exact in screening, Exact is collaborating with TGen to expand its presence in colorectal and MRD cancer treatment and case management.

FDA WATCH

First *De Novo* Clearance Signals that Premarket Pathway Is Open for COVID-19 Tests

Just over a year ago, the U.S. Food and Drug Administration (FDA) granted its first Emergency Use Authorization (EUA) for a coronavirus test. On March 17, 2021, the test review process moved to a new phase when the agency cleared a COVID-19 diagnostic via its traditional premarketing pathway for the very first time, thus allowing for marketing of the test beyond the public health emergency.

The first test to make the transition from EUA to *de novo* clearance status is BioFire Diagnostics' BioFire FilmArray Respiratory Panel (RP) 2.1, which detects 22 different viruses and bacteria associated with SARS-CoV-2 and other respiratory tract infections from a singly nasopharyngeal swab in 45 minutes. The FilmArray RP2.1, which was originally granted EUA clearance on May 1, 2020 (that EUA clearance has now been officially revoked as part of the transition to *de novo* status) runs on the firm's FilmArray 2.0 and higher-throughput BioFire Torch systems. BioMérieux subsidiary BioFire has developed a suite of SARS-CoV-2 diagnostic products, including, among others, a singleplex assay for the FilmArray system and the RP 2.1-EZ Panel that detects the coronavirus and 18 other pathogens in point of care and near patient CLIA-waived settings.

The FDA noted that it based its decision to grant de novo clearance, in part, on a review of analytical studies "which demonstrated a reasonable assurance that the BioFire RP2.1 was safe and effective at identification and differentiation of various respiratory viral and bacterial pathogens."

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FDA Watch: First De Novo Clearance Signals that Premarket Pathway Is Open for COVID-19 Tests, *from page 5*

Data from a clinical study of more than 500 samples was apparently a major factor in the agency's determination. A BioMeriéux statement described it as a multicenter prospective clinical study combining reference of three independent EUA molecular SARS-CoV-2 assays. According to the company, the panel demonstrated positive percent agreement of 98 percent and negative percent agreement of approximately 99 percent.

Impact on Future COVID-19 Test Development

The EUA pathway remains open. Thus, the FDA specifically noted that the FilmArray RP2.1 EUA revocation and *de novo* authorization do not affect the availability of other EUA tests. However, the move serves notice that COVID-19 test makers can also use the traditional premarket pathway if they are looking to develop products for the post-pandemic market. "While this is the first marketing authorization for a diagnostic test using a traditional premarket review process, we do not expect this to be the last and look forward to working with developers of medical products to move their products through our traditional review pathways," noted FDA acting commissioner Janet Woodcock in a statement.

The agency is also working on potential new pathways, including via the establishment of "special controls" for labeling and performance testing. "When met," the FDA explained, "these controls, in combination with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type."

The FilmArray RP2.1 *de novo* clearance also creates a new regulatory classification, which, according to the agency, "means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device."

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Here are some of the other key new FDA EUAs and clearances announced in March:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Abbott Laboratories	EUA for Alinity m Resp-4-Plex assay
Abbott Laboratories	EUA for AdviseDx SARS-CoV-2 IgG II test
Inivata	Breakthrough Device Designation for RaDaR liquid biopsy assay
Zymo Research	510(k) clearance for use of DNA/RNA Shield Collection Tube for SARS-CoV-2 testing

Manufacturer(s)	Product
GetMyDNA (Gravity Diagnostics affiliate)	EUA for GetMyDNA COVID-19 Test Home Collection Kit
Gravity Diagnostics + Assurance Scientific Laboratories	EUA for Everlywell COVID-19 Test Home Collection Kit DTC
Broad Institute	EUA for CRSP SARS-CoV-2 Real-time Reverse Transcriptase-PCR Diagnostic Assay (Version 3)
Adaptive Technologies	EUA for T-Detect COVID-19 Test blood-based antibodies assay
Cue Health	EUA for Cue COVID-19 Test for home + over-the-counter use
Phosphorus Diagnostics LLC	EUA for Phosphorus COVID-19 RT-qPCR Test
Luminex	EUA for expanded version of multiplex NxTag Respiratory Pathogen Panel (RPP) that includes SARS-CoV-2 target
Fluidigm	EUA for Advanta Dx SARS-CoV-2 RT-PCR assay for use with Azova COVID-19 Test Collection Kit
Quidel	EUA for QuickVue At-Home COVID-19 rapid antigen test
Viracor Eurofins Clinical Diagnostics	EUA for Viracor SARS-CoV-2 assay
Clinical Enterprise, Inc.	EUA for EmpowerDX COVID-19 Home Collection Kit DTC
University of Illinois	EUA for CovidShield assay
Agilent Technologies	Clearance PD-L1 IHC 22C3 pharmDx as companion diagnostic for also newly approved Regeneron Pharmaceuticals and Sanofi's PD-1 inhibitor cemiplimab-rwlc (Libtayo) as a front-line treatment for advanced non-small cell lung cancer patients with high PD-L1 expression in their tumors
Inova Diagnostics	510(k) clearance for Nova Lite DAPI dsDNA *Crithidia luciliae* Kit

Emerging Tests: New Genomic Test Can Eliminate Up to One-Third of Medically Unnecessary Prostate Cancer Biopsies

Genetic testing has been shown to be effective in detecting prostate cancer and eliminating the need for unnecessary biopsies. And even though the current commercial market for such tests is crowded, it appears that a new product is about to enter.

The Diagnostic Challenge

Prostate cancer is the most common form of cancer in men, claiming more than 10,000 lives per year. But screening for prostate cancer is more problematic than screening for its sister diseases, breast and cervical

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Emerging Tests: New Genomic Test Can Eliminate Up to One-Third of Medically Unnecessary Prostate Cancer Biopsies, *from page 7*

cancer. The effectiveness of current prostate-specific antigen (PSA) blood testing is marred by the PSA protein's lack of reliability as a biomarker. Thus, while high PSA levels denote prostate cancer, the cancer is often low grade and poses no threat to the patient. High PSA may also indicate infection, inflammation or other disease. But because of the risks involved, physicians commonly order biopsies to rule out prostate cancer for patients whose screening tests show high PSA levels. A large percentage of these biopsies ultimately prove unnecessary.

The Study

A new study published in the *Journal of Urology* (March 2021) reports that a urine test called MyProstateScore can enable physicians to avoid one-third of unnecessary prostate cancer biopsies. Developed by researchers at the University of Michigan's Rogel Cancer Center, the MyProstateScore measures levels of cancer-specific genes. Because half of all prostate tumors contain a genetic anomaly, the genes TMPRSS2 and ERG relocate on a chromosome and fuse together, which switches on prostate cancer.

The MyProstateScore assay uses serum PSA, urinary PSA 3 and urinary TMPRSS2:ERG to calculate a score determining the presence of prostate cancer. Its effectiveness in eliminating unnecessary biopsies is based on the results of a validation study performed on 1,525 patients. The researchers found that 338 of the men (22 percent) had grade group 2 or higher cancer on biopsy. Key conclusions:

- **Using a MyProstateScore threshold of 10** resulted in 97 percent sensitivity and 98 percent negative predictive value for ≥ 2 cancer, meaning the test would have prevented 387 unnecessary biopsies and missed 10 grade ≥ 2 cancers; and
- **Using a MyProstateScore threshold of ≤ 10** resulted in 96 percent sensitivity and 97 percent predictive value and would have prevented 32 percent of unnecessary biopsies while missing 3.7 percent of grade ≥ 2 cancers.

Takeaway

The researchers have formed a start-up company called LynxDx to commercialize the MyProstateScore test. In so doing, they will be joining a crowded market dominated by Prolaris (Myriad Genetics), the Oncotype Dx Prostate Cancer Assay (Genomic Health) and the Decipher Prostate Cancer Classifier (Decipher Biosciences, slated to be acquired by Veracyte).

Genetic Testing: AMP Survey Finds that Inadequate Reimbursement Hinders Use of Molecular Diagnostics

Inadequate reimbursement is hindering utilization of molecular testing. That is the conclusion of a new survey from the Association of Molecular Pathology (AMP). Survey respondents also suggested that providing adequate reimbursement for molecular testing would improve not only patient access to but also the quality of medical care by enabling more data-driven treatment decisions.

The Diagnostic Challenge

Molecular diagnostics is a field of laboratory medicine that analyzes human genes to gain a better understanding of diseases, how they develop and how best to treat them. In addition to enabling earlier and more accurate detection of disease, data provided by molecular diagnostics plays a key role in personalized medicine.

Today, clinical laboratories of all sizes and settings provide molecular diagnostics services, typically via both physicians and qualified doctoral scientists with specialized training and experience. Typically, it requires extensive analysis, interpretation and reporting—often more than six hours per test, according to the AMP survey. That is a considerable investment in time, expertise and professional effort. However, many believe that reimbursement provided by current payment systems is not nearly commensurate with the value of these services.

The AMP Survey

Published on March 16, the AMP survey "Analysis of Professional Work Effort in Molecular Test Interpretation Report" included responses from more than 100 molecular professionals from the AMP and American College of Medical Genetics and Genomics (ACMG). Nearly two in three respondents (65 percent) indicated that molecular diagnostics analysis, reporting and interpretation is "a significant or high burden." Technical complexity, additional research requirements, and placing test results in context were the reasons most often noted for extra effort being required in analysis and interpretation.

Respondents also agreed that reimbursement is inadequate for the time spent performing these activities. They indicated that all molecular tests are completed at a financial loss, with one exception: single gene tests for human genetics.

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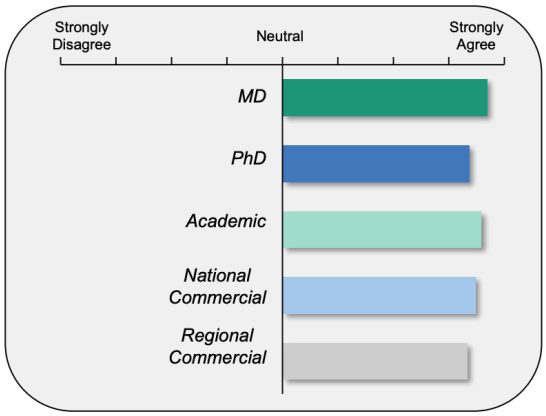
Genetic Testing: AMP Survey Finds that Inadequate Reimbursement Hinders Use of Molecular Diagnostics, *from page 9*

Respondents were asked to rate their personal agreement with the view that reimbursement for analysis, reporting, and interpretation is insufficient for the time they spent performing these activities.

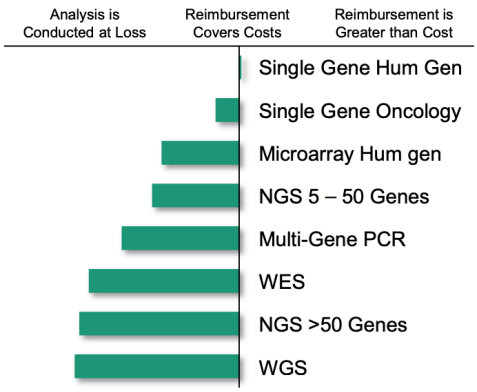
Responses to "Effort spent on data analysis/reporting is NOT sufficiently reimbursed relative to the effort and time commitment required. "

Agreement with Statement



Data analysis and reporting was viewed as insufficiently reimbursed by MDs and PhDs in academic and commercial settings

Reimbursement of Analysis for Individual Tests

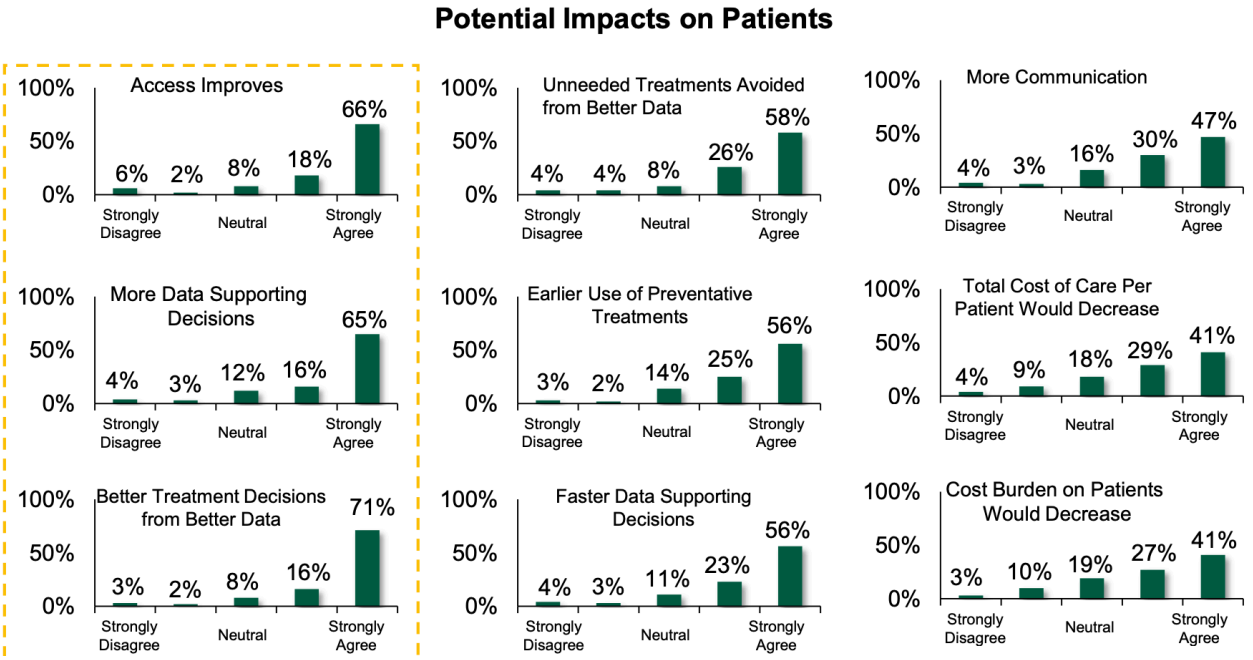


Only single gene tests for human genetics were considered to not result in a loss based on analysis, interpretation, and reporting

Source: Laboratorian Survey; ClearView Analysis.

Furthermore, survey responds agreed that access, data and decision making would improve from better reimbursement for analysis and reporting while there was less confidence in cost reductions.

Questions were asked of respondents to assess the likelihood of improvements in the patient-related factors from adequate reimbursement.



Other key findings:

- Increasing utilization in complex testing paradigms, such as whole genome sequencing, whole exome sequencing and next generation sequencing will likely result in higher analysis, interpretation, and reporting burdens in the future;
- Laboratories are using more non-doctorate case managers for communication, limiting the number of tests offered, and sending out tests to manage costs;
- Current trends and limited reimbursement may compel community laboratories to stop performing molecular tests which would then be redirected to academic and national reference laboratories; and
- Academic and large laboratories could be stressed by an influx of poorly reimbursed tests that other laboratories no longer perform.

Takeaway

The AMP survey raises the warning that unless and until reimbursement patterns change, it may be economically unviable for many laboratories to offer molecular diagnostics services. The AMP makes five recommendations of future steps to address these concerns:

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Genetic Testing: AMP Survey Finds that Inadequate Reimbursement Hinders Use of Molecular Diagnostics, *from page 11*

1. Work to develop informed perspectives on the future testing landscape, including the increasing adoption of more complex tests, and use this data to forecast future analysis burdens on laboratories;
2. Explore case studies to understand how existing analysis burdens impact laboratory function and how this could increase with anticipated changes;
3. Engage with physician and patient groups to better define negative outcomes from slow, expensive or insufficient testing;
4. Advocate for policy changes that will positively impact reimbursement for interpretive services and report preparation for pathologists and qualified doctoral scientists; and
5. Educate payors about the complexities of molecular testing and intricacies involved in analysis, interpretation and results reporting.

FDA to SARS-CoV-2 Test Developers: Evaluate Impact of Genetic Mutations on Test Performance, *from page 1*

development. As a result, diagnostics designed to detect current iterations may be incapable of detecting the mutated virus by the time they are put into use. This creates the risk that the test will produce false negative results.

The concern is that SARS-CoV-2 virus evolution may be following this pattern. Since the original virus was first detected over a year ago, variants of it have turned up across the globe and in the U.S., including the B117 variant first isolated in the U.K., the B1351 South African variant and the P1 Brazilian variant.

To keep up with the pace of evolution, developers of SARS-CoV-2 tests must evaluate how viral mutations may affect test performance. Last month, the FDA issued an alert warning that current tests may be missing the B117 and possibly other variants. The new guidance lays out a series of recommendations about what developers should do to evaluate viral mutation impact on test performance.

Molecular SARS-CoV-2 Tests

Molecular SARS-CoV-2 tests are designed to detect the virus by targeting one or more specific region(s) of the viral RNA genome. But if the genome mutates, the test may seek the wrong target. And when it fails to detect that target, it may produce a false negative finding. The susceptibility of a particular test depends in part on how it is designed. Thus, for example, tests designed to detect multiple genetic targets are less susceptible

than tests that detect a single target. Other factors affecting the impact of genetic variants on molecular test performance include the variant's sequencing and prevalence in the patient population.

The guidance calls on molecular test developers to account for all these factors by:

- Designing their tests so as to minimize the impact of viral mutations on test performance;
- Routinely monitoring for viral mutations that may impact test performance; and
- Clearly communicating any test limitations in the test's labeling.

Developers seeking EUA for a new test should include in their submission a description of how they evaluated test performance across all known variants having mutations in the targeted region, along with a discussion of how test design mitigates the risk of future viral mutations impacting the test performance. The submission should also address whether the labeling should include statements or limitations indicating when the specimens used in clinical evaluations were collected and noting that performance may vary depending on the variants. Developers of tests that have already received EUA should reach out to the FDA to determine whether they need to update the labeling.

The guidance suggests that developers of tests with multiple targets include a "highly conserved pan-SARS-CoV target," that is not specific to SARS-CoV-2 to improve performance with a new genetic variant. If they do, there may be a need for more information on appropriate result interpretation.

The agency also calls on developers to conduct sequence alignment of their primer and probe sequences with available SARS-CoV-2 genomes to determine whether the mutations will impact test performance. If there is an impact, developers should calculate the percentage by which the mutations could reduce performance. If they determine that the impact is 5 percent or more, they should notify the FDA via a supplemental EUA request.

If there is a mutation expected to result in a mismatch within the target primer and probe binding sites, developers should evaluate hybridization changes and give the FDA:

- Information on the results from melting temperature calculations with the primers and probes;
- An analysis on how the melting temperature changes as the salt and primer concentration changes;
- An analysis of the likelihood that the mutation will impact performance;
- An evaluation of that impact on benefits and risks for the tests;

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FDA to SARS-CoV-2 Test Developers: Evaluate Impact of Genetic Mutations on Test Performance, *from page 13*

- A justification for any actions taken based on the analysis outcomes.

Serology & Antigen SARS-CoV-2 Tests

Serology and antigen tests detect SARS-CoV-2 indirectly by detecting, respectively, the antibodies the body produces to fight off the virus and the antigens those antibodies secrete. Mutations in the viral genome may also produce changes to the viral proteins the test targets and result in false negatives.

The guidance says that serology and antigen test developers should touch base with the agency early in the development process and consider the potential impact of genetic mutations and variants already in circulation. Specifically, they should develop a plan to:

- Routinely monitor for new genetic mutations and viral variants; and
- Assess how mutations or viral variants impact test performance, as needed, considering the potential of a given mutation or viral variant to impact their test.

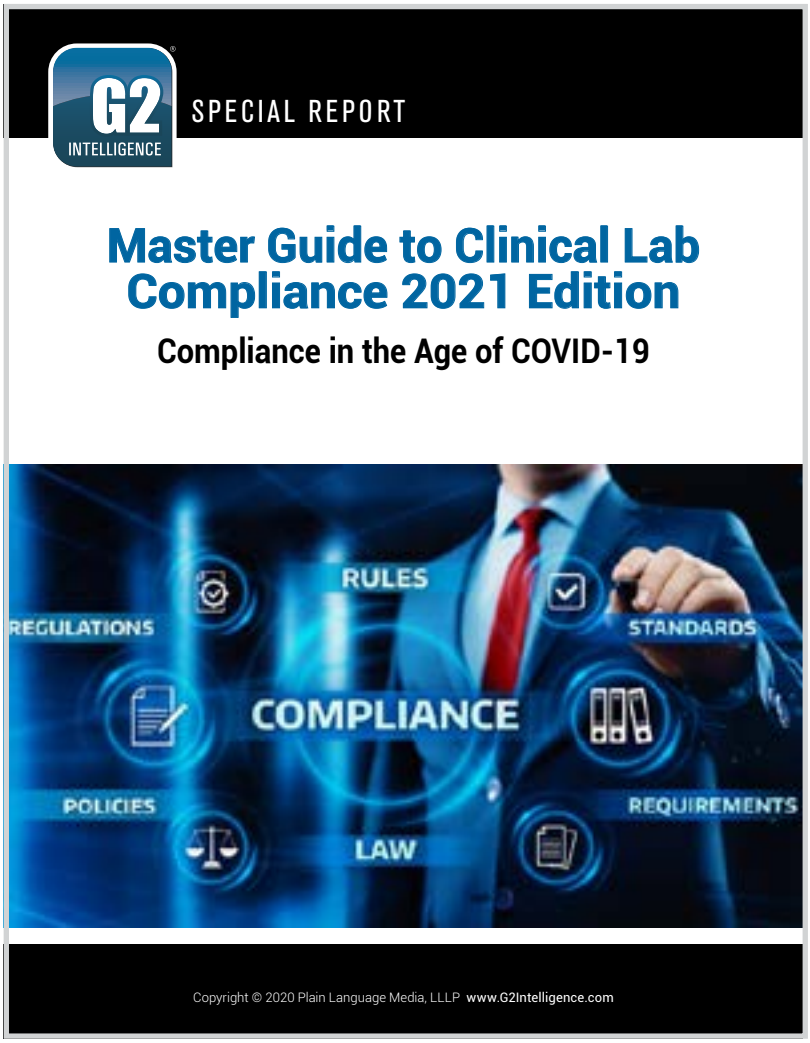
As with molecular tests, developers should measure the potential impact of mutations on test performance and notify the FDA of potential reductions of 5 percent or more.

Takeaway

As of now, the recommendations contained in the guidance are just that—recommendations. However, that is likely to change. The guidance notes that the agency is considering evaluation of virus mutation impact on test performance a mandatory element of the EUA submission. If the FDA goes that route, it will presumably incorporate many if not most of the guidance's recommendations. In any event, the agency promises to immediately notify test developers if viral mutation analysis becomes a requirement of EUA submission.

Master Guide to Clinical Lab Compliance 2021

Compliance in the Age of COVID-19



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