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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Where Is the FDA When Labs Need It Most?

LET'S START WITH AN ESSENTIAL FACT: in the management of almost every outbreak of a novel infectious disease, clinical laboratory tests will be essential in diagnosis of the disease, in monitoring the progress of an infected patient, and in determining if, once cured, a patient has immunity to that disease.

Next, let's recognize another basic fact: clinical lab testing is just 3¢ on the healthcare dollar. The healthcare system gets incredible value when lab tests are used appropriately by physicians.

Unfortunately, since the first days of the SARS-CoV-2 outbreak, it seems federal officials at different agencies and departments are ignoring the truths of the two facts presented above. Their actions involving clinical lab testing have been regularly criticized and second-guessed almost daily in the national news cycle.

It is easy to argue that, following the first COVID-19 patient diagnosed in the United States in late January, the directives and decisions of multiple federal agencies have stymied the efforts of clinical laboratories in the United States to quickly step up with large volumes of SARS-CoV-2 tests that can help authorities better manage the COVID-19 pandemic.

First it was the CDC's distribution of a molecular COVID-19 test in February that was defective. At about the same time, federal authorities issued directives that prevented some of the nation's best labs from speedily developing COVID-19 tests as LDTs and using them for patient care.

It should not be overlooked that Medicare officials contributed their own hurdles to larger volumes of COVID-19 testing when the **Centers for Medicare and Medicaid Services** set reimbursement for molecular COVID-19 at just $51, substantially below what it cost even the nation's billion-dollar labs to run such tests. After a few weeks of negative national press coverage, CMS raised the price of such tests to $100.

For the **FDA**, on March 16, it issued relaxed rules for COVID-19 serological tests. Within weeks, more than 200 such tests were listed on the FDA's website and it was forced to retreat. It issued tighter rules on May 4 that reduced the number of serology tests listed on its website. But now comes information from the agency itself that its own assessment of the first 11 COVID-19 serology tests showed that eight tests did not meet its performance requirements. TDR

Serology Test Review: FDA Says 8 of 11 Tests Fail

Only three of the COVID-19 serology tests with EUAs met the FDA's published requirements when evaluated

CEO SUMMARY: After introducing some 200 serological assays onto the market in March and April with little or no review, as of this writing the FDA website lists only 77 serology tests. Of that number, 11 assays have been evaluated independently and eight of those 11 have been pulled from the market. Also, the FDA says 45 tests should no longer be distributed, and among those tests, 21 had been granted emergency use authorizations and 11 were removed voluntarily by the manufacturers.

NEW EVIDENCE PRODUCED BY FEDERAL RESEARCHERS indicates that a substantial number of COVID-19 serological tests that currently have a **Food and Drug Administration** (FDA) emergency use authorization (EUA) may fail to perform to the minimum requirements established by the FDA.

This situation is a cause of great concern for pathologists and clinical laboratory administrators throughout the country because of the huge—and steadily increasing—demand for accurate and reliable COVID-19 serological tests.

Yet, the latest findings of a federal research laboratory show that 73% of the COVID-19 serology tests with an FDA EUA reviewed to date fail to meet the requirements established by the FDA!

This is extremely bad news for clinical laboratories in the United States. They rely on the FDA to issue standards and clear diagnostic instruments and tests for market that perform reliably, accurately, and produce high-quality test results for use in clinical settings.

Moreover, labs are at risk for liability, malpractice and similar other legal claims if they produce lab test results that fail to meet the standards for accuracy and clinical care. For this reason, the FDA's careful review and clearance of a medical device or a diagnostic test is meaningful and important for clinical laboratories, the physicians who order tests, and the patients being tested.

Since June 1, the FDA has twice released sets of performance data on COVID-19 serology tests with EUAs that were generated by independent evaluations conducted by the FDA and the **National Cancer Institute** (NCI). Based

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on the assessment of each test's performance, the FDA then assigned a marketing status to those tests.

The first data release was on June 4. The FDA announced that, of the three COVID-19 serology tests evaluated, only one could continue to be marketed.

Eleven Tests Evaluated

The next data release came on June 19. The FDA and NCI had completed evaluations on a total of 11 tests and determined that only three can continue to be marketed under the EUAs the agency granted. This meant that eight of the tests reviewed—each of which had an EUA—could no longer be marketed.

These poor results from the FDA's own review of COVID-19 serology tests with EUAs raise major concerns. Across the nation, many labs are negotiating to purchase and validate COVID-19 serology tests that have EUAs.

The fact that of the first 11 such tests reviewed by a federal laboratory, eight tests can no longer be marketed raises a valid point: can a clinical lab be confident that when it purchases a COVID-19 serology test with an EUA for use in patient care, the test will deliver accurate and reproducible results?

In truth, the fact that the majority of COVID-19 serology tests reviewed to date by federal researchers cannot be marketed is now the latest chapter in an ongoing series of bad decisions and missteps happening at the FDA.

Public Criticism

Experts in diagnostics and laboratory medicine have publicly criticized the FDA for certain actions it has taken in its response to the COVID-19 pandemic. At a time when state governors and the president want to unleash the full potential of clinical labs to respond to the pandemic, certain of the FDA's directives have been counter-productive in enabling the nation's labs to deliver the large volumes of testing required to manage the pandemic.

The FDA's release of research lab findings that 73% of COVID-19 serology tests reviewed failed to meet requirements is the latest chapter in a story that began with the COVID-19 outbreak earlier this year. The serological test part of this story began in March.

On March 16, the FDA issued rules allowing lab test manufacturers to market serological tests for the coronavirus with little or no agency review. At the time, the agency said it was granting "regulatory flexibility for developers offering such tests without FDA review and without an emergency use authorization (EUA)."

The test manufacturers needed to notify the agency that they had validated their serological tests and provide disclaimers about the limitations of the tests.

"The FDA does not review the validation or accuracy of the data for these tests unless an EUA is submitted," said the federal agency at that time.

No Performance Analysis

The suspension of FDA review for COVID-19 serological tests was designed to both shorten the time for such tests to reach the market and increase the number such tests available for purchase and use by clinical laboratories.

But listing tests without a traditional review by the federal agency created exactly the problem predicted by critics. They foresaw that the FDA's relaxation of rules governing COVID-19 serology tests would allow companies—many without any operating history—to list a COVID-19 assay with the FDA, supported by minimal data, then offer it in the marketplace.

After the FDA opened the floodgates to test developers, more than 200 serological tests for the coronavirus were listed on the FDA's registry and poured into the market in March and April. It meant clinical laboratories were on their own to determine which of these tests would be accurate and high quality and which would not.

Strong evidence that FDA officials realized the folly of issuing the relaxed

FDA Says 45 COVID-19 Serological Tests Should No Longer Be Distributed for Clinical Use

On the website of the federal Food and Drug Administration, there does not appear to be a list of the 200 or so serology tests for the SARS-CoV-2 coronavirus that were approved for marketing in March.

And, there does not appear to be a full explanation for why the FDA accounts for the disposition of only 77 serology tests for the antibodies. There is, however, a list of 45 tests that the FDA says should no longer be distributed for COVID-19.

In a statement, a spokesman for the FDA said, "Antibody tests on this new removal list include those voluntarily withdrawn from the notification list by the test's commercial manufacturer and those for which there is not a pending emergency use authorization (EUA) request or issued EUA. FDA expects that the tests on the removal list will not be marketed or distributed."

Of the 45 tests on the "not to be marketed or distributed" list, there are 11 that the manufacturers have removed voluntarily. They are:

- **Artron BioResearch/Artron Labs**: COVID-19 IgM/IgG Antibody Test
- **BioMedomics**: COVID-19 IgM-IgG Rapid Test
- **Diazyme Laboratories**: Diazyme SARS-CoV-2 Antibody Rapid Test
- **Genlantis Diagnostics**: CovidQuik Coronavirus (COVID-19) IgM/IgG Antibody Test
- **Hangzhou Testsea Biotechnology**: One Step SARS-CoV-2(COVID-19) IgG/IgM Test
- **Hunan RunKun Pharmaceutical**: SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)
- **IMMY**: clarus SARS-CoV-2 Total Antibody EIA
- **Phamatech**: COVID-19 IgG/IgM Rapid Test
- **Saladax Biomedical**: COVID-19 IgG/IgM Rapid Antibody Test
- **Shenzen Landwind Medical**: COVID-19 IgG/IgM Rapid Test
- **Zhuhai Encode Medical Engineering**: Novel Coronavirus (COVID-19) IgG/IgM Rapid Test

rules for allowing COVID-19 serology tests into the market with review came just seven weeks later. On May 4, the agency reversed course and issued new guidance on serology testing. *(See TDR, "FDA Replaces March 16 Serology COVID-19 Rules," May 11, 2020.)*

Tighter Rules for COVID Tests

The FDA's new guidance required test manufacturers to either register their coronavirus antibody assays with the agency and obtain EUAs to market the tests or to withdraw their tests. Since then, no more than 77 such COVID-19 serology tests are listed on the FDA's site. This number fluctuates almost daily as tests are added and deleted.

Of those 77 tests, the FDA said 11 have been evaluated independently, 21 have been granted emergency use authorizations, and 45 should no longer be distributed. About those 45 tests, however, the agency provides little detail on why they were pulled except to say that the manufacturers of 11 of the 45 tests removed those assays voluntarily.

Most significantly, the FDA, the National Cancer Institute (NCI), and other federal health agencies have collaborated to conduct independent evaluations of 11 of the serological assays for the coronavirus. These evaluations are significant because eight of those 11 tests have been pulled from the market as a result of poor performance, according to the

FDA and NCI, a division of the **National Institutes of Health**.

To the credit of the FDA, it is proceeding with an assessment of COVID-19 serology tests that are listed on its site. This work is being done at the **Frederick National Laboratory for Cancer Research** (FNLCR), a federal research and development center affiliated with the National Cancer Institute (NCI), a division of the **National Institutes of Health** (NIH).

Yet, it is a troubling fact that the first results of these evaluations show that eight of the 11 COVID-19 serology assays evaluated by FNLCR are to be removed from the market. These findings put a cloud over many of the COVID-19 serology tests still listed on the FDA's site.

One expert on diagnostic testing told The Dark Report that the FDA and FNLCR testing program appeared to focus on the "poorly-performing tests coming from China and from other parts of Asia and being offered for sale in the United States." He further noted that "the findings are unsurprising and should not be extrapolated to tests from known and reputable manufacturers."

Test Performance Questions

There is another reason why the uncertainies about the performance of certain COVID-19 serology tests listed on the FDA's website is a problem. It is already obvious in the marketplace that the major IVD manufacturers are devoting most of their available supplies of reagents and test kits to their larger lab customers.

Meanwhile, community hospital labs, independent labs, and physician's office labs that are CLIA-certified as complex labs are not able to buy sufficient quantities of COVID-19 tests from the major vendors to meet even minimum needs.

Therefore, these are the labs most likely to go to the FDA's website and purchase COVID-19 serology tests listed there made by lesser-known companies. Labs relying on the FDA's serology test listings should proceed cautiously. TDR

—Robert L. Michel

Three Serology Tests Can Remain on Market

In its June 19 announcement about the test review, the FDA stated that three COVID-19 serology assays can remain on the market and that each had sensitivity and specificity levels of 90% or higher. Those three tests were:

- **Euroimmun**: SARS-CoV-2 ELISA (IgG),
- **Hangzhou Biotest Biotech**: COVID-19 IgG/IgM Rapid Test Cassette,
- **Healgen**: COVID-19 IgG/IgM Rapid Test Cassette.

Eight tests the FDA said should not be distributed for sale all had sensitivity and specificity levels well below that of the three tests that were authorized for sale.

Among the eight that should not be distributed, the FDA revoked the EUA for **Chembio Diagnostics'** DPP COVID-19 IgM/IgG System. About this test the FDA said: "On June 16, FDA determined that the statutory criteria for issuing an EUA … are no longer met. Specifically, FDA determined that it is not reasonable to believe the product may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the device when used for this purpose outweigh its known and potential risks. FDA also concluded that based on the risks to public health from false test results, revocation is appropriate to protect the public health or safety."

The manufacturers of three other tests withdrew their assays voluntarily. When the FDA shows the marketing status as "should not be distributed—voluntarily withdrawn," the manufacturer has stopped distribution and asked the FDA to remove the test from among those offered for sale. When the marketing status is "should not be distributed—removed," either an EUA request was not submitted on time or the FDA determined not to issue an EUA for the test, the agency noted.

Questions Arise as FDA Assesses Serology Tests

Federal lab is studying COVID-19 serology tests for the FDA, but little is known about this process

CEO SUMMARY: On June 4, the FDA released results of an evaluation of some of the 20 tests offered for sale in this country to identify antibodies for SARS-CoV-2. A quality control expert in clinical labs called the antibody test analysis deeply flawed in part because of the study's design. The FDA evaluated serology assays using 110 samples from patients, including 80 samples expected to be negative, the expert said. But the FDA may not know if any of those 80 samples are from patients who are immunocompromised, or who may have been infected with a similar virus, he added.

FEDERAL SCIENTISTS ARE USING A DEEPLY-FLAWED METHODOLOGY to evaluate serology assays for the novel coronavirus, according to an expert in clinical lab quality control.

If the analysis is flawed, this development would be the latest in a series of poor decisions and counterproductive directives that federal agencies have made regarding diagnostic testing since the COVID-19 pandemic began in the United States in late January.

A flawed analysis means that some of the serological COVID-19 tests that have emergency use authorizations (EUAs) from the **Food and Drug Administration** (FDA) which are currently in use by clinical labs could be withdrawn as a result of being unreliable for clinical purpose.

On May 5, the FDA announced that it would conduct an independent evaluation of antibody assays for SARS-CoV-2 that have EUAs. The FDA and other federal health agencies are doing the evaluations to determine the accuracy of those tests, 20 of which are currently for sale nationwide after the FDA issued EUAs for them without review.

The goal of the analysis of the 20 serology or antibody tests is to determine if each assay or test kit will identify SARS-CoV-2 antibodies when those antibodies are present in a patient's blood, the agency said. The analysis also will determine if the tests do not signal when those antibodies are not present, the FDA added.

COVID-19 Test Reviews

On June 4, the agency released the first findings from its analysis of several of the 20 COVID-19 serology tests from what it said is an independent performance validation study. The serology tests were evaluated at the **Frederick National Laboratory for Cancer Research** (FNLCR), a federal research and development center affiliated with the **National Cancer Institute** (NCI), a division of the **National Institutes of Health**.

In an interview with THE DARK REPORT, a clinical lab professional and expert in quality control processes for clinical laboratory testing questioned the methodology of the analysis. "I am concerned that the foundations of this study are so flawed that use of the results will

have a very high risk of poor regulatory decisions," said Michael A. Noble, MD, Chair of the Clinical Microbiology Proficiency Testing Program, and of the Program Office for Laboratory Quality Management, in the **Department of Pathology and Laboratory Medicine at the University of British Columbia**, in Vancouver.

In its announcement on May 5, the NCI said its researchers would use a validation set of 110 blood samples for each serology test being assessed. Of those 110 samples, 30 would be from individuals who had confirmed SARS-CoV-2 infections, and 80 samples would be from people whose specimens were collected before the pandemic began and so would not have been infected with SARS-CoV-2, the virus that causes the COVID-19 illness. The samples would be used to test for the presence of IgG and IgM antibodies, the NCI said.

Noble cited a number of concerns about the design of the evaluation study. "This analysis is sending off all sorts of danger signals, primarily because the NCI's validation set is badly flawed," he said. One significant problem stems from the use of the 110 validation samples.

"Of those 110 samples, they are hoping that 80 of them (or 73%), will be negative," he explained. "But they probably don't know if any one of those 80 samples is from a patient who had a cold at the time of sample collection and thus could have antibodies to a beta-coronavirus.

Unexpected True Positives?

"Let's assume that of the 80 patient samples, five samples (or 6%) were collected from patients who had colds and thus have antibodies. How would the researchers know if the results from those samples were false positives or unexpected true positives?" Noble asked.

"Another problem is that only 30 (27%) of the 110 samples are from what the FDA calls confirmed cases, but any number of variables could affect the likelihood of those patients having antibodies," he commented. "If any of those patients are over 80 years old and from nursing homes, then the odds are likely that they are poor antibody producers.

"Similarly, if any of those 30 samples are from patients who are obese and diabetic, then they tend also to be poor antibody producers," he noted. "If the samples are from people with autoimmune disorders—such as lupus, rheumatoid arthritis, or who have had a transplant—then those patients likely are on therapy to suppress their immune systems, which would affect the analysis. Also, if the blood came from patients diagnosed with COVID-19 a month earlier, then those patients had a response but are starting to lose the signs of that response."

More Questions to Ask

Noble then identified two other problems with the FDA's positive group. "First, this group is so small that the risk of bias is huge. Second, it seems appropriate to ask that since the NCI is doing this study, are the sera being used from patients the NCI has previously tested? If so, then some of them—and perhaps all—are, by definition, immune-compromised, either by illness or treatment. Such a population is hardly one upon which we can make predictions for the general population."

Other problems that Noble cited about the NCI's methodology would seem obvious to most clinical lab professionals involved in quality control.

"One of the first questions I'd ask is why did the NCI decide to bias the validation panel toward getting a negative result by having more than double the number of specimens from people who probably were not exposed to the virus?" he said. "More important, have they agreed that the 110 samples should all be blinded for the laboratory doing the evaluation so that the researchers have no idea what to expect?

"Also, have the researchers created the sample sets so that the laboratory can

get as many as four copies of the same serum sample from the same patient (and blinded, of course) to ensure that the same sample is read consistently?" he asked.

Noble posed other questions about the researchers' plan to ensure accuracy. In May, NCI said that every sample in the validation panel would be tested by at least two separate labs, but then NCI did not name the labs or provide information about the types of testing those labs do.

As a quality-control expert, Noble has often been critical of the FDA's efforts to evaluate molecular and serological tests for the coronavirus, as well as the speed at which the agency has allowed COVID-19 tests into the market for patient care.

In previous commentary for THE DARK REPORT, Noble emphasized that quality control should be done slowly and methodically, but that the FDA has proceeded too quickly in an effort to get tests onto the market. "This evaluation of the COVID-19 serology tests is another good example of choosing between doing it fast or doing it right," he noted. *(See, DARK DAILY e-briefing, "Chinese Firm to Replace Clinical Laboratory Test Kits After Spanish Health Authorities Report Tests from China's Shenzen Bioeasy Were Only 30% Accurate," April 3, 2020, https://tinyurl.com/y8ps3s4w.)*

Involve 10 Labs in Study

"Considering the importance of this study of the performance of COVID-19 serology tests that already have an FDA EUA, why would these federal agencies accept an answer as valid if there is agreement between only two laboratories?" he asked. "Given the size and significance of the NCI, and the fact that the researchers call this study a federal effort, why not require agreement among something closer to 10 laboratories?

"If a sample is found to have discrepant readings, then at a minimum, laboratories would want to know if concordance is one-out-of-two or nine-out-of-10," he said. "A larger number of labs in concordance would provide more confidence about the COVID-19 serology test undergoing review.

"Also, I would expect the federal agencies to use a variety of laboratories to confirm the samples in the validation panel," he explained. "Because these are all new COVID-19 tests that could be offered in a large number of laboratories nationwide, one would hope NCI would have testing done in a variety of laboratories.

Define Labs by Size, Type

"I understand that federal officials may not want to identify the laboratories, but at least they should be able to define them by size and type," he said. "Are they research laboratories versus clinical laboratories? Or are they community-based private labs, university, or government labs?" he asked.

When the NCI explained its methods last month, it discussed sensitivity and specificity of the coronavirus test results in terms of false-positive and false-negative results. The NCI wrote, "False-negative results could lead people to believe that they haven't been infected when they actually have, potentially preventing them from returning to work, school, or other activities.

"Also, false-positive results would cause people to think they have been infected and have developed an immune response, when they haven't," NCI added. "Incorrect results could also provide a skewed picture of how many people have been infected and the true death rate."

The NCI's explanation about the general understanding of sensitivity and specificity is correct, Noble commented. "And, to their credit, the FDA has recently identified a so called 'gold standard' for this testing in the sense that they are using the results of the ELISA (pan-Ig, IgG, and IgM) assay from the federal **Centers for Disease Control and Prevention** (CDC) and an IgG receptor binding domain (RBD) ELISA that the **Krammer Laboratory** developed," he added. "In my opinion, that's a good development.

"But then problems arise because of the use of the negative samples, and two of those samples tested positive to the gold standard," he explained. "That fact proves my point as to why they are likely to find antibodies to other coronaviruses."

Reactivity in Two Samples

When it started publishing its serology test evaluations this month, the FDA said it noted reactivity in two samples at the FNLCR lab. Sample C0063 showed reactivity in the pan-Ig CDC spike ELISA and sample C0087 showed reactivity in the IgG RBD ELISA, Noble reported. "In 80 samples of supposed-to-be-hard negatives, this result represents a failure rate of 2.5%," he commented. "That result seems to be a potentially big deal.

"It's possible to characterize these two sample reactivity results under the heading of 'no test is perfect,' but politicians and public health officials have put far too much emphasis and pressure on these test results," he added. "The consequence of a false-positive result can mean a patient would need to be hospitalized, which could lead to exposure to nosocomial infections. Or, a false positive also could mean that a patient would lose days or weeks of work and maybe be required to be quarantined or isolated for a period of time.

"If the FDA designed this study with more precision, we might be able to put these false positives into perspective," Noble commented. "But the study's design flaws leave us with more questions than answers.

Antibodies to a Coronavirus

"Just because a person has had symptoms of the new coronavirus, does not mean that person is capable of making antibodies," he noted. "And, just because that person was tested before the pandemic does not mean that individual did not have antibodies to a coronavirus related to but distinct from SARS-CoV-2."

In conclusion, Noble offered some standards that quality control experts might apply when verifying or validating antibody testing for the new coronavirus. "Such studies should require planning that includes sound definitions of what constitutes a positive versus a negative sample," he recommended. "Also, these studies should include a spectrum of samples, including a range of patient ages and conditions, and the studies should be designed in a manner so that the full range of results are available and appropriate for interpretation.

"On its surface, the FDA's study with NCI does not meet any of those requirements or expectations," continued Noble. "I would argue that considering the import and influence this study could have, an independent body of testing specialists should be asked to study and comment on the design. Also, those experts should have access to the patient information associated with the samples and have the authority to comment on and critique the results."

'We Want Results Tomorrow'

Finally, Noble offered an explanation about why the FDA and NCI proceeded as they have with this analysis. "With this study, they've tried to proceed as quickly as possible," speculated Noble. "It's as if someone said, 'We need this done now, and we want the results tomorrow.'

"Designing and implementing a study in this manner, it's as if the goal of federal officials is to complete the analysis as quickly as possible and worry about the details later," he concluded. "From day one of this pandemic, that's been the whole story of test analysis at the FDA for the new coronavirus."

These observations about the design of the FDA's assessment program being conducted at the FNLCR lab show that the entire clinical laboratory profession would benefit from more transparency and more engagement in this process. TDR

—Joseph Burns

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Health Insurers Push Back On COVID-19 Test Claims

Lawyer says payers are finding multiple ways to question claims from labs for coronavirus tests

CEO SUMMARY: Under new federal laws, health insurers are required to pay for testing for the novel coronavirus without cost-sharing, prior authorization, or medical management limits, but insurers are questioning these COVID-19 lab test bills and denying many of the claims, a healthcare attorney said. Payers are challenging the medical necessity of COVID-19 tests, such as for patients needing surgery and when nursing homes, long-term care facilities, and other employers test their employees who are asymptomatic, she added.

After Congress passed two laws in March requiring payment for SARS-CoV-2 lab tests, clinical laboratory administrators and pathologists may have expected payment for their COVID-19 lab test claims to surely follow. That optimism is proving to be misplaced.

Commercial health insurers have questioned a number of the bills clinical labs have submitted for SARS-CoV-2 tests, according to Danielle Sloane, a member of **Bass, Berry and Sims**, a law firm in Nashville. One of the first questions health insurers ask is whether the testing for COVID-19 is medically necessary, she said. Early in the pandemic, the problem of denied payment for COVID testing was quite common and it has continued into June, she added.

"Payers are questioning medical necessity for asymptomatic patients receiving COVID-19 tests before elective surgeries, and when employers, nursing homes, and long-term care facilities submit claims after testing their employees—whether such testing is state mandated or not," she explained. "Payers also are pushing back on claims from out-of-network laboratories or when out-of-network physicians order these tests."

When commercial health insurance companies deny COVID-19 test claims, Sloane has recommended that her lab clients send appeal letters to the insurers explaining that payment for coronavirus testing is required under two bills that Congress passed and President Trump signed into law in March. Those laws are the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security (the CARES) Act.

Guidance Issue by the Feds

On April 11, three federal departments (**Health and Human Services**, **Labor**, and **Treasury**) issued guidance jointly to implement the COVID-19-related coverage provisions in those two federal laws. The legislation requires comprehensive commercial health insurance plans to cover COVID-19 lab testing and related services without cost-sharing.

But ever since that guidance was issued by the three federal agencies, health insurers have denied some COVID-19 lab test claims, Sloane explained. In addition,

certain payers are lobbying Congress and the federal agencies to carve back the requirements enacted under the Families First and CARES Acts that mandate payers pay for such testing, she added.

COVID-19 Test Rules

"The problem with writing about these issues is that the rules are changing rapidly—particularly with respect to state mandates for COVID-19 testing and state department of insurance statements about what COVID-19 testing qualifies as medically necessary," reported Sloane. "Right now, there are good arguments for coverage, but also some risk for clinical laboratories. This is why it is imperative that pathologists and lab managers call their in-house lawyers or outside counsel to understand what COVID-19 tests payers are required to cover.

"This is a big percolating area of concern," Sloane said in an interview with The Dark Report. "These denials were mostly in the context of early testing for symptomatic patients, but it continues even now, particularly over the issue of medical necessity.

"This problem should be relatively easy to solve with an artfully-drafted letter," she advised. "For my clients, I have drafted letters to payers saying, 'You're obligated under law to pay for this COVID-19 lab testing.' But these things take time and each case is different."

Letters Challenge Denials

One problem clinical laboratories face when seeking payment is that health insurers have multiple ways to question their obligations to pay for coronavirus tests.

"When a lab performs COVID-19 tests for symptomatic patients, those claims clearly should be covered," Sloane explained. "But it is also true that SARS-CoV-2 testing is starting to evolve into more than one category."

One such category are patients who need presurgical testing. "A patient about to undergo surgery may be asymptomatic, but if one state mandates COVID-19 testing—or if the hospitals themselves decide that such testing is required—does that mean these new coronavirus tests are medically-necessary as well," she asked.

"In this situation, payers may challenge whether these tests are appropriate," Sloane said. "These health insurers want to know if the COVID-19 testing is to protect the patient, the hospital staff, other patients, or the facility itself."

As a lawyer representing clinical labs, Sloane said that with respect to pre-surgical COVID-19 testing there is likely some argument that the testing is medically-necessary and, as a result, that health insurers are required to pay for those tests. "Otherwise, how would the hospital and staff know if the patient is positive for the COVID illness?" she asked.

Send Appeal Letter to Payer

Therefore, when a payer denies such a claim, an appropriate response is an artfully drafted appeal letter. Often the same template letter can be used repeatedly. Sloan noted that, to date, it seems such letters have produced the desired result: payment to the lab.

Another category of COVID-19 testing that creates problems for clinical laboratories when submitting claims is testing for the purpose of assessing coronavirus infections among workers in nursing homes and long-term care facilities, and for employees returning to work as businesses reopen.

In New York State, for example, employers must test workers for COVID-19 before they can return to offices and worksites. In April, New York Governor Andrew Cuomo issued reopening guidelines requiring that employers do health screenings and symptom checks for workers and essential visitors.

Such screening includes asking about an individual's symptoms, any positive COVID-19 test results, and any close contact with an individual who is confirmed or suspected to have the illness over the previ-

New York State Issues Guidance on Payment for COVID-19 Tests That Other States May Copy

IN APRIL, NEW YORK GOVERNOR ANDREW CUOMO ISSUED EXECUTIVE ORDERS about COVID-19 lab testing for employees who work in nursing homes and long-term care facilities. Then, on May 19, two New York State agencies issued guidance related to these testing requirements: the **Department of Health** (DOH), which regulates lab testing, and the **Department of Financial Services** (DFS), which regulates health insurers.

"In its guidance, DFS essentially said health insurers may not deny coverage for SARS-COV-2 testing for personnel at nursing home or adult care facilities," said Danielle Sloane, a healthcare attorney at **Bass, Berry and Sims** in Nashville. "This means health insurers must cover COVID-19 testing required by the state, including nursing home workers interacting with the public every day.

"To say that health insurers can't deny payment for such COVID-19 testing is significant, because no health insurer can easily refute that they are required to cover the testing," she added. "It's important to note that departments of insurance in other states may follow the lead of the New York DFS by issuing similar rules.

Questioning Necessity

Determining the medical necessity of COVID-19 testing in a nursing home or long-term care facility should not be difficult, she commented. Under New York's regulations, insurers may not deny coverage for COVID-19 testing of personnel at nursing homes or adult care facilities without considering whether the testing was medically necessary, she added.

"For example, if a worker were exposed to the virus, or were symptomatic and ultimately tested positive for COVID-19, then that testing would be medically necessary," she commented.

The New York executive order and DOH guidance go into more detail, saying employees who work in nursing homes are required to be tested for SARS-CoV-2 twice a week. Labs should note, however, that New York recently updated its requirement to allow facilities to test once per week if they have reached the second phase of New York's reopening plan. On June 17, Cuomo said New York City could enter phase two of the state's reopening plan. Other parts of the state have already reopened under phase two.

Medical Necessity

The DOH said that when testing employees, nursing homes can submit COVID-19 test claims to health insurers and those tests would be considered medically necessary under the Coronavirus Aid, Relief, and Economic Security Act, which Congress passed in March. "The guidance contemplates that payers could deny claims and clarifies that facilities must pay for testing if payers refuse," Sloane noted. But state officials may facilitate payment from the **Federal Emergency Management Administration** or from another federal funding source, the DOH added.

"For now, testing must be antigen or molecular, although antibody testing may be considered in the future," Sloane added. "Also, testing should be conducted at least two days apart.

"Employees who had a previous positive diagnostic test or reactive serologic test must still be tested twice per week, but, again, this policy may change in the future," she noted. "Nursing home or adult-care facility staff who work at two or more facilities must be tested twice each week, but any facility can use the documentation provided by another facility to comply with this mandate and each facility must maintain the documentation."

ous 14 days. For nursing home employees, more rigorous testing is required.

"With employer COVID-19 testing programs—such as in New York where testing is mandated in certain cases—health insurers are asking if they need to cover that testing," Sloane explained. "The payers are likely to take the position that such COVID-19 testing isn't related to healthcare, but to workplace safety. If it's workplace safety, then the insurers can argue that payment is a requirement for employers.

"Initially, New York State said it would pay for such COVID-19 testing and it entered into contracts with labs to pay for those tests," she reported. "But then new guidance came out that suggested the state was expecting payers to cover much of the testing. Under the latest guidance, New York said labs could submit COVID-19 test claims to payers because those tests are considered medically necessary."

New York's Shifting Guidance

The shifting guidance in New York shows how regulations have evolved and are rapidly changing.

"There are legitimate questions about how New York can deem that the employer-required weekly COVID-19 testing is medically necessary," noted Sloane. "At the same time, payers are lobbying Congress to carve back the scope of COVID-19 testing that insurers must cover pursuant to the Families First Act."

Another problem for labs is how health insurers, including the federal **Centers for Medicare and Medicaid Services** (CMS), define medically-necessary testing.

"CMS has provided a lot of flexibility with respect to COVID-19 testing, but it has not removed its basic requirement that the testing be medically necessary," Sloane reported. "Also, some states are issuing regulations on such testing, and that means the rules addressing COVID-19 testing are different from state to state.

"If the payers are successful, the next stimulus bill in Congress could include language that rolls back some of the COVID-19 coverage language in the Families First Act and in the CARES Act," predicted Sloane.

Scope of Coverage Changes

"If that happens, clinical laboratories will need to pay attention to when any scope-of-coverage changes take effect," she added. "These are all issues that labs need to follow closely or at least confirm that their legal teams are following.

"For clinical laboratories, what matters is who is responsible for paying for COVID-19 tests, because no laboratory wants payers to later attempt to recoup payments made for COVID-19 tests," concluded Sloane. **TDR**

—Joseph Burns

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Early in Outbreak, Feds Fumble Test Payments

FROM THE START OF THE COVID-19 PANDEMIC, various federal agencies took actions that slowed the responses the nation's clinical labs could take to address the needs for large volumes of COVID-19 tests.

That was true at the federal Centers for Medicare and Medicaid Services (CMS). Early in the outbreak, it set the price the Medicare program would reimburse for a molecular COVID-19 test at just $51. It didn't take news reporters long to discover that this price was below the cost of most labs to perform such tests, along with the fact that many private insurers set their reimbursement rates based on the Medicare Price.

Apparently, the negative news coverage caused CMS officials to rethink that price. On April 14, CMS increased Medicare reimbursement for molecular COVID-19 tests to $100. The **COVID Traking Project** reported that its data showed the number of COVID-19 lab tests doubled in the week after this price increase.

Lab Buys More Instruments as Way to Add Test Volume

Health system lab adds five COVID-19 tests, orders new analyzers, but demand still outstrips capacity

CEO SUMMARY: Severe shortages of supplies for COVID-19 lab testing caused one lab director in the Midwest to buy additional instruments while also validating five different COVID-19 tests to run on analyzers the lab used before the pandemic hit. While this strategy allowed the lab to bump up the number of COVID-19 tests it can perform daily, ongoing shortages of supplies, and uncertainties about when supplies will be delivered, continue to constrain the daily volume of COVID-19 tests this lab can perform, even as daily demand for tests increases.

EVEN TODAY, IN THE FIFTH MONTH OF THE COVID-19 PANDEMIC, clinical labs throughout the United States continue to report that they cannot obtain adequate supplies to fully meet the daily demand for SARS-COV-2 testing coming from the communities they serve.

Demand for COVID-19 testing supplies continues to outstrip the ability of lab vendors to manufacture and deliver enough collection supplies, viral test media, reagents, kits and personal protective equipment. Yet there is one product category in the lab supply chain that seems to be available in sufficient quantities to fill the needs of many labs.

That product category is instrumentation. Across the nation, labs tell THE DARK REPORT that they are able to purchase and take delivery of new instruments and analyzers on a relatively speedy timeline. In fact, one of the most common strategies larger labs are using to maintain and add to the volume of COVID-19 tests they can perform daily is operate multiple analyzers from different vendors in their labs—often as many as four to six different vendors and different COVID-19 tests.

This is true for a health system in the Midwest with a large anchor hospital and several community hospitals in the system. Its laboratory added new analyzers from several vendors and now operates instruments from six different vendors. "Despite being a customer of these vendors, supply shortages continue to limit our lab's COVID-19 testing capacity to about 20% of optimal levels," said the laboratory's director, who asked to remain anonymous so that he could speak freely.

Workarounds to Get Supplies

In an interview with THE DARK REPORT on June 9, he explained the lab's workarounds to the shortage of SARS-CoV-2 testing supplies now in the fifth month from the day of the first diagnosed case in the U.S. (Jan. 19): buy, install, validate, and run as many new molecular-test platforms from different vendors as possible.

"After installing and validating those platforms, our lab has not solved the supply-shortage problem entirely," he noted. "But adding new assays from different vendors allowed our lab to eke out a few hundred more coronavirus tests per day.

"By acquiring new testing platforms, we can shift testing to different analyzers when supplies for one platform run out," he explained. The molecular tests are the reverse-transcription polymerase chain reaction (RT-PCR) assays for the SARS-CoV-2 coronavirus.

During the interview, the lab director identified four lessons the lab staff learned about how to expand COVID-19 test volume while facing crippling supply shortages. They are:

- Don't rely on one vendor for all the COVID-19 testing capacity your lab needs. Acquire and use different tests to adjust as needed.
- Assess inventory of COVID-19 test kits and supplies in order to predict which platforms will have the most supplies of reagents, test kits, specimen-collection swabs, and transport media. Having a longish run of supplies in stock, or due to arrive, is important because such durable capacity means the lab can run tests on one or two machines and possibly avoid the need to switch to other machines.
- Anticipate the need for new equipment when possible and then acquire those instruments and assays. This may be the most important lesson of the three, because the lab acquired five different SARS-CoV-2 tests since March to run on its lab instruments.
- Order a new analyzer to increase overall testing capacity if funding and administration support allow such a capital outlay.

Accurate Predictions Needed

Early in the year, clinical lab administrators and pathologists reacted to reports about how the novel coronavirus was spreading in China, Italy, New York, and Washington State by doing what they could to build up testing capacity.

Although they did not know it at the time, when the federal **Centers for Disease Control and Prevention** (CDC) sent out the first RT-PCR test to labs in February, the delivery of that assay marked the inauspicious start of problems labs continue to face even now.

"In February, everyone was waiting for the CDC assay to test for the coronavirus," the lab director commented. "But it did not go very well."

On Feb. 12, the CDC reported that it would pull the test and reworked it after some state laboratories got inconclusive results during quality-control review for that first test kit.

"At the end of February, our state public health lab began running the reworked CDC assay," he recounted. "Our lab had it up and running by about March 16 or 17. Because the CDC test is a manual test, it has very low throughput. So we started doing COVID-19 testing on the **Luminex** MAGPIX equipment in our molecular lab.

Automating COVID-19 Testing

"We brought up that test on the Luminex MAGPIX at about the same time that we started to run the CDC's reworked coronavirus assay. But we ran the reworked CDC test for only a short time because it never worked very well due to low throughput," he commented. "We still use the CDC assay from time to time because we've had various supply constraints.

"By about April 2, we went live with **Cepheid's** GeneXpert test, giving us the ability to run COVID-19 tests on three different platforms," he explained. "While we waited for Cepheid to get its EUA, we used the Luminex test for most of our COVID-19 testing for about two weeks. Once Cepheid got its EUA, we began the steps to validate that assay so that we could use it for daily testing.

"We wanted to deploy the Cepheid test throughout our health system because we had used it for routine flu testing before COVID-19. So, our health system has it everywhere," he commented.

"Because all our health system labs already had Cepheid instruments, we thought that if we could get everything from Cepheid—meaning test kits,

Toughest Challenge of COVID-19 Testing is How to Increase the Daily Number of Tests Performed

ONE CLINICAL LABORATORY DIRECTOR at a large health system in the Midwest faces difficult questions every day about how to increase the daily volume of tests for SARS-CoV-2, the coronavirus that causes the COVID-19 illness.

To date, he has had answers for most of these questions, but the continuing lack of adequate supplies means the health system's labs have unused capacity to run many more COVID-19 tests daily. "The questions about increasing COVID-19 test volume to meet the needs in our community have been continuous," said the lab director, who asked not to be named. "Each day, we ask: How much testing are we doing and how can we do more? Where are the problems we need to solve? What do we need to do to maintain our testing capacity and supplies in the system?

"In a perfect world, we could test thousands of people daily for COVID-19, but that's only if our lab gets all the supplies needed to run our existing instruments at their full capacity," he added. "That's our goal, and we're doing creative things to get there.

Making Adjustments

"As it stands now, our lab has capacity to safely do COVID-19 tests for at least 3,000 patients a day if we were unconstrained," he noted. "Unconstrained would mean we had no supply chain issues, no swabbing issues, no reagent issues. If we had to do more, we would probably be closer to 4,000 COVID-19 tests per day.

"But we're not even hitting the 1,000 mark," he continued. "Instead, our lab runs somewhere between 500 and 700 SARS-CoV-2 tests daily because we have so many constraints—even to this day."

If the average number of tests run per day for the new coronavirus is 600, and the unconstrained safest level of testing is 3,000 daily tests, then the shortage of lab testing supplies means the lab limps along each day at just 20% of full capacity.

"For our lab to run COVID-19 testing at our full capacity requires a consistent supply chain," he noted. "Problems come when a test-supply vendor says its own supplies will run out at some date in the future. They might tell us that in 30 days they'll be unable to supply what we need. Then what do we do?

"Our molecular lab has tried to figure out the best combination to get us the most durable capacity—meaning from a single vendor that we could keep long term," he explained. "But it's technically challenging, because we want something that everybody can be trained on and that all shifts could operate. If only our most specialized individuals can do it for one eight-hour or 12-hour shift, that doesn't help our lab if we need 24-hour capacity for COVID-19 testing."

reagents, and other supplies—all of our health system's labs could use their existing Cepheid instruments to perform COVID-19 tests. That would mean all our lab sites would be running a common instrument and using the same test kits."

Unexpected Test Demand

This thinking, however, was flawed. "I think no one at Cepheid, or at any of our other vendors, understood what kind of demand our hospitals would have for COVID-19 testing," he added. "High demand for these tests quickly exhausted our lab-test supplies.

"It turned out that we didn't have enough supply of COVID-19 tests to use the Cepheid equipment in all of our hospitals," he explained. "Instead, we deployed it to only two hospitals. Eventually, Cepheid sent us more test kits, which allowed us to test on this platform throughout our entire system.

"We use Cepheid's COVID-19 tests strategically," he noted. "That test helps us manage inpatients because we can use it to assess them quickly. Since it's not a batch test, we can put each patient specimen right on the machine and get an answer in about an hour.

"With that kind of turnaround time, we use it to triage emergency room patients," explained the lab director. "A fairly rapid result allows the hospital staff to determine where those patients should go. If the result is positive, they're cohorted to the COVID-positive units. Or, if it's negative, these patients will go to a COVID-negative unit. Sending patients to different units helps with infection control, which is obviously important for patient care."

A Daily Juggling Act

During April, the health system juggled supplies and ran coronavirus tests on Cepheid and Luminex equipment. When needed, the lab used the CDC's COVID-19 assay as well. "By about the end of April or the beginning of May we added the **Thermo Fisher** test kit in our molecular lab," he said. On March 13, the FDA announced an EUA for that test, the TaqPath COVID-19 Combo Kit.

"Then, during the first week in May we added the BD BioGX test from **Becton Dickinson**, which runs on the BD MAX, a molecular instrument that our lab was using for a different line of testing," he noted. "After BD got an EUA for their new coronavirus test in March, we added that platform too."

Even after adding tests from Thermo Fisher and BD, the lab still operated at less than maximum capacity, he said. So, by the end of May, the lab was working to acquire another analyzer, the **Roche** cobas 6800 instrument. On March 13, Roche announced that the FDA had issued an EUA for the cobas SARS-CoV-2 Test.

"We currently have five testing platforms (the CDC assay, Luminex, Cepheid, Thermo Fisher, and BD Max), and we're working on bringing in the Roche cobas 6800, which would give us six in total," explained the lab director. "With all of these different vendors' analyzers, we can run COVID-19 tests in as little as one hour, or as much as eight hours depending on the platform."

While the strategy of acquiring multiple tests for the new coronavirus allows the laboratory to manage the shortage of supplies more efficiently than it did previously, there is a drawback to this strategy. Changing from one instrument and test to another takes time, slowing production.

"There are technical challenges when changing out from one instrument to another because multiple steps are required before we can run specimens on some of the platforms," he explained. "That's why we prefer to use the platforms where there's no extraction needed, such as the Cepheid GeneXpert and the BD MAX.

"Our lab can run those tests faster and both instruments offer much faster turnaround time than the other molecular tests that are batched and perform 48 or 96 tests at a time," he added. "While these molecular tests enable better throughput, they're still technically challenging for staff to operate."

High Demand Continues

Minimizing technical challenges is important because demand for testing for the new coronavirus remains high and is expected to rise still further in the coming weeks. "In terms of testing volume, we predict we'll see demand like what we've seen for the last couple of weeks," he concluded. "Nothing's changed. We still have the same supply constraints and we still have the same demand for tests."

To date, the lab has been testing symptomatic patients, but soon expects to test people who are asymptomatic. "As we open up the economy, we'll be testing into a new phase," he commented. "That means there'll be a need to test individuals for surgeries, for chemotherapy, and for women going into labor and delivery **TDR**

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

As they scramble to respond to the COVID-19 pandemic, federal officials in multiple agencies are purchasing equipment and supplies from vendors with dubious credentials and little operating history. In recent days, *ProPublica* reported "a fledgling Texas company was paid $7.3 million for test tubes needed in tracking the spread of the coronavirus nationwide. But, instead of the standard vials, **Fillakit LLC** has supplied plastic tubes made for bottling soda, which state health officials say are unusable."

MORE ON: *FillaKit*

ProPublica wrote, "the **Federal Emergency Management Agency** signed its first deal with Fillakit on May 7, just six days after the company was formed by an ex-telemarketer repeatedly accused of fraudulent practices over the past two decades. Fillakit has supplied a total of more than three million tubes, which FEMA then approved and sent to all 50 states. If the company fulfills its contractual obligation to provide four million tubes, it will receive a total of $10.16 million."

HEALTH NETWORK LABORATORIES HAS NEW NAME

Health Network Laboratories of Allentown, Penn., is changing its name to **HNL Lab Medicine**. In a press release, Maria Foster, Vice President of Sales and Marketing said the "rebrand reflects the company's broader vision of inspiring a healthier and better-informed world." The name change became effective this month.

TRANSITIONS

• Pathologist Eugene N. "Gene" Herbek, MD, FCAP, 70, of Omaha, Neb., died on June 4, 2020. Nationally respected, Herbeck was President of the **College of American Pathologists** from 2013 through 2015. He was Medical Director at **Methodist Hospital and Methodist Women's Hospital Laboratory** in Omaha and prior to that was at **St. Luke's Regional Medical Center** in Sioux City, S.D.

• **American Association of Clinical Chemistry** selected Mark Golden as its new CEO. Current CEO Janet Kreizman will retire at the end of June. Golden comes to AACC from the **National Society of Professional Engineers** and prior to that held leadership positions at the **National Court Reporters Association** and the **Personal Communications Industry Association**.

• **COLA** announced the retirement of John T. Daly, MD, the Chief Medical Officer for the laboratory accreditation organization. Daly had served as CMO since 2011 and formerly held positions at **Duke University Health System** and **Lincoln Community Health Center**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 13, 2020.

Resources and Help for Labs During SARS-CoV-2 Pandemic

STAT INTELLIGENCE BRIEFINGS

A Service of The Dark Intelligence Group

Today, every clinical lab is on the front lines of the SARS-CoV-2 pandemic. Pathologists and lab managers face unprecedented challenges and much uncertainty about the best responses.

Cash flow is dropping. Test mix is changing as routine testing falls off and demand for COVID-19 tests increases. Specimen collection and transport is disrupted.

To help you stay informed and provide you with actionable intelligence, The Dark Report and DarkDaily.com launched the COVID-19 STAT Intelligence Service.

Check **www.covid19briefings.com** for daily news and lab innovations.

To share your lab's innovations and successes, contact our Editor at: rmichel@darkreport.com

UPCOMING...

- ***Executive War College Goes Virtual to Present Sessions, Speakers Sharing Essential Insights and Paths Forward for Laboratories.***
- ***Coming Soon to Your Lab: the Opportunity to Earn Revenue by Doing Tests for Employer COVID-19 Screening Programs.***
- ***COVID-19 Testing Programs for Long-Term Care Facilities and Nursing Homes: What All Labs Need to Know.***

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