Volume XXVII, Number 12 Monday, August 24, 2020

BREAKING NEWS!
HHS Says LDTs Don't Require FDA EUAs!
(see pages 3-6)

From the Desk of R. Lewis D...

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

Labs Adjust to COVID-19 as a Regular Part of Care

ONE INTERESTING NEW DEVELOPMENT NOT REPORTED MUCH BY THE NATIONAL MEDIA is that the daily number of new COVID-19 cases in the United States has declined steadily in the past month. It is too early to understand the implications of this development, but clinical lab administrators and pathologists may want to follow a basic statistic.

Here at THE DARK REPORT, we monitor at the CDC's chart of the daily number of new COVID-19 cases. All labs testing for COVID-19 are submitting their test results daily to the federal government, as directed in recent legislation and federal rules. In theory, the daily count of new COVID-19 cases posted on the coronavirus pages of the federal **Centers for Disease Control and Prevention**'s (CDC) website should be as accurate as any other source tracking such data, such as the **Johns Hopkins University** Coronavirus Tracking Center.

As presented by the CDC on its website, the seven-day moving average of daily new SARS-CoV-2 cases in the United States peaked at 66,960 on July 24. Today, one month later, the seven-day moving average of new COVID-19 cases has declined to 44,700. In those four weeks, the fall-off in daily new cases was 29%. It is unclear if this four-week decline will continue until the daily number of new COVID-19 cases in the United States drops to a small number, thus easing the restrictions on normal business and social activity.

The opposite may prove true. After a month or more of decline, the daily COVID-19 case count could increase in what would be recognized as a third wave. Some experts predict exactly that. They point out that—in six weeks—October will bring the start of the influenza season.

Regardless of scenario A: that daily COVID-19 case counts continue to decline in coming months; or scenario B: that the flu season triggers a surge in daily new infections, it will be true that patients, caregivers, and employers will continue to be concerned about SARS-CoV-2 infections. One solid conclusion is that COVID-19 concerns will be prominent in American society for months, if not years, into the future.

Thus, it would be timely for clinical labs and pathology groups to factor this probability into their clinical and business strategies. All labs need to adjust to the reality that COVID-19 is now part of regular care that every patient receives. TDR

HHS 'Stands Down' FDA on Its Oversight of LDTs

With a 252-word statement on Aug. 19, HHS said lab-developed tests are not required to obtain an EUA

CEO SUMMARY: A directive from the federal Department of Health and Human Services (HHS) may have long-lasting implications for the federal Food and Drug Administration's efforts to assert regulatory oversight of laboratory-developed tests (LDTs). In a statement last week, HHS said that labs "are not required" to obtain an FDA emergency use authorization or FDA clearance of LDTs. Clinical labs welcomed the news and experts told The Dark Report that this change in policy could be a significant boost to labs seeking to meet the demand for COVID-19 testing.

THERE'S A NEW TWIST in the **Food and Drug Administration's** (FDA) long-running claim that it should oversee and approve the use of laboratory-developed tests (LDTs). Last week the federal **Department of Health and Human Services** (HHS) said clinical laboratories were not required to obtain an emergency use authorization (EUA) from the FDA for their LDTs.

The HHS' action is a welcome development for many in the clinical laboratory profession. For years, labs and their industry associations have complained that the FDA's attempts to regulate LDTs have been egregious examples of federal regulatory overreach.

Using only 252 words, HHS said that any laboratory seeking an EUA for an LDT, or approval or clearance from FDA for an LDT, is not required to do so. HHS cited two of President Trump's executive orders as granting it the authority to, essentially, tell the FDA to stand down on its efforts to regulate LDTs.

If clinical labs wish to do so, HHS explained, they could submit a premarket approval application to the FDA, make a premarket notification, or request an EUA, and the FDA will adjudicate those submissions.

Issued Aug. 19 on HHS' website is a statement, titled, "Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests." A key phrase in the statement about LDTs is that labs "are not required to" seek FDA review or approval for LDTs *(See sidebar, page 5)*. HHS issued the statement to be consistent with

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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President Trump's executive orders 13771 (Executive Order on Reducing Regulation and Controlling Regulatory Costs, issued in February 2017), and 13924 (Executive Order on Regulatory Relief to Support Economic Recovery, issued in May), the agency said. Also, HHS issued the statement as part of its, "review of regulatory flexibilities enacted since the start of COVID-19."

Increased Liability

While labs may welcome the loosening of FDA's LDT regulations, the change comes with an increased risk of liability. Any lab choosing to use an LDT without FDA premarket review or authorization would not be eligible for immunity protection under the Public Readiness and Emergency Preparedness Act (PREP Act) unless the lab gets approval, clearance, or authorization from the FDA, the statement said.

The PREP Act authorizes HHS Secretary Alex M. Azar II to issue a declaration that would provide immunity from any liability resulting from claims of loss. Such protection from immunity would not apply, however, if willful acts of misconduct are involved, the statement said.

For labs, immunity from liability goes only so far, 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.

Laboratory standard-setting organizations have made it clear that a lack of regulation that requires rigorous test review prior to a test being sold does not mean the lab that developed the test is free of liability, Noble said. "The more you leave open the question of verification and validation of tests, the more variability you'll get with your test results," he commented. "That creates a higher risk of errant results and a higher risk of liability.

"What HHS did is a mistake because it's inconsistent with the goal of developing tests in a rigorous manner with the understanding that the results of those tests will be used on hundreds of thousands or millions of people," he said.

However, according to Roger D. Klein, MD, JD, a former adviser to the FDA and a Faculty Fellow at the Center for Law, Science and Innovation at the **Sandra Day O'Connor School of Law,** the liability issue may not be a serious one for most labs.

"Lawsuits are extremely rare against clinical laboratories—particularly for labs at academic medical centers," he said. "Those labs validate all such tests, meaning they won't run these LDTs unless they work well. Therefore, the risk of a lawsuit is low.

"For big corporate lab companies that run large numbers of tests, this could be an issue," he added. "But for them, liability would be more of a consideration than a real concern. For COVID-19 testing, these labs have typically been obtaining EUAs and thus fall under the protections of current PREP Act immunity."

Still Subject to CLIA

Regardless of whether a lab would pursue an LDT, it would still be subject to the regulations of the federal **Centers for Medicare and Medicaid Services** (CMS) under the Clinical Laboratory Improvement Amendments of 1988, the HHS statement said.

The point about how labs need to continue to comply with CLIA may have been an important consideration behind why HHS issued the statement when it did. Recent developments suggest that one reason COVID-19 testing has lagged in the United States is the FDA's insistence that only those LDTs that the FDA has reviewed and approved can be used in clinical care under its EUA procedures for testing for the SARS-CoV-2 virus.

Late last month, for example, legal scholars wrote an article in the *Yale Law Journal* forum about how the FDA's

HHS: Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of LDTs

HERE IS THE FULL STATEMENT about laboratory-developed tests (LDTs) issued by the Federal Department of Health and Human Services (HHS) on Aug. 19:

The Trump Administration is committed to combating COVID-19, to ensuring that the American people are protected against future pandemics, and to keeping duplicative regulations and unnecessary policies from interfering with those efforts.

Consistent with the President's direction in Executive Orders 13771 (Executive Order on Reducing Regulation and Controlling Regulatory Costs) and 13924 (Executive Order on Regulatory Relief to Support Economic Recovery), and as part of HHS's ongoing department-wide review of regulatory flexibilities enacted since the start of COVID-19, the department has determined that the Food and Drug Administration ("FDA") will not require premarket review of laboratory developed tests ("LDT") absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances.

Those seeking approval or clearance of, or an emergency use authorization ("EUA") for an LDT may nonetheless voluntarily submit a premarket approval application, premarket notification or an EUA request, respectively, but are not required to do so, and FDA will adjudicate those submissions.

Those opting to use LDTs in their laboratories without FDA premarket review or authorization may do so with the understanding that they would not be eligible for PREP Act coverage absent approval, clearance, or authorization and would remain subject to regulation by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, and its implementing regulations at 42 C.F.R. pt. 493.

Those with an active EUA to use an LDT to detect the virus causing COVID-19 or its antibodies are unaffected by this announcement.

actions during the coronavirus pandemic slowed testing nationwide. Those scholars are Barbara J. Evans, PhD, JD, LLM, the Stephen C. O'Connell Chair at the **University of Florida Levin College of Law**; and Ellen Wright Clayton, JD, MD, a Professor of Law Health Policy at the **Vanderbilt University School of Law**.

Although CLIA-regulated labs traditionally have responded quickly to emerging epidemics, their response was slowed this year after the FDA published guidance suggesting labs need EUAs before they can use LDTs, Evans and Clayton wrote.

"Many labs viewed the FDA's 2020 guidance documents as having a practical binding effect even though the FDA lacked clear statutory authority to require EUAs for LDTs developed at CLIA-compliant high-complexity laboratories," they added.

"The FDA's guidance documents led to decreased availability of testing, particularly in the early stages of the pandemic, which contributed to the catastrophic course of the COVID-19 pandemic in the United States," they wrote.

Evans and Clayton then went a step further, explaining that the FDA lacks authority to require EUAs for COVID-related LDTs. They also outlined how the FDA's intervention replicates protections CLIA already provides, they wrote.

Bruce Quinn, MD, PhD, a consultant to clinical laboratories at **Bruce Quinn Associates** in Los Angeles, made a similar point. He noted that the HHS statement

came one day after the *Wall Street Journal* (*WSJ*) published an article showing how testing failed in the United States since February. "The HHS announcement follows within days of a scathing article in the *WSJ* about the administration's handling of COVID testing," Quinn wrote in an email to The Dark Report.

That article detailed problems that HHS, the FDA, and the federal **Centers for Disease Control and Prevention** (CDC) had when introducing LDTs to identify SARS-CoV-2 and how those problems, including the FDA's requirement that labs needed EUAs for LDTs, slowed testing nationwide for three weeks.

HHS Statement

Quinn made three other important points about the HHS statement. First, he noted that HHS' guidance appears on the HHS COVID website, but the wording of the guidance appears to apply to FDA review of any type of LDT. Some of the initial press coverage of the announcement noted that the statement covers COVID testing but, in fact, the statement is not specifically limited to COVID LDTs.

Second, Quinn said all labs should note that some FDA actions involving LDTs were consistent with its role of ensuring lab-test safety. "There have been times when FDA acted with actual safety interests, such as restricting the worst-performing antibody tests for COVID last spring," he said.

But then he added a caveat. "Often, FDA has acted against LDTs by stating that collection devices or other paraphernalia were being used off-label. Since that isn't part of the LDT itself, it's unclear if FDA maintains the power to take those types of actions," he said.

Third, FDA review is still required in some cases, he added. "HHS notes that other policy requirements for clearance and emergency use authorizations may still apply, for example, where they are already written into last spring's coverage and payment laws for COVID tests."

While some regulations remain in place, clinical labs are likely to welcome the new HHS action, Klein said. "What this statement does is confirm flexibility for labs, particularly for smaller labs and academic medical centers," he noted.

"Most labs often want to revise the tests that have EUAs to make them run more efficiently," Klein added. "But the EUA requirements prevent tinkering. Now, labs will be able to adjust these tests as needed.

"The HHS statement could have a significant effect on labs and this is really important, particularly if those labs want to subtly deviate from the procedure specified in the EUA," he explained. "Previously, they could not do that because, if they did, the test would no longer fall within the parameters of the EUA.

"In that way, the HHS statement will help labs that purchase tests which don't fit into their workflows or for which they can't meet the exact EUA specifications of a test within their laboratories," he added.

"For example, some labs might not be able to do the extraction method. In those situations, what commonly happens with FDA-cleared or approved tests is that the lab will fine-tune those tests either to meet their workflows or to make them perform better. The HHS statement allows that to happen," he noted.

Welcome News from HHS

"Another example could be when a lab buys a test from an IVD manufacturer, but maybe there's a reagent shortage for that test," he said. "Under the previous rules, the lab would be unable to run that test. But now, they can use the same reagent from another manufacturer.

"Plus, labs would have the ability to validate that test independently and not have to submit it to the FDA for review, which is an enormous burden on labs using some tests, particularly smaller labs." TDR

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Legal Update

DOJ Indicts Ten Individuals for Pass-Through Lab Test Billing

Defendants alleged to have used rural hospitals to submit $1.4 billion of lab test claims to private payers

PASS-THROUGH LAB TEST BILLING SCHEMES involving rural hospitals and $1.4 billion in fraudulent lab test claims are at the core of multiple indictments announced recently by the federal **Department of Justice** (DOJ).

Ten individuals—including laboratory owners, billing company executives, and hospital administrators—were charged in an elaborate pass-through billing scheme using four rural hospitals in three states to submit fraudulent bills for laboratory testing, federal officials announced June 29.

$1.4 Billion in Test Claims

In a 40-page indictment, the DOJ alleged that from November 2015 through February 2018, the conspirators billed commercial insurance companies about $1.4 billion for fraudulent laboratory testing claims and were paid $400 million.

Filed in **U.S. District Court for the Middle District of Florida** in Jacksonville, the indictment named the conspirators as:

- Jorge Perez, 60
- Ricardo Perez, 57
- Aaron Alonzo, 44
- Nestor Rojas, 45, and
- Neisha Zaffuto, 44, all of Miami;
- Seth Guterman, 54, of Chicago
- Aaron Durall, 48, of Parkland, Fla.
- Christian Fletcher, 34, of Atlanta
- James Porter Jr., 49, of Ocala, Fla., and
- Sean Porter, 52, of Crystal River, Fla.

Through their attorneys, these defendants have denied the charges when contacted by the press for their comments.

Readers of THE DARK REPORT may recall some of these names from previous coverage of this type of scheme in 2018. *(See TDR, "Insurers Sue to Challenge Pass-Through Bill Schemes," May 7, 2018; "Why Lab Companies Buy Bankrupt Rural Hospitals," May 29, 2018; "Rural Hospital Group Says Lab Billing Model Is Legal," July 9, 2018; and "Attorney Explains 70/30 Rule, Pass-Through Bill Arrangements," July 9, 2018.)*

Pass-Through Billing

Using management companies they owned, the conspirators took over small rural hospitals that were struggling financially and then used those hospitals to submit fraudulent lab-testing bills to commercial health insurers, the indictment alleged.

The bills for millions of dollars of expensive urinalysis drug tests and blood tests were conducted mostly at outside laboratories that the conspirators controlled or were affiliated with, court documents show. Most of the laboratory tests were medically unnecessary, the DOJ alleged.

It was after 2010 when fraudsters began to target financially-struggling rural hospitals. They would either obtain management contracts to operate the hospital or would purchase the hospital. Rural hospitals were the ideal platform for the pass-through billing scheme because private health insurers would reimburse nearly all clinical services at higher rates. This was because insurers knew the hospitals were often the only local source of medical services in a community and that

the rural hospitals had much higher costs to provide these services.

The indictment describes how the conspirators also used billing companies they controlled to submit the bills on behalf of the hospitals. "While outside laboratories did most of these lab tests, the conspirators allegedly billed private insurance companies as if these laboratory tests were done at the rural hospitals," the DOJ explained.

The four hospitals named in the indictment were:

- 25-bed **Campbellton-Graceville Hospital** in Graceville, Fla.;
- 40-bed **Regional General Hospital** in Williston, Fla;
- 49-bed **Chestatee Regional Hospital** in Dahlonega, Ga.; and,
- 25-bed **Putnam County Memorial Hospital** in Unionville, Mo.

"The rural hospitals had negotiated contractual rates with insurers that provided for higher reimbursement than if the tests were billed through an outside laboratory," court documents show.

Allegations of Kickbacks

To obtain the urine and other specimens for clinical laboratory testing, the conspirators paid kickbacks to recruiters and healthcare providers, most of whom were affiliated with sober homes and substance abuse treatment centers. After collecting the proceeds, the conspirators engaged in a sophisticated money-laundering scheme to distribute the fraudulent proceeds, the DOJ alleged.

Among the charges the DOJ listed in the 23-count indictment were conspiracy to commit healthcare fraud and wire fraud, substantive healthcare fraud, conspiracy to commit money laundering, and substantive money laundering.

The indictment also includes seven pages listing the assets the defendants could be required to forfeit if found guilty. The list of assets includes millions of dollars in funds acquired through the scheme, jewelry, high-end automobiles, and real property. TDR

Fraudsters Targeted Rural Hospitals

RURAL HOSPITALS MADE IDEAL VEHICLES FOR HEALTHCARE FRAUD because so many of them were—and continue to be—in dire financial straits. At the same time, the local communities they serve are looking for any solution that can keep their communities' only healthcare provider open and functioning.

Thus, when a smooth-talking fraudster showed up with a business plan that promised to bring in millions of dollars in profitable revenue, hospital boards and community leaders were all too eager to sign-up to keep their hospital open and providing care.

Pass-through billing schemes are the most common way dishonest operators generate revenue. The other factor that enables this scheme is that rural hospitals typically are in-network for all health plans and paid much higher rates for all services, since a 25-bed rural hospital does not have the economies of scale as would a 500-bed hospital. Thus, not only did the fraudsters have an entity that could bill any health insurer, but they could bill at highly-inflated prices and be paid much more money per claim than would be true for larger hospitals.

The scale of this fraud is astonishing. THE DARK REPORT wrote about **Blue Cross Blue Shield of Mississippi** suing 29-bed **Sharkey-Issaquena Community Hospital** in Rolling Fork, Miss.; and four Texas-based toxicology lab companies for submitting $39 million in lab test claims (for toxicology tests) in just 120 days! *(See TDR, June 5, 2017.)*

THE DARK REPORT also wrote about Aarron Durall's pass-through billing arrangement with 37-bed **Sonoma West Medical Center** (SWMC) in Sebastopol, Calif. In 2018, **Anthem, Inc.** sued to recover $16 million for toxicology testing. *(See TDR, Aug. 20, 2018.)*

Specimen Volume Returns at Dallas-based ProPath

Despite the pandemic, patient visits to doctors are increasing, generating more case referrals

CEO SUMMARY: Like other physician specialties, anatomic pathology saw a dramatic collapse in the number of daily procedures with a corresponding decline in cash flow as the COVID-19 pandemic hit with full force in March, April, and May. The good news is that the daily volume of tissue referrals is increasing steadily as patients decide it will be safe to visit their physicians. In Dallas, ProPath, a private practice with 50 pathologists and 500 employees, reports that its daily flow of tissue cases is back to 95% of pre-pandemic levels.

As patients return to physicians' offices and as hospitals in most regions again perform elective procedures, the daily volume of anatomic pathology tissue referrals has been climbing back to pre-pandemic levels.

This is a welcome development for the pathology profession, still attempting to recover financially from the extreme collapse in the volume of tissue referrals and cash flow from March through June.

As of July, many pathology groups reported increased volumes of daily test referrals after governors eased restrictions on social and business activities. Patients were encouraged enough to begin returning to their physicians for normal screening and other preventive services. At **ProPath** in Dallas, the daily volume of case referrals has returned and so has revenue, said Cory A. Roberts, MD, the group's President, Chairman, and CEO.

In February, when the number of cases of COVID-19 were rising in the United States, Roberts told the ProPath team that some staff and some of the group's 50 physicians would be furloughed and that the group would need to conserve cash to survive the pandemic. *(See, "To Stay Afloat, Dallas AP Group Cut Staff, Payroll," TDR, May 11, 2020.)*

One of the nation's largest physician-owned pathology groups, ProPath has almost 500 employees, including sales and support staff in 10 states. Its 50 pathologists serve as medical directors in 26 Texas hospitals.

Earlier this month, Roberts told The Dark Report that specimen volume at ProPath had returned to about 95% or more of pre-pandemic levels, and revenue had risen as well.

Cautious Confidence

While cautiously optimistic about revenue for the remainder of 2020, Roberts also had concerns about the many patients who put off screening tests in the spring due to COVID-19.

"As some of these patients return to visit their physicians, they may be diagnosed with more advanced stages of disease and thus suffer worse outcomes and even death," observed Roberts.

A study that researchers at **Quest Diagnostics** conducted confirmed his observations. In a study published in *JAMA Network Open* (*JAMA*), the researchers reported that Quest saw the number of newly-diagnosed cases of six major types of cancer decline by 46% during March. *(See, "Quest Reports 46% Decline in New Cancer Diagnoses in March," page 12-13.)*

"After seeing this study in *JAMA*, I would suggest that the data on how much the volume of pathology case referrals dropped could be worse than what Quest reported," Roberts said.

"In that study, Quest compared data from January and February with data from the following months, and rightly so, because that was a comparison of pre-COVID and post-pandemic numbers," he said. "But in gastroenterology, for example, many people don't get screening colonoscopies early in the year. People with high-deductible health plans typically defer screening colonoscopies and other diagnostic procedures until after they meet their deductibles. Otherwise, they might bear more of the cost.

"That's why office visits to gastroenterologists and other specialists in January and February are typically lower than they are at other times in the year," he noted. "That reluctance could mean even more people may have missed their screening appointments during COVID than the article suggests.

Fewer Screening Tests

"Also, some people with less financial means may be more at risk for not getting care and screening tests," he added. "For these individuals, screening visits might not have been a high priority even before the pandemic. Then, during COVID, screening tests are an even lower priority.

"It's possible that some people delayed screening for a few months while others may put off screening visits for an entire year," Roberts said. "When these delays are combined with other economic factors and a lack of income due to being unemployed, it's likely that a lot of diagnostic work got pushed further down the road."

For these reasons, anatomic pathologists could see a surge in specimen volume later in the year or into 2021, he added. "It'll be interesting to see what happens as we go forward and if there is an increase in cases, worse patient outcomes, or even morbidity due to missed patient visits," he said.

Income Stability Restored

Meanwhile, Roberts reported specimen volume at ProPath had returned to about 95% of the group's forecasted levels, which has helped to stabilize income. The group also supplemented cash flow by running COVID-19 molecular tests. In August, it was performing 800 to 1,500 polymerase chain reaction tests per day for the novel coronavirus, boosting revenue by about $2 million, he added. *(See sidebar, "Adding COVID Testing Cushioned Financial Blow," page 11.)*

"Our volume of tissue referrals is back almost to the levels we expected, but it varies from day to day and week to week, of course," he noted. "The outpatient situation is different from what's happening with inpatients. Outpatient is largely back, while inpatient volumes depend on where those hospitals are located.

"If those hospitals are in a hotspot for infections, then specimen volume may still be at about 80% of where it was," he said. "So, while outpatient volumes are effectively back, inpatient volumes are still lagging in North Texas, though variable, even within our region.

"Another factor that affects our group's outpatient revenue—and this is not unique to us—is that some procedures are taking much longer than they did before the pandemic," he noted.

"Colonoscopies are a good example. These procedures take longer because of the need for extra personal protective equipment and for air-handling proce-

dures in those rooms," he added. "In some cases, gastroenterologists can't let people in and out of the procedure room or have to wait longer in the room. Therefore, patient throughput is slower. Not being able to do as many cases as they did before in the same number of hours, they have extended hours and added days for scoping to try and offset that lower throughput."

For Roberts, the COVID testing and the return to almost-normal AP specimen levels are positive signs, but his optimism was restrained.

"We started to see our outpatient work return in the second half of May," he reported. "Since then we've grown specimen volume gradually. At the end of July, our group was closer to 90% of forecasted volume. Now, in August, we're closer to 95%, exclusive of SARS-CoV-2 testing.

70% Decline in Specimens

"That's a big improvement from the collapse of specimen volume and cashflow back in March and April, when our work went down to about 30% of forecast," he said. That 30% of volume is a result of comparing volume in the second quarter of 2020 with the company's forecasted growth for 2020.

While volume in the summer was better than it was in the spring, the numbers were a reminder that without the pandemic, volume might have been even higher. "Our group specimen volume in the first quarter of 2020 was running about 11% above 2020 levels, slightly ahead of forecast," he commented.

"Now that we're in August, it's great that we're back to 95% or better, compared to forecast," he noted.

"But going forward for the balance of 2020, we view our current situation with extreme caution. I expect additional surges in viral infections when kids go back to school. And we'll face the usual respiratory viruses in the fall." TDR

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Adding COVID Testing Cushioned Financial Blow

ONE FACTOR HELPING PROPATH WEATHER THE ECONOMIC STORM FROM THE SARS-COV-2 CORONAVIRUS is the COVID-19 testing the lab added to help its hospital partners test patients before surgery.

"Our COVID testing has been a big help because that's a whole new revenue source, said Cory A. Roberts, MD, the group's President, Chairman, and CEO. "We collected about $2 million in COVID testing revenue through the middle of August, and we only started testing in late May.

"Testing protocol rules vary from hospital to hospital, but generally every hospital wants a pre-procedure or pre-op COVID test 48 to 72 hours before the procedure," he added. "Our test turnaround time is 24 hours.

"Right now, we average about 800 PCR COVID tests per day, but that varies depending on patient demand and supply constraints," he added. "We've done as many as 2,000 tests in one day.

"We've had huge supply-chain problems and that currently caps us at 800 tests per day," he said. "Too often we don't have enough consumables or reagents because every part of the supply chain has had problems.

"Our goal is to manage the demand for COVID-19 testing so that we can turnaround tests in 24 hours and avoid a huge backup," Roberts explained.

"We run the PCR tests on the **Hologic** Panther platform and plan to introduce our own laboratory-developed test (LDT) for COVID by the end of August," Roberts noted.

"For our LDT, we anticipate the same supply chain constraints, specifically with pipette tips. Therefore, we'll probably run about 200 of those tests each day. We also did some antibody testing, but demand has never been very high.

Pathology Update

Quest Reports 46% Decline in New Cancer Diagnoses in March

Data on six of the most common types of cancer; attribute drop to decline in patient visits to doctors

Once shelter-in-place orders were enacted in March because of the COVID-19 pandemic, the number of new diagnoses of cancer declined sharply in the United States. Newly-published data confirms this fact.

The data also support the warnings of anatomic pathologists that—because of the pandemic and shelter-in-place directives—fewer patients visited physicians' offices, meaning many cases of cancer and other conditions could go undiagnosed.

In new data published earlier this month in *JAMA Network Open*, researchers from **Quest Diagnostics** reported on the decline in new diagnoses for six common cancers: breast, colorectal, esophageal, gastric, lung, and pancreatic cancer.

Systemwide Concerns

Beginning March 1 and extending through the end of the month when the decline leveled off, the number of diagnoses declined by more than 46% for the six cancers, the researchers wrote. The study, "Changes in the Number of US Patients with Newly Identified Cancer Before and During the Coronavirus Disease 2019 (COVID-19) Pandemic," was published online on Aug. 4.

During the pandemic, the weekly number fell 46.4% (from 4,310 to 2,310) for the six cancers combined, ranging from 24.7% for pancreatic cancer (from 271 to 204) to 51.8% for breast cancer (from 2,208 to 1,064), researchers wrote.

In an interview with The Dark Report, the study's lead author, Harvey W. Kaufman, MD, Quest's Senior Medical Director, said the data are significant by themselves and serve as a proxy for other diagnostic work AP groups and clinical labs have done during the pandemic.

Pent-up Demand for Care

"As much as our research applies to cancer—as it should because cancer carries more weight than other medical conditions—the message from this work applies to everything else in healthcare," he said. "It certainly applies to dental care, for example, but it also applies to lipid screens, diabetes screens, chronic kidney disease, and other conditions.

"It applies to all other diagnoses because during the lockdown people were told not to go for routine care," added Kaufman. "Doctors' offices were closed and there was little normal care in emergency rooms."

Other healthcare experts have said that the months of shelter-in-place directives created pent-up demand for care that will result in increased testing volume when those patients return to visiting doctors' offices for screening tests and other diagnostic work.

"That means everyone in healthcare needs to re-engage so that we can capture what was missed," Kaufman commented.

Some patients have returned to get care they missed, he added. "Our volume has bounced back, although not totally. In particular, it has not come back in Florida," he explained. "But overall, we've had an excellent return of testing volume as more doctors' offices opened and more patients see doctors and get screened for cancer.

"It's comforting that more patients are getting screened, but there's still a gap between what we had for test volume last year and what we see now because not everyone has returned," Kaufman noted. "Clearly, people are concerned about going out in public, about traveling, and about going into healthcare facilities where there are other patients.

Patients Still Have Concerns

"Patients are concerned about going to doctors' waiting rooms where there are likely to be patients who are asymptomatic or symptomatic with COVID-19," Kaufman commented.

What does a decline in cancer screening visits mean for patients? The researchers answered that question, writing, "While residents have taken to social distancing, cancer does not pause."

Therefore, the delay in diagnosis could cause patients to visit physicians at more advanced stages of disease, leading to poorer outcomes and death. "One study suggests a potential increase of 33,890 excessive cancer deaths in the United States," the researchers wrote.

"To put that number in perspective, an estimated 34,000 excess cancer deaths would be 5% to 6% over and above the projected 600,000 deaths from cancer last year," Kaufman commented. "That's not on the same scale of more than 170,000 excess deaths from COVID-19, but it's a real number, and every life is significant."

Possible Surge in Demand

For lab directors and anatomic pathologists, the researchers suggested the data could indicate a need to plan for how to address a surge in demand for testing. Urgent planning to address the consequences of delayed diagnoses may include a wider use of telehealth screening and more tools to allow patients to schedule screening visits with clinical specialists, the researchers wrote. TDR

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Weekly Data Show Declines in All Cancer

FOR A STUDY PUBLISHED in *JAMA Network Open* on Aug. 4, researchers analyzed weekly changes in the number of patients with newly-identified cancer before and during the COVID-19 pandemic.

The researchers included U.S. patients whom Quest Diagnostics tested for any cause and whose ordering physicians assigned them an ICD-10 code associated with breast, colorectal, esophageal, gastric, lung, and pancreatic cancer from Jan. 1, 2018, to April 18, 2020.

The mean weekly numbers of patients newly diagnosed during the baseline period of Jan. 6 through Feb. 29, 2020, were compared with the mean weekly number of patients diagnosed during the COVID-19 period of March 1 to April 18, 2020. In the study, 258,598, or 92.8%, of the patients were from the baseline period, and 20,180, or 7.8%, from the COVID-19 period.

In the baseline period, the mean weekly number of newly-identified patients showed 2,208 were diagnosed with breast cancer, 946 had colorectal cancer, 695 with lung cancer, 271 with pancreatic cancer, 96 with gastric cancer, and 94 with esophageal cancer.

During the pandemic, the researchers found significant declines in all cancer types. "The decrease had generally leveled beginning the week starting March 29, 2020," they added.

The Quest findings are similar to that of researchers from other countries.

The lead author of the study was Harvey Kaufman, MD, Quest's Senior Medical Director. His colleagues from Quest were Yuri Fesko, MD, Medical Director of Oncology, and Senior Health Informatics Analysts Zhen Chen, MS, and Justin Niles, MA.

Clinical labs help coordinate state's response to COVID-19

Wisconsin Lab Network Feeds Valuable Data to State Health Lab

➤➤ *CEO SUMMARY: From the earliest days of the COVID-19 pandemic, the 138-member Wisconsin Clinical Laboratory Network has reported to the state health lab the number of COVID-19 tests, the number of positive results, as well as other data that includes data on lab testing supplies and capacity. Founded 20 years ago, the network is a public-private partnership that allows participating labs to identify supply shortages, exchange test supplies when needed, and enlist state officials to ask vendors to boost supply shipments.*

If timely and detailed clinical lab test data is king during a pandemic, then the experience of the 138 labs in the **Wisconsin Clinical Laboratory Network** (WCLN) since the earliest days of the COVID-19 pandemic demonstrates the truth of that statement.

This is also a story about how a 20-year history of interaction and collaboration between different hospital labs and their state's public health laboratory enabled all participants to share ideas on where to get supplies, how to introduce new tests to identify infected patients, and ways to get the most from the lab-testing equipment they have.

In most states, collaboration among clinical laboratories is mostly uncoordinated. But not in Wisconsin where the **Wisconsin State Laboratory of Hygiene** (WSLH) at the **University of Wisconsin-Madison** has fostered cooperation among the state's 138 clinical labs for more than 20 years through the WCLN.

The network's stated purpose is to provide communication and support to clinical laboratories to ensure timely and effective responses to public health needs, including emergency preparedness and disease surveillance.

In this way, the WCLN serves as a critical resource for the state's clinical laboratories by assisting state health officials in responding to the coronavirus pandemic, which may be the most significant challenge the network has ever faced.

State officials and clinical lab scientists in Wisconsin have learned at least three important lessons from the close working relationship that the WCLN member labs have with the state health lab.

➤Lessons Learned

These lessons could be applied in other states seeking to coordinate SARS-CoV-2 testing and infectious-disease data reporting to assist with surveillance and control of outbreaks.

First, the network's participating laboratories regularly report test volume, test capacity, and which labs are unable to test because lab test supplies have run short. Using that data allows state officials to ask the manufacturers of lab test reagents (or kits) directly for more supplies.

In some cases, even Wisconsin Gov. Tony Evers has intervened by writing to the manufacturers about the pressing need for more tests and more test supplies, said Alana Sterkel, PhD, D(ABMM), SM(ASCP)CM, an Assistant Director of the Communicable Disease Division at the state lab.

Second, early during the pandemic, data from WCLN member labs helped WSLH recognize that certain supplies—such as specimen-collection swabs and viral transport media—were needed in vast quantities. That information led to a contract with two Wisconsin companies, **Gentueri** and **WVDL**, neither of which made these supplies before state officials asked them to make enough supplies to support the testing statewide.

➤Labs with Supply Shortages

Third, WSLH uses WCLN data to identify which labs have shortages and which labs have supplies or may soon run out.

"This information has allowed WSLH to facilitate trades between labs to optimize the limited resources we have available," Sterkel explained.

Since the WSLH ran its first SARS-CoV-2 test on March 2, data from the WCLN has helped state health officials to understand where the virus was spreading, how clinical laboratories were responding to the outbreak, and what those laboratories needed to increase and continue testing.

"Having this regional laboratory network allows us to develop a robust public health response that has been mutually beneficial, not only for state health officials, but also for the clinical labs themselves," added Sterkel.

"As a subject matter expert in lab testing, I've been embedded in the state's

Emergency Operations Center (SEOC) and so have been in contact with the White House and federal agencies such as the **Federal Emergency Management Agency**," Sterkel said in an interview with The Dark Report.

Survey of State's Labs

Lab data posted on the state health website is derived from a survey that WCLN member labs complete. The survey is used to provide information to state decision makers as often as needed and at any time, Sterkel explained.

"We ask that labs update their survey answers anytime there is a change, such as when they go live with testing, when they change testing, or to report supply shortages," she said. "In a weekly report to WCLN member labs, we summarize lab surveillance data based on what the clinical labs report to us."

State officials and the public can monitor testing trends on the DHS COVID-19: Wisconsin Summary Data page *(https://www.dhs.wisconsin.gov/covid-19)*, which updates daily at 2 p.m. Data from the last week of June provides a useful example. In that week, officials in all but five states saw a spike in COVID-19 cases and positive test results, while rates of infection due to the SARS-CoV-2 coronavirus had been dropping in Wisconsin.

Efforts to Manage Outbreak

"Those declining rates in Wisconsin came as a result of efforts to increase testing, institute stay-at-home orders, and conduct contact tracing," she said. "Until recently, we've seen a drop in the number of COVID-19 tests. But, along with the spike in new cases we see testing increase again," noted Sterkel.

"For the week ending Aug. 14, labs reported running an average of 10,000 test per day for a total of more than 1.08 million by Aug. 19 and had a percent positivity of 6.2% overall for the whole state.

"Also, we had a seven-day average of 7.7% positive results on Aug. 19," she reported. "At the moment, our rate of positive results is concerning."

"On the state Department of Health Services webpage, you can see that COVID-19 cases have risen and fallen in fits and starts," Sterkel observed.

"There is an interesting correlation between the rise in cases and how mobile Wisconsin residents are. A big part of how we've controlled the disease has been a combination of all public health efforts, and testing is a key part of the whole strategy."

WSLH went live with testing on March 2, using the initial CDC assay. In the following weeks, the number of labs running the molecular tests rose from two on March 2, to 50 on April 25, to 75 by June 27, and to 83 on July 13.

Lab Test Capacity

WCLN data show clinical lab capacity in a variety of ways. "We can see—and the public can see as well—which instruments those labs are using and which they plan to use in the future if they had the supplies they need," she commented.

"Currently, 83 labs are actively testing, and 27 more plan to bring up testing, except they don't have enough supplies," Sterkel reported. As of Aug. 19, the network-member labs had the capacity to run 27,211 molecular COVID-19 tests per day.

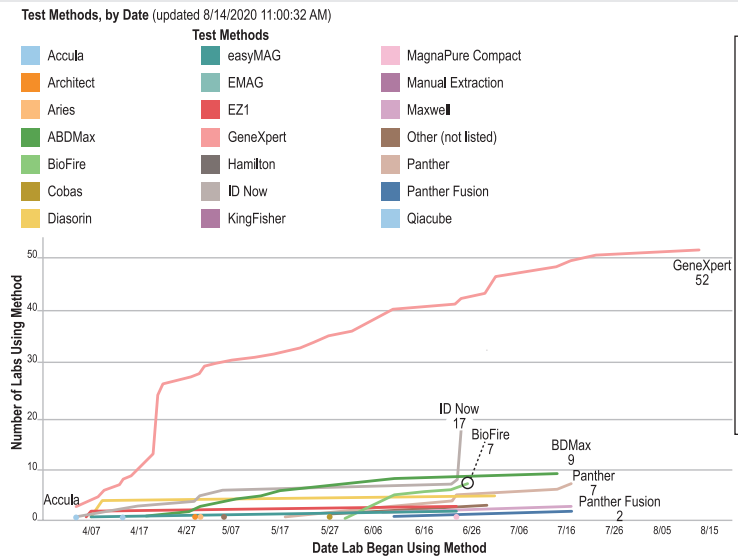
"From that data, the clinical laboratories can report when they're experiencing shortages if they're not getting certain kinds of supplies," said Sterkel. "We can use that data to advocate on their behalf to get them the quantities of supplies they need to increase testing capacity.

"Most laboratories in Wisconsin are using the **Cepheid** GeneXpert system," Sterkel added. "Many more labs would like to use the Cepheid test, but the supplies have been slow to come to Wisconsin," she warned. "This is an area the SEOC is focusing on so that we can increase supply allocations for the clinical laboratories that need them.

Data from Wisconsin Clinical Lab Network Shows the COVID-19 Test Methods Being Used

BECAUSE OF HOW WISCONSIN'S DEPARTMENT OF HEALTH SERVICES (DHS) collects data about COVID-19 testing, it is possible to see the number of labs using tests supplied by different *in vitro* diagnostics (IVD) manufacturers.

Below is a chart produced from data that can be viewed on the DHS website. The chart shows "active test methods statewide" and shows the number of labs using COVID-19 tests from different manufacturers. The chart indicates that just a handful of companies provide the largest proportion of COVID-19 tests to those labs that report to the DHS.



Active Test Methods

Company	# Labs
Cepheid GeneExpert	52
Abbott IDNow	17
BD Max	9
Hologic Panther	7
BioFire FilmArray	7
Diasorin LiasonMDx	5
All Others	23
Total all reporting labs	120

Source: Wisconsin Department of Health Services.

"The numbers tell us how many of the labs in the network are using the Cepheid GeneXpert and how many labs need supplies for that test," she commented. "Based on this information, we asked the governor to write to Cepheid to request more tests or other supply allocations. Or, the governor could ask how we could work with Cepheid to help them to meet our needs.

"Just seeing those needs allows us to monitor in real time when a lab is no longer able to test because they've run out of supplies," she said.

"Even in my lab, we had a very limited supply of extraction reagents early on," she noted. "Also, we had more plastics than liquids. At the same time, a clinical laboratory nearby had more liquids than plastics. Both of us were going to run out of testing supplies. So, we did a trade that allowed us to continue COVID-19 testing. This redistribution allowed both of our labs to keep going," Sterkel reported.

Collaborative Approach

The collaborative approach has worked well during the pandemic. "We have been building up testing in the clinical labs and in some commercial labs as well," she noted.

"The advantage of working with our clinical and commercial labs is that those SARS-CoV-2 tests are close to where the patients are. That means we can give people the fastest turnaround time and the

closest connection to medical care that we can provide."

For COVID-19 tests that must be sent out, slower-than-usual turnaround times at national reference labs have frustrated Wisconsin's pathologists and clinical lab directors.

"It's a constant problem for clinical laboratories in our state," Sterkel said of the limited supplies and kits. "We've been monitoring the supply shortages as much as we can and we hoped that the supply constraints we saw earlier would be lifted by now. But some supplies are still coming in at a trickle.

"The result is that our clinical labs have taken on diverse strategies by doing testing on multiple different platforms," she reported. "Here at the state laboratory, we've developed COVID-19 testing on six different methods. This means that as the test supplies dry up on one method, we can switch to another without having to stop testing.

Send-Out Testing

"Other lab facilities are trying to take that same approach," she said. "If they don't have another test to use, they have to send out COVID-19 tests to reference laboratories. Some labs are sending testing to two or three different places depending on availability, pricing, and turnaround times, among other factors.

"But with some of the national reference labs, it can take seven to 10 days to get a result back, at least in the beginning," she added. "Fortunately, that turnaround time seems a bit better now, but it's still three to four days for a large out-of-state reference lab."

Among Sterkel's concerns about the near future is how Wisconsin's labs will respond when pressed to increase COVID-19 testing when schools reopen and during the flu season this fall.

"It's inevitable that the influenza will come back this fall. What's that going to look like?" she asked. "And how will we manage our COVID testing when people are symptomatic for COVID and other respiratory viruses?

"Here at the state laboratory, we're working to bring on combined multiplex testing that can test for COVID and the flu at the same time," she reported. "We're also working with our clinical labs to help them develop strategies for how they're going to manage these patients as well as the increased volume that we expect in the fall."

Possible Multiplex Test

One solution Sterkel and other lab professionals have considered for multiplex testing is the Cepheid GeneXpert system because the manufacturer announced in June that it was developing the Xpert Xpress SARS-CoV-2/Flu/RSV four-in-one test. "That could be a useful test," commented Sterkel.

The company expects the assay to detect SARS-CoV-2, Flu A, Flu B, and respiratory syncytial virus (RSV) from a single patient sample. Patients with any of these infections have similar clinical presentations, Cepheid explained.

Many WCLN-member labs have run Cepheid's Rapid SARS-CoV-2 test on the company's GeneXpert systems. "That test is really fast in that it delivers a result in about 40 minutes, and it's trusted and accurate," Sterkel commented.

Demand for Lab Instruments

"It's available widely because Cepheid machines were already placed in many labs around the state, meaning it's a great way to get testing done everywhere," she added. State data show that other machines in high demand are **BioFire** and the **Hologic Panther**.

Since March, the WSLH has been seeking to buy two Hologic machines but found demand outstripped supply. "We had to get in line behind 200 other labs that put in orders for these instruments," she noted. "That shows there's definitely a demand for the instrumentation associated with COVID testing."

Wisconsin State Laboratory of Hygiene Asked Governor to Help Ease Supply Shortage

LEVERAGING THE CLOUT OF THE WISCONSIN STATE GOVERNMENT has helped the Wisconsin State Laboratory of Hygiene (WSLH) to address COVID-19 shortages of supplies and tests in two ways. One was to have the state contract directly with supply manufacturers. The other was for state labs to enlist the help of Gov. Tony Evers.

"From the first days, supplies ran short and we had limited shipments coming from our normal commercial sources," said Alana Sterkel, PhD, D(ABMM), SM(ASCP)CM, Assistant Director in the Communicable Disease Division of the Wisconsin State Laboratory of Hygiene.

"So, we worked out a relationship with two local businesses in Wisconsin that make specimen collection kits—although not necessarily kits for COVID-19 testing," she recalled.

"We asked them to switch over to producing collection kits for COVID-19 testing and we helped them get up and running.

"One of our local companies—Gentueri—could source FDA-approved swabs from China," she said. "This was essential to the success of this endeavor."

"The **Wisconsin Veterinary Diagnostic Laboratory** also stepped up to establish a new production system for collection kits.

This is not their normal type of business, but they wanted to help," she said. "We then partnered with the state's Emergency Operations Center to get the supplies out to where they were needed most."

The second way to improve the supply chain was to ask Evers to intervene. "The governor has worked with us to send letters about our requests to the big manufacturers and to HHS," said Sterkel. "He's written letters to all of the most-used manufacturers. "We hope it leads to additional allocations. We're trying everything we can."

WCLN survey data show which labs are running which tests. As of Aug. 19, the top five tests were in use at 52 member labs running the Cepheid machines, while 32 labs were planning to add testing from Cepheid.

The data also showed: 18 labs were running the Abbott ID NOW and 16 wanted to do so. The BD Max: nine now and none planning to add that test. The BioFire: eight now and 17 planning. And the Hologic Panther: eight now and 10 planning to add that test.

"The BioFire test is a fairly fast, one-hour assay that's easy to use. But that test has been slow to come on the market. So, if the BioFire equipment is all they have, they can't test until they get the assay," Sterkel said.

"Wisconsin received some BioFire supplies, but 17 labs are still waiting to get these supplies," she said. "So, there's definitely a gap for getting the supplies where they're needed."

The Cepheid GeneXpert is another example of a test for which supplies often run short. "Although we have 52 labs running that test now, some labs have had to stop testing because they haven't received enough of those tests to keep up with the demand," she said.

Supply Chain Challenges

"Even labs that have received some testing cartridges have stopped getting the supplies they need, and so they've stopped testing," explained Sterkel. "It's difficult to bring on a test and then have to stop again. Physicians get accustomed to using that test, and they may prefer it because it's fast and reliable. Another test may take longer and not have the same result profile." TDR

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IVD Update

Thermo–Qaigen Merger Stopped, More IVDs Report Q2 Earnings

Quarterly earnings statements confirm ongoing and strong demand for COVID-19 supplies, tests

EACH TIME A MAJOR *IN VITRO* DIAGNOSTICS (IVD) COMPANY reports its quarterly earnings, clinical lab executives and pathologists gain useful new perspectives as to how the COVID-19 pandemic is fueling demand for IVD instruments, tests, and lab consumables.

In this round-up of the most recent quarterly earnings reports, we provide details about **Thermo Fisher Scientific**, **Agilent Technologies**, **bioMerieux**, **Bio-Rad**, and **Sysmex Corporation**.

IVD companies with products that are used in routine clinical care experienced a decline in orders and revenue for the second quarter, ending on July 31. IVD firms with products that support SARS-CoV-2 testing reported strong increases in revenue. The IVD executives typically provide useful insights about how the lab testing marketplace is changing during their earnings calls with analysts.

ThermoFisher SCIENTIFIC

Thermo Fisher Scientific: Qaigen Acquisition Canceled, 'Extraordinary Quarter' Because of COVID Testing

Since the COVID-19 outbreak began spreading worldwide in February, it has been an interesting roller-coaster ride for **ThermoFisher Scientific** of Waltham, Mass. On March 3—amidst the earliest weeks of the SARS-CoV-2 outbreak—Thermo and **Qaigen NV** of Venlo, Netherlands, announced an agreement for Thermo to pay $11.5 billion to acquire Qaigen.

Qaigen, with sales of $1.5 billion in 2019, is familiar to clinical lab administrators and pathologists because of its presence in molecular and genetic testing. It has product lines for specimen handling and preparation, diagnostic assays, and bioinformatics software.

But this merger was stopped by some Qaigen investors who thought the company was worth much more than the approximately $46 per share that was the basis of the original agreement. Leading opposition to the acquisition was Qaigen investor **Davidson Kempner Capital Management**.

Executives at ThermoFisher disclosed on Aug. 13 that the merger agreement between the two companies was canceled. Only 47% of Qaigen shares were tendered and this fell short of the number of shares required for the transaction to move to a closing. As part of the original merger agreement, Qaigen will pay Thermo $95 million as a break-up fee.

Earlier, on July 22, Thermo announced its second quarter revenue grew by 10% year-over-year to $6.92 billion, according to a news release. The financial performance during the height of the coronavirus pandemic came somewhat as a surprise to company leaders.

"We were prepared for the most difficult quarter we've seen in the 18 years I've been with Thermo Fisher, and we successfully navigated the environment to deliver truly extraordinary performance," Marc Casper, Thermo Fisher Chairman, President, and CEO, told investors during a Q2 earnings call in late July.

"We met incredible demand for COVID-19 testing and were able to deliver growth of just over 70% in Q2. We're providing customers with our proprietary diagnostic test kits, instrumentation, and viral transport media, as well as reagents used for laboratory-developed tests," said Casper.

In its coverage of Thermo's earnings report, *Motley Fool* wrote, "There was one primary factor behind Thermo Fisher's Q2 success—COVID-19. The company said that it generated around $1.3 billion in revenue related to the COVID-19 pandemic." Thermo's best-performing division was life sciences, with products used in SARS-CoV-2 testing. It saw Q2-20 revenue of $2.6 billion, a year-over-year increase of 52%.

During the earnings call, Thermo executives disclosed that the company is developing a total antibodies serology test in collaboration with **WuXi Diagnostics** and **Mayo Clinic**.

Agilent

Agilent Technologies: Revenues Declined by 1% Overall, Diagnostics Down 8%

Based in Santa Clara, Calif., **Agilent Technologies, Inc.'s** third quarter ended on July 31. In a news release, the company announced Q3-20 revenue of $1.26 billion, down 1% compared to Q3 2019.

Agilent says it "serves the life sciences, diagnostics and applied chemical markets ... and has three business segments: life sciences and applied markets business, diagnostics and genomics business, and Agilent CrossLab business."

Because many of its molecular and genetics products are used in standard care, the dramatic fall-off in patient visits to hospitals and physicians' offices following the outbreak of SARS-CoV-2 in March and April was a major factor in the lack of revenue growth during Agilent's third quarter.

During the earnings call with financial analysts, Agilent President and CEO, Mike McMullen, shared insights on how the COVID-19 pandemic is evolving in different regions throughout the world. "In all regions, we see improvements in lab access for our customers and increased non-COVID-19 testing volumes. There are, however, regional market differences in the pacing of improvement," he said. "Lab access improved through the quarter, although still not at pre-COVID-19 levels. Globally lab access was limited in academia, non-COVID-19 research, and [non-COVID] testing labs."

BIOMÉRIEUX

bioMÉRIEUX: Pandemic Boosted Molecular Testing in Second Quarter

bioMérieux, based in Marcy-l'Étoile, France, issued a short statement about Q2-20 earnings on July 9 and will release a detailed Q2-20 earnings report on Sept. 2.

The company, a major global player in infectious disease testing, reported sales of US$1.74 billion for the first six months of 2020, which is up 15.7% from 2019. "In the second quarter, bioMérieux recorded solid growth of nearly 11% compared with the same period of 2019," said the press release.

bioMérieux said that, during the second quarter, lower patient traffic in hospitals due to the pandemic contributed to an "adverse impact" in the year-over-year performance of the microbiology and immunoassay product lines. Two high points in bioMérieux's short statement about Q2-20 earnings were that "the BioFire FilmArray syndromic testing line made a major contribution to the Group's solid performance, with 62% growth compared with the second quarter of 2019. Other molecular biology product lines related to COVID-19 epidemic saw a strong demand as well."

Sysmex Corporation: SALES DOWN 12%, ANTIBODY MEASUREMENT TECHNOLOGIES DEVELOPED

Sysmex Corporation, with its head office in Hyogo, Japan, said sales in the Americas fell 12% compared to the same time last year.

"In North America, instrument sales were up in the hemostasis field. However, sales in the region were down due to lower sales of instruments, reagents, and maintenance services in the hematology field mainly due to the spread of the COVID-19 pandemic," company executives wrote in Sysmex's financial results report released Aug. 5.

Forbes called it a "rough" quarter for Sysmex as it experienced revenues falling 12% or $569 million, while profit plunged 33% to $42 million.

Sysmex also reported this news:

- Establishing four antibody technologies for IgG and IgM antibodies and launch of lab assay service using the testing technology.
- Launch of a lab assay service for research on cytokines and SARS-CoV-2 treatment effects.

When Sysmex reported results for the full year 2019, the company posted revenue of $2.77 billion. It also noted that there are 3,800 blood-analyzing instruments in the United States.

Bio-Rad Laboratories: ROBUST PANDEMIC SALES MAKE UP FOR OTHER PRODUCT SLOWDOWNS

Bio-Rad Laboratories, Inc., Hercules, Calif., reported net sales in Q2-20 of $536.9 million, a decrease of 6.2% compared to Q2 2019, a statement noted.

"While sales of many of our core products across Life Science and Clinical Diagnostics were slow, sales of products associated with the coronavirus pandemic were robust and provided some counterbalance," said Norman Schwartz, Bio-Rad President and CEO in a news release.

"We estimate that the COVID-19-related sales were about $71 million in the quarter. Sales of the Life Science Group in the second quarter of 2020 were $252.1 million compared to $212.4 million in Q2 of 2019, which is an 18.7% increase on a reported basis and a 20% increase on a currency-neutral basis," said the press release.

Bio-Rad's statement called attention to an interesting application of their PCR (polymerase chain reaction) products, stating "the majority of the year-over-year growth in the second quarter was driven by our core PCR products—Droplet Digital PCR and Process Media."

Ilan Daskal, Bio-Rad's CFO, said in the statement, "During the current pandemic, these products are being deployed to monitor SARS-CoV-2 prevalence in wastewater streams," adding, "sales of the Clinical Diagnostics products in the second quarter were $283.2 million compared to $357.1 million in Q2 of 2019, which is a 20.7% decline on a reported basis and an 18.7% decline on a currency-neutral basis."

"During the second quarter, Clinical Diagnostics segment experienced weakness across all of its product lines due to the reduced demand from lower non-critical hospital and clinic visits," continued Daskal. "On a geographic basis, the Diagnostics Group posted declines across all regions. We continue to execute on our new product development strategies as well."

➤Understanding IVD Marketplace

THE DARK REPORT is now providing business intelligence about *in vitro* diagnostics (IVD) companies and lab informatics firms to help lab administrators understand which companies are doing well and which may be struggling. This is to help inform buying decisions when labs and pathology groups purchase instruments, tests, informatics systems, and services. TDR

Lab Regulatory Update

CMS Publishes Proposed 2021 Medicare Physician Fee Schedule

Clinical labs get a reprieve from PAMA reporting, pathology professional fees may be cut by 9%

MEDICARE'S PROPOSED PHYSICIAN FEE SCHEDULE (PFS) RULE was announced on Aug. 4, 2020. The rule had one positive development for clinical laboratories and hospital laboratory outreach programs and a negative development for anatomic pathologists.

Clinical laboratories and hospital outreach labs will welcome the news that the proposed 2021 rule would delay the next Clinical Laboratory Fee Schedule (CLFS) reporting period by an additional year This means applicable laboratories would not need to report private payer lab test price data until Jan. 1, 2022.

No Decrease in Lab Fees for 2021

The other positive element of the proposed 2021 rule extends phased-in reductions to the CLFS through 2024, with a 0% reduction for 2021 and a 15% reduction cap for each of the next three years. These provisions were part of the Coronavirus Aid, Relief and Economic Security (CARES) Act, passed on March 27.

Anatomic pathologists will not welcome one significant change. Under the proposed PFS rule for 2021, pathologists may face a 9% cut to Medicare payment for pathology services. CMS also proposed to reduce technical component reimbursement for pathology labs by an average of 5%. *(See page 26.)*

For clinical laboratories and hospital outreach laboratories, the proposed 2021 PFS rule modifies how federal officials are to implement certain sections of the Protecting Access to Medicare Act of 2014 (PAMA).

As enacted, PAMA directed the federal **Centers for Medicare and Medicaid Services** (CMS) to conduct a study of private payer lab test prices and use that data to establish a market-based payment system under the CLFS, with Medicare rates set every three years based on laboratory reporting. The first round of reporting took place in 2017, and new payment rates began Jan. 1, 2018.

In December 2019, under the Further Consolidated Appropriations Act of 2020 (FCAA), the second PAMA private payer lab test price reporting period was delayed from 2020 to 2021, meaning that applicable clinical laboratories would have had to report their private payer test price data to CMS beginning Jan. 1, 2021, through March 31, 2021.

However, the proposed PFS rule—in implementing the CARES Act—would further delay this second reporting period from 2021 to 2022, while also exempting CLFS laboratory tests from market-based payment reductions for 2021. Annual reductions would be capped at 15% from 2022 through 2024.

Data Collection Period Unchanged

While the second collection period for PAMA private payer lab price reporting has been delayed until 2022, the CARES Act does not modify that collection period. Thus, the collection period dates of Jan. 1, 2019, through June 30, 2019, remain the same. When collected and analyzed by CMS, this data will be used to set fees for the three years of 2022,

2023, and 2024. Fee cuts cannot exceed 15% for a test in each of these three years.

The delay in reporting and implementation of the next round of fee cuts may be beneficial to the clinical laboratory industry. "The primary value in this is if you keep kicking the can down the road, the chances are going to increase that before labs have to report again, the **American Clinical Laboratory Association** (ACLA) will prevail and perhaps get some significant changes made that will make the whole thing more palatable to labs," said Karen Lovitch, chair of the Health Law Practice at **Mintz** in Washington, D.C.

Some Benefit to Clinical Labs

Another lab industry expert, Mark Birenbaum, PhD, administrator of the **National Independent Laboratory Association (NILA)**), believes that the reporting delay benefits clinical laboratories, at least in the short run. "With labs still trying to increase COVID-19 testing, I think the delay in PAMA reporting will help relieve some of the strain labs are experiencing," he said.

"I'm also pleased that clinical labs get an extra year for reporting private payer lab test prices," he added. "NILA still believes that PAMA is deeply flawed in the mechanism that CMS uses to calculate the weighted medians. NILA will continue to push for changes to address those problems.

"The fact that there are no additional cuts to the Medicare CLFS in 2021 means that Medicare payments will be status quo during the pandemic," Birenbaum continued. "It keeps the flawed price cuts in place, which is not good. However, for planning purposes, clinical laboratories won't have to deal with new lab test price cuts to the Medicare CLFS until 2022."

Birenbaum also believes it is important for clinical laboratories to continue educating federal legislators and government officials about how the Medicare price cuts undermine the financial stability of many community laboratories, which, in turn, means Medicare beneficiaries lose access to high quality lab tests in their area. "Labs must convince either CMS to change the PAMA regulations or Congress to change the PAMA statute, but it's difficult to predict how that will turn out," he observed.

Fewer Labs Today in the U.S.

"The COVID-19 pandemic is exposing major problems created by a long period of downsizing the nation's laboratory infrastructure," explained Birenbaum. "There are fewer labs today because of the constant reduction of payment rates for lab tests. It is increasingly difficult for community and regional labs to stay in business. As a national resource, clinical laboratories have been weakened over the past 15-20 years, and that is being exposed during the current pandemic when high quality community and regional laboratories are really needed.

"In fact, the national news media has rightly called attention to all the problems that have been created by lack of testing capacity, lack of instrumentation, and fewer labs able to perform essential SARS-CoV-2 testing. **LabCorp** and **Quest Diagnostics** have struggled at times to keep COVID-19 lab test turnaround times within the target range and some of NILA's community labs have stepped in to help," noted Birenbaum.

Role of Community Labs

"The COVID-19 pandemic demonstrated that the United States cannot simply depend on a handful of billion-dollar lab companies—especially in times of emergency," he added. "This really highlights the role of the community lab, not just during a pandemic, but also during other emergencies, like natural disasters. It is essential that the nation maintain and nurture an infrastructure of community and regional labs." **TDR**

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Additional Proposed 2021 Medicare PFS Changes of Interest to Clinical Labs, Pathology Groups

HIGHER PAYMENTS FOR COVID-19-RELATED SPECIMEN COLLECTION FEES AND ASSOCIATED TRAVEL ALLOWANCE for clinical laboratories are being reconsidered with the proposed 2021 Medicare Physician Fee Schedule (PFS) rule.

On April 6, 2020, the federal Centers for Medicare and Medicaid Services (CMS) established that Medicare will pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID-19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients.

To identify specimen collection for COVID-19 testing specifically, CMS established two new level II HCPCS codes

- **Code G2023** (specimen collection for severe acute respiratory syndrome coronavirus (SARS-CoV-2) (Coronavirus disease [COVID-19], any specimen source); and,
- **Code G2024** (specimen collection for severe acute respiratory syndrome coronavirus 2 (SAR-CoV-2) (Coronavirus disease [COVID19]), from an individual in an SNF or by a laboratory on behalf of an HHA, any specimen source), for independent laboratories to use when billing Medicare for the nominal specimen collection fee for COVID-19 testing during the public health emergency.

CMS is now requesting comment on whether it should delete those two HCPCS codes once the COVID-19 public health emergency ends. Specifically, it is seeking public input on why these codes, and their corresponding payment amounts, which are higher than the nominal fees for specimen collection for other conditions, would be necessary or useful outside of the context of the public health emergency.

Additional Changes:

- **Conversion Factor.** CMS is proposing a conversion factor of $32.36, a decrease from the CY2020 conversion factor of $36.09. This change would result in a 10.6% reduction.
- **Non-Physician Supervision of Diagnostic Tests.** The proposed rule would allow the following practitioners to supervise the performance of diagnostic tests subject to state scope of practice laws: nurse practitioners, clinical nurse specialists, physician assistants, and certified nurse midwives.
- **Medicare Telehealth Services.** During the public health emergency, CMS added approximately 135 telehealth services for reimbursement under Medicare. CMS is proposing to permanently allow some of those services to continue via telehealth and to extend payment for certain services, such as emergency department visits and home visits, through the calendar year in which the emergency ends.
- **Direct Supervision through Telehealth.** CMS proposes that practitioners be permitted to supervise services virtually using real-time, interactive audio and video technology until the end of the calendar year in which the public health emergency ends, or Dec. 31, 2021, whichever is later. CMS noted this extension will allows clinicians and CMS time to consider whether to adopt this policy permanently, due to patient safety concerns.

Comments on the proposed rule are due by 5 p.m. on Oct. 5, 2020, and can be submitted electronically or by mail. Due to the COVID-19 public health emergency, CMS says it likely will not be able to publish the final rule 60 days prior to the start of 2021 as it usually does. As a result, CMS expects to provide a 30-day delay in the effective date of the final rule.

Pathology Update

Proposed Medicare 2021 PFS Cuts Pathology Fees by 9%

If the proposed Medicare 2012 Physician Fee Schedule (PFS) rule—published by the **Centers for Medicare and Medicaid Services** (CMS) on Aug. 4—takes effect as currently written, pathology professional fees will be cut by 9%, effective Jan. 1, 2021.

This was not welcome news for the anatomic pathology profession. The proposed 9% cut to Medicare payment for pathology services is the result of CMS deciding to change policy on evaluation and management (E/M) coding.

More for Primary Care Docs

CMS is selectively applying this policy change to certain services. Effectively, CMS would pay primary care physicians more, but to comply with budget neutrality, the agency would shift funds from specialists, like pathologists, who do not bill E/M codes.

The **College of American Pathologists** (CAP) was quick to respond to the publication of the proposed PPS rule. "These cuts come at a terrible time in light of COVID-19 for pathologists and the laboratories they lead," said President Patrick Godbey, MD, FCAP, President of CAP. "Reductions in Medicare payment, coupled with ongoing financial pressures of the COVID-19 pandemic, will have negative implications for pathologists—particularly those in rural and healthcare shortage areas."

CAP called on Congressional leaders to delay the proposed non-E/M cuts in 2021, and asked that the budget neutrality requirements for the E/M policy change be waived. This would allow CMS to implement increases in payment for E/M visits, while avoiding drastic payment cuts to other physician services to offset them. In fact, CAP already helped to secure the signature of 93 members of Congress on a letter to House leadership calling on them to include language waiving budget neutrality before the end of the year.

Mick Raich, owner of **Vachette Pathology**, a pathology practice management firm, notes that since the E/M changes were designed to offset increases in payment to primary care physicians, the current pandemic might render those increases unnecessary.

He points out that one consequence of the COVID-19 pandemic is that more patients and more primary care physicians are using telemedicine for patient visits. "Telemedicine has become more acceptable and payable," said Raich. "As the proportion of visits using telemedicine increases, there are significant cost changes in primary care delivery.

Lower Cost for Telemedicine

"The cost for a telemedicine visit is about half the cost of an actual visit. If this is taken into account, do primary care providers need a pay raise and lower overhead at the same time?" he asked. "If I were CAP, I would work this angle.

"Also, should the pathology cuts be finalized as proposed, salaried pathologists are likely to take a pay cut, as they are employees of large health systems or corporations and these organizations will reduce pathologist compensation to offset the lower Medicare fees," added Raich. "Private pathology groups have more options. To offset lower fees, they will look for ways to increase efficiencies. That can include hiring pathology assistants and implementing better technology, such as digital pathology." TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Currently at least 15 veterinary laboratories in the United States perform COVID-19 tests. This fact was confirmed by Adm. Brett Giroir, MD, the Assistant Secretary of the **Department of Health and Human Services** (HHS), during an interview last month conducted by *CNN*. Officials at HHS confirmed this development and explained that these labs had received CLIA certification and that the federal agency is expediting its review of the applications submitted by other veterinary labs to obtain CLIA certification.

MORE ON: *COVID Tests at Veterinary Labs*

The urgent need for larger volumes of COVID-19 tests is why veterinary labs are establishing SARS-CoV-2 testing capabilities. But that will not greatly increase the available supply of such tested, as noted by Amesh A. Adalja, MD, a Senior Scholar at the **Johns Hopkins Center for Health Security** in Baltimore. In an interview with *Healthline*, he said, " I think the issue is more about reagents and actually having lab space to process it. So, it may be that veterinary labs may be able to only marginally improve the situation because they still face the same reagent shortages that everybody is facing."

NFL TROUBLED BY FALSE POSITIVE COVID-19 RESULTS

Yesterday, news was breaking that the **National Football League** (NFL) was dealing with positive COVID-19 test results from players for teams in several cities. *ESPN* reported that **BioReference Laboratories, Inc.**, of Elmwood Park, N.J., was performing the SARS-CoV-2 tests. ESPN said that the NFL was looking into the possibility of both false positive and false negative results. Pathologists understand why diagnostic technologies can generate false positive and false negative results.

TRANSITIONS

- **Myriad Genetics** of Salt Lake City appointed Paul Diaz as President and CEO. Diaz previously held positions at **Cressy and Company**, **Kindred Healthcare**, and **Mariner Health Care Group**.

- **Genomic Health** of Redwood City, Calif., announced that Kim Popovits is its new Chairman, CEO, and President. Popovits joined Genomic Health in 2002. She previously served at **Genentech** and **American Hospital Supply**.

- Nancy Andes retired on Aug. 3 from **ARUP Laboratories** in Salt Lake City. Andes was Senior Vice President of Marketing and worked at ARUP for 43 years.

- Also retired this month from ARUP is Anne Daley. Daley formerly served at **Chi Solutions**, **Ascendium**, **Roche Diagnostics**, **Laboratory Sciences of Arizona**, and **Maricopa Integrated Health System**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 14, 2020.

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