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Newest on COVID-19 Pandemic!

- U.S. Labs step up with testing
- Lab revenues plummet 50% or more
- Federal money flows to labs, pathologists

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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R. Lewis Dark

Founder & Publisher

Clinical Labs Step Up, But Serious Problems Ahead

ACROSS THE UNITED STATES, CLINICAL LABORATORIES ARE LIVING a good news/bad news story. The good news is that the essential role every lab plays in enabling fast, accurate diagnoses is now at the top of the news cycle. Daily, citizens of this country hear from the President and health officials that it's a clinical laboratory test for SARS-CoV-2 which is essential for managing every aspect of the COVID-19 pandemic.

The bad news is the collapse in the number of specimens coming into the nation's labs since the week ending March 14. That decline is as much as 60%, averaged across all labs in this country. Fewer specimens mean fewer claims. Fewer claims mean less revenue.

Cash flow is now inadequate to sustain the ongoing operations of many labs. Further, this cash crunch is compounded by the fact that claims sent by labs to Medicare carriers and private payers are not being processed in a timely fashion, due to shelter-in-place orders in most states. This means claims processing staff for payers cannot come into their offices to verify claims and issue payment to labs, thus further delaying payments to labs. *(See pages 6-9.)*

Complicating the management challenges facing all clinical labs and pathology groups is the fact that every aspect of the SARS-CoV-2 pandemic has no precedent. There is no accepted playbook that hospitals, doctors, and labs can follow with confidence to bring the outbreak under control.

Each day, there is a new and unexpected twist in the pandemic and society's response to it. The biggest question of all is when the COVID-19 outbreak may burn itself out in ways similar to the outbreaks of SARS, H1N1, and MERS.

Related to that is another important question. At the end of the COVID-19 pandemic, will hospitals, physicians, and labs see a surge in patients who need to get the healthcare they deferred during the pandemic? If this happens, will clinical labs be ready to handle a big surge in daily routine testing? Will they have adequate cash to recall laid off and furloughed lab staff?

Not every lab organization will survive the SARS-CoV-2 pandemic. The multi-year cuts to lab reimbursement by Medicare and private payers left many labs in this country at the knife's edge of insolvency. The financial consequences of this pandemic may push a significant number of laboratories into financial collapse. TDR

Lab, Path Finances Crash; Next Test Wave: Serology

It's a paradox! As laboratories' cash flow crashes, the nation asks for large numbers of COVID-19 tests

CEO SUMMARY: For clinical laboratories and anatomic pathology groups, the day-by-day impact of the COVID-19 pandemic is unfolding much like Hurricane Katrina hitting New Orleans in 2005. Every 24 hours, labs get unwelcome news, along with uncertainty about whether it will get worse before it gets better. As of today, labs are watching their daily cash flow fall below operating costs, even as government and public health officials call on labs to increase COVID-19 test volumes.

SARS-CoV-2 IS A MAJOR FINANCIAL DISASTER MOVING ACROSS THE ENTIRE CLINICAL LAB INDUSTRY AND ANATOMIC PATHOLOGY PROFESSION. Yet this consequence of the pandemic has yet to be recognized by federal and state lawmakers.

At the same time that labs throughout the United States watch their specimen volumes collapse and cash flow dwindle to unsustainably low amounts, the health-care establishment—along with the president, state governors, and officials at the CDC—want the nation's laboratories to do more in response to the SARS-CoV-2 pandemic, and do it with urgency.

THE DARK REPORT has confirmed from multiple, credible sources that, over the four weeks from March 8 through April 4, the cumulative drop in specimen volume (and the revenue associated with these specimens) is about 60% for clinical labs and hospital outreach labs, compared to first quarter 2020 and the same time period in 2019. The average specimen decline for anatomic pathology groups is about 45% and some subspecialties have experienced as much as an 80% drop in biopsy specimens. *(Detailed information about this situation is provided on pages 6-9.)*

The unraveling finances at labs across the nation is happening with incredible speed. Understandably, government leaders and public health officials are focused on the COVID-19 outbreak itself and how to control spread of the disease. They may not yet recognize the extent of the revenue decline in the very labs they depend on to immediately deliver huge volumes of accurate, reproducible tests for an infectious agent of which little is known.

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It is now an established fact, that, even as specimens and revenues are crashing for almost every lab in the United States, these same labs are being asked to acquire, validate, and offer large numbers of COVID-19 tests. To accomplish this, labs are digging deep into their financial reserves, even as incoming cash flow is inadequate to sustain operations.

Revenue from COVID-19 Tests

There has been some revenue benefit to performing these molecular tests in volume. As you will read on pages 6-9, in recent weeks, clinical labs doing COVID-19 tests generated enough specimen volume and revenue to equal a 33% increase. But this is only true for labs performing rapid molecular COVID-19 tests.

It is important for lab administrators and pathologists to understand that COVID-19 testing will come in two waves. The first wave involved use of rapid molecular assays for SARS-CoV-2 to test individuals who were symptomatic for a respiratory virus. Those efforts started in earnest in February. By mid- to late-March, a growing number of labs were beginning to perform sizeable numbers of these tests. This testing wave may soon crest and will extend at least into the summer months.

Now, the nation's labs are poised to undertake the second wave of testing, which involves serology tests. By looking for antibodies to SARS-CoV-2, these tests are useful to understand how many people may have been infected with COVID-19, but showed minor or no symptoms.

Requests for More Tests

All levels of government and healthcare are calling on clinical labs to immediately deliver more of the testing needed to manage the COVID-19 outbreak. They want labs to build capacity to perform ever-greater numbers of rapid molecular COVID-19 tests. With equal urgency, they also want labs to acquire and validate test kits for COVID-19 serology testing, then swiftly add new instruments to deliver huge volumes of these antibody tests.

Meanwhile, the **Food and Drug Administration** (FDA)—stung by press criticisms for its slow response in getting rapid molecular tests cleared for clinical use—is accepting applications for serology tests for COVID-19 under its emergency use authorization (EUA) process. News reports say that upwards of 70 to 80 companies now have EUAs for their COVID-19 serology tests.

Some of the savvier news reporters are already writing stories with headlines touting the "Wild West of COVID-19 Testing," because they understand that obtaining an EUA for a COVID-19 serology test is a different—and much lower—standard than if a test manufacturer was going through the FDA's regular pre-market approval (PMA) process.

PAMA Price Cuts Delayed

If there is good news for the clinical lab profession in the midst of this pandemic, it is that Congress and federal agencies such as the **Centers for Medicare and Medicaid Services** (CMS) both recognized that implementing the next round of deep PAMA-mandated price cuts to the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) would be counterproductive. Those price cuts were suspended as part of the new legislation.

How long this pandemic lasts remains an open question. During press conferences, no elected official or public health officer has been willing to associate the end of a typical influenza season as a possible time for the pandemic to ease. However, during these same press conferences, there is recognition that SARS-CoV-2 could reappear "before the end of the year." This is code-speak for the novel coronavirus reappearing as the 2020-21 influenza season commences sometime in October or November. TDR

—Robert Michel

Seven Predictions for Clinical Labs about the Coming Wave of COVID-19 Serology Testing

THE DARK REPORT HAS SEVEN PREDICTIONS about the coming wave of COVID-19 serology tests, as described below.

One, the healthcare system will support running large numbers of these tests for months into the future. Public health officials and researchers need the test results so they can understand the true number of people infected with SARS-CoV-2. This information enables them to determine the actual rates of infection and mortality. This information will also be needed to understand whether people who were infected have immunity and to help develop vaccines for SARS-CoV-2.

Two, funding for these serology tests will be available. Hopefully, coverage guidelines for this testing will be written so labs can be reimbursed without difficulty or complications. What has yet to be determined is whether reimbursement for COVID-19 serology tests is "one price for all labs" and based on the economies of scale of the nation's billion-dollar public lab companies, or whether the government and private payers are willing to set higher reimbursements for community labs and community hospital labs.

Quality Differences in Kits

Three, there will be great differences in the quality of the serology test kits for COVID-19 that come to market with an FDA emergency use authorization (EUA). Thus, many labs will buy COVID-19 antibody kits that quickly turn out to be inaccurate or unreliable. It is already widely reported that both Spain and the United Kingdom spent tens of millions of dollars on serology test kits for COVID-19 that didn't work. THE DARK REPORT advises, "Lab buyers beware!"

Four, as is true with every type of new lab test, expect to see fraud and abuse associated with COVID-19 testing. Generally, this will involve individuals from outside the profession of lab medicine who see the opportunity to ride the COVID-19 serology test wave to big riches. As we report on pages 22-23, federal prosecutors already filed criminal charges against an individual for paying illegal kickbacks to refer patients for COVID-19 testing reimbursed by federal health programs.

Five, a larger number of labs in this country will be able to perform serology tests because they already have immunoassay analyzers in use and these systems are automated and capable of large throughput. It will also be relatively simple to validate the COVID-19 test kit they want to use on their existing instruments.

Supplies, Sensitivity, Trust

Six, a large number of labs will struggle to get adequate supplies of COVID-19 seriology kits. The highest-quality kits will be manufactured by the major IVD companies and demand for these kits will outstrip manufacturing capacity. These IVD vendors will give priority to their biggest medical laboratory customers. Community laboratories and community hospital labs will have to fight to get enough kits shipped that allow them to serve all the testing needs of their client physicians in smaller towns and rural areas.

Seven, clinical labs running any manufacturer's COVID-19 test kits will be challenged to perform quality control and trust that the sensitivity and specificity of the tests is at acceptable levels. Several experts have described this situation in a similar fashion. They point out that, as the FDA accepts a kit manufacturer's data and application, it is effectively clearing that COVID-19 serology test kit as the equivalent of a "waived test"—in this case, only to be performed by a lab with a high-complexity CLIA certification.

From Mid-March, Labs Saw Big Drop in Revenue

Labs and billing companies report a cumulative drop in specimen volume of 50% to 80% or more

CEO SUMMARY: In response to the coronavirus outbreak, patients stopped seeing their doctors for routine care and hospitals ceased doing elective services. With fewer test referrals, clinical labs and pathology groups were hit with a substantial decline in revenue. One of the nation's largest revenue cycle managers serving labs reported that—over the four weeks beginning in the second week of March—revenue for clinical labs and anatomic pathology groups dropped precipitously.

In the second half of March, clinical laboratories and pathology groups experienced a sharp decline in daily lab testing volume and revenue that was unprecedented in American history.

The drop in routine test volume ranged from a low of 44% for some AP groups to almost 60% for some clinical labs, according to data from **XIFIN**, a company in San Diego that provides revenue cycle management services for clinical laboratories and pathology groups.

Fewer Patient Visits

As the COVID-19 pandemic widened, government officials issued shelter-in-place orders in cities and states nationwide. In response, patients stopped making routine visits to physicians and hospitals canceled elective procedures. Beginning about Monday, March 9, the volume of routine tests and regular anatomic pathology specimens dropped sharply.

At the same time, the SARS-CoV-2 pandemic also required labs to run large volumes of virus tests. Payment for these tests has helped to offset some of the revenue lost from the decline in routine test volume, even though those payments were slow to arrive and initially barely covered lab costs, reported Kyle Fetter, XIFIN's Executive Vice President and General Manager of Diagnostic Services.

"Starting in the third week of March, we saw labs suffer a sharp drop in routine testing," Fetter said. "But at about the same time, many labs began to offset those revenue losses with testing for the novel coronavirus."

The steep decline in routine testing led to a fall-off in revenue that ranged from 44% for some AP specimens to 70% to 80% for some specialty AP work, Fetter said. Clinical labs had a drop in routine testing volume of 58%, hospital outreach testing declined by 61%, and molecular lab volume went down by 52%.

Not Business as Usual

"The outbreak of COVID-19 caused providers to shift away from business as usual," noted Fetter. As physicians sought to reduce the risk of exposure to the virus, they limited office visits when possible, and hospitals stopped elective surgeries and routine inpatient and outpatient care.

"The changes physicians and hospitals made showed up in the number of lab transactions we saw," said Fetter. "Over four weeks beginning March 9, we saw a cumulative drop in test volume from all of our lab clients of just over 40%.

"The effects are being felt widely and depend on what type of testing each laboratory does," he commented. "In anatomic pathology, testing has decreased across the board by about 50%. But for labs serving dermatologists or doing Pap tests, the volume may be down closer to 70% to 80%."

Big Losses, Some Gains

Since the beginning of April, testing volume for clinical labs began to tick up due to an increase of requisitions for COVID-19 tests. That increase allowed labs performing those tests to recoup just under half of the volume they lost, he said.

Clinical laboratories and AP groups also had trouble getting health plans to address problems with payment, according to Fetter's analysis.

"Private payers have mostly failed to respond to labs' questions about payment denials," he said. "One reason is because so many staff members at billing companies, health insurers, and some clinical laboratories are working from home. The result is slower payments."

By tracking specimen volume and revenue from hundreds of laboratories and pathology groups, XIFIN can show, in detail, how much lab test volume declined over each week beginning during the week of March 9 to 15.

"We track volume for our lab clients daily and weekly," Fetter explained. "On our side of the billing transaction, we have a delay of one day or several days from when a lab gets a specimen and when we can see the billing report from the lab. So, for clinical lab testing, we can see that drop either the same day or within a couple of days.With genetic or other long-term tests, it can take a week or two for us to see those reports.

Cash Flow Crashes at Labs, Path Groups

FROM MARCH 9 TO APRIL 6, routine test volume (and cash collections) declined for clinical, molecular, and hospital outreach labs and for anatomic pathologists. Over the same period, testing increased for the new coronavirus at these same labs, but virus testing for AP groups was flat to negligible, according to data from XIFIN.

Lab Specialty	Routine Volume	COVID-19 Testing
Clinical Labs	- 58%	+ 33%
Hospital Outreach Labs	- 61%	+ 13%
Molecular Labs	- 52%	+ 31%
Anatomic Pathology	- 44%	+< 1%
AP Dermatology	- 70%	
Other AP subspecialties	- 80%	

"Those numbers showed us not only the decline but also a slight increase in testing volume when labs started getting requisitions for coronavirus testing," Fetter reported.

XIFIN's data show the steep drop in routine test volume came approximately in mid-March, at about the same time that some clinical labs saw a slight increase in coronavirus testing.

Tracking the Volume Drop

"The requisitions for virus testing arrived just before the week ending March 15," Fetter noted. "That coincided with when we saw the early shelter-in-place orders going out in the major populated areas.

"This is right at the time when the material decrease in testing volume became visible," he added. "For the week ending March 14, we saw test volume from our lab customers drop by about 4.5%.

"During the week ending March 22, volume dropped an additional 14% from the previous week," he reported. "Then, in the week ending March 29, volume dropped by 21% over the previous week's numbers.

"Collectively, these data show a drop in testing volume among all of our lab customers of about 40% during those three weeks," he noted.

"That was the average across all segments of the lab industry—meaning some labs might have had a steeper drop in test volume and some labs might not have dropped that far," Fetter said.

"Then during the week ending April 5, lab test volume was down about another 3% to 4%," he added. "Since then, the daily numbers from April 6 through 12 have been basically flat.

Cumulative Drop of 40%

"The cumulative decline in lab test volume across all client labs for those four weeks was just over 40%," he said. "But in that time, some of our lab customers were hit with a decline of maybe 50% to 60% in test volume.

"Since then, labs bringing up COVID-19 tests have seen those tests add back maybe 15% to 20% of volume," he added.

Before mayors and governors issued shelter-in-place orders, patients were continuing to book appointments for routine blood work and other screening tests and were scheduled for elective or other surgeries as usual.

"Testing that originates from a patient visiting a doctor for routine work—such as blood testing—may have been affected the most," Fetter explained. "Those patients stopped seeing their doctors. That also affected the downstream testing that would normally result from those visits—such as biopsies.

"In fact, biopsies is one category of lab tests that has declined the most," he added. "Some labs have seen a 70% to 90% reduction in those referrals. The correlated testing from those visits is being kicked down the road."

At about the same time, Fetter noticed that testing for coronavirus patients began to rise but the payment lagged. "Even though they were running those tests in March, the majority of labs started to get paid for COVID testing in April," he noted. "Payers were simply not prepared to pay for those tests."

On March 18, President Trump signed the multibillion-dollar Families First Coronavirus Response Act that included free diagnostic testing for the virus.

"Some payments for COVID testing started to come in during the first week or so of April," Fetter reported. "We've got examples where our laboratory clients would be down about 55% to 60%, but when their COVID-19 test volume is added back, then their revenue is down only by 33% to 38%.

"Most commercial payers weren't ready to process COVID payments until the first week of April," he noted. "Medicare started making payments for virus testing after April first. Based on normal turnaround times, more COVID-19 payments from Medicare were likely to show up during the week of April 13 or so."

Early in March, the federal **Centers for Medicare and Medicaid Services** (CMS) said it would pay $35.91 for each CDC test and that labs could begin billing in April for tests run after Feb. 4. Also, labs using non-CDC tests would be paid $51.31 per test. These rates for tests done manually did not cover the typical lab's cost to perform such tests.

Virus Tests Come Online

"Even when labs do get paid for the manual test, they mostly just cover their direct costs," he reported. "And, in some cases they were probably losing money."

On March 30, CMS said it would pay new specimen collection fees for COVID-19 testing, and then two weeks later, CMS raised what it pays for certain SARS-CoV-2 tests that use high-throughput machines to $100, effective April 14 and through the duration of the emergency.

While most labs are running fewer tests overall, the workload remains high because there's a demand for testing for the new virus. At the same time, the need to validate new tests and the equipment for such tests takes time. "Our lab customers are

Working from Home Affects Health Insurer and Billing Company Response Times

SINCE THE CORONAVIRUS BEGAN TO SPREAD NATIONWIDE, clinical laboratories and pathology groups have suffered a one-two punch to revenue.

First, since the middle of March, most labs saw routine lab test referrals drop by 44% or more. Second, the outbreak has disrupted most health plans' normal operations, causing extensive delays in payments to labs and pathology groups.

Electronic Submission

"Payments to labs that submit claims on paper will be slower than those to labs submitting claims electronically," said Kyle Fetter, Executive Vice President and General Manager of Diagnostic Services for **XIFIN**. "Delays are noticeable whenever a lab sends paper claims to health insurers, or insurers send paper responses to labs.

"Payers' explanations on paper usually go to one location and the lab might have trouble retrieving those notices," he added. "If checks go to a lockbox, for example, the lab might have a problem because—in some cases—the banks that process those checks may not even be open."

Most payers that have automated claims processing get paid sooner. "For labs electronically interfaced with payers, those capabilities have gone on unhindered and issues with claims have been fairly straightforward," Fetter noted.

Manual Processing Delays

"Also experiencing delays are molecular lab testing companies that do large numbers of proprietary genetic tests which often require manual review of claims," he said. "Manual review already takes time, and when staff work from home much of that manual review is not happening—at least not quickly.

"Also, many labs that run expensive genetic tests send in paper documents," he continued. "But now there may not be anyone at the payer to review them or to put them into the system for review. The more manual parts there are involved in health plan review, the longer it takes, even during normal times. When staff are working from home, that just adds time to the process. And, those claims are among the most expensive that labs submit."

working to set up these new platforms as fast as possible," Fetter commented. "That process requires them to address different issues that arise when introducing new tests, and when receiving new requisitions that arrive with varying levels of information. They're probably swamped in terms of that type of work.

Work-from-Home Challenges

"Making this work more burdensome is the fact that some lab staff are working from home," he noted. "Many labs didn't have the technology to support remote work, or their staff didn't have the equipment they needed at home.

"Working from home is not a big problem for some labs because they use our web-based platform and that gives them the revenue cycle tools they need to work from home," he said.

While much of the news about lab testing has been grim, there was a glimmer of hope in recent weeks that virus testing volume would rise. "That's the good news," Fetter commented. "Specifically, labs are running their own LDTs, and that's obviously good because those tests have high specificity and sensitivity.

"Some labs will progress to higher throughput by using automated tests that IVD companies introduced," he concluded. "In addition, labs may begin running a large volume of serological testing." TDR

—Joseph Burns

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Labs May Qualify for Relief Under New Federal Laws

➤Loans, grants, and tax credits are available under the CARES Act and other stimulus programs

➤➤CEO SUMMARY: After routine testing and specimen volume declined last month, so too did the associated revenue. In response, clinical laboratories and anatomic pathology groups want to bolster their finances quickly or risk incurring more financial damage to already-fragile balance sheets. Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, and other stimulus plans from Congress, labs and pathology groups may be eligible for financial assistance.

Since mid-March, routine clinical lab and pathology testing and the associated revenue have dropped precipitously as the novel coronavirus spread into every state. In response, Congress passed a series of laws, making loans, grants, and tax credits available to clinical labs and anatomic pathology groups.

Recognizing that the finances of labs and AP groups took a beating when routine testing declined due to the many stay-at-home orders that governors and mayors issued in March, consultants serving these labs and path groups have heard horror stories from clients.

For example, Robert Tessier, Senior Reimbursement Consultant with **HBP Services** in Woodbridge, Conn., said he learned that referred volume from physician practices to anatomic pathologists dropped by 90%, while hospital volume for inpatients and outpatients dropped 70% to 75% from previous levels.

Mick Raich, CEO of **Vachette Pathology**, concurred, saying AP and clinical lab volume dropped by 75% to 90% from previous levels.

Given the questions health policy experts now have about when shelter-in-place orders might be lifted, it's impossible to predict when routine clinical lab testing, pathology specimen volume, and revenue may start to rise, Raich added. To offset lost revenue, he recommended that labs and pathology groups apply for funding under one or more of the stimulus programs Congress passed this year.

➤Relief in Sight

On March 27, for example, Congress passed, and President Trump signed into law, the Coronavirus Aid, Relief, and Economic Security Act. "The CARES Act authorizes about $2.2 trillion in relief and includes a number of programs for labs and other healthcare providers," commented Raich. Also, he advised lab directors and executives at pathology groups to act quickly because demand for relief is high.

One already-depleted funding source was the Paycheck Protection Program (PPP), which ran out of money on April 14. Congress set aside $350 billion for PPP loans to businesses with fewer than

500 employees feeling the effects of the pandemic and the economic downturn.

Those loans were intended to help companies make payroll and cover other expenses from February 15 to June 30 (the designated end of the national pandemic emergency). As of press time, it was unknown if Congress would provide additional funding for PPP. *(See sidebar, "AP Group Used Federal Money to Offset Losses," this page.)*

In another initiative under the CARES Act, employers can get what the IRS calls an employee retention tax credit (or Employee Retention Credit) to keep employees on the payroll despite economic hardship related to the virus.

Tax Credits Available

Tax credits also are available under the Families First Coronavirus Relief Act, which Congress passed March 18. The law requires certain employers to pay sick or family leave wages to employees unable to work due to the virus. Employers are entitled to refundable tax credits for payments for the required leave. There are limits, however, and some wages cannot be counted for both credits, the IRS said.

The Tax Foundation, a nonpartisan tax policy organization, explained that employers are eligible for a 50% refundable payroll tax credit on wages paid up to $10,000 during the crisis.

"The credit would be available to employers whose businesses were disrupted due to virus shutdown and those that had a decrease in gross receipts of 50% or more as compared to the same quarter last year," the foundation said. "The credit can be claimed for employees who are retained but not currently working due to the crisis for companies with more than 100 employees, and for all employee wages for companies with 100 or fewer employees."

In another initiative under the CARES Act, Congress allowed the federal **Centers for Medicare and Medicaid Services** (CMS) to expand and extend

AP Group Used Federal Money to Offset Losses

BASED ON NUMBERS FROM HIS PATHOLOGY GROUP CLIENTS, Robert Tessier, Senior Reimbursement Consultant with **HBP Services** in Woodbridge, Conn., expects some AP practices to see a decline in income of 70% to 75% in May and June.

This income shortfall is based on comparing projected income for May and June of this year with income the groups received in May and June of 2019.

"These groups have almost nothing coming in from their referring physicians' offices," he said. One group expects to counter losses in income with loans and grants from federal relief funds.

"The practice projects that it will lose $300,000 per month in May and June for a total loss of $600,000," he added.

"To offset that loss, they expect to get a $30,000 federal grant and a $350,000 loan from the Paycheck Protection Program," Tessier reported. "Of the $350,000 loan, the government may forgive $310,000, leaving $40,000 that the practice will pay back in a form of loan payments."

"On a net basis over two months, here's how it works out," he explained. "The group will have reduced patient care receipts of $600,000, but also lower billing costs (at 8%) for a savings of $48,000. Therefore, the net loss to the practice will be $552,000.

"But then we can add back in the grant income of $30,000 and, assuming that Congress approves a second round of PPP funding, the group could get forgiveness under the PPP of $310,000, for a total of $340,000 in relief from federal stimulus programs," he added.

"Therefore, strictly from an income perspective, this group will have a net reduction of $212,000.

"But we have no idea what will happen between now and June or what will happen after that," he said.

its Accelerated and Advance Payment Program for providers under both Medicare parts A and B.

"The advantage of this program is that it's not new, and so the guidelines are already in place," noted Ann Lambrix, Vachette's Vice President of Client Services. "The disadvantage is that payback is required and could begin within 120 days of receipt of the funds. The question for clinical labs and pathology groups is whether revenue will approach normal levels by then."

Lori Anderson, a Senior Product Manager at **XIFIN** and revenue cycle management consultant, explained in a blog post that labs can request as much as 100% of the total amount billed over the past three months.

One potential problem under this program is that 120 days after the funds are disbursed, CMS will begin applying claims payments to offset the loan amount for new claims and claims submitted during the initial 120-day operating period, Anderson warned.

Eligibility Requirements

To be eligible, labs would need to have billed Medicare within 180 days immediately before requesting the funds, cannot be in bankruptcy or under any active medical review or integrity investigation, and cannot have any delinquent or outstanding Medicare overpayments, she wrote.

Clinical laboratories would need to request loan applications and make loan requests to their Medicare Administrative Contractors, Anderson added. The estimated time for review is seven calendar days, and the program runs through June 30, or the duration of the public health emergency.

The CARES Act also allows the federal **Small Business Administration** to offer funding under the Economic Injury Disaster Loan program. Businesses are eligible for as much as $2 million in loans at an interest rate of 3.75%, and principal and interest payments can be deferred for as long as four years, Raich said.

Also included in the CARES Act is $100 billion in the Public Health and Social Services Emergency Fund that Congress allocated to hospitals, physicians, and other healthcare providers, according to the **American Academy of Family Physicians**. Because these funds are grants, they do not need to be repaid, AAFP said.

Funds Go to Providers

The funds would go to the organization, meaning a hospital, physician practice, or pathology group, that receives Medicare fee-for-service (FFS) payments, and not to individuals. All facilities and health professionals that billed Medicare FFS in 2019 are eligible for the funds, AAFP added.

On April 10, the federal **Department of Health and Human Service**s (HHS) said it would pay out $30 billion from this fund in direct proportion to the share of Medicare FFS payments the organization received under its taxpayer identification number (TIN), Tessier explained.

To calculate how much a hospital, clinical lab, or pathology group would get under this program, a hospital, lab, or group would need to know how much it received in FFS Medicare payments last year. Medicare Advantage payments are excluded. Care does not need to be specific to treating COVID-19 patients, HHS said.

Clinical laboratories and pathology groups that use billing companies should be aware that if the billing company accepts checks and posts payments for your organization, these funds would be exempt from the billing company's calculations of "payments received."

Tessier offered an example of how a group could estimate its payment. "Let's say a pathology group received Medicare FFS payments of $1 million in 2019. Since

the $30 billion distribution is 6.2% of the total that Medicare paid out in FFS in 2019, the practice would get roughly $62,000," he calculated.

In addition to the aid coming from federal sources, health plans, and the CMS have loosened some policies on claims filing and enrollment for clinical labs, pathologists, and other providers.

For example, in March, CMS approved requests from 11 states to waive the Medicaid requirements under Section 1135 of the Social Security Act to provide relief from prior authorization and provider enrollment rules, to suspend some nursing home pre-admission reviews, and to facilitate payment to providers for care delivered in alternative settings after facilities are evacuated. The waivers are effective as of March 1, and are in place through the end of the declared emergency.

Medicare Sequestration

In other changes, CMS suspended the reduction in Medicare payments under sequestration, meaning labs will get an increase of 1.6% in total on lab test payments from Medicare through the end of the year. When Congress passed the Budget Control Act of 2011, it required across-the-board reductions in federal spending, also known as sequestration.

CMS also froze payment levels under the Protecting Access to Medicare Act at the current level rather that cut payments under PAMA by 15%, as the law allows. In addition, CMS also revised another rule under PAMA, saying it would not require labs to report payment data from health plans until the first quarter of 2022.

Commercial health plans also altered their requirements. **UnitedHealthcare**, for example, loosened its prior-authorization rules and relaxed some claims-filing deadlines beyond the normal 90 days. TDR

—Joseph Burns

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Stay-at-Home Order Slows Lab Payments

ONE PROBLEM CLINICAL LABORATORIES AND PATHOLOGY GROUPS FACE during the coronavirus pandemic is that stay-at-home orders are slowing or stopping payments from health insurers and billing companies, said Mick Raich, CEO of **Vachette Pathology**, a revenue cycle management company.

Shelter-in-place rules affect labs and pathology groups that have in-house billing departments and that send such work to billing companies, he commented.

"Labs and billing firms that have sent workers home may see productivity decline," he explained. "Often, the lab or the billing company does not have the tools or the information technologies in place to allow remote workers to function at optimal productivity. Not only do billers have people working from home, but many billers have laid people off.

"One company had 100 people who couldn't work at all because they were not allowed in the building. We know of six billing companies that now have staff working at home," Raich added.

"Offshore billing companies usually have large numbers of staff who work together closely in cubicle farms," he explained. "I suspect these billing companies had to send staff home. That means a client lab's claims will not get processed, and the lab will experience increased denials, especially if its billers have operations offshore in India, Costa Rica, and Singapore, for example."

Not only will the number of denials rise, but also appeals will not get filed. Plus, billers likely will fail to capture all charges, meaning labs will need to retain all claims records so that when billers return, labs can verify that all test claims get paid, Raich advised.

"Billing will be a true train wreck this year," he warned."

NEWSMAKER INTERVIEW

Italy's SARS-CoV-2 Outbreak Brings Out Best in Clinical Labs

"Serological testing for COVID-19 should provide intriguing data, not for the diagnosis, but for monitoring the outbreak and understanding the epidemiology of the virus."
—Mario Plebani, MD

CEO SUMMARY: Italy was one of the first countries outside of China to experience an explosive outbreak of COVID-19 and its northern provinces were hit hardest by this novel coronavirus. In this exclusive interview with The Dark Report, internationally-known pathologist Mario Plebani, MD, discusses how his clinical laboratory in Padova responded to the pandemic in the Veneto Region.

Second of Two Parts

IN ITALY THE COVID-19 OUTBREAK HIT EARLY AND HARD. The nation has large numbers of cases concentrated in the northern regions where death rates have been puzzlingly high.

As the first COVID-19 cases were diagnosed, pathologist Mario Plebani, MD, and his team in the Department of Laboratory Medicine at **University-Hospital of Padova**, responded to patients' needs in some of the hardest-hit communities in Northern Italy.

A professor of clinical biochemistry and clinical molecular biology at the **University of Padova**, Plebani explained during an interview with THE DARK REPORT that clinical lab professionals have much to learn about the steps the Italian healthcare system took—and the steps not taken—to address one of the world's largest clusters of COVID-19.

As was the case in many other nations, Italy's health system was unprepared, he said. From his lab in the Veneto region, Plebani had a close-up view of the outbreak as it spread through the neighboring region of Lombardy, breaking out rapidly in the towns of Bergamo, Milan, Brescia, and Vó.

We conducted this interview on March 25, shortly after the peak rate of new confirmed cases per day in Italy reached more than 6,000 on March 20. As of April 13, the daily number had dropped to 1,363 new cases, with 103,616 total positive cases. Since the first case of COVID-19 in Italy was reported on Jan. 20, the country reported 181,228 cases and 24,111 deaths by April 19, according to the **Johns Hopkins Coronavirus Resource Center**.

Third Hardest-Hit Nation

While the daily number of new cases had declined somewhat, the number of deaths due to the novel coronavirus made Italy the third hardest-hit nation in the world (behind the United States and Spain).

On April 10, among regions of Italy, the Lombardy region had the most confirmed cases (56,048) and deaths (10,238), according to data from the **World Health Organization**.

As the Editor-in-Chief of the **American Association for Clinical Chemistry's** journal, *Clinical Chemistry and Laboratory Medicine* (*CCLM*) and Co-Editor-in-Chief of the **Society to Improve Diagnosis in Medicine's** journal *Diagnosis*, Plebani is well known to pathologists and clinical laboratory professionals in the United States. The interview is presented below and edited for clarity:

EDITOR: As you know, pathologists and clinical laboratory scientists in the United States are watching the outbreak of the novel coronavirus closely as it spreads worldwide, and particularly in your home country of Italy. What should lab professionals understand about COVID-19?

PLEBANI: There are many issues to understand, but first, I would say that we were totally unprepared to manage this coronavirus outbreak at the beginning. It was unexpected because we didn't know where it came from and who was the first case in Italy. There was some talk about some people who came here from China, but that is not true.

EDITOR: Were the first diagnosed cases of COVID-19 in communities near your clinical laboratory?

PLEBANI: Initially, two areas had a lot of cases. One—the area of Vó—is near me, and the other area was Lodi in Lombardia. In both areas, officials ordered a lockdown, but by the time they issued that order, it

was too late. From Lombardia, the virus spread to Milan and that vicinity and into Bergamo—which is a big city not far from Milan. Also, we saw a high number of cases in Brescia, which is not far from Bergamo. In these areas, there have been many, many cases, and—unfortunately—there have been severe cases of COVID-19, with many deaths.

EDITOR: News accounts have reported that a high proportion of cases in those regions of Italy are serious and required hospitalization.

PLEBANI: As I mentioned, we saw a lot of deaths in the area of Bergamo where the epidemic has been a nightmare. In addition to having many deaths there, we've had large numbers of hospitalizations, including many admitted to intensive care units. I don't know exactly why the COVID-19 outbreak was so severe in that community. We would like to evaluate why as soon as possible. We do not understand why the mortality rate is so high in those areas, particularly since is seems to be so different from the mortality rate in China.

EDITOR: Have you communicated with pathologists, physicians, or health officials in China about this difference?

PLEBANI: Yes. Recently, I had a conference call with experts in Shanghai and Wuhan and learned that the mortality rate in China is much different from one area to another. In particular, one area had a mortality rate of 5%, but in Shanghai the death rate was only 1%. Those numbers show that the problem of understanding the mortality rate stems from not knowing the denominator.

EDITOR: Will you explain why knowing the denominator is important?

PLEBANI: That's a very important number because without that number, how can you know how many cases there are and how many patients are asymptomatic? At the beginning of the outbreak, we didn't know that asymptomatic patients would be contagious—either within their families or in the cities and towns where they lived. That's the main question clinical laboratory testing can help us to answer.

Mario Plebani, MD

➤"At the beginning of the outbreak, we didn't know that asymptomatic patients would be contagious—either within their families or in the cities and towns where they lived."

EDITOR: And what level of infection have you seen in your region of Veneto?

PLEBANI: In my region, the rate of infection has been much better. The mortality rate is not so high, and our intensive care units are not completely full. If we had more COVID-19 testing from the start, we might have been able to tell why the number of deaths was different in those various areas of northern Italy. In response to the outbreak, a lot of testing and a strict quarantine has had an effect on the death rate.

EDITOR: Was lab testing done in tandem with the quarantine?

PLEBANI: In Vó, for example, there was a program to implement a quarantine and to test everyone twice using the molecular test. We gained many insights from COVID-19 testing that was done in Vó, where there are about 3,000 citizens. After 14 days under the quarantine, all the residents were tested again and there was a decrease in the number of patients testing positive, including no new positive results. That's what we learned from the second molecular test.

EDITOR: Are there plans to do more testing in these regions?

PLEBANI: Next, we want to use the serological test, which up until now we have not been able to do. Serological testing should provide intriguing data, not for the diagnosis, but for monitoring the

outbreak and understanding the epidemiology of the virus. We expect that the serological test could give us more data than the molecular test can give us in terms of epidemiology.

EDITOR: What serological tests for COVID-19 do you plan to use in your clinical laboratory?

PLEBANI: At the moment, of the different assays used to test for SARS-CoV-2 infections, we don't know which serological test would work best in terms of the specificity and sensitivity. Until now, most serological tests have been developed in China, and we need to know more about the performance of those tests. Recently, we published a paper in *CCLM* dealing with the analytical validation of an automated-chemiluminescent assay and the kinetics of COVID-19 IgM and IgG. The main question about serological tests is, in fact, that we need to better understand their analytical quality and clinical usefulness both for qualitative (rapid) and for quantitative assays.

EDITOR: Will you have access to blood specimens from patients diagnosed with COVID-19 that you can use for serological testing?

PLEBANI: In Vó—where we repeated the molecular test after 14 days—it was impossible, unfortunately, to collect blood from those same subjects. That was a pity because we missed the opportunity to have data about how the serological tests might perform versus how the molecular test performs. That comparative data would have been very useful.

EDITOR: While we wait for anything you can tell us about how serological tests perform, we wanted to ask how quickly Italian labs were able to get a COVID-19 molecular test up and running?

PLEBANI: I can speak only about our experiences here in the north of Italy, because that's where the outbreak started. In our area—that's the Veneto region—the microbiology and virology department in my University-Hospital immediately developed a home brew or lab-developed test for COVID-19. Once we validated that test, we gave that same test to other microbiology departments around Veneto. So in terms of efficiency, that went rather quickly.

EDITOR: Do you have the supplies to collect specimens and perform the tests you need to run? Here in the United States, there are shortages of swabs, face shields, and other personal protective equipment.

PLEBANI: Yes, fortunately, we have had the personal safeguards we need, and we have been assured—at least up to now—that all people working in hospitals have the masks, gloves, and other safety gear they need. That's been true so far in the Veneto region, but we know that problem is increasing in other parts of Italy, and we are worried about the future, the maintenance of future procedures.

Mario Plebani, MD

"The main question about serological tests is, in fact, that we need to better understand their analytical quality and clinical usefulness both for qualitative (rapid) and for quantitative assays."

EDITOR: Has your lab been able to access instruments, reagents, and consumables to increase the number of COVID-19 tests it can perform?

PLEBANI: The need is to test a large number of subjects, and the increasing number of COVID-19 cases puts great demands on all labs in terms of workload and workflow. Not only in the analytical phase, but also in the pre-analytical phase, on our information systems and so on. We are working to address these challenges, but all those steps take time. Also, we don't know if we have enough reagents or enough of the instrumentation required for this testing. Italy is like

all other European countries, unfortunately, in that we have a rising number of patients to be tested.

EDITOR: Within the European Union, is there a shortage of lab instruments and supplies for COVID-19 testing?

PLEBANI: In Germany, for instance, they want to run these COVID-19 tests on instrumentation produced in Germany. Does that mean labs here in Italy won't be able to get the instruments we need?

EDITOR: In the United States, the FDA has approved COVID-19 test kits that a growing number of IVD manufacturers have developed under emergency-use rules. One of those IVD companies is **Roche Diagnostics**, which has manufacturing and distribution plants in Europe. Are you getting access to those kits in Italy?

Mario Plebani, MD

➤"We need to implement a scheme of proficiency testing or at least a better quality-assurance system as soon as possible. We need a benchmark for quality and a way to do comparisons against that benchmark among different laboratories."

PLEBANI: Oh, yes, Roche offered a lot of cooperation to our government and to our national institute of health. But I know that our government now has the problem of understanding the number of COVID-19 tests that we need. It's not the offer of assistance. It's how many tests do we need—not only in Italy, but in other European countries. As you know, Roche is not established in Italy. It's established in Switzerland and partly in Germany. So, we have problems because it's not easy to manage the shipment of reagents and instrumentation. It's much more difficult now than it has been in the past.

EDITOR: Labs in the United States are having similar problems. And that issue raises another question: Is your lab getting the specimen-collection supplies it needs for patients who qualify for COVID-19?

PLEBANI: Yes. Up to now we have enough supplies to allow us to collect the specimens we need. Instead, the problem has been that some IVD companies cannot assure us that we have what we need to produce high-quality testing. It's not a matter of quantity. It's a matter of quality.

EDITOR: Are you referring to the data necessary to understand the performance of different COVID-19 assays and what affects the sensitivity and specificity of different assays?

PLEBANI: By quality, I mean that laboratory medicine professionals need to share any information we have, and we need to make that information available to scientists all over the world. I say that because we have to win the fight against this virus.

EDITOR: What would help you and your lab team in regard to quality?

PLEBANI: In order to ensure that we are getting high-quality results with our COVID-19 testing, we need to implement a scheme of proficiency testing or at least a better quality-assurance system as soon as possible. We need a benchmark for quality and then we need a way to do comparisons against that benchmark among different laboratories. That's the only way to assure patients that labs are producing the same quality results, whether positive or negative, regardless of where that testing is done. If we can't do that, we can't be sure that any other diagnostic and therapeutic step is performed correctly. That is our duty right now.

EDITOR: In other words, all medical laboratories should be collecting COVID-19 in the same way and those tests should be run in the same way. Is that correct?

PLEBANI: Yes, that's it exactly. We need to be sure that the pre-analytical, the analytical, and the post-analytical phases

are done correctly. The turnaround time is very important as well and so we have to ensure that we have a fast turnaround time. Otherwise, if a lab notifies a positive patient after five or six days, that doesn't make sense for the health of the patient.

Mario Plebani, MD

"Our labs would like to use serological testing to better understand this disease and help predict what could happen in the future. More specifically, it is important for us to understand how many asymptomatic subjects have been infected."

EDITOR: What type of COVID-19 testing does your lab do now? Is most of the testing now being done manually or have you automated some of this testing?

PLEBANI: It is impossible to work manually because of the heavy workload and how that volume of tests affects workflow. Also, doing these tests manually increases the risk of mistakes. In our University-Hospital, the microbiology department is performing about 2,500 COVID-19 tests a day. By next week, we'll have new instrumentation and should be able to perform more than 3,500 tests. Up to now, we've had good throughput, but in our region, we will need to increase the number of tests because the number of patients who need tests is likely to grow.

EDITOR: Did you apply any lessons from what officials did in China and South Korea to control the spread of the pathogen? As you know, those countries acted quickly to reduce the number of new infections.

PLEBANI: Yes, we did. In particular, South Korea's approach to using molecular tests for COVID-19 was useful for us. As was done in South Korea, we would like to extend the molecular tests to asymptomatic patients and to understand the vicinities of close friends and associates who would be at risk of infection.

EDITOR: What about new digital approaches to tracking the outbreaks, such as was done in South Korea, Taiwan, and Singapore to track people who may have been exposed to SARS-CoV-2?

PLEBANI: In South Korea, they use some devices—such as mobile phones and other technologies—to track the virus. However, legislation in Italy does not allow us to do that. To safeguard the health of people, we should adopt some strategies that South Korea used in other parts of this province. I'm quite comfortable with the South Korea paradigm.

EDITOR: Have healthcare providers done COVID-19 testing outside of hospitals by, for example, sending out healthcare professionals to collect swabs in people's homes? Or are you collecting swabs at drive-through locations, rather than having patients go to a hospital or to patient service centers?

PLEBANI: Yes, with the help of the Red Cross, we began to collect specimens in patients at home. In the Treviso area, which is not far from Padua, this has begun, and we would like to follow this strategy to increase the number of subjects tested without moving them to the hospital. Within about a week or so we will probably start doing this in our region with the help of the Red Cross.

EDITOR: Do you have any COVID-19 lab test result data that allows you to predict where the spread of the virus may go in the coming days or weeks?

PLEBANI: Not at the moment. But every day our government reports the data about the number of infected patients and the number of deaths. Our labs would like to use serological testing to better understand this disease and help predict what could happen in the future. More specifically, it is important for us to understand how many asymptomatic subjects have

been infected and we can help them to stay healthy.

EDITOR: What are your lab's plans to bring up a serological test for COVID-19 and test a large number of subjects?

PLEBANI: We don't know exactly and this is a problem. We don't know how long it takes for the immunoglobulin M (IgM) antibodies to be produced. These are the first antibodies humans make to fight a new infection. Nor do we know how long the IgM will stay high. Next, we don't know when we will see the immunoglobulin G (IgG) antibodies in a serological test result or how long the IgG antibodies will remain in the blood. Few papers have been published on serological tests for SARS-CoV-2 tests. Even China doesn't have much comprehensive and better evidence-based data on antibody testing.

EDITOR: Do you have concerns about how labs will introduce serological tests for COVID-19 throughout the world?

PLEBANI: Good science and good laboratory medicine are always based on quality data. Labs must understand the analytical performance of the serological test. We need to know these tests will perform because some authorities want to introduce a rapid test—whether positive or negative. I worry about this, because our lab community doesn't know exactly how these tests would work and, lab scientists know, there can be a wide range of variability from one subject to another. All these reasons make it difficult to understand the quality of serological testing for the virus.

EDITOR: You mentioned that if only patients who have symptoms are tested, but patients who are asymptomatic do not get tested, it will be difficult to know the true levels of sensitivity and specificity for a serological test.

PLEBANI: That's correct. As the Editor-in-Chief of *CCLM*, I reviewed a paper that researchers from China submitted about a serological test for SARS-CoV-2. In that paper, they said their experience was better in terms of sensitivity and specificity than the molecular test. But that conclusion raised a lot of questions because the gold standard for diagnosis has been the molecular test. So, how is it possible that these researchers would conclude that a serological test should be considered the gold standard? When we were unable to get satisfactory answers to these questions, we had no choice but to reject the paper. Having said that, you are correct in that we need a better understanding about how antibodies work in our population, and then we need to know how well serological tests work in comparison to molecular tests. We also need to understand if we can test using a serological assay alone or do we need a molecular test too? Right now, these are open questions.

Mario Plebani, MD

➤"...we need to know how well serological tests work in comparison to molecular tests. We also need to understand if we can test using a serological assay alone, or do we need a molecular test too?"

EDITOR: What is your thinking about how the typical influenza season in the northern hemisphere might have a role in containing the outbreak of COVID-19? Historically, cases of influenza, coronaviruses, and other respiratory viruses tend to fall off as the weather warms and summer arrives.

PLEBANI: Well, I don't know. There are expectations that it could disappear with warmer weather. Past experience says that should be the case, but nobody really knows. This is a new strain of the coronavirus that we do not understand. Here in Italy we still have cold weather here in the northern regions, and so I believe some flu is still coming to our population.

EDITOR: Do you have any lessons to share with pathologists and lab directors about how to manage testing in the midst

of this outbreak? What steps should U.S. labs take now, for example?

PLEBANI: If at all possible, clinical laboratories in the United States should be prepared to monitor patients in any way they can, even with some traditional testing, particularly hematology. There is a new methodological index to assess the severity of the disease by testing for an increase or decrease of lymphocytes, an increase in neutrophils, and a decrease in platelets. Also, D-dimer is interesting, because an increase in D-dimer could be useful in testing the severity of the COVID-19 disease.

EDITOR: The news media has not publicized these methods of using standard clinical laboratory tests to aid in diagnosing COVID-19 patients here in the United States.

PLEBANI: I also have another recommendation for labs in the United States, which is to be prepared to establish and perform tests that are not commonly requested. For example, in Italy, there are clinical trials—including at my university—on the use of a new drug for coronavirus patients that has been used to treat patients with rheumatoid arthritis. That drug is monitored with a molecular test. That is why labs need to be ready to perform tests that are not commonly requested.

EDITOR: What other insights would you suggest to your laboratory colleagues in the United States?

PLEBANI: From what we've learned here, I would make a number of points. First, for those working in laboratories, it is very important to ensure safety for your lab staff as they work with closed tubes in the lab. And, as point-of-care testing becomes available, those working in the lab, and those collecting specimens, need to be careful in how they handle the SARS-CoV-2 pathogen.

Second, I would add that this outbreak provides an opportunity to increase the visibility of laboratory medicine and the work of pathologists and clinical laboratories to save lives, to make the correct diagnosis, and to monitor patients accurately. We need make the work we do in the laboratory more visible by getting this information out to the general public in the United States and throughout Europe and Italy.

Third, I hope you can manage this outbreak more effectively than we did when the infection was beginning here in Italy. And I would stress the point that the infection rate is high, not only in patients who are older (meaning in their 70s and 80s). We know that people with existing health conditions are at risk of severe disease. We also have seen that even young patients suffer from severe disease from COVID-19.

Fourth, be careful. Pass along the message to all people that what we've learned in Italy is that we have to stay home. We have to discourage people from going out to visit or stay with other people. The lockdown we've had here has been very effective, at least up to now, and a lockdown probably should be activated at least in some parts of the United States as soon as possible. That's the only way we know to block the outbreak. And we learned that you need to start from the beginning. Do not start late.

EDITOR: Dr. Plebani, thank you for taking the time to tell us about your experiences with the COVID-19 outbreak in Italy. Your insights and recommendations for clinical lab scientists in the United States are appreciated.

PLEBANI: Thank you. I've welcomed this opportunity to share the experiences of our lab team. I hope our lessons learned can help clinical laboratories everywhere to meet the challenges of this COVID-19 pandemic. TDR

—Joseph Burns

Contact Mario Plebani, MD, at mario.plebani-@unipd.it.

Lab Fraud Alert

DOJ Says Georgia Man Got Kickbacks for COVID-19 Tests

Certain labs paid defendant a kickback of between $125 and $250 for each cornavirus test referral

JUST WEEKS AFTER THE FIRST CASES of SARS-CoV-2 appeared in the United States, federal prosecutors filed criminal charges in a COVID-19 lab test fraud scheme. Erik Santos, 49, of Braselton, Ga., was charged with conspiracy to defraud federal and private healthcare programs by submitting fraudulent testing claims for COVID-19 and genetic cancer screenings.

This may be a sign that federal healthcare investigators will act swiftly during the SARS-CoV-2 outbreak to bring criminal charges and civil actions against clinical labs and others violating the federal anti-kickback statute and other laws. All lab owners should take this as a warning that there is heightened risk to participate in schemes involving illegal inducements and medically-unnecessary orders for COVID-19 tests.

In the Santos case, he was charged with one count of conspiring to violate the federal Anti-Kickback Statute (AKS) and one count of conspiring to commit fraud. He faces 10 years in prison on the conspiracy charge and five years on the charge of conspiracy to violate the AKS. Also, he faces a fine under both offenses of $250,000, or twice the gross gain, the DOJ said.

The DOJ did not say if any of the physicians, diagnostic labs, or others who conspired with Santos would face charges.

Some information the DOJ collected in the case came from a cooperating witness (CW1) who was previously involved in a scheme to commit healthcare fraud, court records show. The cooperating witness had a financial interest in a marketing call center and in a clinical laboratory (Lab 1) that worked together to arrange for a variety of medical tests. The laboratory could bill Medicare for cancer genetic (CGx), coronavirus, and respiratory pathogen panel (RPP) tests, the DOJ said.

In court documents, the DOJ explained that Santos and others engaged in a fraudulent kickback scheme in which lab companies paid Santos on a per-test basis for referring CGx, coronavirus, and RPP tests to the labs. Some of the tests would be conducted through Lab 1.

Combined Testing

After cases of COVID-19 were identified in the United States, Santos encouraged physicians to order COVID-19 tests and respiratory pathogen panel (RPP) tests, and the physicians agreed to order both tests even if not medically necessary, according to the DOJ. Also, Santos got kickbacks from three clinical labs for generating referrals from physicians, the documents show.

"Santos offered kickbacks in exchange for medically unnecessary tests—including potentially hard-to-obtain COVID-19 tests—thus preying on people's fear in order to defraud the government and make money for himself," commented U.S. Attorney Craig Carpenito.

According to court documents, the COVID-19 and RPP test scheme grew out of a scheme that Santos ran to generate cancer genetic (CGx) screening tests, the documents show. Santos ran a marketing company that generated leads for clinical

laboratory testing from physicians for cancer screening since November 2019. Santos worked with others to "defraud Medicare by soliciting and receiving kickback payments from companies involved in clinical and diagnostic testing in exchange for steering to those companies individuals eligible for testing that Medicare would reimburse," court records show.

The CGx testing scheme ran from about November 2019 through March of this year. In that time, the labs paid Santos kickbacks of approximately $33,250 for qualified patient leads and completed tests. "The leads and tests submitted by Santos to the testing companies were intended to be billed to Medicare for a total of approximately $1.2 million in reimbursements," the documents show.

The labs paid kickbacks to Santos on a per-test basis for submitting CGx screening tests to the labs, regardless of medical necessity, records show. "Santos' scheme aimed to submit more than $1.1 million in fraudulent claims to Medicare," the DOJ explained.

COVID Testing Added

When news reports showed growing demand for coronavirus tests, Santos expanded his schemes so that he could be paid kickbacks on a per-test basis for COVID-19 tests, court records show. To do so, the COVID-19 tests were bundled with a more expensive RPP test that does not identify COVID-19, records show.

Beginning last month, and running from about March 12 to 26, Santos ran a scheme to generate leads for coronavirus tests, court records explain.

In a conversation the DOJ recorded on March 19, Santos said he was working with three laboratories (called the Santos Laboratories) and had processed about 5,000 bundled coronavirus and RPP tests, records show. Also, Santos told CW1 that because Lab 1 could not run tests for COVID-19 or the RPP tests, Santos could arrange for a lab-to-lab reference relationship between Lab 1 and one of the Santos Laboratories to run those tests. Doing so would allow Lab 1 to submit claims to Medicare and act as both a referring lab and a billing lab, records show.

"Santos explained that Medicare paid about $35 for each coronavirus test, but that the RPP Test reimbursement was much higher, records show. Therefore, Santos told CW1 that doctors would order both a coronavirus and an RPP test.

Kickback of $125 Per Test

"If a Medicare beneficiary tested positive for COVID-19, the prescription directed the laboratory to then run a partial RPP test, which Medicare would reimburse for approximately $300 to $400 per test," court records show. "In that circumstance, Santos would expect a kickback of approximately $125 per test. If a beneficiary tested negative for COVID-19, the prescription directed the laboratory to then run a complete RPP test, which Medicare would reimburse for approximately $650 per test. In that circumstance, Santos would expect a kickback of approximately $250 per test."

The goal of the scheme was to target Medicare beneficiaries who were asymptomatic and otherwise unlikely to test positive for the virus, records show. Doing so would increase the chance of being paid at the higher kickback rate of $250 for a complete RPP test, documents show.

Santos expected to generate 8,000 to 10,000 completed tests for the combined coronavirus and RPP tests from patients in assisted living facilities, hospitals, urgent care centers, and medical practices, the records show. Also, Santos revealed that not one doctor refused to prescribe both tests, regardless of medical necessity, documents explain.

The fact that not one doctor refused to order medically-unnecessary tests in this scheme shows why federal prosecutors need to file cases against the physicians who order these tests. It is their lab orders that make possible this type of lab fraud. TDR

—Joseph Burns

Chicago Lab Launches LDT, Finds 20% Positive

NorthShore University HealthSystem decided it was best to launch a lab-developed test for the coronavirus

CEO SUMMARY: After seeing the novel coronavirus spread quickly in China, staff in the Department of Pathology and Laboratory Medicine developed a test to identify the pathogen in patients in Chicago and its suburbs. With the CDC's assay in hand, it started work on its own lab-developed test. In early April, the lab tested more than 10,000 patients and approximately 20% were positive and 5% needed immediate care.

In January, news of an outbreak of the novel coronavirus in China caught the attention of the staff in the Department of Pathology and Laboratory Medicine at **NorthShore University HealthSystem** outside Chicago. As the number of infections and deaths rose quickly in China, the lab staff began to worry that the virus was likely to spread worldwide.

"That news reminded us of the swine flu outbreak in 2009, so we began to think about how we could prepare our lab—just in case," said Karen L. Kaul, MD, PhD, Chairman of the department. Just as lab professionals were doing worldwide, Kaul and her staff recognized that the epidemic in China had the potential to become a pandemic.

Based on the experience gained from testing for swine flu (also known as H1N1) and other pathogens, Kaul and the staff in the molecular lab knew they would need to take steps early to prepare for an influx of patients. Only accurate tests done in large enough quantities would help clinicians understand how quickly the virus was spreading and to identify infection hot spots.

For NorthShore, the early steps the lab took proved to be the proper course. Within weeks, the lab had begun testing patients and by the first week in April was running more than 10,000 tests per day.

In an interview with The Dark Report, Kaul explained how foresight and planning allowed the NorthShore lab to increase testing volume just as the infection rate was rising in the Chicago metropolitan area. Since then, the lab has expanded test capacity and throughput to serve more patients.

SARS-CoV-2 Pathogen

"When the CDC published the details of its assay for the virus and its primer sequences, we ordered that test and prepared to do the necessary validation," said Kaul, a specialist in molecular medicine who leads the Molecular Diagnostics Laboratory in NorthShore's **Mark R. Neaman Center for Personalized Medicine**. At the time, the lab staff was preparing to develop its own test for the SARS-CoV-2 pathogen.

Early in February, the FDA issued an emergency use authorization (EUA) allowing CDC-designated and CLIA-

certified laboratories to apply for approval to validate and run the CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel. At the time, only a small number of labs were allowed to do the validation, one of which was the lab at NorthShore.

"Once we had the CDC's assay, we ordered PCR primers and decided to develop our own test in house, meaning a lab-developed test (LDT)," she explained. "Because of the FDA's regulatory stance, we thought the fastest way to get our test approved for emergency use was to duplicate the CDC test in our lab.

CDC's COVID-19 Test

But first, we contacted the CDC to ask if they would distribute their test to us," she added. "They said no. They couldn't distribute that test to labs in hospitals. They can distribute those tests only to public health laboratories.

"Next, we tried to determine if we could be certified to become a public health laboratory, but that avenue was not available to us either," said Kaul. "So, we decided to duplicate the CDC test and validate it in-house.

"For that process, the biggest challenge was getting the reference materials, and initially there weren't any available," she explained. "We tried our regular sources, and, over time, found a couple of commercial sources. One of those was **BEI Resources** in Washington D.C." The **National Institute of Allergy and Infectious Diseases** established BEI to provide reagents to research and other labs studying pathogens and emerging infectious disease.

"The Illinois state public health lab and other labs sent us viral RNA—material that is not infectious," Kaul explained. "We are part of a network of laboratories that share resources to help each other when needed. That's how we were able to develop our test.

"In that way, we were like every lab that was scrambling to get the reagents and other needed supplies," she said. "Those other labs have helped us and we've helped other labs too.

"For any LDT, we have to follow the validation rules under CLIA and CAP to verify accuracy, reproducibility, detection limits, and other values," she said.

"Ultimately we want to look at a panel of positive and negative patient samples to evaluate our own processes and to ensure the LDT performs accurately," she added.

NorthShore Lab Now Does COVID-19 Tests Daily

SINCE THE DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE AT NORTHSHORE UNIVERSITY HEALTHSYSTEM began testing patients for the SARS-CoV-2 pathogen, it has seen the number of tests it runs for the novel coronavirus approximately double every other day, said department Chairman Karen L. Kaul, MD, PhD.

"At that point in March, we estimated that our lab had tested a total of about 10,000 patients," Kaul commented. "Initially, our aim was to test about 1,000 patients each day. That was our capacity then. On March 18, for example, we tested 276 patients, but then shortly thereafter we began testing about 400 patients each day.

"More testing for the novel coronavirus is necessary because the results will tell us what's going on in the population," she reported. "Right now, as is true of most labs, we are testing only symptomatic patients because our lab doesn't have enough capacity to test those who aren't symptomatic.

"Plus, we don't know what the test would mean in someone who's not symptomatic," Kaul commented. "That's because we don't know how long after a person is exposed to the virus that we can expect to see the virus in a test result.

"Until we know that, it's not worth testing those who are not symptomatic," she noted.

The lab then compared its results against those the state public health lab reported. "We did parallel testing with the laboratory at the **Illinois Department of Public Health**," she said. "They were running their version of the CDC's test, and the two assays performed identically. With their okay, we went live March 12.

"The next step was to submit our findings and the data we collected to the FDA for our EUA authorization," Kaul said. "On Feb. 29, the FDA outlined a more streamlined process for its lab-developed test review. That streamlined process makes it more feasible than it would be normally for hospital laboratories to pursue an approval for an LDT.

"The FDA's usual approach for LDT approvals is geared toward independent laboratory companies," she commented. "That method can be expensive and time consuming. The new streamlined approach is better for us as a health system laboratory."

Respiratory Virus Testing

Before developing its LDT to identify the SARS-CoV-2 infection, the lab was using a molecular respiratory virus panel (RVP) to identify patients with a variety of respiratory viruses, including the flu and other coronaviruses. By the time the LDT was ready for use, the lab could use the RVP and follow up with the LDT, if appropriate.

"We used the RVP because we were still seeing a fair amount of flu in the community," Kaul explained. "Using the RVP first means we can avoid wasting the coronavirus tests when they wouldn't be appropriate for those patients."

If the RVP was negative for a symptomatic patient, the next step was to use the LDT that NorthShore developed for the SARS-CoV-2 infection. "The coronavirus test is something new and separate in the clinical community. Therefore, we are prescreening those patients by taking a nasopharyngeal swab and testing that specimen using the RVP," she said. "If that test is negative, then we test for SARS-CoV-2.

"At first, our goal was to report results in a day or two and we met that standard," she said. "This turnaround time is important for hospital inpatients because a positive test result has implications for discharge and other reasons.

Are Patients Positive, or Not?

"For example, it's important for bed control, meaning whether those patients get isolated or not," she added. "Our care teams need to know the status of whether patients are positive or negative and they need to know that quickly."

"By the end of the first week in April, we passed the 10,000 mark for the number of tests run in NorthShore's lab," Kaul reported. "Approximately 20% of those patients tested positive and about 5% of that group needed immediate care.

"Since April 11, our lab has been processing COVID-19 tests for the state testing location on West Forest Preserve Drive in Chicago," she noted. "The criteria that state health officials set for that site is the testing is for first responders, healthcare workers, and people over 65 who have respiratory symptoms.

Turnaround Times

"Our goal is to return results within 24 to 48 hours," Kaul added. "The National Guard will drop off the specimen collections to **NorthShore Evanston Hospital** daily for processing.

Reporting test results quickly was a challenge because running the SARS-CoV-2 test required some manual processing at first. "To address that problem, we're adding some automated platforms because we want to be able to bring in tests from the other laboratories," she added. "For that work, big automated instruments are very helpful." TDR

—Joseph Burns

Contact Karen Kaul, MD, PhD at KKaul-@northshore.org.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Not only did the outbreak of SARS-CoV-2 in the United States show how unprepared the nation was for an event like this, but it exposed numerous problems and weaknesses in the federal agencies tasked with protecting the health and safety of the American public. One high-profile failure happened when the **Centers for Disease Control and Prevention** (CDC) shipped defective COVID-19 test kits to public health laboratories in early February. It took almost a month for the federal agency to address the problem and ship accurate test kits. Last week, the *Washington Post* reported that the problem with the unreliable kits was due to contamination during the manufacturing process.

MORE ON: *CDC's COVID-19 Test Kits*

As reported by the *Post*, the problem was only corrected after the **Food and Drug Administration** (FDA) worked with the CDC team, and **Integrated DNA Technologies, Inc.** (IDT), of Coralville, Iowa. They determined that the issue was contamination during the CDC's manufacturing process. With the problem identified, IDT then manufactured the kits and materials that the CDC distributed to public health labs at the end of February. IDT is authorized by the CDC to sell COVID-19 primer and probe kits.

TRACKING COVID-19 IN WASTEWATER HINTS AT WIDER SPREAD OF DISEASE

One new tool for tracking an infectious disease outbreak is to check sewers and wastewater plants for the infectious agent. Recently, water at a major urban treatment facility serving a large area of Massachusetts was tested for COVID-19. *Newsweek* reported that researchers on the team came from **Biobot Analytics**, the **Massachusetts Institute of Technology** (MIT,) **Harvard University**, and **Brigham and Women's Hospital**. Tests done from March 18-25 found higher quantities of SARS-CoV-2 than what had been originally predicted. Researchers consider this strong evidence that a much greater number of people are infected with the novel coronavirus.

TRANSITIONS

• Pathologist Roger D. Klein, M.D., J.D., FCAP, was appointed Chief Medical Officer at **OmniSeq** of Buffalo, N.Y. He maintains his consultancy, **Roger D. Klein, MD, JD, Consulting**. Previously, he served at the **Arizona State University College of Law**, **Cleveland Clinic**, **BloodCenter of Wisconsin**, and **Moffitt Cancer Center**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 11, 2020.

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

Coming Soon!

COVID-19 STAT Intelligence Service

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 are launching the COVID-19 STAT Intelligence Service. It will operate through the end of the pandemic.

Check **www.covid19briefings.com** for launch date and details.

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

UPCOMING...

- ***Coming Next to Your Laboratory: Serology Tests for COVID-19: Essential Steps Experts Say You Should Do to Be Prepared.***
- ***Are All SARS-CoV-2 Rapid Molecular Tests and Serology Tests Equal in Accuracy? What Lab Directors Quietly Fear.***
- ***Checking on Financial Status of Clinical Labs, Pathology Groups: Latest Data on Current Specimen Volumes, Settled Claims.***

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