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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

INSIDE THIS ISSUE

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Might Politics Sway Calif. Lab's CLIA Compliance?

Is it a conflict for a state government to build and operate a CLIA high-complexity clinical laboratory and have the same department that manages this lab facility also conduct the CLIA-mandated inspections and oversight of the lab's compliance, as required by the federal Clinical Laboratory Improvement Amendments (CLIA)?

That is the situation in California today. Last August, the state government issued a no-bid contract worth as much as $1.7 billion to **PerkinElmer**, which requires the company—on an accelerated timeline—to find a location, design, and build a lab facility, install and validate instruments and assays, hire and train staff, and have the entire lab operation produce an ambitious 150,000 molecular SARS-CoV-2 tests per day by early March. That level of daily test production would make it one of the nation's largest genetic testing laboratories. From concept to 150,000 COVID-19 tests per day was planned to take just 180 days! *(See TDR, "California Builds COVID-19 Lab: $25 Million or $1.7 Billion?," Nov. 16, 2020.)*

Since the State of California's **Valencia Branch Laboratory** (VBL) became operational last fall, news outlets have reported about various problems, as we describe on pages 6-8 in this issue. Numerous whistleblowers are talking to different news outlets. One of the senior lab directors—who no longer works for VBL—went public with her concerns. Since she previously worked as a clinical lab inspector for the state, she should have credibility.

These developments raise a question of great interest to all pathologists and clinical laboratory professionals. Normally, as a regulator, a state wants to protect public health, safety, and welfare. For lab testing, California does this through its **Laboratory Field Services** (LFS), which is part of the **California Department of Public Health** (CDPH). But the Valencia Branch Laboratory is owned and operated by the State of California, which has committed to spend as much as $1.7 billion to grow this lab into one of the nation's largest genetic testing labs. Does this not create a major conflict of interest? How can this lab, operated by a state government agency—the CDPH—be inspected and regulated by its internal department, the LFS? To avoid blame for any problems, will elected officials and government bureaucrats blunt CLIA inspections of this lab and surpress publication of identified deficiencies?

Events so far do not inspire confidence that the right things will happen. TDR

New Year Brings Three New Clinical Lab Trends

Demand for routine testing continues to rebound, while COVID-19 test reimbursement is inconsistent

CEO SUMMARY: Since the year began, three trends have affected clinical laboratories and anatomic pathology groups. First is a continuing surge in COVID-19 test volume. Second is inconsistent payment from government and commercial insurers for SARS-CoV-2 test claims. Third is growing consumer acceptance of digital devices to monitor their health, a trend that leads them to order more and pay cash for direct-to-consumer tests. Labs doing strategic planning should consider the influence of these trends.

THREE SIGNIFICANT TRENDS ARE TAKING HOLD IN THE CLINICAL LABORATORY INDUSTRY. Two are linked directly to the COVID-19 pandemic and the third is boosting testing demand because it reflects changes in patient behavior that are bringing increased cash flow to clinical labs.

Lâle White, Executive Chairman and CEO of **XIFIN**, identified the trends as a result of the work her company does in processing clinical lab test claims and in helping labs manage payment processes.

The first of the three trends is the latest surge in COVID-19 test volume. This increase in testing for the SARS-CoV-2 virus is forcing labs to balance rising demand against a steady increase in the need for routine tests.

"We have seen a rather robust bounce-back in the volume of routine testing," noted White. "When the pandemic began last March, health systems shut down as COVID-19 cases rose and patients stayed away from doctors' offices. Now, almost a year later, routine test volume is climbing as patients decide they can no longer delay the healthcare they didn't get last year."

The second trend in labs is inconsistent payment from government and commercial health insurers for claims resulting from the rising number of COVID-19 tests. "We have seen this inconsistency in reimbursement payment as a drop in payment rates since Jan. 1," added White. *(See sidebar, "As Health Insurers Adjust to New COVID-19 Billing Codes, Payment Has Been Inconsistent," page 05.)*

The third trend is growing interest among consumers in digital health. For example, wearable devices are used to measure the user's heart rate, hours of sleep,

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daily steps, and other activities. "This rising interest in digital devices is a positive development for labs because it drives demand for direct-to-consumer (DTC) testing," she said. "That's good for clinical labs since consumers will pay cash for DTC testing.

"Experts predict this trend will continue long-term, in part because digital devices tend to raise consumers' interest in their personal health," she said. "For labs, such increased interest motivates consumers to get DTC tests to identify any health problems as early as possible, rather than find out later when cancer or another condition is a bigger problem."

Identifying Variants

As clinical labs see an increase in testing for the novel coronavirus, they also are getting more inquiries about identifying variants to the virus, but payment for identifying variants is not considered in current reimbursement rates, White noted.

"Right now, viral load reporting and variant-identification of SARS-CoV-2 are included in the price of the test because there's no additional fee associated with reporting these elements," she added. "Even so, many labs started reporting patients' viral load once its significance in disease management was determined.

"Typically, there is not a big cost to labs associated with adding variant sequencing, other than the investment in research and development to introduce such assays," she noted.

As virus mutations began to emerge, many labs revised their COVID assays to provide variant-identification results. "But from early in the pandemic, a number of labs have produced information on variants because they knew that identifying variants would be needed," explained White. "So, while some clinical labs have had viral load and variant information, they have not necessarily been reporting that data. But soon, they will do so.

"At the same time, clinical labs will also need to report any information they have on variants to public-health authorities in their cities and states," she added.

"The increased need for information on viral load and variants means we'll continue to see a fairly healthy volume of SARS-CoV-2 PCR testing in clinical diagnostic labs," White predicted, "particularly since that information is unavailable in at-home or over-the-counter tests."

As to the surge in testing, White explained that labs saw a drop in lab test volume in January and February, partially due to the introduction of vaccinations and to winter weather. At the same time, routine clinical lab-test volume returned almost in full this year after a slowdown in the first six months of 2020. And in the last two weeks of January and into February, labs also saw molecular diagnostic tests and genetic testing volumes surge, she added.

"The base testing business in clinical laboratories continues to be very strong and high in some cases," she noted. "But molecular diagnostics and genetic testing for other diseases are seeing the highest increases in testing volume. In those two areas, volume is higher this year than pre-COVID volumes by 15% or so.

More Oncology Testing

"Mostly that increase in testing is coming from oncologists for cancer-related testing, primarily because patients delayed getting those tests last year," she speculated. "That's a good portion of the increase in standard testing that we see."

At the same time, anatomic pathology testing has risen about 10% to 15% over pre-COVID volumes and that increase could be due to delayed cancer testing from 2020, she added. The story is similar for hospital labs, where test volume increased by about 10% to 15% over pre-COVID volume. Most of that increase is coming from routine lab testing, said White.

"Also, even as these clinical labs do more testing, they also are dealing with a huge volume spike in testing for COVID-19, which continues to be strong," she commented. "At this stage, even with the

As Health Insurers Adjust to New COVID-19 Billing Codes, Payment Has Been Inconsistent

AFTER THE FEDERAL CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) introduced new billing codes for COVID tests starting on Jan. 1, payment has been inconsistent, said Lâle White, Executive Chairman and CEO of XIFIN, which processes testing claims and helps labs manage payment processes.

In October, CMS said it would pay $100 per test to laboratories that complete high-throughput COVID-19 diagnostic tests within two calendar days of specimen collection, but would pay only $75 per test when results take longer than two days. At the same time, CMS introduced a new CPT code (U0005) for meeting the two-day-turn-around time for these high-complexity COVID-19 tests.

Then, on Jan. 6, CMS introduced more new codes to identify conditions related to COVID-19 and said all the new codes were effective on Jan. 1. The new codes include Z11.52 for screening for COVID-19; Z20.822 for contact with and suspected exposure to COVID-19; Z86.16 for personal history of COVID-19; M35.81 for multisystem inflammatory syndrome; M35.89 for other specified systemic involvement of connective tissue; and J12.82 for pneumonia due to COVID-19.

"It doesn't appear that government and commercial payers were ready to process all the new CPT and ICD-10 codes introduced in January," White explained. "At the beginning of January, a lot of payers weren't recognizing the new codes, even though they had said previously they would be ready. For example, many of the **Blue Cross Blue Shield** plans said they would be ready, but they had difficulties paying for those codes.

"To be fair, many insurers were paying for U0005 almost across the board," White noted. "That code was announced in October and it has had fairly good acceptance. But we've seen many claims-payment problems for COVID-19 testing because some insurance companies just weren't timely in understanding the new codes and updating their payment systems appropriately.

"For these reasons, there has been some erosion in payment for SARS-CoV-2 tests," she added. "One reason for the erosion is the lack of preparation to implement the new codes in January, when these codes were not even announced until after that date. To their credit, insurers have fixed most of those problems.

"Another reason for the erosion in payment is clinical labs have not been able to show that they have run 100% of their high-complexity COVID-19 PCR tests in the two-day turnaround time," she said. "Also, some clinical labs have not been able to show that at least 51% of their high-complexity COVID-19 PCR tests done in the previous month were completed in the two days that CMS requires."

declining volume, we continue to see a strong demand for COVID-19 testing."

Factors that may contribute to a softening in demand for COVID-19 testing volume are the rising numbers of Americans getting vaccinated and a fall-off of the need for testing related to Christmas travel and family gatherings over the holidays, White said.

"Meanwhile, when you see anatomic pathology, genetic testing, and hospital laboratory testing all have an uptick in their core business, it's safe to say that such increases are coming from people who delayed their healthcare services last year," White concluded. **TDR**

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Whistleblowers Disclose Issues in Calif.'s COVID Lab

State government may spend up to $1.7 billion for COVID-19 tests at its new lab facility in Valencia

CEO SUMMARY: Whistleblowers at the State of California's brand-new COVID-19 Valencia Branch Laboratory are telling reporters about staff sleeping on the job, unlicensed staff handling specimens, and other significant issues. Given the reports of several news outlets, one relevant question for the clinical laboratory profession is whether state lab inspectors, federal CLIA officials, and the College of American Pathologists will hold this government-owned lab fully accountable to all regulations.

SERIOUS DEFICIENCIES IN COVID-19 LAB TESTING AND SLACK MANAGEMENT OF EMPLOYEES are some of the latest problems associated with the **Valencia Branch Laboratory** (VBL) at California's brand-new clinical lab facility located in Valencia.

This is the start-up lab facility that the State of California is funding, after the **California Department of Public Health** (CDPH) awarded a no-bid contract last August to **PerkinElmer** of Waltham, Mass., that may be worth as much as $1.7 billion. The plan is for the diagnostic test developer and life science company to build and operate that lab. One goal is for the laboratory to perform 150,000 molecular SARS-CoV-2 tests per day in early March and report those results within 48 hours of testing. *(See "California Builds Its Own COVID Lab: $25 Million or $1.7 Billion?" TDR Nov. 16, 2020.)*

Once news surfaced last fall that the the state government would spend up to $1.7 billion to build and operate a laboratory for COVID-19 testing, news outlets throughout the state began to cover the story.

As pathologists and clinical laboratory managers know, building a new clinical laboratory, validating instruments and assays, and launching operations is one of the most complex tasks in laboratory medicine—primarily because of the risk that the new and untried systems could produce inaccurate results that would harm patients. News reporters are learning about these risks and multiple whistleblowers within VBL are talking to reporters.

Multiple Lab Whistleblowers

In one news story broadcast on Feb. 8, news reporter Julie Watts of *CBS13* in Sacramento, said "*CBS13* has interviewed more than half a dozen whistleblowers and obtained dozens of internal records and quality control reports. The documents detail problems ranging from contamination causing inconclusive results to swapped samples and inaccurate results sent to patients. Records indicate that employees handling patient specimens had not been signed off for competency on crucial skills," she added in her report.

The COVID-19 Valencia Branch Laboratory started operations on Nov. 1, 2020. During a routine inspection, on Dec. 8, staff from CDPH's **Laboratory Field**

Services (LFS) found significant numerous deficiencies, according to reporting from the *Associated Press* on Feb. 22. CDPH inspectors and state officials attributed those deficiencies to the rapid increase in testing that CDPH required under its contract with PerkinElmer, the *AP* added.

PerkinElmer Provided Data

The lab continues to operate, and PerkinElmer said some of the information it provided to CDPH since the inspection was not included in the inspection report and that the company believes the deficiencies have been resolved.

LFS inspectors said the lab was unable to test about 250 samples (0.017%) due to lab errors, and that the lab issued corrected reports for about 60 (0.0039%) samples, the *AP* reported. "A fraction of 1% of the more than 1.5 million tests processed at the VBL had problems," the state said in a preliminary report. But **California Health and Human Services** Secretary Mark Ghaly, MD, MPH, said, "one incorrect test result is one too many," the *AP* reported.

"California takes these findings seriously" and continues working with the contractor "to ensure Californians have accurate, timely, high-quality test results," Ghaly added.

In addition, CDPH also is investigating the whistleblower allegations of incompetence and mismanagement, including reports of workers sleeping on the job, *CBS13 TV* reported.

Last week, PerkinElmer was reported to be suing a whistleblower who spoke to *CBS13* and indicated that the company may sue others. *(See sidebar at right.)*

CBS13 also found that in addition to swapped samples, contamination caused inconclusive test results and inaccurate results were sent to patients. CDPH acknowledged that at least "38 samples were reported incorrectly" because of mix-ups in samples, but added that patients were notified quickly.

The station said documents showed some employees handling patient speci-

PerkinElmer Is Suing Lab Whistleblower

ON FEB. 24, *CBS13 TV* IN SACRAMENTO reported that PerkinElmer, the lab company running California's COVID Valencia Branch Laboratory, filed a lawsuit against one named whistleblower and 25 other unnamed whistleblowers who may be named later.

The TV station's investigation began with one whistleblower and then other workers at the lab made allegations about management practices at the state's new COVID testing lab, saying those practices pose a significant risk to public health, *CBS13* reported.

"*CBS13* obtained documents that back up the allegations, which whistleblowers reported to us and, in some cases, to regulators," the news station added. "They say their prior complaints to management were ignored.

"Most of the whistleblowers asked that we conceal their identities out of fear of retaliation, but former lab manager, Dr. Mahnaz Salem agreed to show her face. She reached out after seeing our initial reports and, like many, confirmed the allegations," the station noted.

CBS13 also said "... after seeing our reports, former Laboratory Manager Mahnaz Salem, PhD, reached out and offered to speak on the record. 'I really want (the) public to know that this lab should not continue operating like this,' explained Dr. Salem, who recently resigned from the lab. She was previously a state laboratory inspector."

In the lawsuit filed Feb. 22, *CBS13* reported that the lab company alleged that Salem emailed herself proprietary information in violation of a confidentiality agreement, and that Salem had used such information "to PerkinElmer's competitive disadvantage."

mens were unlicensed and inadequately trained. State officials said then that "a handful of individuals" were retrained or moved to assignments that fit their credentials.

The VBL has 600 employees and the capacity to run 100,000 tests per day and eventually to run as many as 150,000 molecular COVID-19 tests per day starting in March. But testing volume in California is lower than it was during the last few weeks of 2020. Still, the state is expected to send the lab 502,000 specimens each week, or about 72,000 tests per day.

Whistleblowers' Concerns

Even after the latest reporting on the state inspection, several of the whistleblowers told *CBS13* that they continue to be concerned by the official narrative that the lab deficiencies have been addressed. The whistleblowers, who work in the lab, have said that lab managers have ignored their concerns.

"It is still just as disorganized as it was three months ago when I first started," one whistleblower told *CBS13* in a report broadcast on Feb. 22.

In the report, *CBS13* said whistleblowers have continued to see unlicensed lab techs sleeping on the job and incorrect results being released to patients and physicians without a procedure to notify patients who received incorrect results. The whistleblowers also said unsupervised staff have been processing patient samples before completing training or before being rated as competent for the job they will do, as required by law, *CBS13* reported.

"The staff are very untrained and unsupervised," one whistleblower told the TV station. And lab management has not been forthcoming about the training of its workers, the whistleblower added.

In response to the concerns broadcast on Feb. 22, state officials said all individuals working at the laboratory and handling specimens "are credentialed and trained."

CBS13 also reported that one day after its initial report, state officials started their own investigation at the lab. "Investigators are now inside the California Department of Public Health-PerkinElmer COVID testing lab following concerning allegations from more than a half-dozen whistleblowers," *CBS13* reported on Feb. 8. "However, the state's initial response to the allegations is raising more questions."

Will the allegations reported in these news accounts put pressure on the state lab inspectors, federal CLIA officials, and the CAP to act decisively in formally noting the deficiencies in this lab and putting them on record? A government-owned lab should be held to the same standards as the nation's other clinical labs. TDR

PerkinElmer Response on Calif. Lab Issues

PERKINELMER, THE LAB COMPANY RUNNING THE COVID-19 VALENCIA BRANCH LABORATORY'S (VBL), said in a statement issued on Feb. 22 that it received the routine lab inspection report on Feb. 19 and was preparing a response that is due to state officials on March 1.

"During the months of December and January, the VBL supplied additional information at LFS' request. Upon review, it appears that LFS had not yet incorporated this extensive information into its routine inspection report. PerkinElmer believes that the deficiencies identified by LFS have long since been resolved," the company said.

In addition, inspectors from the **College of American Pathologists** (CAP) visited the VBL on Feb. 19 as the first step in the process to accredit the lab, PerkinElmer added.

"The VBL is seeking accreditation from the CAP so that Californians have no doubt about the quality of the services at the laboratory," the company said. "Once accredited, the VBL will join PerkinElmer's labs in Pennsylvania, India, and China that already have the CAP accreditation."

Pathology Lab Transforms, Runs 1M COVID-19 Tests

Histopathology lab adapts its molecular capabilities to handle ever-greater numbers of SARS-CoV-2 tests

CEO SUMMARY: Last spring, a histopathology lab in Illinois began running molecular COVID-19 tests and decided the clinical side of the lab would focus exclusively on PCR testing for COVID-19. The challenge was how to access a reliable source of test kits, reagents, and supplies to operate 24 hours a day, seven days a week. The answer came in the form of a multi-million-dollar lab supply contract that allowed the lab to perform more than one million SARS-CoV-2 tests within eight months.

In the 1950s television series of the same name, a narrator told viewers there were "eight million stories in The Naked City." Today there may be eight million stories about COVID-19 testing, but few are likely to be as improbable as the one **Reditus Laboratories** has to tell.

Founded in 2019, this moderate-sized histopathology lab in Pekin, Ill., started running polymerase chain reaction (PCR) tests for COVID-19 in April. Since then the clinical laboratory has focused exclusively on PCR testing while continuing to support its anatomic pathology business. Since the fall, Reditus has run 15,000 to 17,000 COVID-19 tests each day.

Million Test Milestone

"By late November, we hit our first million COVID-19 PCR tests," Reditus CEO Aaron Rossi, MD, said in December. "Now, we've already performed 1.35 million tests, meaning we could hit our second million in the next few weeks.

"Just before the middle of April, we went live on one machine with our first PCR test for COVID-19," Rossi added. "In those early days, we used the **Thermo Fisher** EUA test for the coronavirus. Within a few months, we had run several thousand tests, and now we're tracking at a much higher level."

For Rossi and the lab's 250 employees, the journey from being a histopathology lab to running clinical lab tests for SARS-CoV-2 has been chaotic at times because testing volume has grown so quickly as a result of two strategies that Rossi employed.

First, the clinical side of the lab has focused exclusively on PCR testing. Second, once it was running PCR tests, the lab needed to feed the beast, so to speak, every day. To accomplish that, Reditus, like every clinical lab, needed enough lab testing supplies to run those tests around the clock.

Rossi solved that problem by signing a multi-million lab-supply contract with Thermo Fisher. Under that contract, the lab has maintained a high-throughput strategy since April, while going from a few hundred tests per day to doing more than 600 tests per hour, or about 15,000 tests every 24-hours.

To accommodate the growing test volume, Reditus is increasing the size of its 14,000-square-foot Pekin lab to

accommodate more PCR testing equipment, including six of Thermo Fisher's QuantStudio 5 Real-time PCR Systems and eight of the KingFischer Flex Systems for molecular particle extraction.

By focusing exclusively on PCR tests, Rossi explained that the lab has been successful in testing for Illinois cities, towns, and state agencies. Since the spring, these clients have steadily increased their demand for COVID-19 tests. While test volume has risen and turnaround times have lagged occasionally, Reditus has reported most SARS-CoV-2 results in about 13 hours, Rossi said.

"We provide testing for municipalities and for the state of Illinois within about a 150- to 200-mile radius," he reported. "For those clients, we're very cognizant of our quality and turnaround time. To do that, we focus on quality over quantity. We don't over-commit and under-deliver."

Turnaround Times

Despite that goal, Reditus was in the news in May and again in August when some test turnaround times reportedly stretched to four and seven days and beyond, according to published reports.

For the state of Illinois' Emergency Management Agency, Reditus has run drive-up testing sites in Bloomington, Peoria, and five other Illinois cities. Also, Reditus had a contract last year with **eTrueNorth**, a lab testing company operating drive-through testing sites nationwide under a contract with the federal **Department of Health and Human Services**. *(See "Texas Company Operates 400 COVID-Collection Sites," TDR, Aug. 24, 2020.)*

"We struggled to meet the demand for COVID-19 testing when Illinois officials shifted from having the National Guard do some of the specimen collections to having us do that collection and testing," Rossi said.

To ensure that the lab can add volume without slowing turnaround times, Rossi has not introduced any other form of COVID-19 testing that might divert attention away from PCR testing. The lab does not pool specimens, for example, and it has not introduced antigen, antibody, or saliva tests for SARS-CoV-2, he said.

'Stayed in Our Wheelhouse'

"We never got involved in any other form of COVID-19 testing because we're not in the screening business," Rossi commented. "Instead, we stayed in our wheelhouse, which is diagnostic testing using PCR."

Adding any other form of testing could jeopardize an operation that needed to stay focused on getting specimens in, testing those patient samples quickly, and getting the results out to patients and treating physicians, he explained.

"We're sticking to a basic business plan that requires we take our time with each step in the process and make sure we do everything right," noted Rossi. "When a lab runs 24/7 and receives 16,000 to 17,000 specimens a day, any type of workflow disruption can cause a massive back-up.

"If our lab's workflow is disrupted for even a few hours, the backup can quickly rise to 8,000 specimens," he warned. "When that happens, new specimens don't stop coming in. Instead, we have a back-up lab if needed. No lab wants to be in the news for not getting results out in time.

News Coverage of Pandemic

"Everybody looks at COVID-19 as a celebrity, and the news people like to talk about all the bad stuff," he added. Some of the nation's largest labs have been in the national news when turnaround times for COVID testing ran over a week or more."

Another reason Reditus could manage a steady increase in testing and large volumes of specimens for molecular assays is because the histopathology lab already had an operational and financial management system that could be adapted to support the clinical lab, Rossi explained.

Before the pandemic, Reditus was a fast-growing histopathology business that ran the **LigoLab** LIS (laboratory information system) and revenue cycle manage-

Illinois Pathology Laboratory Steadily Increased COVID-19 Test Volume by Adding New Clients

FOR REDITUS LABORATORIES CEO AARON ROSSI, MD, one key to introducing COVID-19 testing successfully, was to add clients slowly and steadily.

"When we started SARS-CoV-2 testing last spring, we had three or four substantial accounts," he said. "By doing testing for these accounts, we showed we were capable of doing COVID-19 testing even though we had never done that testing before.

"Within a few months, the State of Illinois needed more clinical laboratories to meet the demand for SARS-CoV-2 testing at community-based testing sites (CBTS)," noted Rossi. "Initially, we had one CBTS that sent us about 500 specimens a day under a state contract. From there, we slowly added more volume as additional state CBTS referred specimens to us."

Today, about 75% of the lab's COVID-19 test volume comes from 10 drive-through and mobile-testing sites for the Illinois **Department of Public Health**. The remainder comes from work for the state **Department of Corrections**, area hospitals, and long-term care facilities.

In the spring, Rossi and the Reditus lab team were establishing the processes needed to ensure that every part of the operation—from accessioning to reporting results—ran smoothly and efficiently. "Just like any lab trying to get off the ground, we had growing pains as we added more testing sites," he commented.

As COVID-19 test volume grew, Rossi found that—as every other lab discovered—the need for a reliable source of reagents, testing supplies, and equipment was critical. "From the beginning, we had worked closely with Thermo Fisher," he reported. "It seemed like they prioritized our lab, and so we asked for the supplies and equipment we needed, and they responded.

"From there, we started to build our rapport with Thermo Fisher and signed a contract so that we could be allocated the reagents we needed," he noted. "After that, we discussed going to an exclusive reagent deal with them and that became a big leap for us. That was a $14 million contract in which Thermo-Fisher agreed to supply what we needed in reagents and other supplies.

"As a result of that supply contract, we never had any serious slow down or drop off in SARS-CoV-2 testing," he said. "We never had a shortfall of reagents, pipette tips, plastics, or other consumables of any kind."

ment systems. "That platform includes the modules we needed, not only for anatomic pathology but also for clinical laboratory and molecular diagnostics," Rossi said.

Seamless Transition

"Having those capabilities in our LIS helped to make the transition from histopathology to COVID-19 testing relatively seamless," he concluded. "When we started doing PCR testing, we already had significant operational and financial infrastructure in place to do that molecular diagnostics testing."

In response to the outbreak of COVID-19 last winter, the team at Reditus Laboratories recognized an opportunity to achieve two important goals. The first goal was to support the community and the region with essential molecular SARS-CoV-2 testing done locally. The second goal was find new clients and accounts so that the lab could generate the cash needed to support SARS-CoV-2 testing while also keeping the lab financially stable throughout the course of the pandemic. TDR

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Variant sequencing helps track source of COVID-19 infections in hospitals, schools

SARS-CoV-2 Variant Sequencing Offers Clinical Opportunities

CEO SUMMARY: In Wisconsin, an oncology research lab started sequencing variants of the SARS-CoV-2 virus and found multiple uses for such test results to help hospitals, health systems, schools, and municipalities identify infection sources and track the virus' spread. In one case, the lab identified a sub-strain of the virus that appeared to be linked to young people socializing in bars. The lab also did variant sequencing in municipal wastewater to detect a virus mutation before a surge in cases, suggesting that such testing may have some utility in forecasting COVID-19 outbreaks.

In recent weeks, interest has been building for clinical laboratories and anatomic pathology groups to do molecular SARS-COV-2 testing to identify and report genetic variants of the deadly virus. This trend is the latest example of how the pandemic has created the potential for a clinical opportunity to generate a new stream of revenue—once payers institute reimbursement for variant sequencing of SARS-CoV-2 specimens.

One laboratory director whose lab has tested for genetic variants since the earliest weeks of the pandemic has identified multiple ways that such information could be useful, such as identifying new variants as they emerge, as well as for tracing the spread of the virus in the population. This is essential for hospitals, health systems, schools, businesses, and other organizations that need to distinguish between virus outbreaks and random COVID-19 infections.

"Over the course of the pandemic, our ability to report genetic variants of the COVID-19 virus helped a dialysis center avoid shutting down after administrators found higher-than-normal rates of COVID-19 infections and feared those infections meant the facility had an outbreak that only a shutdown could contain," explained Paraic A. Kenny, PhD, Director of the **Kabara Cancer Research Institute** (KCRI) of the **Gundersen Medical Foundation**, in La Crosse, Wisconsin. "Much to the relief of administrators, variant sequencing in our lab showed that the infections were the result of unrelated infections."

In an interview with The Dark Report, Kenny explained how his lab pivoted from doing cancer research in March 2020 to sequencing SARS-CoV-2 positive specimens from the 22 counties that the **Gundersen Health System** serves in western Wisconsin, northeastern Iowa, and southeastern Minnesota. He also outlined how KCRI has identified clinical and business opportunities for clinical labs and AP groups that can sequence variants to SARS-CoV-2.

Sequencing Variants Has Value

In the past 12 months, KCRI has done fascinating work that other labs seeking to add variant sequencing to their menu of tests could do. Consider, for example, these three examples:

In one case, Kenny's lab identified a sub-strain of the virus that seemed to be linked to young people socializing in bars.

In a second case, the lab did variant sequencing for municipalities showing that a virus mutation was detectable in wastewater before a surge in cases, suggesting that such testing may have some utility in forecasting COVID-19 outbreaks.

In a third case, the lab followed the spread of one strain of SARS-CoV-2 over six weeks, from its origin at a meatpacking plant in Postville, Iowa, to individuals in 13 cities in seven counties across the three states—a region spanning hundreds of square miles. In this case, KCRI's work showed the public health consequences of failing to mitigate the spread of the virus from one industrial setting into the surrounding communities.

In work KCRI did for a hospital-based dialysis center in Wisconsin, the lab identified five cases of COVID-19 infections that occurred over 11 days in November among patients with end-stage renal disease. Facility-wide testing and analysis of genetic sequencing results showed no link among these cases, allowing the facility to remain open.

The following is an edited version of an interview Joseph Burns, Senior Editor of The Dark Report, conducted with Kenny early last month.

EDITOR: Would you describe the clinical and financial opportunities for clinical labs and AP groups capable of identifying variants to the virus from positive specimens and then tracing those infections? In other words, could such work be a viable strategy for labs that are testing patients for COVID-19 to add variant sequencing?

KENNY: Yes, there are a variety of potential uses for variant sequencing technology, and the dialysis center is a good example. Since about this time last year, we've spent all

of our time trying to understand the links between SARS-CoV-2 cases as the virus has spread and mutated. The cases in the dialysis center showed why a small number of samples were unconnected, and that information was significant for those who manage the center. Without that information, the center might have been forced to shut down at least temporarily.

Paraic Kenny, PhD

➤"Variant testing of the cases in the dialysis center showed why a small number of samples were unconnected and that information was significant for those who manage the center. Without that information, the center might have been forced to shut down at least temporarily."

EDITOR: Are schools—including colleges and universities—interested in knowing the genetic variants from the COVID-19 testing of their students, faculty, and workers?

KENNY: There are definitely similar opportunities to do this work in schools. In fact, schools are probably more vulnerable in many ways than dialysis centers or other treatment facilities. When the number of cases rises in a community and you see the co-occurrence of cases in a classroom, people can get anxious about the potential risks of widespread infection. That's when sequencing can eliminate the possibility that something intrinsic is going wrong in the school or among these infected individuals. Without sequencing, for example, we look to see if the infected students all had hockey practice together or if many of the students go to the same church. All of these cases could be completely unrelated. But we don't know that without sequencing the virus from infected individuals.

EDITOR: Are you saying that without sequencing, schools, businesses, other organizations, and cities and towns tend to implement mitigation strategies based on guess work?

KENNY: That is often the case. Organizations commonly enact policies to mitigate COVID-19 infections without a meticulous understanding of how the disease is spreading and without knowing all of the risk factors in a variety of situations. That's where sequencing to identify variants can provide a fuller understanding of how the virus spreads and how to contain the spread.

EDITOR: Is it correct to assume that a sales staff for a clinical lab or an AP group could make the argument that variant sequencing could help all kinds of institutions, including schools, hospitals, and businesses, avoid the need to shut down if they know the source of an outbreak?

KENNY: In theory, yes. In fact, that's the situation we had with the dialysis facility. Our local public health department was concerned about infections in that facility because they involved a number of cases occurring together in a congregate setting among high-risk patients. In Wisconsin, the requirement is to do facility-wide testing every seven days until that site can demonstrate a certain number of consecutive days with no new COVID-19 cases. Essentially, the dialysis center was mandated to do facility-wide testing. That much testing is not cheap. Therefore, identifying the variants involved in this case had the potential to save at least some of the costs of facility-wide testing.

EDITOR: Is it correct to assume, then, that facilities with COVID-19 testing programs can justify the cost of variant testing by doing a cost-benefit analysis to analyze facility-wide versus variant sequencing?

KENNY: The short answer is yes. A more complete answer is that organizations doing SARS-CoV-2 testing recognize how knowledge about the presence or non-presence of variant strains determines if additional testing is needed. Our work was useful because sequencing basi-

cally showed why the outbreak that everyone feared was occurring was actually not happening. Having that information may have prevented at least two more rounds of testing, which could have cost $8,000 to $10,000 per round. There's definitely an economic value right there.

EDITOR: But these organizations would still need to pay for variant sequencing, and there's a cost for that work, right?

KENNY: Yes, and mostly the way clinical laboratories test for variants is actually just to do the sequencing on positive specimens. So, from a business point of view, and from a clinical care point of view, there needs to be a rationale to test any individual positive specimen for a variance.

EDITOR: How would a clinical laboratory develop such a rationale?

KENNY: Given the current knowledge about the virus, one way is to identify the presence of the so-called spike in the virus that identifies a potential variant. Labs have seen that spike in numerous places around the world on distinct virus lineages, and we know that at least one spike predicts resistance to the monoclonal antibody therapies.

EDITOR: How might that knowledge be useful?

KENNY: With that information, a health system or health insurer might want to consider doing variant sequencing before implementing monoclonal antibody drug therapy because that therapy could be completely ineffective for a patient who has the virus with a certain spike on its genome. We don't know yet if there's a break-even point for deploying a test like that. But if certain variants become more widespread and some number of patients are being considered for infusion with monoclonal antibody drugs, there might then be a value proposition for health systems, clinical labs, and payers to consider.

EDITOR: You've described a theoretical path to reimbursement. But your lab has done variant sequencing on SARS-CoV-2 specimens for almost a full year now. How does your lab get paid for that work?

KENNY: The first case of COVID-19 in our region last year happened on March 18. Our lab had its first genome completed sometime around March 25 or 26. At the time, we were about the 15th lab or so in the United States to report a COVID-19 genome sequence to **GISAID**, which means we were very early adopters. The GISAID Initiative is a global effort to promote the sharing of data from all influenza viruses and the coronavirus that causes the COVID-19 illness.

EDITOR: Were your lab's early gene sequencing efforts financed internally?

KENNY: The institute is a research lab, and, just as in any lab, we get economies of scale by doing more sequencing of the virus. The more viruses a lab can sequence in parallel, the cheaper it gets when costs are averaged on a per-sample basis. So, for us, it costs about $200 per sample when we roll in all labor and all of our other costs into the variant sequencing work we do. That said, the research department here at Gundersen has borne most of the costs of this work because they see the value that our efforts add to the other research we do and to the organization itself.

Paraic Kenny, PhD

➤"From a business point of view and from a clinical care point of view, there needs to be a rationale to test any individual positive specimen for a variance.

EDITOR: Given that KCRI's lab is unusual in that respect, how would other labs address the cost of adding variants to their COVID-19 test reports?

KENNY: In certain labs with certain equipment, I would estimate that the cost could be a lot less than $200 per sample. In our lab, we basically have one sequencer—the **Thermo Fisher** Ion

Torrent S5—which works really well for us and has the kind of throughput we need. Many clinical laboratories will have instruments capable of much higher throughput and more robotics to help bring the cost down substantially. Some labs might be able to do variant sequencing for below $200 and possibly as low as $100 per specimen. That means that our cost of $200 may be on the upper end of the scale.

EDITOR: How would you describe the value that variant sequencing brings to COVID-19 testing programs?

KENNY: We've published articles on the variant sequencing we did for the dialysis facility and for other organizations. All of that work helps to justify our existence because those are significant contributions to our healthcare system. But in addition, we are learning useful information about COVID infections and SARS-CoV-2 variants.

Paraic Kenny, PhD

➤"We've published articles on the variant sequencing we did for the dialysis facility and for other organizations. All of that work helps to justify our existence because those are significant contributions to our healthcare system."

EDITOR: One of the most interesting results your lab has produced so far came from sequencing wastewater for SARS-CoV-2. *(See sidebar, "Lab's Work in Testing COVID-19 in Wastewater Helped Determine Source of Student Infections," on page 17.)* How did your lab connect a variant detected in wastewater testing to young people socializing in bars?

KENNY: In the summer of 2020, when we were sequencing all of the COVID-19 cases in our region, we saw an emerging cluster among many people who had similar and close-to-identical versions of the virus. Because we work under protocols that our institutional review board has approved, we had access to the medical records on all of the patients who tested positive for SARS-CoV-2. That meant we had their demographic data showing they were all young people between the ages of 20 and 35.

EDITOR: What other data in the medical records helped your team make this connection?

KENNY: Before an individual can get a COVID test in Wisconsin, he or she must answer demographic and other questions, and those answers then get documented in the medical record. Patients are asked if they have had a known positive exposure to the virus and where was that exposure. In those answers, we saw that people said they were at a bar with friends or they were at a pontoon party out on a river, or something like that. At the same time our local public health agency was flagging spread within bars as being a source of concern.

EDITOR: Were there any community factors that contributed to your findings?

KENNY: If you look at the epidemic curve in Wisconsin, we did fairly well until about the middle of May when the governor's order to close bars was rescinded. Then, infection rates pretty much went haywire. Collectively, there were many data points that were consistent with the spike that we saw in June being driven by younger folks socializing in bars or other settings.

EDITOR: Thank you, Dr. Kenny, for sharing these insights. Your work will help other labs understand how they might benefit from including information about variants in their COVID-19 test reports.

KENNY: We appreciate the opportunity to share what we have learned with other clinical laboratories.

Contact Paraic Kenny, PhD, at pakenny@gundersenhealth.org.

Lab's Work in Testing COVID-19 in Wastewater Helped Determine Source of Student Infections

DURING THE PANDEMIC, TESTING WASTEWATER FOR THE SARS-CoV-2 CORONAVIRUS has proved useful in some surprising ways. In the case of the clinical lab of the Kabara Cancer Research Institute (KCRI) of the Gundersen Medical Foundation, in La Crosse, Wisc., wastewater testing helped source an outbreak among college students in the region.

Paraic A. Kenny, PhD, Director of KCRI, provided insights into how variant sequencing of the novel coronavirus played a key role in determining the source of this particular outbreak.

EDITOR: How did your lab get involved in doing surveillance testing on wastewater? And, did you have a variety of wastewater sources?

KENNY: Early in the pandemic, we were talking with some of the data scientists and epidemiologists in the Gundersen system who were asking if we could use testing to forecast impending COVID-19 surges. At the time, we were brainstorming ideas about the different tests we could do. We knew that COVID-19 is shed efficiently in feces. So, we suggested that we consider testing wastewater for SARS-CoV-2. At that time, we didn't know if we could sequence specimens from wastewater, but if we could, that might give us a sense of what kind of diversity of spread we would have in our community. And maybe that testing would give us a warning of an impending spike.

EDITOR: How did you get wastewater samples for testing?

KENNY: During one of the meetings we had on testing, Corey Zarecki, the Director of Gundersen's Envision sustainability program, said he knew people who worked at the wastewater plant here in La Crosse. We decided that we needed a pint of sewage to start with. At the time, our COVID-19 cases in the city were really low and we wondered if there would be enough virus in wastewater to detect it. In that first sample, we didn't see very much of the novel coronavirus. But then we got samples every two to three weeks for a couple of months. When we saw a big spike in June, we used the variant data to try to find a source.

EDITOR: What did you learn?

KENNY: This spike seemed to be driven through bars and young people socializing. We knew that because we saw that the key defining genetic variant in the wastewater specimens was the same variant that we had sequenced prior to the start of that outbreak.

EDITOR: And does that mean that doing variant sequencing on wastewater can help in identifying a spike before it occurs? In other words, is there some predictive ability in sequencing?

KENNY: I would be cautious about using the word predictive because we saw that we could have predicted a spike perfectly—but only in hindsight. Therefore, I'm sure it's not actually a prediction. We haven't been sequencing COVID specimens in wastewater for a while, but if we did, and we saw a new variant in wastewater, I don't know what that would mean exactly. We don't know that such a finding would predict a surge. Much more work needs to be done in calibrating the results of such sequencing, and we need to determine if such results would be a quantitative predictor. There may be a link between specific surveillance of wastewater for individual variants such as identifying new worrying substrains of the virus. That may be a role for testing wastewater. But for now, we have stepped away from that testing.

Pathologist's Prison Term Is a Warning for AP Groups

➤VA pathologist guilty of criminal manslaughter, sentenced to 20 years in prison and a $500,000 fine

➤➤CEO SUMMARY: In January, a former VA pathologist was sentenced to 20 years in federal prison following his conviction on charges of involuntary manslaughter and mail fraud. The facts in this case show why leaders of clinical labs and pathology groups need to be aware of individuals who are impaired on the job due to drug or alcohol abuse. Failing to act in such cases could lead to criminal or civil liability under negligent retention of an impaired employee or to medical malpractice claims, says an attorney who reviewed this case.

IT IS NOT OFTEN THAT A PATHOLOGIST WOULD BE CONVICTED of felony crimes committed while practicing medicine. Yet that happened in the case of pathologist Robert Morris Levy, who worked at a **Veterans Administration Hospital** in Arkansas and was sentenced in January to 20 years in federal prison and fined almost $500,000.

The federal **Department of Justice** (DOJ) alleged that Levy's diagnostic errors happened while he worked under the influence of alcohol and drugs over multiple years and resulted in the deaths of at least three patients because they did not get correct or timely treatment for their conditions.

The Levy case is a reminder that every anatomic pathology group faces such risks, particularly since a lab professional who abuses drugs or alcohol can hide his or her condition while continuing to work in clinical settings. The malpractice and medical liability cases associated with Levy's alleged misdiagnoses have not been reported publicly. But in a typical community hospital, even a single diagnostic error that was preventable but led to a patient death can become a significant news stories that can damage a laboratory or pathology group's reputation in the community.

➤Facts of the Arkansas Case

"The facts in the Arkansas case show that clinical lab directors and leaders of AP groups need to be well aware of any individuals who are impaired due to abusing drugs or alcohol while working in a clinical lab or in an AP practice," commented Danielle Holley Tangorre, a shareholder in the Health Law practice at the law firm of **O'Connell and Aronowitz** in Albany, N.Y.

On Jan. 22, Levy, age 54, of Fayetteville, Ark., was sentenced to 20 years in federal prison and ordered to pay $497,746 in restitution on charges related to mail fraud and involuntary manslaughter, the DOJ announced.

In the sentencing order, U.S. District Court Judge Timothy L. Brooks said Levy would serve two prison terms concurrently and then serve three years of supervised release. Levy was ordered to serve

20 years for mail fraud and eight years for involuntary manslaughter.

Levy had worked as the Chief of Pathology and Laboratory Medical Services at the **Veterans Health Care System of the Ozarks** in Fayetteville from 2005 until his employment was terminated in 2018, the DOJ said. In August 2019, a federal grand jury indicted Levy, and he pleaded guilty to the charges in June. *(See "Pathologist's Errors Associated with 12 Deaths at Arkansas VA," TDR Feb. 25, 2019, and "Arkansas Pathologist Faces Three Manslaughter Charges," TDR Sept. 3, 2019.)*

Appeared to Be Intoxicated

In 2015, Levy was reportedly under the influence of alcohol while on duty reviewing cases, and in 2016, he appeared to be intoxicated while on duty, the DOJ announced. After a drug and alcohol test showed Levy's blood alcohol content was 0.396.0 mg/dL, the Fayetteville VA suspended Levy's privileges to practice medicine, the DOJ noted.

Following a three-month in-patient treatment program, Levy was reinstated. But his problems continued, leading the VA to terminate his employment, the DOJ said. *(See sidebar, "DOJ Outlines Facts Leading to Pathologist's Sentencing," pages 20-21.)*

"For anyone working in clinical labs or in anatomic pathology, this is an important case, because, by all accounts, Levy's superiors were aware of his problems," Tangorre commented. "They knew because he was getting tested for drugs and alcohol abuse and he was concealing his impairment.

"That level of concealment showed that the pathologist was impaired, and that impairment led, at least in part, to the finding of manslaughter," she added. "As employers, clinical labs and AP groups have a responsibility to other employees and to patients and physicians to be aware of impaired individuals on the job.

"One factor labs and anatomic pathologists need to consider is that any employer could be liable for failing to address an employee's drug or alcohol abuse, particularly if that employee's ability to perform the job is impaired," Tangorre warned. "Under the legal theory of negligent retention, an employer can be held liable for the actions of an employee who could harm a patient.

"Using the negligent retention theory, plaintiff attorneys could bring a legal action against clinical labs and AP groups if they fail to take appropriate steps to address any situation in which a pathologist or other employee is found to be impaired on the job," added Tangorre. "In the case of the VA pathologist, there were red flags—such as the high rate of errors—that could have been caught earlier in an audit.

"In addition, there were suspicions about how that pathologist was hiding his addiction," she noted. "These facts are lessons for labs that such problems need to be addressed as soon as they're uncovered.

Negligent Retention Claim

"A plaintiff attorney could bring a claim of negligent retention or medical malpractice against the whole entity," Tangorre advised. "Such legal claims are possible, particularly when a case involves a misdiagnosis, a high error rate, or any action that raises the possibility of a failure to follow standard practices.

"As employers, clinical labs and pathology groups cannot simply bury their heads in the sand and ignore signs of drug and alcohol abuse," she said. "Sometimes, employers turn a blind eye to issues related to job performance.

"We saw something similar in the VA pathologist's case," she added. "Litigants can charge that a lab or AP group has failed to supervise employees properly. Under this theory, the employer has an obligation to supervisor all employees.

"There are times when employers also fail to act on problems stemming from other employment situations, such as sexual harassment, which is not related to this case," she noted. "But, as employers, they need to be aware of such problems, and they need to act to prevent harm to patients and to other employees.

"Sometimes, employers may think they cannot be held responsible if they are unaware of such workplace problems," Tangorre commented. "But that thinking is incorrect. Employers have an obligation to be aware of issues workers face, and they need to have written policies about the steps they will take when such problems become known.

"Once those policies are written, labs need to apply them consistently," she advised. "As employers, clinical laboratories and anatomic pathology groups need to act, because failing to do so can trigger concerns about discrimination or disability.

➤Lab's Obligation to Report

"When your lab has an employee who has an alcohol and substance abuse problem, the lab cannot simply terminate that individual's employment," she noted. "The lab would need to do its due diligence, which means looking into the circumstances of the case to determine if the lab has any reporting requirements in your state. Also, other steps besides firing may

Department of Justice Outlines Facts Leading to P

WHEN IT ANNOUNCED THE SENTENCING OF VETERANS ADMINISTRATION PATHOLOGIST ROBERT MORRIS LEVY IN JANUARY, the federal Department of Justice outlined the facts that led to a plea agreement in the case of involuntary manslaughter and mail fraud in the U.S. District Court in Fayetteville, Arkansas.

In 2005, the **Veterans Health Care System of the Ozarks** hired Levy to serve as the Chief of Pathology and Laboratory Medical Services, a position he held until the VA terminated his employment in 2018.

"In 2015, Levy was interviewed by an administrative fact-finding panel regarding reports that Levy was under the influence of alcohol while on duty," the DOJ said. "Levy denied the allegations. In 2016, Levy appeared to be intoxicated while on duty, and a subsequent drug and alcohol test revealed Levy's blood alcohol content was 0.396.0 mg/dL.

"As a result, the Fayetteville VA summarily suspended Levy's privileges to practice medicine and issued Levy a written notice of removal and revocation of clinical privileges," the DOJ noted. "Levy acknowledged that the pending proposed removal and revocation of clinical privileges was 'due to unprofessional conduct related to high blood alcohol content while on duty,' and in July 2016, Levy voluntarily entered a three-month in-patient treatment program, which he completed in October 2016.

"Toward the end of the treatment program, Levy executed a contract with the **Mississippi Physician Health Program** and the **Mississippi State Board of Medical Licensure** in anticipation of returning to practice medicine at the Fayetteville VA," the DOJ added. "In the contract, Levy agreed to maintain sobriety to ensure his ability to practice medicine with reasonable skill and safety to patients.

"Levy agreed to 'abstain completely from the use of … alcohol and other mood-altering substances' and to submit to random urine or blood drug screens," the department reported. "Noncompliance would potentially subject Levy to loss of his medical license and, in turn, his employment by the Fayetteville VA. Levy returned to work at the Fayetteville VA in October 2016.

be required. That can include counseling, employee monitoring, and random drug screening. There is no one-size-fits-all approach.

"Should a lab ignore a situation where there's a likelihood of criminal action, or if anyone in the lab or group knew about it and management ignored it or turned a blind eye, there could be potential criminal liability," she warned.

"And, depending on how you handle these problems in your lab, there is the potential for civil liability," Tangorre said. "Or, your lab could be joined in a medical malpractice suit that could be brought against a lab professional or a pathologist. Both the individuals involved and the organization itself could face liability in civil and criminal cases.

"Keep in mind that while individuals will be named in civil and criminal cases, there is a belief among plaintiff attorneys that the organization itself has more insurance coverage for medical malpractice cases and more money to pay out in these cases," she commented. "That's why plaintiffs' attorneys would try to bring a case based on the failure of the lab directors or leaders of an AP group to do the oversight that's necessary when an employee has a drug or alcohol problem." **TDR**

Contact Danielle Holley Tangorre at 518-462-5601 or dhtangorre@oalaw.com.

Pathologist Levy's Plea Agreement and Sentencing

"As part of the contract, Levy randomly provided urine specimens and blood samples for drug testing from November 2016 through June 2018," the DOJ wrote. "Each blood sample and urine specimen tested was reported negative for the presence of drugs and alcohol.

"On 12 occasions beginning in June 2017 and continuing through 2018, while Levy was contractually obligated to submit to random drug and alcohol screens, Levy purchased for personal consumption 2-methyl-2-butanol (2M2B), a chemical substance that enables a person to achieve a state of intoxication but is not detectable in routine drug and alcohol testing methodology," the DOJ noted.

"On July 2, 2017, in furtherance of the scheme to defraud, Levy caused a package containing 2M2B to be shipped in interstate commerce from a chemical supply company in Virginia to Levy's residence in Fayetteville, the department said.

"On Feb. 4, 2014, Levy conducted a cursory and rudimentary workup of a biopsy of a tumor in the lymph node of an Air Force veteran and rendered a diagnosis of diffuse large B cell lymphoma," the DOJ said. "The government's evidence would show this diagnosis was incorrect and that Levy's workup prior to finalizing the incorrect diagnosis was cursory and rudimentary. The government's evidence also showed that Levy made a patently false entry in the veteran's medical record by stating that another pathologist agreed with Levy's diagnosis, when in truth and in fact, Levy well knew when he made the false entry in the veteran's medical record that no other pathologist agreed with Levy's diagnosis.

"The evidence also revealed that prior to Levy entering the false diagnosis, another pathologist had written to Levy, urging Levy to perform more diagnostic tests in the case due to the concern that Levy's diagnosis of large B cell lymphoma was wrong," the DOJ wrote.

"The veteran died on July 26, 2014, of small cell carcinoma for which the veteran received no treatment to prolong his life. The veteran was not treated for small cell carcinoma due to Levy's grossly and criminally negligent conduct that demonstrated a wanton and reckless disregard for the veteran's life," the DOJ said.

Legal Update

Hospitals Say New UHC Policy on Lab Network Is Anticompetitive

American Hospital Association asks CMS and FTC to review UnitedHealthcare's new lab-network policy

It's not often that hospital associations will directly oppose the changes that health insurers want to make in how they pay for clinical laboratory tests. But that is now happening with **UnitedHealthcare's** new lab test payment policy that directly reduces what many hospital labs are paid for outreach laboratory test claims.

In February, the **American Hospital Association** (AHA) sent letters to the **Federal Trade Commission** (FTC) and the **Centers for Medicare and Medicaid Services** (CMS). It asked officials at each agency to challenge a new lab network policy from UnitedHealthcare (UHC).

Calling UHC's new Designated Diagnostic Provider (DDP) program anticompetitive, the hospital group said that when the program becomes effective on July 1, it will confuse patients about which clinical labs are included for coverage as "in network" labs, and thus could result in surprise medical bills.

UHC's DDP program is confusing because it proposes to eliminate coverage for diagnostic tests at all freestanding and hospital labs—including those that are in its network—unless the labs go through the process to be designated as a DDP, the letter said. UHC may expand this policy to other types of diagnostic services, according to a published report.

On Feb. 4, the AHA called on CMS' acting administrator Elizabeth Richter to take immediate action to prevent harm to beneficiaries in the Children's Health Insurance Program and in health plans purchased from the federal Health Insurance Marketplace, Medicaid managed care, and Medicare Advantage.

The AHA wrote that UHC's program could eliminate coverage for diagnostic tests at most freestanding and hospital labs while UHC continues to list these labs as being in-network. "This policy would result in substantial confusion among patients about which providers are covered by their health plan, and, as a result, also likely increase the incidence of surprise medical bills that will not be prevented by recent changes in federal law," the letter said.

'Anti-Competitive Conduct'

The AHA made similar arguments in a letter the same day to the FTC's Acting Chairwoman Rebecca Slaughter. In the letter, the hospital group said the DDP is a form of anticompetitive conduct that is "a bait-and-switch coverage policy." Under the DDP program, UHC would eliminate coverage for diagnostic tests at all freestanding and hospital labs, including those in the health plan's network, unless the facilities are established as a DDP, the letter said.

In its earlier coverage of UHC's new policy, The Dark Report noted that UHC appeared to be using the new policy as a way to prevent hospital labs from using inpatient lab test prices when they submit outreach lab test claims to UHC. *(See TDR, "New UnitedHealthcare Policy For Hospital Reference Tests," Mar. 9, 2020.)* TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Even as the nation's clinical laboratories work to expand the number of molecular COVID-19 tests they can perform daily, the demand for such tests is plunging. That's one conclusion in a news story published by the *Associated Press* in recent days. The *AP* illustrated this fact with the situation in Los Angeles County. Reporter Matthew Perrone wrote, "Just five weeks ago, Los Angeles County was conducting more than 350,000 weekly coronavirus tests, including at a massive drive-thru site at Dodger Stadium, as health workers raced to contain the worst COVID-19 hotspot in the U.S. Now, county officials say testing has nearly collapsed. More than 180 government-supported sites are operating at only a third of their capacity."

MORE ON: *Demand for COVID-19 Tests Drops*

The *AP* said that, "U.S. testing hit a peak on Jan. 15, when the country was averaging more than two million tests per day. Since then, the average number of daily tests has fallen more than 28%." This situation has many implications and clinical lab administrators will want to carefully align their lab's COVID-19 testing capacity with changes in demand.

GENETIC VARIATIONS IN MIDDLE EAST POPULATIONS

Recognizing that different regions and different populations will have unique genetic variations, a research team at **Qatar Foundation** (QF) in Quatar recently published what is considered to be the first and largest genetic association study in the Middle East. It can be found in the online, peer-reviewed journal *Nature Communications*. The study identifies genetic associations with 45 clinically relevant traits in the Qatari population. The *Arab American News* wrote, "The research confirms that the existing global dataset of human genomes, which over-represent European populations, does not accurately reveal the genetic architecture of diseases affecting Arab populations in the Middle East. The study serves as a foundation for implementing precision medicine in the region." Arab populations have a long tradition of consanguinity due to socio-cultural factors. That is why knowledge of these genetic variants is expected to help achieve better patient outcomes.

TRANSITIONS

- **Ultivue** of Cambridge, Mass., appointed Mark Rees, PhD, as its Vice President of Corporate Development. Previously, Rees held positions at **StatLab**, **Enzo Life Sciences**, and **Leica Biosystems**.

- **Infinity BiologiX**, of Piscataway, N.J., announced Sameer Kalghatgi, PhD, as its new Senior Director, Laboratory Operations. He formerly held executive positions at **Coriell Institute for Medical Research**, and **EP Technologies**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 22, 2021.

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