Volume XXVIII, Number 15 Monday, November 8, 2021

Specialized Information Publishers Foundation
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EXCLUSIVE

For all CLIA laboratory directors!

Attorney Matthew J. Murer, JD, evaluates pathologist's testimony in Theranos trial, discusses CLIA risks, possible sanctions

(See pages 12-19 inside.)

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

It's Flu Season and COVID-19 Cases Continue

SUBSTANTIAL NUMBERS OF NEW COVID-19 CASES continue to be reported weekly. No one yet understands whether SARS-CoV-2 may disappear at some future date (as did the 1918 influenza pandemic and SARS outbreak in 2003) or whether SARS-CoV-2 will become endemic and stay with us for years.

Meanwhile, the next influenza season has commenced. Since Oct. 1—considered the start of the annual fall/winter flu season—data posted by the federal **Centers for Disease Prevention and Control** (CDC) show that clinical laboratories are reporting about 50 positive flu tests per week for the entire nation. Were those statistics to continue into the winter, it would be the second year in a row where the incidence of influenza stayed considerably below the historical experience in this country.

Clinical laboratories have a major stake in following the number of new cases of both types of respiratory viruses. They are the front line of diagnostic testing. It is essential that they have enough testing supplies and staffing to meet future demand for COVID-19 and influenza tests. This is equally true of the *in vitro* diagnostics (IVD) industry. These companies must supply adequate quantities of collection supplies, transport media, primers, and test kits to support influenza and COVID-19 testing by their clinical laboratory customers.

The additional wild card in this deck is the supply chain. The 200 container ships moored offshore from the Los Angeles and Long Beach harbor complex must wait weeks to unload. Manufacturers and distributors of clinical lab supplies and kits are scrambling to keep their inventories stocked to levels that allow them to meet the demands of their clinical laboratory customers.

For all the players in the clinical laboratory industry, this is a high-stress time without any precedent in the history of modern medicine. Medical labs are uncertain about the demand for COVID-19 and influenza tests at the same time that IVD companies and distributors cannot confidently manage their own supply lines to ensure an adequate flow of product to their lab customers.

If there's good news in all of this, it's that most physicians, hospitals, and other providers are seeing a more regular flow of patients. In turn, that means a steady stream of lab test referrals to clinical labs and pathology groups, helping them bolster their finances during these unpredictable times. TDR

New Lab, Pathology Trends at Exec War College 2021

Success of this conference may help encourage other laboratory associations to schedule live events

CEO SUMMARY: Hundreds of lab leaders traveled to San Antonio last week for the 27th annual Executive War College on Laboratory and Pathology Management. After almost two years of virtual conference and meetings using Zoom, attendees were ready to gather for a live event, complete with speakers, networking, meals, and receptions. Speakers addressed the need for labs to become more proficient at gathering data and using that data to add value for physicians, patients,and payers.

It was a live *Executive War College* for the first time since 2019! Last week, 400 lab executives, managers, and pathologists traveled to San Antonio to attend the conference in what turned out to be a high-energy learning and networking event.

That may be one of the most interesting and relevant outcomes of this year's *Executive War College on Laboratory and Pathology Management*. Attendees were eager to attend the sessions and enthusiastic about the networking opportunities.

"It was obvious that this group of attendees came prepared to fully participate in all the activities of this year's conference," observed Robert L. Michel, Founder of the meeting and Publisher of The Dark Report. "At the same time, all participants respected the need to follow the health and safety protocols for social distancing, use of masks, and daily screening procedures required of everyone each day before they could enter the conference area."

The success of this *Executive War College*—the 27th since its founding in 1996—is a good omen for other lab industry meetings and gatherings. For example, each attendee was screened before entering on all three days and no attendee was flagged as requiring an on-site rapid PCR COVID-19 test before entry.

As clinical laboratory professionals, they understood the need for compliance with **CDC** recommendations at live gatherings and were appreciative of the need to clear the temperature check and related procedures before entering the event each day. Rapid PCR tests were also available for some attendees who required a negative COVID-19 test result before

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

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returning to their hospital or organization after their travel to San Antonio.

Having cleared the safety and screening protocols each day, participants could give their full attention to the sessions and speakers. One primary theme found in a large proportion of the presentations was the importance of having a strategy to collect, store, and analyze data, and use these capabilities to deliver more value to hospitals, physicians, patients, and payers.

Importance of Mastering Data

"This was true whether the session was conducted by a lab manager, consultant, or lab vendor," Michel noted. "On the vendor side, more companies now sell products to their lab customers that use artificial intelligence (AI), machine learning, and other digital technologies to give their products and services more punch for the labs using them.

"A theme common to speakers from lab billing/coding/collection companies is how they are incorporating 'smart' features in their software offerings," he continued. "For example, these AI-powered functions can instantly verify the identity and health insurance coverage of patients upon their arrival at a patient service center. This helps speed the billing and collection of a patient's claim because the information on the claim is more accurate and more complete. This also contributes to cutting the lab's labor cost of billing a claim.

More Use of Digital Tools

"Clinical laboratory administrators speaking at this year's *Executive War College* also described their increasing use of digital tools and computerized analytics solutions," Michel said. "These are often middleware solutions that are used to streamline daily lab operations, help manage lab test utilization in near-real time, and produce timely management reports to support continuous improvement projects in all areas of the laboratory."

One interesting facet of this year's *Executive War College* is that both speakers and attendees wanted to learn what is ahead for healthcare and the clinical laboratory industry. Because of their front-line role in fighting the pandemic, lab executives and pathologists had little interest in hearing presentations about how labs responded to the unprecedented demand for huge volumes of COVID-19 tests. For them, this story was old news.

By contrast, interest was keen in learning more about what is different in healthcare today—compared to the pre-pandemic era. Speakers discussed those changes.

Two healthcare trends accelerated by the pandemic and discussed by some speakers involve increased use of telehealth and more self-testing by consumers in their homes. One dynamic accelerating the adoption of these two trends is the preferences of Millennials.

Millennials Use Telehealth

Millennials—Gen Y—will make up 75% of the workforce by 2025. That's just 25 months away. It is recognized that Millennials are more comfortable seeing their physicians via a telehealth visit, compared to older generations.

Millennials are also one factor in the growing acceptance of consumer self-testing at home. But, as pointed out by Larry Worden, Principal of **IVD Logix, LLC**, in Dallas during his presentation, it is not only the preference of Millennials. The COVID-19 pandemic introduced consumers of all generations to the ease of doing a SARS-COV-2 test in the safety and comfort of their own homes. Worden predicts that the *in vitro* diagnostics (IVD) market has been changed significantly by these aspects of the pandemic.

More broadly as a force for change is the interest more clinical labs and pathology groups have in developing novel testing services that, because they add value, produce new streams of revenue. Many speakers described the mix of testing services they are launching that are expected to generate new streams of revenue. These

Presentation Highlights from Speakers at the 27th Annual Executive War College

LAST WEEK'S *EXECUTIVE WAR COLLEGE* FEATURED 44 SESSIONS AND 52 SPEAKERS OVER TWO DAYS. The unifying theme was "preparing your clinical laboratory and pathology group for post-pandemic success."

Speakers recognized the unusual circumstances of healthcare today. The good news is that the daily number of new cases of COVID-19 has declined substantially from peak levels last January. The troubling news is that—despite the ongoing increase in the number of people vaccinated (or with antibodies from an earlier SARS-CoV-2 infection)—hospitals throughout the United States continue to admit and treat patients with COVID-19 at a worrisome rate.

Recognizing this situation with the pandemic, many speakers noted that their respective parent hospitals and lab organizations were again developing strategies to serve the regular, ongoing needs of patients, physicians, and payers. Collectively, these speakers stated the importance of finding new sources of revenue, as both government and private health plans continue to reduce reimbursement for lab tests and other services.

To illustrate this, Monique Dodd, PharmD, PhC, MLS(ASCP)CM, spoke about how she is working with integrated delivery networks, labs, and physicians in New Mexico in what is one of the nation's first examples of placing pharmacists in a laboratory's patient service centers with the goal of reducing gaps in care and improving patient health.

As patients arrive to provide lab samples, pharmacists meet with them one-on-one to discuss gaps in care, develop a plan of action with the patient, and update prescriptions as appropriate. Dodd is the Manager of Enterprise Clinical Solutions, for **Rhodes Group** in Albuquerque, N.M. She explained that New Mexico is one of a handful of states that has passed medical scope-of-practice laws for specified health conditions that allow pharmacists to diagnose, treat, and monitor patients in the same manner as physicians.

Another opportunity for clinical laboratories to develop a new source of revenue is to approach self-insured employers with proposals that incorporate lab test data in ways that improve the health and workplace productivity of their employees. That was one recommendation made by Kristine Bordenave, MD, FACP, Strategic Consultant, Precision Medicine, **KKBordenave Consulting Group**, based in Chicago.

Bordenave encouraged clinical lab leaders to approach the health benefits administrators at self-insured companies and demonstrate how a well-designed program of lab testing could solve a major problem for employers: presenteeism.

This was a new term for the audience. Bordenave defined presenteeism as productivity loss resulting from real health problems. As a practicing physician, earlier in her career Bordenave had worked with employers and her patients to address health conditions that reduced the productivity of employees who were on the job.

One example caught the full attention of the audience. Bordenave said that multiple published studies showed that an individual with elevated levels of A1c above 7.0 is 20% less productive. She used this example to illustrate how a clinical laboratory could work with a self-insured employer to identify employees with elevated A1c scores, then help these employees and their care teams to bring the A1c score into the normal range, thus improving daily productivity of those workers.

new testing services invariably incorporate AI or machine-learning technologies that assess large pools of data to create intelligence that is actionable by physicians and payers.

Test Utilization, Care Gaps

"What we heard from numerous speakers at this *Executive War College* is that innovative lab organizations are building their clinical, operational, and financial strategies around intense use of data," Michel observed. "Two of the most common initiatives labs are developing specifically to add value involve managing lab test utilization and helping physicians and payers identify and close gaps in the care of individual patients.

"To achieve these goals, the lab needs do two things," he said. "First, the lab must gain access to additional data beyond the lab test results it has always produced and stored. For instance, to help close gaps in care, the lab wants access to the EHRs of the parent hospital and/or referring physicians so as to gather ICD-10 codes and other relevant information about individual patients.

"Second, the lab must have data analysis tools that can work with these expanded sets of data," Michel stated. "The data analysis tools identify opportunities to improve lab test utilization and to identify patients with care gaps, particularly those patients at high risk for an acute event."

Recordings of All Speakers

All the sessions at this *Executive War College* were recorded. These recordings include the powerpoints used by each speaker. Lab leaders who were unable to attend in person can use these recordings to catch up on all the innovations and insights shared at the conference. These recordings can also be shared with team members as part of strategic planning activities. Information about the recordings and how to order can be found at *www.executivewarcollege.com*. TDR

Michigan Health Info Network Helps to Develop Use Cases

ONE TECHNIQUE THAT HELPED the **Michigan Health Information Network** (MiHIN) encourage collaboration and exchange of data across different organizations is the "use case" approach.

During his presentation, MiHIN's Executive Director Tim Pletcher, DHA, explained that MiHIN identifies a specific function that MiHIN could provide that would be valuable to a broad range of stakeholders. It then organizes working teams to define the use case, identify needs, and begin developing a solution.

At one MiHIN-sponsored "connectathon," MiHIN reported that attendees developed solutions incorporating HL7 "to streamline the data flow from clinical settings to payers to facilitate quality measurement and care coordination." Solutions presented at the end of this connectathon included:

- An A1c data exchange solution using **Salesforce** that enables patients to receive discounts on their health insurance by regularly checking their A1c level and working to keep it within the normal parameters.
- A mobile medication reconciliation tool for health insurance members to log in to confirm the medications they are taking following a hospital discharge.
- An emergency department tool that measures HEDIS (Healthcare Effectiveness Data and Information Set) and identifies potential unnecessary visits to the ED.
- An application that reduces the number of a patient's hospital admissions, while improving quality measure scores by calculating risk measures and notating these in the electronic health record to be addressed at the patient's next office appointment.

Physician Salary Survey Ranks Pathology at 14th

Experts in pathologist compensation say it is a rosy financial picture for new graduates

CEO SUMMARY: In its 28th Annual Physician Compensation Survey, Modern Healthcare put pathology income at number 14 of 23 medical specialties. It reported the range of pathologist compensation during 2020 at $287,000 to $409,528, with the salary midpoint at $384,264. However, that's not the full story, said two experts in pathology recruitment and compensation arrangements. They pointed out the Modern Healthcare survey did not account for experience or different practice settings.

Demand for pathologists is at its highest level in 20 years. Yet one annual national survey of physician income ranks pathology at number 14 of 23 medical specialties.

This data came from *Modern Healthcare's* 28th Annual Physician Compensation Survey. Published in July, *Modern Healthcare* reported that pathologist compensation ranged from $287,000 to $409,528.

Based on the survey's pathology compensation range, the midpoint for a pathologist salary is $348,264. Pathologists, on average, make $68,724 less than the average paid to physicians in 2020. *(See sidebar on page eight for the complete list of medical specialties included in the survey.)*

Overall, doctors' compensation "plateaued" in 2020, increasing about 0.5% in 2020 to $416,966, *Modern Healthcare's* survey said. Pre-pandemic, however, physicians got on average a 2.7% salary boost in 2019 over 2018, the survey added.

Modern Healthcare's report analyzed salary data from 10 consultancies, physician search firms, and associations. The highest reported compensation for pathologists of $409,528 was shared by **Sullivan-Cotter**, a Chicago consulting firm, while the lowest of $287,000 came from **Merritt Hawkins**, a Dallas-based physician search firm.

When showed the *Modern Health* physician compensation data, experts in pathologist recruitment, retention, and compensation advised caution in how pathologists and pathology practice managers use that information. They recommended this report only be as a baseline that provides a general overview of physicians' salaries.

Not a 'Holy Grail'

The experts pointed out a proper compensation analysis would provide more complete data about:

- The survey sample size of pathologists;
- What compensation is offered by different types of employers (such as hospitals, private practices, commercial labs, and academic institutions); and,
- Productivity in medical laboratories involved in the survey.

"The survey provides a general overview of the market for physicians and

relative differences in how individual physician specialties are paid," said Rich Cornell, President, **Santé Consulting**, a pathologist and laboratory medicine recruiting firm based in St. Louis. "But it is not 100% representative of the profession because the subset of pathologists reporting data may be quite small."

Cornell's opinion was mirrored by another expert in pathology group management and compensation arrangements. "My feeling is you have to make the distinction in these national surveys between those pathologists that are lumped together, those that are broken out by private practice, and those who are salaried by the hospital," noted Robert Tessier, Founder and Principal, **HBP Services**, Woodbridge, Conn., and Panelist, **Panel of National Pathology Leaders** (PNPL). At HBP, which stands for Hospital-Based Physician, Tessier's responsibilities include advising hospitals on their contracts with pathology groups.

"There is a big gap in the range of annual pathologist compensation reported by *Modern Healthcare*. It goes from a low of $287,000 to a high of $498,528," Cornell noted. "There are many variables within that gap. Someone in private practice for 10 years may make $409,000 and someone in practice for three years may make $287,000. Pathology practice administrators should not be using this survey data as a 'Holy Grail,'" Cornell said.

Variables in Pathologists' Pay

Tessier shared key data from a **Pinnacle Healthcare Consulting** study commissioned for HBP. Unlike the *Modern Healthcare* survey, the Pinnacle study focused on pathologist productivity and compensation. Findings varied based on employer type—either private practice or hospital-employed—and work relative value units (wRVUs).

For example, the Pinnacle study determined that median compensation in 2019 for anatomic and clinical pathologists employed in private practice was $375,997 as compared to $363,528 for those employed by hospital laboratories. However, the wRVUs per FTE, according to this study, were a median of 6,614 in private practices and 6,110 in the hospitals.

Private vs. Hospital Settings

"One obvious conclusion from these data are that a pathologist in private practice is paid slightly more [than in a hospital setting], but doing more work," Tessier observed. He also noted a trend for salary surveys, generally, to be more representative of hospital-employed pathologists over private pathology practices. "Those (with hospital-based data provided by **American Medical Group Association**, for example) are the ones who dominate surveys and drag the salaries down," he explained.

"The key point here is that a study of pathologist compensation must be put in the context of productivity," Tessier continued. "Further, many physician compensation studies fail to include the value of fringe benefits, payroll taxes, and coverage for malpractice insurance.

"Again, it is important to recognize the difference in practice settings," he added. "Most hospitals quote fringe benefits worth 25% of compensation. By contrast, evaluations of compensation from private practice groups show fringe benefits as representing approximately 17% to 18% of compensation."

Other variables affecting pathologists' compensation include individual experience and subspecialty, according to Cornell. The highest compensation goes to dermapathologist at $300,000, followed by molecular pathologist at $275,000, and pathologists specializing in gastroenterology or genitourinary at about $275,000, said Cornell, who based these numbers on his work with employers.

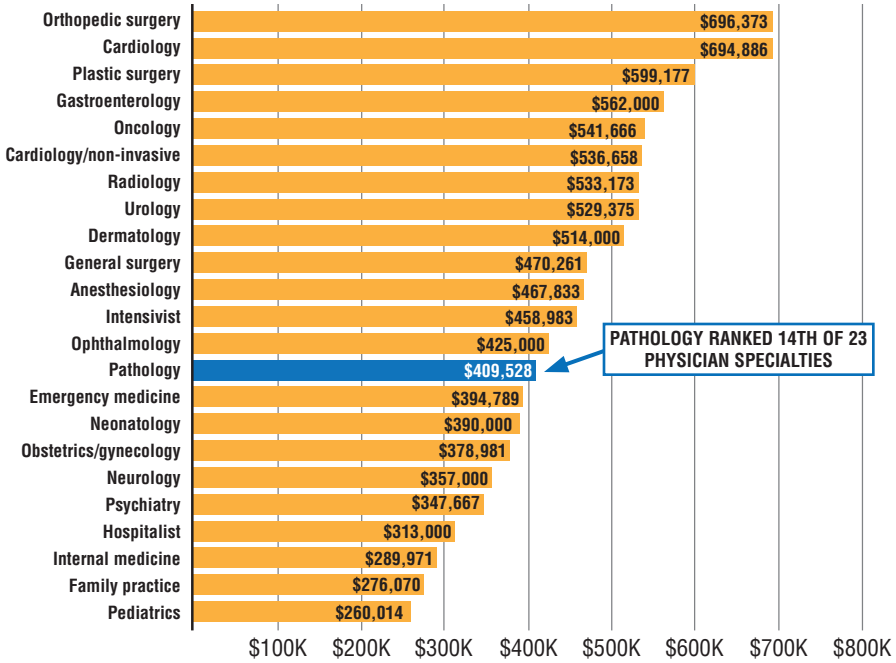
"The above estimates are for graduating fellows with no experience and entering into the private sector," he noted. "Pathologist compensation in academic settings is, of course, different."

Modern Healthcare's Physician Salary Survey Ranks Pathology at 14th of 23 Specialties

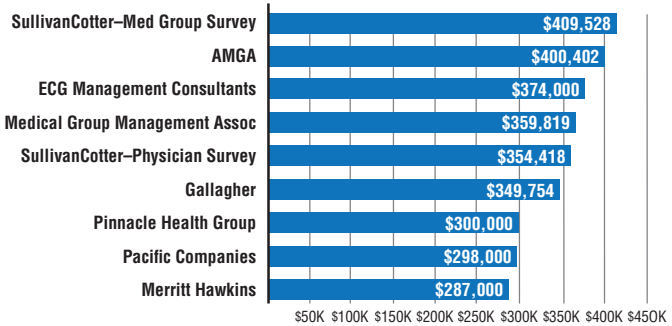
EACH YEAR, *MODERN HEALTHCARE* CONDUCTS A PHYSICIAN COMPENSATION SURVEY. This year, it combined data gathered by 10 different associations, consulting firms, and physician recruitment companies on physician compensation in 2020. The survey recognized 23 different medical specialties with pathology ranking 14th on the list. *Modern Healthcare* determined that "the average of the reported median compensation" across all specialties in 2020 was $416,966, which is slightly above the $409,538 reported for pathology.

Annual Compensation by Specialty for 2020

(Income is based on the average of all sources reported for each physician specialty.)



Pathology Compensation for 2020



Source: Modern Healthcare, Survey: Physician Compensation, July 5, 2021.

The good news is that pathology salaries are up by about 10% in 2021 after a tough-go in 2020, according to Cornell.

"We see overall increases in starting compensation over 2019 of up to 10%," he noted. "Further, bonus structures this year are more conservative because of the financial disruptions experienced by pathology groups last year. If there is a bonus, it is not guaranteed.

Hiring Freeze in 2020

"When the pandemic first hit, most healthcare systems, pathology groups, academic centers and labs enacted a hiring freeze. And they made adjustments in compensation, not knowing when volumes would come back," Cornell added.

"It was not until the third quarter of 2020 when testing volumes rose and demand increased as more patients went to see their doctors," he recalled. "That demand is still high and is fueling a competitive compensation model that's driving up pathologist salaries."

This demand, he said, is greater than the number of pathologists who are completing fellowships or who are actively looking for jobs. *(See TDR, "Record 600 Pathologist Jobs Open Nationwide," Aug. 16, 2021.)*

"This results in a more competitive hiring market across all of the employment sectors that utilize pathology professional services," Cornell commented. "What these organizations paid pre-COVID is not the norm post-COVID, as there's a 5% to 10% or more increase across the board—from junior pathologists to senior pathologists in all regions and subspecialties across the country."

Not only are employers paying more to recruit a new pathologist, they are also boosting pay of recently-hired employees to bring them to parity with each other, Cornell said.

"If a pathology group does not bring a person they hired last year to the same level of their new hires this year, they risk an unhappy employee within the group because of 'water cooler discussions' about salaries that inevitably happen," Cornell warned.

Pathology has been impacted by other factors beyond the pandemic. The Dark Report recently explored the issue of an aging pathologist workforce, even more dire in light of residency training programs with fewer pathologists. *(See TDR, "Record 600 Pathologist Jobs Open Nationwide," August 16, 2021.)*

"The number of pathologists we are seeing retire is the highest I have ever seen in 30 years of doing this. And that cliff is not going to plateau, in my opinion, for the next couple of years," Cornell said.

"Residency slots are not being filled, medical students who choose pathology as their field enrollment is down, and over a period of time it is going to impact lab workflows," Cornell added.

An anatomic pathologist signing out 4,000 surgical cases a year may need to sign out 5,000 cases a year until things start stabilizing and catching up, Cornell said, noting that digital pathology (DP) can change that. "We are not there yet. Some pathology groups are doing a good job in digital volume. Also, academic physicians are laser-focused on educating medical students on pathology as a career."

Other Hiring Trends

Still, pathology may have to brush off a so-so image. "Pathology, compared to other professions, is not as glamorous," Cornell observed. "Aspiring medical students go into medicine to save lives and have patient interactions.

"And for many years the perception (held by medical students) was there are no jobs in pathology. Now, it's a hot job market, with great quality of life, limited call, great work-life balance. Pathology, unlike many other specialties, is involved with every single organ system there is." TDR

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Legal Update

Third CLIA Lab Director Testifies in Trial of Elizabeth Holmes

This third individual was added to the Theranos CLIA license at the same time as a dermatologist

Something new and unexpected seems to pop up each day in testimony taken during the federal criminal trial of Elizabeth Holmes, founder and ex-CEO of **Theranos**, the defunct and discredited clinical laboratory company.

Last Thursday, a third individual who served as CLIA laboratory director at Theranos was called to the witness stand. It was Lynette Sawyer. *The Wall Street Journal* reported, "Dr. Sawyer's name was added to Theranos' lab license, as its co-director, in late 2014. Dr. Sawyer testified that she has a doctorate degree in public health and experience working in public health, including on HIV research, and was the lab director at a number of biotechnology companies."

According to testimony, Sawyer was placed at Theranos by **Laboratory Consulting Services** and her name was added to the CLIA license (which already listed the the name of Sunil Dhawan, MD, who earlier testified that he was Ramesh "Sunny" Balwani's dermatologist). Balwani is the ex-COO of Theranos who was also Holmes' boyfriend at the time. He is charged with nine counts of wire fraud and two counts of conspiracy to commit wire fraud. He will be tried separately.

Sawyer testified that this CLIA lab directorship was to be a temporary job lasting about three months. From testimony given by Sawyer and Dhawan, neither seemed to be aware that the other had been hired by Theranos for the same position and was serving at the same time.

In its coverage of her testimony, *Ars Technica* wrote, "Sawyer said she was sent documents via Docusign that covered standard operating procedures on 'ordinary, FDA-approved assays' performed on standard lab equipment. She never visited the lab, wasn't invited to, and didn't review data from Theranos' proprietary devices. In fact, Sawyer said she didn't even know that Theranos was using its own devices in the government-regulated lab. Despite being hired for only a few months, Theranos kept her on until she left of her own accord after about six months. 'As that time wore on and on, I grew increasingly uncomfortable in the way things were done,' she said. 'I was very uncomfortable with the lack of clarity about the lab.'"

Two CLIA Lab Directors

As the court record shows, following the resignation of Adam Rosendorff, MD, a board-certified clinical pathologist who had been the Theranos lab director from April 2013 through December 2014, Theranos hired two individuals as CLIA lab directors who seldom or never visited the lab and testified that their primary activities were to sign documents.

In the story that follows on pages 12-19, The Dark Report presents an interview with an attorney experienced in advising CLIA lab directors. Using questions asked by the prosecution and the defense of Rosendorff's actions, he analyzes different situations that can put CLIA lab directors at risk of non-compliance. TDR

Matthew J. Murer, JD

CEO SUMMARY: Elizabeth Holmes' criminal trial is a case study for clinical lab directors in how not to run a medical lab, according to an attorney with 30 years of advising labs on CLIA-enforcement issues. During the trial, federal prosecutors cited the Clinical Laboratory Improvement Amendments multiple times. In each instance, the DOJ has presented Holmes in an unfavorable light. The defense, on the other hand, has used the CLIA regulations to shift blame away from Holmes and onto the laboratory director and lab staff, the attorney said.

Pathologist testifies for days during trial of ex-Theranos CEO Elizabeth Holmes

CLIA Lab Director Testimony Shows Risks to Pathologists

FIRST OF TWO PARTS

As the jury trial of **Theranos** Founder Elizabeth Holmes continues, clinical laboratory directors are getting a series of significant lessons about the importance of following the federal regulations of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

Pathologists who hold the position of laboratory director of a CLIA-certified laboratory understand they can be held accountable for violations of federal and state laws. In cases involving patient harm from inaccurate lab-reported test results, the pathologist can face career-ending sanctions from federal regulators. Also, patients have named CLIA lab directors in medical malpractice lawsuits as a result of inaccurate lab-reported test results.

Federal Criminal Charges

In the criminal fraud trial known as United States vs. Elizabeth Holmes, Holmes faces 10 counts of wire fraud and two counts of conspiracy to commit wire fraud in the **U.S. District Court for the Northern District of California** in San Jose.

Understanding how to comply with CLIA and how to manage risk makes the recent testimony from the pathologist who served as the CLIA laboratory director for Theranos in the federal trial of Holmes a rare and significant teaching moment for all CLIA lab directors.

Federal prosecutors and defense attorneys kept this pathologist, Adam Rosendorff, MD, Theranos' former pathologist, on the witness stand for days. Under questioning, Rosendorff explained how he managed compliance with CLIA requirements and how he responded to the directives from Holmes and Theranos management that—in a number of instances—conflicted directly with his responsibilities as defined under CLIA.

Rosendorff's testimony provides real-world examples of situations in which the lab's owners and executives have told the CLIA lab director to operate the lab in ways that violate CLIA regulations and may even put patients at risk of harm.

Moreover, as a witness for the prosecution, Rosendorff's experience at Theranos has added a new twist to the unfolding story involving Holmes and Theranos. That is because the federal CLIA regulations have become a proxy issue and a hammer for prosecutors since the trial began on Sept. 8, according to attorney Matthew J. Murer, a partner with Chicago law firm **Polsinelli**.

Murer has almost 30 years of experience as a lawyer assisting clinical laboratories facing federal and state charges of violating CLIA. He also is the firm's Health Care Department Chair.

"What's interesting about this case is that the federal **Department of Justice** (DOJ) has claimed that Holmes and Theranos defrauded investors," Murer said in an interview with The Dark Report. "The government's argument is that Theranos defrauded those who invested in the lab-testing company.

CLIA Regulations

"The DOJ lawyers are arguing that Holmes and the company knew they had problems with their testing equipment and that they hid these issues and intentionally promoted their testing and their equipment as being reliable to investors," Murer explained. "To bolster their case that Holmes and the company knew about the problems, the government lawyers are relying heavily on the CLIA regulations. In that way, CLIA has become a key part of their fraud case."

Compliance with CLIA Regs

To make their case, both the prosecution and the defense in the Holmes trial have raised questions about how Theranos operated. The government has attempted to show the jury the various ways that the lab's employees failed to follow the federal CLIA regulations.

"Federal prosecutors are attempting to show that Theranos' employees knew that something was wrong and that they lied about that," Murer said. "To make that case, the government has relied on the lab's CLIA

issues to demonstrate that Holmes knew the lab was committing fraud.

"At the same time, the defense has tried to use CLIA to argue that Holmes is not to blame for the company's problems," Murer continued. "The defense attorneys have attempted to shift culpability away from Holmes and to the lab's other employees, particularly the laboratory directors Theranos employed.

Reliance on Lab Director

"This strategy from Holmes' defense attorneys is significant because I expect that they will ultimately argue that Holmes was relying on the lab staff, and more importantly the lab director, to correct any issues and to ensure that the lab testing was being done correctly," he noted.

The issue of Rosendorff's responsibility is important because under CLIA, the laboratory director is ultimately responsible for the lab's operations as well as the accuracy of its testing. And while the lab director is responsible for informing management about CLIA violations, the ultimate responsibility for the accuracy of the testing rests with the lab director and not management under CLIA.

So, should the lab director resign if those warnings fail to produce changes? This question will be instructive for all clinical laboratory directors because it illustrates the dilemma of when a lab director should resign.

"At its heart, CLIA provides a full set of detailed operational and quality requirements for all clinical laboratories, and in that way, the CLIA regulations provide a framework for both compliance and liability," Murer explained. "Under CLIA, all labs are required by federal law to comply with these specific requirements.

"Then, if the pathologist serving as lab director doesn't follow the requirements of CLIA, an argument can be made that there is liability for the lab and the lab director." he noted. "The CLIA regulations support potential liability in all three possible ways. One is regulatory liability, the second is civil liability, and the third is criminal liability, which is what Holmes and Theranos are facing.

"Another reason CLIA is so important in this trial is that there hasn't been any significant evidence of widespread patient harm," he explained. "Therefore, there are no claims of injury and there is no liability for patient deaths.

"Without the CLIA compliance issues, the defense might try to argue that the issues with the testing were so minor that they wouldn't have had an impact on the investors' decision to invest," Murer commented. "The DOJ is going to highlight to jurors that CMS felt so strongly about Theranos' CLIA compliance that it revoked the lab's CLIA certificate. It will be difficult for the defense to argue that this action wouldn't have impacted whether investors decided to invest.

Matthew J. Murer, JD

➤ "...the defense has tried to use CLIA to argue that Holmes is not to blame for the company's problems. The defense attorneys have attempted to shift culpability away from Holmes and to the lab's other employees, particularly the laboratory directors Theranos employed."

"Patient harm claims are still possible when clinical laboratory tests are involved and those lab tests were not performed properly," Murer added. "When that happens, physicians may use those improper lab test results to guide their treatment decisions and those decisions may negatively affect patient outcomes.

"In addition, we should note that, while there were some cases of patient harm that have been reported in the press and in other public sources that the prosecution could cite, they weren't able to present strong statistical data on the overall reliability of the testing because the govern-

ment was unable to access Theranos' lab testing database prior to the trial. And there appears to be no way for that data to be recovered," Murer commented.

"Because the DOJ was unable to access that database, the prosecution cannot parse through all those test results and create a chart showing how many tests Theranos ran and how many were accurate versus inaccurate," Murer stated. "The fact that the DOJ couldn't access that database was a significant loss for the prosecution.

"Additionally, the defense has argued that without this data there should be no mention of the lab test data during the trial," he added. "Holmes' defense team asked the judge to leave out any discussion of that lab test data. They asserted that mentioning the data would be unfair to the defense because any discussion of inaccurate test results would be anecdotal without being able to have all the data to contextualize what happened. Without that data, it's too prejudicial even to bring up the existence of that data, the defense argued."

Lab Director is Responsible

This background on the case is important for lab directors because, as Murer pointed out, CMS has made it clear that the lab director is ultimately responsible for everything that happens in a clinical laboratory under CLIA.

"In fact, CMS has published a document known as Brochure Number Seven, titled, 'Lab Director,'" Murer commented. "This document is a very good starting point for any lab director because it explains the lab director's full responsibilities." *(See sidebar, "CMS Spells Out Lab Director's Responsibilities," page 19.)*

Given that CLIA has been at the heart of the case the DOJ has presented to date, the editors of THE DARK REPORT asked Murer to put into context some of the issues raised in the federal case related to CLIA regulations during the Holmes trial. The editors highlighted eight questions that lawyers for the government and for Theranos have pursued while questioning the former CLIA lab director and other witnesses. Murer was asked to address each one. *(See sidebar above, "Eight Questions for a CLIA Lawyer.")*

Eight Questions for a CLIA Lawyer

THE ONGOING FEDERAL FRAUD TRIAL OF ELIZABETH HOLMES, founder and ex-CEO of now defunct blood-testing company Theranos, has raised important questions for all clinical lab directors. Here are eight of the most pressing questions as the trial continues in the U.S. District Court for the Northern District of California, in San Jose.

We address the first four questions in this intelligence briefing and will address the other questions in a future issue.

1. Why is proficiency testing so important in this fraud trial?
2. Who is responsible when a lab fails to use analyzers correctly?
3. Who is responsible when a lab produces inaccurate test results?
4. What obligation did the laboratory director have to issue warnings to management?
5. What obligations did the lab director have to notify regulators?
6. What problems arose over the CLIA lab director of record?
7. What possible punitive actions does Elizabeth Holmes face?
8. Is it okay for lab directors to send company materials to their private email address?

QUESTION 1: Why Is Proficiency Testing So Important in This Fraud Trial?

This question is significant because on Oct. 1, Rosendorff, who formerly served as lab director at Theranos, testified that the company's proprietary finger-stick technology went through a set of profi-

ciency-testing (PT) steps that differ from what commercial labs use, according to *The Wall Street Journal* (*WSJ*). For the Theranos devices, Rosendorff testified that he had approved an alternative assessment procedure, known as an AAP, the newspaper added.

Matthew J. Murer, JD

➤ "PT testing and the allegations about cherry-picking data are so important in this trial because these issues go right back to what CMS says about all lab directors' responsibilities. Lab directors have to ensure that the lab has a quality-systems approach and that it provides accurate and reliable patient test results."

In September, Erika Cheung, a whistleblower and clinical laboratory scientist at Theranos from October 2013 through April 2014, testified that the Theranos lab manual did not say how outlier test results should be identified. To get the company's proprietary blood-testing devices to pass quality checks, employees could decide which results to keep, essentially cherry-picking data, she testified. Also, Cheung testified that Theranos did not follow the lab's proficiency-testing steps.

➤Lab Director Resigns

Cheung and Rosendorff resigned from Theranos over concerns about the company's testing technology, the *WSJ* reported.

"PT testing and the allegations about cherry-picking data are so important in this trial because these issues go right back to what CMS says about all lab directors' responsibilities," Murer explained. "Lab directors have to ensure that the lab has a quality-systems approach and that it provides accurate and reliable patient test results. CMS takes those responsibilities very seriously, as we have seen many times when CMS has repeatedly quoted that language in lab deficiency reports.

"Essentially, CMS is saying that lab directors need to follow those directives at all times, when doing PT, when implementing quality control, and when monitoring quality-control efforts to ensure that all steps are followed properly at all the times," he said. "If PT testing or quality control are not done correctly, then the lab director needs to take corrective action. CMS has published a brochure explaining how labs should conduct PT. It's called 'Proficiency Testing and PT Referrals Do's and Don'ts.'

"Under CLIA, PT testing is unusual because if the lab fails to follow the proper procedure when testing, it creates almost automatic liability that could trigger revocation of a lab's license," Murer warned. "For all labs, CLIA PT regulations are designed to confirm the accuracy of all testing equipment and all testing procedures.

➤Rules to Prevent PT Cheating

"The CLIA regulations include rules meant to prevent cheating in how PT is done," he noted. "Those rules prevent labs from sharing PT specimens or sharing any information about PT with other labs.

"It's not unusual to hear lab staff complain about how strict CMS can be about the CLIA rules, but when Congress passed the CLIA amendments, Congress was specific about how CMS should write those rules," Murer noted. "That's why the CLIA rules are incredibly strict, and that's why there is very little wiggle room when it comes to CLIA violations relating to PT testing.

"In addition, the CLIA rules address what labs must do when running an unregulated test to demonstrate the accuracy of the testing. Essentially, the lab needs to show its homework," he added. "By that, CMS means the lab needs to demonstrate to a high degree of statistical reliability that the lab staff has established a process to confirm the validity of each test. Once you

know that, you can see why cherry-picking lab test results is so concerning.

"Cherry-picking data is not allowed under any circumstances for two reasons," Murer continued. "First, a laboratory doesn't have a legitimate test if it's cherry-picking the results. And, if it's cherry-picking results, it doesn't have a legitimate process for validating its test. Second, that cherry-picking of data is arguably a deceptive practice or fraud, which is not allowed, for obvious reasons."

QUESTION 2:
Who Is Responsible When Lab Fails to Use Analyzers Correctly?

This question is significant because it shows how Holmes' defense team attempted to shift blame away from Holmes and instead implicate Rosendorff, who, as the CLIA lab director, was legally responsible under CLIA for many of the problems reported at Theranos, Murer explained.

Among those problems were inaccurate test results, the improper use of FDA-cleared lab analyzers, failure to perform PT testing properly, and the failure to report the lab's problems to CLIA regulators.

During the trial, witnesses testified that lab staff was diluting fingerstick drops of blood to make enough liquid so that each sample could be run on **Siemens** instruments used in the Theranos lab. This dilution was done in violation of the FDA's protocols.

Another reason this question is significant is that Siemens' service technicians knew the instruments were being used in this fashion, but there is no public record that Siemens notified officials at CMS or at the FDA about this improper use, according to press reports. On this issue, lab directors will want to know: What should the service technicians have done in this case and what responsibility does the CLIA lab director have when an instrument is run in a manner contrary to the FDA clearance?

"The question of allegedly diluting specimens goes to the heart of the DOJ's case," Murer commented. "If, as the government has alleged, Theranos was diluting patient samples, then they're changing the testing protocol, which can be a serious CLIA violation. Whenever a sample is handled in a way that deviates from the manufacturer's instructions, and the lab can no longer verify the accuracy of testing on that analyzer, there is going to be a CLIA compliance issue.

"That's a problem that will probably create some form of liability for the lab director or for the lab's owners or both," he said. "To answer the question, I would say the lab staff is responsible for reporting failures to use lab analyzers correctly to the lab director, and the lab director would need to report that failure to lab ownership and management.

"But the problem at Theranos is that it's possible that the lab staff, the lab director, and the lab owners all knew they were violating CLIA by diluting specimens. I don't know that, but it's possible," Murer speculated.

Liability of an IVD Vendor?

"That said, it's still a far cry from saying that Siemens or any of its technicians would have any liability if they were aware that Theranos was diluting specimens," he added. "I'm not aware that a service technician would have any legal obligation to report what he or she saw in the lab.

"Of course, every lab has FDA reporting requirements, but those requirements apply primarily to the lab itself, particularly the lab director," he added. "If a manufacturer uncovers a problem with its product (e.g., it's defective), it should be reported. But that's different from what is alleged at Theranos.

"I suspect that the defense raised the issue about Siemens' service technicians in an attempt to blame somebody else," he noted. "If so, that's a red herring that the defense has introduced hoping that the

jury will blame the technician rather than Holmes or Theranos.

"But, again, what's not at issue in this case is whether a company that makes specimen analyzers is at fault," he cautioned. "The issue in this case is whether the lab's owners knew the test results were inaccurate, and then did they lie to investors about it in order to get them to invest?"

➤➤QUESTION 3:
Who Is Responsible When Lab Produces Inaccurate Test Results?

This question follows the previous one because, once a lab knows its results are inaccurate, the lab director is responsible for reporting any inaccurate results in accordance with the lab's policies, and for taking action to correct the testing or cease testing, Murer explained. In the Theranos case, however, this question goes deeper than that.

"Who's responsible for reporting inaccurate test results is one of the most interesting questions in this case," Murer noted. "In the testimony, we've heard that Holmes and the former President and COO of Theranos, Ramesh 'Sunny' Balwani, opposed or negated Rosendorff's recommendations.

➤CLIA Duties Not Fulfilled

"But then, the defense presented evidence from witnesses showing that Rosendorff did not fulfill his duties under CLIA," he added. "The defense even raised the issue that Rosendorff should be held responsible for inaccurate lab results and that those inaccurate results put patients at risk of harm. In addition, the defense suggested that Rosendorff was responsible for the lab's failure to perform proficiency testing properly and for the failure to follow federal and state lab regulations. In my opinion, this is just another red herring. While Rosendorf may be responsible for the operation of the lab under CLIA, Theranos and Holmes had a responsibility to be honest with investors. Those are two separate issues."

➤➤QUESTION 4:
What Obligation Does Lab Director Have to Issue Warnings to Lab Management?

After Murer established that Rosendorff was responsible to correct any problems in the lab that led to inaccurate test results, the next question involved Rosendorff's responsibility to warn management. The defense argument—that Rosendorff continued as laboratory director but should have notified his superiors about the lab's problems—is significant for all lab directors because it illustrates the dilemma of when should a lab director resign.

Matthew J. Murer, JD

➤ "...that raises the question of what obligation does Rosendorff have if he informed management and management failed to act? Should he have resigned?"

"Under CLIA, we know that the CLIA lab director has specific responsibilities to ensure that the lab produces accurate test results in a fully-compliant manner," he said. "But then, that raises the question of what obligation does Rosendorff have if he informed management and management failed to act? Should he have resigned?

"The answer is that the CLIA regulations are very clear," Murer noted. "Over the years, we've seen a number of cases in which lab directors have raised issues with management and said they shouldn't be held liable because they brought those issues to the attention of the labs' owners.

"Other lab directors have claimed that they were not involved in day-to-day operations, saying they didn't have any knowledge about what was going on in the lab," he explained. "In those cases, the

lab directors were wrong. Everything that goes on in the lab is the ultimate responsibility of the lab director under CLIA.

"In some cases, lab directors have argued that they knew about and reported the problems in the lab to management and/or ownership—including issues with inaccurate test results or failure to follow the PT rules," Murer recounted from his experience. "We also know that the labs' owners in some of those cases decided to override the lab director's authority. But administrative law judges have consistently found that the buck stops with the lab director.

"The ultimate responsibility for all operations in clinical labs resides with the lab director who is fully responsible for the quality of all lab testing and the accuracy of all test results," he added.

"So, what could Rosendorff do in that situation?" Murer asked. "In my opinion, as a lawyer who has represented labs and lab directors in these cases, when a lab director believes the lab is not being run properly, and he or she cannot get ownership to agree that the lab is not being run properly, those lab directors should resign. They should walk away because they have that responsibility.

Ultimate Responsibility

"The title of laboratory director is not an honorific," he emphasized. "It is a title that under CLIA carries the ultimate responsibility for the lab. Some laboratory directors have failed to understand their responsibility or they chose to ignore those responsibilities.

"I've seen many instances where lab directors did not fully understand that CMS would hold them personally responsible for failures in the lab—whether the failures are PT discrepancies, inaccurate lab test results, or failure to provide adequate quality control," he warned.

"As we've seen in other lab cases, CMS can bar a lab director from acting in another position as lab director for two years," he added. "When they're barred for two years, laboratory directors will complain that the penalty is Draconian. But whether they like or not, it's still the penalty. They can't shift blame to management or to the lab staff.

"The lab director is fully responsible," he concluded. "If they can't get the lab to a place where it needs to be, then they should resign and find another job."

Part two of the interview with Murer will address his insights about the last four of the eight questions about the responsibilities of a CLIA laboratory director. These were issues raised during the Theranos trial by the federal prosecutors and defense attorneys that centered on the responsibilities of pathologists who serve as the laboratory director of a CLIA-certified lab. TDR

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CMS Spells out Lab Directors' Responsibilities

IN CMS BROCHURE SEVEN, titled, "Lab Director," the federal **Centers for Medicare and Medicaid Services** outlined the responsibilities of each clinical laboratory director. Using a question-and-answer format, the brochure answers the first question, "What Are My Overall Responsibilities?"

"As laboratory director, you are responsible for the overall operation and administration of the laboratory, including the employment of competent qualified personnel," the brochure explains. "Even though you have the option to delegate some of your responsibilities, you remain ultimately responsible and must ensure that all the duties are properly performed and applicable CLIA regulations are met. It is your responsibility to ensure that your laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results."

Post-COVID: Repurposing Excess PCR Instruments

➤Question confronting many labs today: What to do with multiple automated PCR instruments?

➤➤CEO SUMMARY: Currently, there are hospital, health system, and independent clinical laboratories that have between two and five different PCR testing platforms. These analyzers were acquired during the pandemic as one way to increase the daily number of SARS-CoV-2 their labs could perform. Today, with the demand for COVID-19 PCR tests dropping steadily, these same labs now must decide which systems to keep active and which systems to take out of daily service.

With the pandemic easing, clinical laboratories across the nation are confronted with a common problem: what to do with all the PCR (polymerase chain reaction) analyzers they bought to meet the urgent demand for huge numbers of molecular COVID-19 tests.

The numbers tell the story of the substantial overhang of PCR instruments that exists today in the United States. As medical laboratories deployed multiple testing methodologies during the SARS-CoV-2 outbreak, molecular testing became a $23.9B global market in 2020, nearly tripling in size from $7.7B in 2019!

That growth continued, with estimates that it will be $33B worldwide in 2021, according to data compiled by **IVD Logix** from *in vitro* diagnostics (IVD) companies' sales volumes. The Dallas-based firm offers IVD strategic consulting and market research. The global molecular SARS-CoV-2 market, in particular, was $17.2B and expected to be $26B in 2021, IVD Logix data show.

"Molecular testing increased dramatically in 2020 and continued in 2021. In 2020, other testing disciplines decreased in volume because of the decrease in patient procedures in hospitals. As a result, labs diverted resources to accommodate an increase in SARS-CoV-2 volume," said Lawrence Worden, Principal, IVD Logix, in an exclusive interview with The Dark Report.

Clinical labs were purchasing open PCR platforms used for genetic testing in genetic labs. "They were commandeering the platforms and diverting them from their regular tests to SARS-CoV-2," Worden added. "Labs still had difficulty meeting demand. Many of them were scrambling to bring in additional platforms wherever they could find them."

➤Too Many PCR Analyzers

Now, as the pandemic appears to be waning and COVID-19 test orders are declining, Worden says labs have too many PCR instruments on-hand. Lab administrators and pathologist may need to make some decisions about what to do with them.

"There's going to be a backlog of deferred menu additions to prior platforms that will occur once SARS-CoV-2

Winners in the Automated PCR Marketplace Will Be Sample-to-Answer Platforms

ONE CONSEQUENCE OF THE COVID-19 PANDEMIC is that many clinical laboratories and anatomic pathology groups in the United States bought PCR instruments and SARS-CoV-2 test kits from multiple vendors.

Today, it is common to find a hospital or health system laboratory that has operated PCR instruments manufactured by three to five different vendors. In the early days of the outbreak, this was one lab management strategy to obtain enough throughput and test kits to serve the needs of the parent hospitals.

Now that much of the population is vaccinated and daily new cases of COVID-19 are declining, labs must decide which PCR platforms to keep and what to do with the remaining instrument systems.

Experts say that the PCR technology likely to be kept and used by integrated delivery systems are the automated sample-to-answer platforms. Some of these systems extract a virus' genetic material or DNA/RNA as part of the process and enable results in less than an hour, explained a blog article from **DiaSorin** Molecular, developer of the Simplex COVID-19 Direct Kit (which eliminates RNA extraction).

Other higher-volume systems, such as the **Roche** cobas 6800 or **Abbott** Alinity systems, reportedly require a sample prep and extraction process but integrate it into a single automated instrument. These systems are more likely to remain in central laboratories but will be used for a broader menu than just respiratory pathogens.

In contrast to sample-to-answer systems, there are open PCR platforms that require separate steps to extract DNA or RNA, purify, and amplify or multiply the virus genetic material, even before the specimen is on the instrument. Higher qualifications of medical technologists are needed and these systems potentially require validation of laboratory developed tests (LDTs) that are run on these analyzers.

In a study conducted by IVD Logix, a consulting company, respondents indicated a preference for sample-to-answer platforms that pair with **U.S. Food and Drug Administration**-cleared assays, compared to LDTs (laboratory-developed tests). "Sample-to-answer PCR platforms don't require specially-trained medical technologists, and they will probably be the ones labs will keep as they have broader application and lower overhead," stated Lawrence Worden, Principal of IVD Logix.

Even labs with the wherewithal, staff skill level, and CLIA certificate to develop and run their own LDTs may choose not to take this approach, according to IVD Logix research.

"In a study we recently conducted of highly complex molecular labs, we found that approximately 20% will only adopt FDA-cleared assays, 45% would adopt an LDT if there is no FDA-cleared alternative, and 35% are equally open to either," Worden noted.

Similarly, a survey done by the Association for Molecular Pathology (AMP) found that 62% of labs used COVID-19 testing kits with FDA emergency use authorization (EUA), 5% tapped LDTs only, and 26% relied on a combination of EUAs and LDTs.

subsides. That will cover a portion of the excess capacity," Worden said. "But some labs will have to answer: 'How am I going to use this equipment? Mothball it? Sell it? What should be done with it?'"

A survey from the **Association for Molecular Pathology** (AMP) found that 80% of academic medical centers and community hospital/health system labs used three or more testing methods for

COVID-19. And large healthcare systems used seven or more methods, Worden said.

"So, it was a whole new arrangement of test volume and test location within laboratories and a total concentration on SARS-CoV-2 testing," Worden added.

He highlighted these possible solutions for excess PCR analyzers:

- Seeding equipment in new sites.
- Finding value in sample-to-answer platforms.
- Expanding testing menu on platforms.

Put Analyzers in New Places

"Some labs will want to hold onto the new testing platforms they purchased during the pandemic," Worden said. "Some health system labs may find ways to seed CLIA-waved or moderately complex instruments in physician practices or other sites.

"Clever lab managers will take advantage of the available PCR platforms," he continued. "There will be some dissemination of testing throughout the health network. These instruments could be placed in remote labs where they may not otherwise have offered tests. For example, they might support laboratory testing at a remote site with the **Abbott** ID NOW COVID-19 test (a portable rapid molecular test)."

Most clinical laboratories may have not contemplated putting these PCR instruments in satellite lab facilities. The labs may not have contemplated such ideas before, because they did not want to make the investment. But now they have available technology.

"Pre-pandemic, lab managers may not have thought it cost-effective to perform PCR tests at other locations or made that expense," Worden observed. "But now they have this inventory. And instruments can be seeded in appropriate places that have the volume to justify the quality control burden, the training, and the management of overhead required of systems in alternative sites."

Lab leaders may need to creatively use the equipment they have instead of reaching for something new. According to Worden, healthcare organizations are tapped out by the costs of the pandemic, and not much capital remains in many organizations' coffers for new technology.

"Labs will have to adapt the equipment they have for future testing. Due to the pandemic, a lot of capital budgets in these institutions are exhausted. The market for new equipment placements will be limited by available capital for new acquisitions," Worden said.

"The focus of the industry and the laboratory is going to be on use of the installed base of equipment that resulted from the pandemic," he continued, noting that expansion of the respiratory test menu on the platforms is an option for labs to offer in primary care sites.

"There's the possibility they could expand the menus on these near-patient or point-of-care platforms to include new sexually-transmitted-infection lab test panels," Worden pointed out.

Rise of At-home Lab Testing

The pandemic also accelerated a shift to at-home testing, especially respiratory testing, he noted. Worden spoke on this topic during his presentation, "*How COVID-19 Forever Changed the In Vitro Diagnostics Marketplace: What Both Clinical Labs and IVD Companies Need to Know about the Growth of Consumer At-Home Testing and Other Key Trends*," at the *Executive War College* on Nov. 2.

"We were doing a lot of work with companies prior to the pandemic—looking at respiratory testing that can be purchased at pharmacies and done at home. It required a healthcare infrastructure change because test results need to connect from Bluetooth to a smartphone app and to a caregiver," Worden explained. "Much of that infrastructure is in place, and it is possible it may soon be used for regular testing as well as SARS-CoV-2," he concluded. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last week, the State of California auto-renewed its controversial COVID-19 testing contract with **PerkinElmer** to run the Valencia Branch Laboratory. Designed, built, and operated by PerkinElmer, the lab began SARS-CoV-2 testing in the fall of 2020 and immediately was in the news for a range of issues. The original award was a no-bid contract worth as much as $1.7 billion to PerkinElmer.

MORE ON: *Valencia COVID-19 Laboratory*

To date, PerkinElmer has been paid $716 million to operate the Valencia Branch Laboratory, according to statements by Sami Gallegos, a spokesperson for the **California Health and Human Services Agency**. What is noteworthy for pathologists and lab managers is that, earlier this year, *CalMatters* wrote that "state health inspectors gave this lab an 'immediate jeopardy' designation—which represents 'the most severe and egregious threat to the health and safety of recipients.'" California State officials promised to release the full report in March. Seven months later, that report has still not been released to the public.

ANY LAB TEST NOW MAKES LIST OF FASTEST-GROWING

For the sixth year in a row, Alpharetta-Ga.-based **ANY LAB TEST NOW** has made *Entrepreneur's* 2021 Franchise 500 and Franchise 500 Best of the Best lists. The company serves consumers with a broad menu of clinical laboratory tests. It now has a network of 190 franchise locations throughout the United States. The multi-year growth of ANY LAB TEST NOW and its expanding network of franchises demonstrates that consumers are both interested in ordering their own clinical laboratory tests and are willing to pay cash for these tests.

TRANSITIONS

- **Agilent Technologies, Inc.**, of Santa Clara, Calif., appointed John Palma to the position of Vice President, Medical Affairs. Palma previous held executive positions at **Roche**, **RedPath Integrated Pathology, Veridex**, **Affymetrix**, and **Metabolix**.

- Steve Pemberton is the new Senior Vice President of Commercial Development at Cambridge, Mass.-based **Ultivue**. Prior executive positions were with **Haematologic Technologies**, **Bionique Testing Laboratories**, **Rheonix**, **Ventana Medical Systems**, and **Abbott Laboratories**.

- **Enzo Biochem** of New York announced the selection of Hamid R. Erfanian as its new CEO. Erfanian formerly held positions at **Euroimmun**, **Diagnostica Stago**, **Beckman Coulter**, **Abbott Laboratories**, **Quest Diagnostics**, **PharmChem, Corning Clinical Laboratories**, and **Labcorp**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 29, 2021.

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