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Is a COVID-19 Test Audit Coming Soon to Your Lab?

Lab attorney's prediction: Medicare and private payers to increase audit activity.
(See pages 8-11.)

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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

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Data Innovation Plays a Key Role on Future Fronts

BETTER COLLECTION AND USE OF CLINICAL DATA WAS A PROMINENT THEME discussed by attendees at last month's annual *Executive War College Conference on Laboratory and Pathology Management* in New Orleans.

Laboratory directors and pathologists have long known that such data can be considered a holy grail in healthcare. However, reaping a financial windfall from this information proved elusive—until recently—as there is now clear demand for aggregated data and a means to analyze it.

As you will learn in this issue of THE DARK REPORT, the more data clinical labs can analyze about patients—including diagnoses and past/current test results—the greater the ability physicians have to identify care gaps and improve patient outcomes. Technology helps in this endeavor, but such data innovation also requires clinical labs to change how they operate and support their parent organizations.

An interesting example of this changing landscape is **Intermountain Health's** new merger with **SCL Health**. As we explain elsewhere in this issue, the consolidated system now has 33 hospitals and 385 health clinics. One of Intermountain and SCL's goals with the merger is to bring a successful population health model to more patients. Population health seeks to treat conditions and improve outcomes in groups of people and lab data is essential to attain these goals. "The merger provides a healthcare model for the rest of the country," said Intermountain CEO Marc Harrison, MD, in a statement. That's a lofty goal, but it highlights for lab directors where the nation's 11th largest health system—one that operates in the black, at that—is heading.

A key to population health is clinical data—the topic that was so often on the lips of speakers and participants at *Executive War College*. Population health technology brings a combination of features that can collect clinical data from various sources, including clinical lab records, and analyze the data set.

Illustrating this bridge between data innovation and news of the merger between Intermountain and SCL demonstrates why THE DARK REPORT and *Executive War College* are valuable to laboratory leaders, clinical lab directors, and pathologists who think strategically. Such timely information keeps laboratories and pathology practices on the cutting edge of clinical excellence in a financially sustainable manner. TDR

Innovation Showcased at Executive War College

Innovative technologies and powerful trends to reshape how labs operate and deliver value

CEO SUMMARY: This year's Executive War College on Laboratory and Pathology Management proved to be a high-energy event. A record 900 attendees showed up and responded enthusiastially to visions and predictions of a post-COVID-19 healthcare system that hungers for large volumes of lab test data. Speaker after speaker emphasized that clinical laboratories willing to be innovative will enjoy more revenue from the added value they deliver.

Is it time for clinical laboratories to put the COVID-19 pandemic in the rear view mirror? Most speakers and attendees at this month's *Executive War College on Laboratory and Pathology Management* would say "Yes!"

"The general consensus that emerged at this year's event is that the pandemic itself is no longer the dominant factor in the management of clinical laboratories," stated Robert L. Michel, Director of the *Executive War College* and Editor-in-Chief of The Dark Report.

"Rather, the nation's more innovative clinical labs and pathology groups are now responding to several powerful trends in healthcare that the pandemic accelerated," he continued. "These trends represent opportunities to deliver more value, develop new streams of revenue, and increase the profitability of the lab—whether an independent lab company or the laboratory operated by a not-for-profit hospital system."

In particular, four trends identified and discussed by multiple speakers represent the best opportunities for lab administrators and pathologists who want to position their respective lab organizations as essential clinical contributors. They are:

- **One:** Consumers becoming more proactive about their care, including use of telehealth services, ordering and/or buying their own home test kits, and wanting full access to their complete medical record.
- **Two:** Disruptive new players in primary care, including national retail pharmacy chains.
- **Three:** Importance of access to data to support healthcare big data at the macro level and precision medicine at the micro (patient) level.
- **Four:** Swift adoption of services incorporating artificial intelligence (AI)

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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across the full span of healthcare operations and clinical services.

Artificial Intelligence

In her keynote address at the *Executive War College*, Lale White, CEO at **XIFIN** in San Diego, said increased use of artificial intelligence will lead to greater aggregation and analysis of clinical lab data.

"AI allows your lab and others to process unstructured data," she explained, referring to digital information that is typically difficult to analyze because it is not assembled in a predetermined data model. One example of unstructured data generated by labs are the pathologist notes in an anatomic pathology diagnostic report.

White said an underlying challenge for clinical labs when using these AI-powered technology innovations is to obtain the substantial storage capacity to handle the needed computing power and scaling. "This challenge requires a cloud storage strategy," she added.

AI, Cloud, and Data

Another keynote speaker agreed. Pathologist and physician scientist Jason Hipp, MD, PhD, Chair of Computational Pathology and AI at **Mayo Clinic** in Rochester, Minn., said AI, the cloud, and data are all technology factors influencing lab diagnostics. "AI requires adequate storage and lots of data to be practical," he explained.

To illustrate the large volumes of data generated by labs, Hipp described how Mayo launched a project to digitally scan 25 million tissue samples on glass slides—some more than 100 years old. As part of the endeavor, the medical center wants to digitize five million of those slides within three years and put them in the cloud.

Next, Hipp described how his computational pathology team at Mayo Clinic is a bridge between pathologists and the data science engineers who develop AI algorithms. Both sides must collaborate to move AI forward, he commented, yet many labs have not yet developed those important relationships.

"We want to embed both sides into the workflow," Hipp said. "We need the data scientists working side by side with the pathologists. That practical part is missing today."

Another area of interest in lab management is compliance with federal and state laws. Probably the single biggest issue in that regard is what type of sales commissions can by paid by clinical laboratories and providers that complies with federal law. This because there is conflicting language on this matter in the federal Anti-Kickback Statute (AKS) and the federal Eliminating Kickbacks in Recovery Act of 2018 (EKRA).

This issue was addressed by attorney David Gee, a Partner at **Davis Wright Tremaine** in Seattle. Speaking to attendees at a legal panel during the conference Gee noted that there is the potential for labs to run afoul of EKRA.

Gee suggested to that it is time for clinical lab managers and pathologists to rethink percentage-based compensation arrangements. EKRA generally prohibits payments of sales commissions that are based on the volume or value of patient referrals from the sales representative's client. *(See TDR, "Labs Should Be Cautious about 'Surprising' EKRA Ruling," Feb. 22, 2022.)*

"I'd tell sales directors that it's a new day and to move away from percentage-based commissions," Gee advised. "There are other ways."

For example, a lab could instead institute a sales bonus based on meeting a predetermined threshold of clean reimbursement claims, which hinges on the types of clients a sales representative brings to the laboratory, suggested Gee.

Optimism about the Future

One factor that many attendees commented about was how optimism was bubbling throughout the presentations, as well as in the informal discussions that took place in the hallways and during the conference. "Lab professionals gave their

all during the past 30 months of the pandemic," Michel observed. "Now that the worst of the SARS-CoV-2 outbreak seems to be behind us, many lab leaders are ready to again focus their lab organizations on helping physicians improve patient care."

Michel commented on the themes presented by White and Hipp. "Both of these experts emphasize that labs should use informatics—in other words, the design and study of digital technology to help patients—as the platform to support collaboration with providers and insurers," he noted. "This is a demonstrated way that a clinical laboratory can deliver more value from its test data and be paid more for that additional data.

In Healthcare: Data is King

"Across the entire spectrum of healthcare providers, data is quickly becoming king," Michel said. "As a result, expect a wave of products and solutions labeled by their developers as artificial intelligence.

"Innovation just doesn't happen during testing and diagnoses," Michel concluded. "My advice to savvy clinical laboratory directors is to take stock of your lab's business operations, look for opportunities to improve or simplify processes, and then prioritize how to make those changes."

There are other technologies under development that have the potential to substantially transform clinical lab testing as it is done today. For example, one session was delivered by **Babson Diagnostics**, of Austin, Texas. Babson is developing methods to collect blood specimens that would not require a trained phlebotomist to do a venipuncture.

Another session was delivered by **Clarapath, Inc.**, of Hawthorne, N.Y. This company is working to automate up to 20 separate histology processes in one system. These presentations gave the 900 attendees at this year's *Executive War College* a first-hand look at disruptive technologies that may soon be ready for clinical use. TDR

Role for AI Across Many Clinical Lab Activities

ENHANCEMENTS TO THE PROFESSIONAL AND TECHNICAL COMPONENTS of anatomic pathology will herald a more modern approach within the profession.

Labcorp in Burlington, N.C., is using artificial intelligence (AI) to re-evaluate how both clinical laboratory and anatomic pathology processes will operate in the future, with an eye toward greater efficiency, said Stan Letovsky, PhD, Vice President for AI, Data Sciences, and Bioinformatics.

"If pathologists want to grow and improve their revenue, they have to be more productive," Letovsky told attendees at the *Executive War College*.

Anatomic pathology's technical component of the future, as outlined by Letovsky, will be centralized and highly automated. It will include routine digital pathology imaging and large-scale data storage. Artificial intelligence-powered analysis plug-ins will integrate with other technology in the practice.

Meanwhile, the professional component will feature the ability for primary and secondary anatomic pathologist reviews to migrate throughout a healthcare organization based on available capacity. Another benefit is that AI-based annotation will increase a pathologist's productivity.

"Labcorp is applying AI models across the enterprise," Letovsky said. "We're committed to continued investment in this technology."

Competing labs should take note of Labcorp's investment in artificial intelligence and the company's ongoing deployment of AI throughout its clinical laboratories and anatomic pathology labs. This is market evidence that the rapid advances in technologies used in AI are now capable of improving lab operations and contributing to better diagnostic accuracy.

Intermountain Health Merges with SCL Health

This expanded health system now operates 33 hospitals and 385 clinics in seven western states

CEO SUMMARY: Mergers and acquisitions involving large integrated delivery networks (IDNs) are not only reshaping the nation's hospital industry. These transactions also transform the way hospitals organize their clinical laboratories. Last month's merger of Intermountain Health and SCL Health in the Rocky Mountain states comes on the heels of February's merger in Michigan of Beaumont Health and Spectrum Health. Following such deals, it is common to standardize lab testing services.

On April 5, it was announced that the merger of **Intermountain Health** and **SCL Health** had been completed. This deal creates a regional mega-integrated delivery network (IDN) that spans seven states and demonstrates that consolidation in the hospital/health system industry is alive and well.

The combined enterprise will continue as a not-for-profit organization and will be called Intermountain Healthcare. A press release about the transaction said, "This combination employs more than 59,000 caregivers, operates 33 hospitals (including one virtual hospital), and runs 385 clinics across seven states while providing health insurance to one million people in Utah and Idaho. With the close of this merger, Intermountain Healthcare is the eleventh largest nonprofit health system in the U.S."

The announcement further stated, "SCL Health's Catholic hospitals retain their distinctive Catholic names and continue to operate according to existing practices." News reports indicate the new IDN is estimated to produce annual revenue of $14.2 billion.

The consolidation of these two health systems—including the 25 hospitals owned by Intermountain and the eight hospitals owned by SCL—has interesting consequences for the clinical laboratory profession and *in vitro* diagnostics (IVD) manufacturers.

Laboratory Standardization

It is typical for a hospital or health system merger to quickly tackle standardization of clinical laboratory testing services because it is easier to move specimens within the system than patients.

Standardizing test methodologies and lab analyzers throughout all the laboratories within the health system makes it easier to move staff between different lab sites. Given the large rural areas served by the combined system's 33 hospitals, this would help with lab staffing, particularly given the shortage of lab staff that is universal throughout the United States.

For IVD manufacturers, the Intermountain/SCL merger eliminates one buyer as a distinct customer and makes the now-larger IDN a bigger buyer of supplies, tests, automation, and instru-

ments. From this perspective, it means that the IVD industry loses one client and the leading IVD companies must fight more intensely to capture the much larger business of the expanded Intermountain Health.

Many mergers and acquisitions between hospitals and health systems are motivated by poor finances. That does not seem to be the case with Intermountain Health and SCL. Both health systems reported black ink in recent years.

Instead, principals behind this merger see value in combining the best of both health systems. Last September, in a video about the merger announcement, Intermountain CEO Marc Harrison said, "We feel strongly that American healthcare needs to evolve towards population health and value," adding that the merger would create "a model system for rural healthcare for the rest of the country."

Size Brings Benefits

Clinical lab administrators and pathologists should understand that this merger of two big healthcare systems in the Rocky Mountain region—along with the merger earlier this year of **Beaumont Health** and **Spectrum Health** in Michigan *(see sidebar at right)*—is evidence of the continuing market pressures on hospitals and health systems to grow larger to protect market share and gain clout when negotiating contracts with payers.

Another dynamic in play is the shift in Medicare enrollment from Part A and Part B (fee-for-service) programs to Medicare Advantage, under which the providers (both hospitals and physicians) are paid a fixed amount that is risk-adjusted to provide care to Medicare beneficiaries. Enrollment in Medicare Advantage is growing annually by double digits. Hospital administrators recognize that a sizeable proportion of their patients are senior citizens enrolled in a Medicare Advantage plan. Therefore, a larger health system that is vertically integrated is better positioned to compete for these patients. TDR

Beaumont-Spectrum Merger in Michigan

EARLIER THIS YEAR, ANOTHER MAJOR TRANSACTION combined two large integrated delivery networks (IDNs) in Michigan. On Feb. 1, Beaumont Health of Southfield and Spectrum Health of Grand Rapids completed their merger.

Post-merger, the entity operates under the temporary name of **BHSH Health**. Both Beaumont and Spectrum continue to use their original names within their respective service regions.

BHSH Health immediately became the largest health system in Michigan. Along with 22 hospitals of more than 5,000 licensed beds, BHSH has more than 300 outpatient locations, 11,500 affiliated and employed physicians, 64,000 employees, and annual revenue that exceeds $13 billion.

Of note, BHSH has a health plan, **Priority Health**, that serves 1.2 million beneficiaries. This positions BHSH to further evolve into a one-stop, fully-integrated healthcare solution that provides both insurance coverage and the needed medical services, similar to **Kaiser Permanente** and **Geisinger Health**, for example.

This merger of two already-large IDNs in Michigan confirms that hospital consolidation is a continuing trend. It can be expected that BHSH will want to standardize test menus and instrumentation across all its laboratory facilities. That may include consolidating test volumes into one or more large core laboratories as a way to reap economies of scale that also increase the productivity of its medical technologists. This would be most attractive at this time, due to the recognized shortage of skilled laboratory professions throughout the United States.

It is uncertain what role the pandemic played in this merger, which was announced in June, 2021, more than a year after the onset of the COVID-19 outbreak.

Labs Can Expect COVID-19 Test Audits, Investigations

Federal agencies will seek to verify that federal funds went to legitimate testing efforts

Matthew J. Murer

CEO SUMMARY: ***Billions of federal dollars were paid out for needed SARS-CoV-2 testing during the pandemic. Now, even the best-run clinical laboratories and pathology groups may have compliance matters to address during upcoming government audits, according to healthcare attorney Matthew Murer. Some sites—including pop-up COVID-19 testing labs—are already feeling the sting of federal investigations.***

CLINICAL LABORATORIES AND PATHOLOGY GROUPS testing patients for the SARS-CoV-2 virus can expect a new level of scrutiny from federal regulators, according to an attorney who represents labs and pathology groups in compliance matters.

Over the next two years or more, clinical lab directors should anticipate that federal agencies will ask them questions about how their labs spent the funds the government allocated for COVID-19, warned Matthew J. Murer, the Healthcare Chair for the Chicago law firm of **Polsinelli**. Murer specializes in clinical laboratory compliance.

In addition, health insurers will conduct similar reviews of COVID-19 testing they've already paid to labs. To recover overpayments for coronavirus testing, three Blues plans have filed lawsuits in the past year against **GS Labs** of Omaha, Neb. *(See sidebar, "Three Blues Plans Sue Nebraska Lab," page 11.)*

"Not surprisingly, a lot of companies got into the COVID-19 testing business despite the fact that they had not previous done any clinical lab testing," Murer said. "Now some of those lab testing companies are under investigation," he added.

The most recent indication that regulators are concerned about fraudulent testing for the coronavirus came on April 20 when the federal **Department of Justice (DOJ)** announced a nationwide investigation into healthcare fraud related to COVID-19. In its announcement, the DOJ said several cases involve defendants who allegedly offered COVID-19 testing to induce patients to provide their personal identifying information and a saliva or blood sample.

Fraudulent COVID-19 Claims

"The defendants are alleged to have then used the information and samples to submit false and fraudulent claims to Medicare for unrelated, medically unnecessary, and far more expensive tests or services," the DOJ said.

Another early sign of the concern that federal investigators have about COVID-19 came earlier this year when the **Federal Bureau of Investigation** (FBI) raided several labs in the Chicago area.

On Jan. 23, *USA Today* reported that the FBI executed a search warrant at the headquarters of a nationwide chain of labs called the **Center for COVID Control**.

Illinois Lab Investigation

State and federal officials are investigating the lab company in Rolling Meadows, Ill., after the lab got more than $124 million in federal payments for coronavirus testing, the newspaper added. Other news reports about similar investigations followed. *(See Dark Daily, "Large Operator of COVID-19 Collection Sites Suspends Operations and Clinical Laboratory Testing Following State and Federal Probes," March 4, 2022.)*

But those news stories were just the beginning of investigations that could ensnare not only the so-called pop-up testing labs in Chicago and elsewhere, but also larger, legitimate clinical lab companies that have been in business for many years, Murer warned.

"Any lab company that took money from the billions of dollars in funding that the federal government made available for COVID-19 testing may face investigations from federal regulators and audits or repayments from private health insurers," Murer explained.

"From the federal government's standpoint, it made sense to pay as many labs as possible to do COVID-19 testing," he noted. "The government wanted to ramp up testing as quickly as possible for the good of the country, the economy, and for public health.

New Labs Enter Marketplace

"When there's a lot of money to be made in clinical lab testing, everybody piles into the testing business," Murer added. "That's what happened with COVID testing starting in 2020, and it continues even now, although to a lesser extent."

The investigations into the pop-up labs may be just the start. Other clinical labs should closely monitor what's happening with pop-up investigations, Murer noted.

"Look at how much money these pop-up labs got from the federal government. In most cases reported in the press, it was more than $100 million," he emphasized. "In and of itself, that level of payment is not proof of guilt or wrongdoing. But it shows that if the government is willing to pay this much money, a clinical lab company should perform testing correctly and maintain detailed documentation because audits may follow."

In early 2020, during the first months of testing for the coronavirus, almost all clinical labs were swamped with more tests than they could handle in the time required.

"That's one problem that we saw repeatedly," Murer explained. "Consumers were told they'd get their test results within 24 to 48 hours, but some were waiting weeks to get results. That became an area of complaint that is leading to a lot of the government's investigations.

Lying to Customers

"Telling consumers they'll get their results in a day or two while making them wait for a week or more is like lying to them or defrauding them," he said. "The **Federal Trade Commission** (FTC) is involved in a number of these cases and looking into whether any business is lying to consumers while taking their money and defrauding them."

For the FTC, another area of investigation is the quality of testing, he added. "There are a number of anecdotal stories about people who got SARS-CoV-2 test results that initially were negative," Murer noted. "However, because those same consumers had COVID-19 symptoms, they were motivated to go to another testing lab where they would then get test results indicating they were positive for COVID-19 all along."

While it is unusual for the FTC to oversee testing, Murer sees such action as well within the agency's purview. "The FTC is really interested in whether labs were providing testing at the quality standard that

Federal Prosectors Have Prosecuted Multiple Cases Involving SARS-CoV-2 Testing Fraud

In May 2021, the Federal Department of Justice announced an enforcement action that involved the prosecution of multiple defendants who offered COVID-19 tests to Medicare beneficiaries at senior living facilities, drive-through COVID-19 testing sites, and medical offices to induce the beneficiaries to provide their personal identifying information and a saliva or blood sample, the DOJ said at the time.

The defendants are alleged to have then misused the information and samples to submit claims to Medicare for unrelated, medically unnecessary, and far more expensive laboratory tests, including cancer genetic testing, allergy testing, and respiratory pathogen panel tests, the DOJ reported.

"The proceeds of the fraudulent schemes were allegedly laundered through shell corporations and used to purchase exotic automobiles and luxury real estate," the agency added.

Those cases were similar to those that the DOJ cited in April. In one of the most recent cases, two owners of a clinical laboratory in the Central District of California were charged in a healthcare fraud, kickback, and money laundering scheme that involved the fraudulent billing of over $214 million for laboratory tests, over $125 million of which allegedly involved fraudulent claims during the pandemic for COVID-19 and respiratory pathogen tests," the DOJ said in April.

In two other cases—one in the District of Maryland and one in the Eastern District of New York—the owners of medical clinics allegedly obtained confidential information from patients seeking testing at drive-through COVID-19 testing sites and then submitted fraudulent claims for lengthy office visits even though those office visits never happened, the DOJ said.

"The proceeds of these fraudulent schemes were allegedly laundered through shell corporations in the United States, transferred to foreign countries, and used to purchase real estate and luxury items," the agency added.

they represented, meaning whether labs were delivering results in 24 hours and the obvious standard that these tests would be done correctly," he explained.

Similar cases occurred when consumers would get a negative COVID-19 test result, but then the lab would call a few days later to say the report was incorrect. "The same lab would call to say, 'Sorry, we had it wrong. Your test result was positive,'" Murer said.

These anecdotes are not evidence of misdeeds or fraud, he added. "In fact, labs that failed to keep promises of turning around test results in 24 to 48 hours—or labs that reported one result and then corrected that result within a day or so—will claim they were simply overwhelmed," explained Murer. "Or the labs will say, 'We didn't have enough test kits to meet the demand.'"

Such an explanation will likely prompt investigators to dig for the truth, Murer said. "The way regulators, including the FTC, DOJ, or the federal **Centers for Medicare and Medicaid Services** (CMS) will do their investigations is to start at the bottom of the organization," Murer explained. "They may start with the person working in reception or with a lab tech. They do that to get to someone who really knows what was going on.

"The investigators will say, 'You can cooperate with us by telling us what was really going on, and we'll give you immunity.' Or, they may say, 'We'll give you a plea deal that's better than you would get normally,'" he explained.

On the other hand, investigators could also threaten lab workers with stiff penalties. "They might say, 'If you don't tell us any-

thing, we'll make sure that you get charged with the full force of the law,'" Murer said.

"It's not hard to imagine investigators telling a lab worker, 'Once we do that, why would you want to risk going to jail when you're not the one who made the hundreds of millions of dollars?'" he noted.

Such tactics can be convincing and usually persuade employees to talk if they witnessed problems or wrongdoing, Murer added.

"Investigators don't have to talk to too many people before they get to somebody who says something like, 'The lab was operating in total chaos,'" he noted.

The source who provides such details may explain that the lab hired someone who knew nothing about testing, that staff weren't properly trained, or that whole batches of tests were ruined. "That's how the government will build these cases," he said.

Things Can Go Wrong in Labs

"Again, I don't know if any of those allegations are true," he noted. "However, labs were running thousands and thousands of tests every day during the height of the pandemic. In that environment, things will go wrong in even the best-run labs. In any lab company that is not well run, I'm certain a lot of things could go wrong. Investigators will be looking for these types of things."

In May 2021, the DOJ announced criminal charges against 14 defendants, including several clinical laboratory owners, for their alleged role in various healthcare fraud schemes that exploited the COVID-19 pandemic and resulted in over $143 million in false billings, Murer noted.

Multiple defendants in these cases allegedly offered COVID-19 tests to Medicare beneficiaries at senior living facilities, drive-through COVID-19 testing sites, and medical offices to induce the beneficiaries to provide their personal identifying information and saliva or blood samples, the DOJ reported.

Allegedly, the defendants misused the personal healthcare information and patient samples to submit claims to Medicare for unrelated, medically unnecessary, and expensive laboratory tests, including cancer genetic testing, allergy testing, and respiratory pathogen panel tests, the DOJ added. *(See TDR, "Florida Laboratory Owner Gets 82-Month Jail Term," Nov. 29, 2021.)*

In some cases, the COVID-19 test results were not provided to the beneficiaries in a timely fashion or were not reliable, risking the further spread of the disease, the DOJ said. "The proceeds of the fraudulent schemes were allegedly laundered through shell corporations and used to purchase exotic automobiles and luxury real estate," the agency added in a news release. TDR

Contact Matthew J. Murer at mmurer@polsinelli.com or 312-873-3603.

Three Blues Plans Sue Nebraska Lab Firm

SINCE JULY 2021, THREE BLUES PLANS HAVE FILED LAWSUITS against **GS Labs**, a laboratory company in Omaha, Neb., that operates 27 lab facilities in 13 states, according to *Modern Healthcare*.

On March 1, **Blue Cross and Blue Shield of Minnesota** filed a lawsuit in U.S. District Court of Minnesota, alleging that GS Labs committed fraud in the past year by submitting tens of thousands of claims for coronavirus testing using inflated cash prices, the news magazine reported.

In October, **Premera Blue Cross** of Seattle, Wash., filed a lawsuit against GS Labs in U.S. District Court for the Western District of Washington, alleging that the lab company forced commercially insured patients to take unnecessary, expensive tests to defraud Premera of $26 million, according to *Modern Healthcare*.

In July, **BCBS Kansas City** accused GS Labs of upcharging the insurer $9.2 million for COVID-19 tests, the news magazine added. GS Labs did not respond to a request for comment.

Lab Market Update

California Cancels COVID-19 Test Contract with PerkinElmer

Cancellation letter from state officials provided no details about the Valencia Branch Lab's future

CALIFORNIA HAS SHED MORE LIGHT ON THE DECISION to terminate **PerkinElmer's** valuable contract to run the **Valencia Branch Laboratory** (VBL). The lab has been embroiled in controversy for much of its existence.

The state noted that SARS-CoV-2 testing options for the public played a large part in ending the contract. PerkinElmer notified the **U.S. Securities and Exchange Commission** on March 31 that its $1.7 billion agreement to operate the state-owned lab would soon cease. *(See TDR, "PerkinElmer Says California Terminated COVID-19 Contract," April 4, 2022.)*

The diagnostics company, based in Waltham, Mass., had run the lab since it opened in November 2020.

Response Pushes Testing

In February, California rolled out its next phase of COVID-19 response, known as the SMARTER Plan. SMARTER stands for Shots, Masks, Awareness, Readiness, Testing, Education, and Rx. According to the **California Department of Public Health** (CDPH), ample choices for both polymerase chain reaction and rapid antigen tests allowed state health officials to reassess the need for VBL.

"As highlighted by the California SMARTER plan, antigen testing is now a major component of our ongoing testing response, and the commercial laboratory capacity has been dramatically increased over the last 18 months with constant changes in testing approaches and capabilities," Timothy Bow, CDPH's Contract Officer for COVID Emergency Operations, wrote to PerkinElmer in a March 31 letter.

"As such, it is time for California to leverage the now-sufficient laboratory capacity of the commercial market and the flexibility it brings," Bow continued. "Therefore, we are notifying you that we are terminating the contract in 45 days."

Under that timeline, PerkinElmer's oversight of the VBL ended on May 15.

Lab Operated for 16 Months

PerkinElmer entered into the agreement to operate the VBL in October 2020. The contract automatically renewed in October 2021.

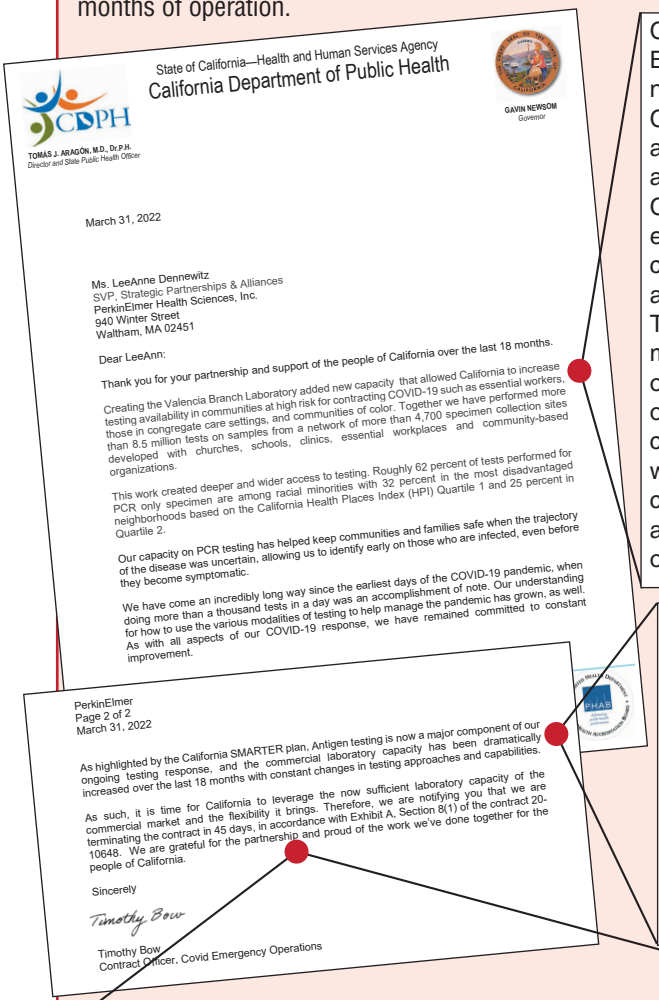
However, that renewal was steeped in controversy. A series of clinical laboratory inspections earlier in 2021 revealed dozens of deficiencies, some of which placed patients in immediate jeopardy, according to regulators. *(See TDR, "California Agency Problems Deepened Valencia Branch Laboratory Saga," April 4, 2022.)*

The state's letter to PerkinElmer praises the company's work and never mentions the history of deficiencies. That omission may fuel further debate about whether CDPH shrugged off the problems at the lab. It is not clear what the VBL's role will be going forward. The site performed more than 8.5 million COVID-19 tests from 2021 until now.

"At this point in the pandemic, and as part of the SMARTER Plan, testing capacity will be provided through a network of commercial partners rather than the Valencia Branch Laboratory," CDPH's media office told THE DARK REPORT. TDR

State of California Terminates Contract with PerkinElmer for COVID-19 Testing Lab

EFFECTIVE THIS WEEK, THE STATE OF CALIFORNIA ENDS ITS COVID-19 TESTING CONTRACT WITH PERKINELMER. It was in the summer of 2020 when the state government gave PerkinElmer the contract, potentially worth as much as $1.7 billion, to design and construct a new clinical laboratory facility in Valencia, Calif., and then operate the lab. Here is the letter PerkinElmer received from state officials, closing the lab after less than 18 months of operation.



State of California—Health and Human Services Agency
California Department of Public Health

CDPH

TOMÁS J. ARAGÓN, M.D., Dr.P.H.
Director and State Public Health Officer

GAVIN NEWSOM
Governor

March 31, 2022

Ms. LeeAnne Dennewitz
SVP, Strategic Partnerships & Alliances
PerkinElmer Health Sciences, Inc.
940 Winter Street
Waltham, MA 02451

Dear LeeAnn:

Thank you for your partnership and support of the people of California over the last 18 months.

Creating the Valencia Branch Laboratory added new capacity that allowed California to increase testing availability in communities at high risk for contracting COVID-19 such as essential workers, those in congregate care settings, and communities of color. Together we have performed more than 8.5 million tests on samples from a network of more than 4,700 specimen collection sites developed with churches, schools, clinics, essential workplaces and community-based organizations.

This work created deeper and wider access to testing. Roughly 62 percent of tests performed for PCR only specimen are among racial minorities with 32 percent in the most disadvantaged neighborhoods based on the California Health Places Index (HPI) Quartile 1 and 25 percent in Quartile 2.

Our capacity on PCR testing has helped keep communities and families safe when the trajectory of the disease was uncertain, allowing us to identify early on those who are infected, even before they become symptomatic.

We have come an incredibly long way since the earliest days of the COVID-19 pandemic, when doing more than a thousand tests in a day was an accomplishment of note. Our understanding for how to use the various modalities of testing to help manage the pandemic has grown, as well. As with all aspects of our COVID-19 response, we have remained committed to constant improvement.

PerkinElmer
Page 2 of 2
March 31, 2022

As highlighted by the California SMARTER plan, Antigen testing is now a major component of our ongoing testing response, and the commercial laboratory capacity has been dramatically increased over the last 18 months with constant changes in testing approaches and capabilities.

As such, it is time for California to leverage the now sufficient laboratory capacity of the commercial market and the flexibility it brings. Therefore, we are notifying you that we are terminating the contract in 45 days, in accordance with Exhibit A, Section 8(1) of the contract 20-10648. We are grateful for the partnership and proud of the work we've done together for the people of California.

Sincerely

Timothy Bow

Timothy Bow
Contract Officer, Covid Emergency Operations

Creating the Valencia Branch Laboratory added new capacity that allowed California to increase testing availability in communities at high risk for contracting COVID-19 such as essential workers, those in congregate care settings, and communities of color. Together we have performed more than 8.5 million tests on samples from a network of more than 4,700 specimen collection sites developed with churches, schools, clinics, essential workplaces and community-based organizations.

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IVD Update

IVD Firms Grow During 2022, but COVID-19 Revenue Dropped

Point-of-care testing services appear to be a bright spot for in vitro diagnostics

Most major *in vitro* diagnostics (IVD) manufacturers started strong in 2022 as their base businesses regained steam and made up for the significant falloff in COVID-19 diagnostic test revenue.

During first quarter 2022 earnings calls with investors, leaders at publicly traded IVD companies said clinical laboratories are interested in expanding test menus on technology platforms previously used for COVID-19 testing.

SARS-CoV-2 testing will continue to be needed, they said, but it will make significantly less contribution to bottom lines. The pandemic also has propelled some of the IVD companies to accelerate point-of-care (POC) testing outside of medical laboratories. This would be consistent with the trend of more consumers wanting to buy their own diagnostic tests.

IVD manufacturers during quarter one were impacted by supply chain challenges and COVID-related lockdowns in China. Clinical laboratory directors and pathologists will note some common developments, based on the recent earnings reports:

- At-home testing for SARS-CoV-2 proved to be profitable. It is likely the public will continue to grow more comfortable testing themselves for a variety of infections and health conditions.
- Consolidation of the IVD market continues, with two companies in The Dark Report's list of the Top Global IVD Companies involved in acquisitions during the last 12 months.

Here is a summary of information released by 13 of the leading IVD companies. *(For past coverage of the IVD market, see TDR, "IVD Companies Report Record Sales as 2021 Draws to Close," Dec. 21, 2021, and "Rankings of the World's Largest IVD Corporations," Sept. 7, 2021.)*

Roche

ROCHE: Diagnostics Revenue Up 24%, Huge Jump in POC Services

Roche Group, in Basel, Switzerland, reported "good momentum" in Q1 2022:

- Group sales increased 11% to 16.4 billion Swiss francs (CHF) (US$10.7 billion).
- Diagnostics revenue climbed 24% to 5.3 billion CHF (US$5.4 billion).
- COVID-19 testing sales were $1.9 billion CHF (US$1.98 billion) and expected to fall later in the year.

"We started the year with strong demand for our diagnostics base business, our broad portfolio of COVID-19 tests, and our new medicines," said CEO Severin Schwan.

During an earnings call, Thomas Schinecker, PhD, CEO at **Roche Diagnostics**, released these details on diagnostics sales:

- Core lab revenue increased 6% to 1.8 billion CHF (US$1.83 billion)—immunodiagnostics up 11% and clinical chemistry up 8%.
- POC services increased 82% to 1.4 billion CHF (US$1.43 billion)—POC immunodiagnostics up 107%.
- Molecular lab increased 19% to 1.1

billion CHF (US$1.12 billion)—POC molecular up 83%.
- Pathology lab grew 13% to 318 million CHF (US$325 million)—advanced staining up 14% and companion diagnostics up 19%.

Roche announced a molecular test aimed at differentiating SARS-CoV-2 Omicron variants "in hours versus a week for sequencing," he explained.

Also, Roche is collaborating with **Bristol Myers Squibb** on artificial intelligence (AI) and digital pathology patient treatments. *(See TDR, "Intelligence: Late-Breaking Lab News," April 25, 2022.)*

ThermoFisher SCIENTIFIC

THERMO FISHER: Clinical Laboratory Products and Services Segment Soars 51%

Thermo Fisher Scientific in Waltham, Mass., shared data on Q1 2022 revenue overall and for its business segments as compared to Q1 2021:
- Revenue increased 19% to $11.8 billion, compared to $9.9 billion.
- Laboratory products and services segment soared 51% to $5.4 billion from $3.5 billion.
- Analytical instruments revenue was up 9% to $1.5 billion from $1.3 billion.
- Life sciences revenue grew 1% to $4.2 billion.
- Specialty diagnostics revenue fell 8% to $1.4 billion from $1.6 billion.

During the first quarter earnings call, Chief Financial Officer Stephen Williamson told investors growth in clinical diagnostics was strong. "In the first quarter, we saw a strong underlying growth in our healthcare market channel, transplant diagnostics, and clinical diagnostics businesses, which was [enough to] offset lower COVID-19 testing revenue versus the year-ago quarter."

Thermo Fisher plans to pursue precision medicine, said CEO Marc Casper during the call. "We signed an agreement with precision diagnostic company, **Oncocyte**, to develop two new assays … to improve cancer tumor profiling and advanced precision medicine," he said.

In response to an analyst's inquiry, Casper said China's COVID-related lockdowns and customers' closed businesses are impacting revenue from that nation. "We're predicting that in the back half of the year Q3 and Q4 are normal in China," he said.

DANAHER BECKMAN COULTER Cepheid A better way. Leica MICROSYSTEMS

DANAHER Corporation: Diagnostics Jumps Nearly 22% as Patients Resume Screenings

For **Danaher** in Washington, Q1 2022 shaped up well year over year:
- Sales grew 12% to $7.6 billion.
- Life sciences revenue rose 9.5% to $3.8 billion.
- Diagnostic revenue increased 21.5% to $2.6 billion.

"The clinical diagnostic market volumes remain at healthy levels in most geographies as patients are returning for wellness checks, routine screenings, and other elective procedures," said CEO Rainer Blair during an earnings call.

Danaher foresees customers using the company's technology for other tests as COVID-19 transitions to an endemic disease. Customers, including some who purchased Danaher's COVID-19 instruments, have expressed interest in expanding their test menus, Blair noted. The company also wants to sell more of its POC molecular testing products.

BD

BECTON, DICKINSON AND COMPANY: Base Business Earnings Up, COVID-19 Revenue Down

For **Becton, Dickinson and Company** (BD) in Franklin Lakes, N.J., the period ending March 31 marked the end of the company's second quarter (Q2). BD released the following financial data:

- Revenue increased 2.1% to $5 billion in Q2 from $4.9 billion in Q2 2021 due to growing revenue from base business amid COVID-19 testing declines.
- COVID-19 testing revenue fell to $214 million from $474 million in Q2 2021.
- Revenue in life sciences, which includes diagnostics services, was down 6.4% to $1.4 billion in Q2 from $1.5 billion in Q2 2021.

"We delivered another quarter of strong growth across our base business through continued, focused execution despite a dynamic and challenging macro environment," said CEO Thomas Polen.

BD managers told investors during an earnings call that the company experienced higher than anticipated demand for its new flu/COVID-19 combination test and strong demand for specimen management products by labs resuming pre-COVID-19 workflows.

Abbott
A Promise for Life

ABBOTT LABORATORIES: COVID-19 Testing at $3.3B, Diagnostics Sales Climb 32%

Abbott in Abbott Park, Ill., shared data on the company's performance during Q1 2022:

- Total sales increased 13.8% to $11.9 billion.
- Diagnostics sales soared 31.7%, up to $5.3 billion.
- Global COVID-19 testing sales were $3.3 billion mostly due to at-home rapid testing products.
- Excluding COVID-19 testing-related sales, core laboratory diagnostics and molecular diagnostics sales increased 2.4% and 24.8%, respectively.

During an earnings call, CEO Robert Ford attributed Q1 performance to solid laboratory instrument sales and growing test menus. In response to a caller's question about the company's future momentum, Ford said Abbott has an opportunity to escalate POC testing. "COVID-19 has allowed us to further accelerate what we believe was a key trend in diagnostics, which is the expansion and decentralization of that testing outside of the lab into pharmacies, into people's homes, and it being connected," he added.

BIO-RAD

BIO-RAD LABORATORIES: Sales Down Slightly, World Events Impacting Earnings

Bio-Rad Laboratories, in Hercules, Calif., shared these Q1 2022 results:

- Sales of $700.1 million were down 3.7% to $726.8 million.
- COVID-19 testing revenue was $45 million, compared to $94 million in Q1 2021.
- Clinical diagnostics sales fell 1.9% to $351.8 million.
- Life sciences sales were down 5.3% to $347.2 million.

CEO Norman Schwartz noted effects of world events on the company's financial indicators. "We are encouraged by the underlying strength of our core business as COVID-related contributions subside," he said. "We continue to monitor key macro issues, such as pandemic-related lockdowns in China, the Russia invasion of Ukraine, and the supply chain environment—all with an eye to managing accordingly."

SIEMENS Healthineers

SIEMENS HEALTHINEERS: Diagnostics Gets 37% Boost from Rapid Antigen Tests

Siemens Healthineers reported on the period ending March 31. The company in Erlangen, Bavaria, Germany, released the following Q2 figures:

- Revenue growth of all segments grew to €5.5 billion (US$5.81 billion), which was 15.8% over Q2 2021.
- Diagnostics revenue grew to almost €1.8 billion (US$1.9 billion), a 37.2% jump.
- Rapid COVID-19 antigen tests earned nearly €680 million (US$718.5 million),

compared to €190 million year over year.

Much of the overall revenue growth was attributed to the sale of rapid at-home tests, the company stated.

"Despite the macroeconomic and geopolitical challenges, comparable revenue growth was excellent at 16%," CEO Bernd Montag told investors in an earnings call. "This was driven by outstanding 37% growth in diagnostics, including €680 million of rapid antigen test sales."

However, supply chain restrictions remained a concern for company executives, as did prolonged lockdowns in China. "The lockdowns in China at the end of the quarter impacted revenues, mostly in the diagnostics business," said CFO Jochen Schmitz, PhD.

BIOMÉRIEUX: Business Environment Evolves, Microbiology Sales Grow

For **bioMérieux**, in Marcy-l'Étoile, France, microbiology and industrial applications growth made up for lower results in other areas during Q1 2022:

- Sales fell 0.9% to €837 million (US$879 million) compared to Q1 2021.
- Clinical applications sales (84% of company sales) decreased 6.3% to €703.7 million (US$741.5 million).
- Molecular biology sales decreased 6.7% to €319 million (US$335 million).
- Microbiology sales were up 4.9%, to €266.8 million (US$281.2 million).
- Immunoassay sales were down 15.9% to €104.5 million (US$110.2 million).
- Industrial applications, including reagent sales, grew 6.1% to €133.4 million (US$140.6 million).

"Sales growth was particularly solid in both microbiology and industrial applications and in line with our expectations on molecular biology and immunoassays," said CEO Alexandre Mérieux.

SYSMEX CORPORATION: Sales Up 22% During Nine-Month Reporting Period

Sysmex in Hyōgo, Japan, reported financial results for nine months of its fiscal year ending March 31:

- Sales of ¥258.9 billion (US$1.9 billion) were up 22.2% as compared to 2021.
- Sales in North America grew 31.7% to ¥55,848 million (US$429 million).

During an earnings call, a Sysmex spokesperson said, "In the hematology field, sales increased by double digits due to a recovery in the number of tests that had declined due to the impact of the coronavirus, growth in instrument sales in the Americas, and an increase in reagent sales."

Sysmex announced plans to pursue regulatory review and market its automated hematology analyzers outside of Japan.

HOLOGIC: Omicron Leads Women to Postpone Routine Diagnostic Visits

Women's health company **Hologic** in Marlborough, Mass., announced its Q2 earnings ending March 26:

- Revenue decreased to $1.4 billion for Q2, 6.6% less than Q2 2021.
- Diagnostics revenue decreased 7.3% to $987.1 million.
- COVID-19 revenues, including assay revenue of $584.1 million decreased 13.8%.
- Excluding COVID-19 earnings, diagnostics saw a 2.8% increase in revenue year over year.

"The [diagnostic] division's results early in Q2 were negatively impacted by the Omicron COVID-19 variant," CFO Karleen Oberton noted in an earnings call. "Our base diagnostics business is inversely correlated to spikes in the pan-

demic, as women tend to postpone office visits when COVID-19 cases surge."

For example, female patients likely postponed cytology and perinatal appointments during the Omicron spike.

"Our cytology and perinatal businesses were essentially flat compared to the prior year as these segments were also impacted by COVID-19's influence on women's wellness visits," Oberton said.

QUIDEL: Q1 Revenue Surges to $1b, Ortho Clinical Deal Finalizing

San Diego-based **Quidel** released these Q1 results:

- Revenues increased 167% to $1 billion from $375.3 million year over year.
- Sales of COVID-19 products increased 211% to $836.1 million, from $269.1 million.
- Sales of influenza products were $89.1 million compared to $16.4 million.

Quidel reported its revenue increase was largely due to soaring sales of at-home COVID-19 tests, which were lightly affected by decreased sales of cardiometabolic immunoassays and molecular diagnostic products.

Meanwhile, flu-related sales show there is demand for traditional seasonal illness testing, CEO Doug Bryant noted during an earnings call.

"This highlights the importance of diagnostic testing and the significance of having a differentiated menu, which is part of our post-pandemic strategy to widen our point-of-care footprint and introduce our full portfolio of assays to both patients and healthcare providers," Bryant said.

Quidel is expected to close on its $6 billion acquisition of **Ortho Clinical Diagnostics** at the end of May. *(See TDR, "Ortho Clinical Diagnostics to Be Acquired by Quidel," Jan. 10, 2022.)*

This acquisition will give Quidel a higher ranking on the list of the world's largest IVD manufacturers.

Ortho Clinical Diagnostics

ORTHO CLINICAL: Steady Earnings Despite Supply Chain Mishaps

Separately, **Ortho Clinical Diagnostics**, in Raritan, N.J., released these Q1 2022 financial results:

- Revenue decreased 0.9% to $495 million from $499.3 million in Q1 2021.
- Revenue in the Americas was down 1.2% to $310.3 million from $313.9 million in Q1 2021.

"We believe revenue growth would have been two to three percentage points higher if we had been able to ship all the products that had been negatively affected by supply chain challenges," said CEO Chris Smith.

During an investor presentation, Ortho Clinical noted other highlights:

- Clinical lab revenue declined 4% but grew 1% year over year excluding COVID-19 testing.
- Transfusion medicine grew 11% with gains in immunohematology.

DIASORIN: Serology and Molecular Diagnostics Boost Revenue

DiaSorin in Saluggia, Italy, intends to strengthen its molecular diagnostics market via its acquisition of **Luminex**, a biotechnology testing firm in Austin, Texas.

DiaSorin—a new addition to THE DARK REPORT's top IVD companies reporting—released these Q1 results:

- Revenue grew 34.1% to €358 million (US$377 million) compared to Q1 2021.
- COVID-19 serology and molecular tests decreased 5.2% to €97 million (US$102 million).
- Molecular diagnostic revenue (without COVID-19 testing) grew 137.6% to €46.3million (US$48.8 million) due to the Luminex inclusion.

During an earnings call, CEO Carlo Rosa noted that DiaSorin is growing its business in U.S. hospital labs. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Chalk up another lab outreach deal for **Labcorp**. The Burlington, N.C.-based company has agreed to acquire certain assets of **AtlantiCare's** clinical laboratory outreach business. The deal was announced on May 9, with no financial terms disclosed. The outreach business of AtlantiCare, based in Egg Harbor Township, N.J., services **AtlantiCare Physician Group** and affiliated physicians in the southern part of the state. Labcorp now will operate many of AtlantiCare's physician office phlebotomy sites and outpatient collection services. In February, Labcorp entered an agreement to manage dozens of hospital labs on behalf of **Ascension Health** based in St. Louis. Labcorp also spent $400 million to acquire certain assets of Ascension's outreach lab services.

MORE ON: *AtlantiCare Deal*

AtlantiCare's patients will be able to access Labcorp's test menu through the latter company's network of patient service centers, including at **Walgreens**. This is the latest sign of clinical laboratory testing moving away from hospitals and physician offices and into retail pharmacy spaces, a trend largely driven by changing consumer preferences for how they access healthcare.

NASHVILLE'S PATHGROUP HAS NEW INVESTOR

Last Friday, it was announced that Nashville-based **PathGroup** had a new majority investor, **GTCR** of Chicago. In addition to the new investor, the press release disclosed that "Dave King, the former Chairman and CEO of **Labcorp**, will join the PathGroup Board as Chairman." As part of this transaction, PathGroup's founder and CEO, Ben Davis, MD, and members of the PathGroup management team "made a substantial reinvestment in the company." **Pritzker Private Capital** and **Vesey Street Capital Partners** will continue to retain a minority ownership stake in the laboratory company.

FULGENT GENETICS BUYS INFORM DIAGNOSTICS

Avista Capital Partners, a private equity firm in New York City, has closed on the sale of **Inform Diagnostics** to **Fulgent Genetics** for $170 million. Inform Diagnostics is a pathology lab based in Irving, Texas, with 1,300 clients representing 2,700 physicians. Fulgent Genetics in Temple City, Calif., is a next-generation sequencing company. Avista bought Inform Diagnostics from **Miraca Life Sciences** in 2017 to form a standalone company.

TRANSITIONS

- Rob Albert joined **Versant Diagnostics** in February as Chief Development Officer. He was previously VP/GM of the Northwest Region for Labcorp before leaving in 2019.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 6, 2022.

Executive Publisher: Bob Croce *bcroce@darkreport.com*
Editorial Director: Scott Wallask *swallask@darkreport.com*
Editor-In-Chief: Robert L. Michel *rmichel@darkreport.com*
Managing Editor: Michael McBride *michaelmcbride58@gmail.com*
Senior Editor: Joseph Burns *joeburns@capecod.net*
IVD Reporter: Donna Marie Pocius *donna11019@att.net*
Legal/Compliance Reporter: Kim Scott *kmscott2@verizon.net*