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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

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COMMENTARY & OPINION by...

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Despite COVID-19, Regular Lab Testing Expands

TIMES ARE GOOD FOR THE REGULAR RANGE of clinical laboratory and anatomic pathology testing services. Despite the COVID-19 pandemic, the daily number of routine test specimens is near pre-pandemic levels and certain sectors of lab testing—particularly genetic tests and some high-cost assays—are showing substantial growth this year, compared to 2019.

It may surprise many clinical laboratory administrators and pathologists to learn these facts, in part, because they continue to be fully occupied with the demands of providing adequate numbers of molecular SARS-CoV-2 tests even as their laboratories must also deliver the regular range of diagnostic tests used daily in patient care.

The volume of routine testing had returned to pre-pandemic levels during the summer of 2020. As you will read on pages 10-14, the two billion-dollar public lab companies—**LabCorp** and **Quest Diagnostics**—both told investors on their recent fourth quarter 2020 conference calls that the daily number of routine test specimens had declined by high-single digit percents in the early fall. That drop off has continued into the first months of 2021.

At the same time, both lab companies report that they see robust demand for specialty tests and for genetic tests. Also, LabCorp executives mentioned during their earnings call that they had seen an increase in the average number of tests per requisition in recent months. That partially offsets the decline in the daily number of requisitions from regular testing activities. They attribute the increase in average number of tests per requisition to physicians needing to order more tests during a patient's office visit, because so many patients stopped coming in for regular office visits after the onset of the pandemic.

It's not just regular clinical laboratory testing that shows signs of returning to a pre-pandemic level. In the *in vitro* diagnostics (IVD) industry, companies continue to bring new products to market and to acquire up-and-coming diagnostic companies. On pages 15-18, you will read about **Truvian Sciences** and its technology designed to enable more near-patient testing for 40 of the most common clinical laboratory tests. Similarly, on page 9, you can read about **Roche Diagnostics** spending $1.8 billion to acquire **GenMark Diagnostics**. These are examples that demonstrate how the diagnostic and lab testing marketplaces are steadily moving back to a more normal state. TDR

Revised Stark, AKS Rules Are Good News for Labs

Federal regulators wanted to incorporate common definitions into both sets of regulations

CEO SUMMARY: It must be rewarding for federal rulemakers at the Centers for Medicare and Medicaid Services and the Office of the Inspector General to hear that attorneys representing clinical labs and pathology groups consider the new final rules for the Stark Law and the Anti-Kickback Statute to be helpful for clarifying how labs and other providers are to comply with these two rules. At the same time, federal regulators have yet to address the conflicting language in the EKRA statute.

COMPLIANCE BY CLINICAL LABORATORIES AND ANATOMIC PATHOLOGY GROUPS with the federal Anti-Kickback Statute and the Stark Law should be less confusing following the publication of a new final rule for each law last December.

This is positive news for the clinical lab industry. Attorneys representing labs say these finalized changes to the Stark Law and the anti-kickback statute will give clinical laboratories more flexibility in routine business arrangements they make with physician practices.

"Not only do we now have some nice synergies between the Stark Law and the anti-kickback law, but we also have new guidance in areas where well-meaning laboratories have gotten tripped up in the technicalities over the years. These new rules are really refreshing because I think they will help us get through some of those technical lapses," said Jane Pine Wood, legal counsel for **Bio-Reference Laboratories**, when she spoke during the annual meeting of the **American Clinical Laboratory Association** (ACLA) on March 10 (held virtually).

Karen Lovitch, an attorney with **Mintz**, agreed. "This is a rare instance where the provider community really wants these changes to go into effect," she said. "That doesn't happen very often."

Changes to these laws were first proposed on Oct. 9, 2019. The revisions were finalized Dec. 2, 2020, by both the **Centers for Medicare and Medicaid Services** (CMS) and the **Health and Human Services Office of Inspector General** (OIG) and became effective Jan. 19, 2021. CMS published the revised rules on the Stark Law while the OIG published rules on the Anti-Kickback Statute. *(See TDR,*

"Feds Revise Stark Law, Anti-Kickback Statute," Dec. 7, 2021.)

When announcing the final rules, the federal **Department of Health and Human Services** (HHS) said that both rules seek to reduce the burden laboratories and other providers face when engaging in value-based or coordinated-care arrangements by lowering the barriers that labs face when contracting with health insurers and physician groups in care-coordination arrangements.

In recent years, the Medicare program has taken strong steps to encourage closer coordination of care across providers, as well as ensure different forms of reimbursement are based on the value delivered by providers. Federal officials recognized that the Stark Law and AKS, as currently written, were impeding progress in both areas.

Strict Liability-Based Law

Because the Stark law is a strict liability-based statute and compliance with an exception is obligatory, clinical laboratory arrangements that comply with Stark are likely to also comply with AKS, explained Wood. The Stark law is also more complex, which is why most attorneys tend to focus on that first when analyzing arrangements for compliance.

In general, the Stark law prohibits the referral of certain designated health services—including clinical laboratory and anatomic pathology services—if there is any ownership or compensation relationship between the laboratory and the referring physician, and if the services are covered by the Medicare program.

The AKS prohibits individuals and entities from a willful and knowing payment of remuneration—or anything of value—in exchange for patient referrals that are reimbursable by a federal healthcare program.

One significant change to both Stark and the AKS is that CMS has now decoupled the two sets of regulations. Previously, many of the exceptions to the Stark Law also included a requirement that the arrangement also fall under a safe harbor in the AKS. CMS has now removed that requirement for most exceptions (but not for the fair market value exception).

But What About EKRA?

While recent changes to the Anti-Kickback Statute (AKS) may provide clinical laboratories with more flexibility in setting up routine business arrangements, there is no such flexibility under the Eliminating Kickbacks in Recovery Act (EKRA), which significantly restricts how lab sales and marketing representatives are paid.

EKRA, passed in 2018, creates criminal penalties for any individual who solicits or receives any remuneration for referring a patient to a recovery home, clinical treatment facility, or clinical laboratory, or pays or offers any remuneration to induce a referral.

EKRA also prohibits payments made by an employer to an employee or independent contractor if that person's payment is determined by or varies by the number of individuals referred, the number of tests or procedures performed, or the amount billed to or received from a payer. EKRA applies to arrangements reimbursed by all payers (including commercial and third-party payers), not just federal healthcare programs, as is the case under the AKS.

EKRA Is More Restrictive

EKRA is more restrictive than the AKS and actually prohibits certain compensation that is expressly permitted under the Anti-Kickback Statute, says Emily Johnson, an attorney with **McDonald Hopkins**.

"Specifically, AKS includes a safe harbor for bonafide employees that gives an employer wide discretion in how employees are paid, including permitting percentage-based compensation," wrote Johnson in a special report, titled, "Getting Paid for COVID-19 Test Claims," soon to be published by THE DARK REPORT. "EKRA

CMS, OIG Recognized Need to Update and Align Stark Law and Anti-Kickback Statute

KIMBERLY BRANDT, FORMERLY PRINCIPAL DEPUTY ADMINISTRATOR FOR POLICY AND OPERATIONS at the Centers for Medicare and Medicaid Services (CMS) and currently a partner at **Tarplin, Downs, and Young LLC**, helped draft these changes while she worked at the agency. She explained that one goal in modifying these regulations was to ensure that definitions are similar or the same in both the Stark Law and AKS regulations.

"Because Stark is a strict liability statute, and anti-kickback is an intent-based statute, some people inadvertently got tripped up on Stark law technicalities, at times as simple as a situation where they just didn't get something signed prior to commencing the relationship," explained Brandt. She said that, while working with CMS, "one of our goals was to decouple those regulations where appropriate, so someone didn't mistakenly get caught in the gap."

In 2018, CMS, in conjunction with the Health and Human Services' Office of Inspector General (OIG), asked for comment on how the Stark Law and AKS regulations could be modified to make more sense while still accomplishing the goal of prohibiting fraud. The agency received thousands of pages of suggestions, notes Brandt, who says the real goal was to simplify the regulations and make them easier to understand and apply.

"We really wanted to make sure they were more understandable," she said. "CMS and the OIG spent hundreds of hours walking through examples and thinking about the impact on clinical laboratories and other providers. We wanted to make commonsense changes that would stand the test of time and help people be more creative in delivering coordinated care and value-based care. That's the new focus these days."

"This is why it's so important for clinical laboratories to comment when they're able, because these are really wonderful changes, for the most part, that will help labs from inadvertently tripping up in areas where old regulations may have gotten in the way of conducting routine business," noted Jane Pine Wood, legal counsel for Bio-Reference Laboratories.

does not afford bonafide employees that same protection."

Although the recent changes to the Stark Law and AKS provide more flexibility to clinical laboratories, there has been no similar guidance or flexibility issued with respect to EKRA, says Johnson.

"As such, an arrangement that qualifies for a Stark waiver, and/or exception or AKS safe harbor, must still be analyzed independently to determine if it complies with EKRA," she wrote. "While it is believed within the lab industry that EKRA was intended to address issues within the recovery industry and was not intended to apply to all clinical laboratory arrangements, without further regulatory clarification or other guidance from Congress or the government agencies, EKRA remains in place as originally drafted and implemented in 2018."

Johnson notes that since its implementation in 2018, the government has settled multiple cases of EKRA violations, which is evidence of its intent to enforce this broad-sweeping regulation. TDR

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Understanding Key Parts of New AKS, Stark Law Rules

➤Certain of the revisions to both final federal rules should help clinical laboratories with compliance

➤➤CEO SUMMARY: Both the federal Stark Law and Anti-Kickback Statute have been revised and the final rules became effective on Jan. 19. The good news for clinical laboratories and anatomic pathology groups is that federal regulators from the Centers for Medicare and Medicaid Services and the Office of the Inspector General made it a goal to harmonize the language of the two new rules. Attorneys advising labs say the changes will make it easier for labs to understand how to comply.

OVERALL THE RECENTLY PUBLISHED CHANGES to the Stark Law and the Anti-Kickback Statute will ease regulatory uncertainty for clinical laboratories and anatomic pathology groups.

Although CMS made many changes to the Stark Law, below we highlight some of the more important regulations for clinical laboratories and pathology practices.

➤Definition of a Physician

Previously, the definition of "physician" used in the Stark regulation was not consistent with the Medicare statute. The Dec. 2 regulation makes the definition consistent, so that a "physician" includes an MD, a DO, a dentist, a chiropractor, and an optometrist.

➤Collection and Surgical Supplies

In the past, supplies provided by laboratories to physicians typically fell under an exception to the definition of remuneration under the Stark law, but the regulation specifically carved out "surgical" items, such as reusable aspiration and injection needles and snares, from the exception.

"This been a hot topic over the years, with numerous CMS advisory opinions about it," explained Karen Lovitch, an attorney with **Mintz**. "CMS has come to the logical conclusion that it doesn't make sense to carve out all surgical supplies from the exception. It will now consider how a device, item, or supply is actually used in practice. This will be a helpful change for clinical labs and pathology groups."

Jane Pine Wood, legal counsel for **Bio-Reference Laboratories**, noted that most laboratories have the ability to track supplies and how they are being used, which helps in making the determination.

➤Exceptions to Compensation Arrangements

There are a number of exceptions to the prohibition on self-referrals under Stark. Most of these exceptions require a written arrangement, a commercially reasonable arrangement, and that the compensation be at fair market value, set in advance, and cannot vary with the value or volume of referrals. The sections that follow address specific factors covered by the revisions made with the Stark Law revisions.

Limited Renumeration to Physicians

This is a new exception that permits payment of up to $5,000 to a physician in a calendar year without a written agreement or compensation that is set in advance.

This could be applicable in a situation where a laboratory director quits and a temporary replacement needs to be brought in immediately. Brandt noted that the agency considered payments of $3,500 to $10,000 and that $5,000 was a compromise.

Modifying Arrangements

CMS is extending the grace period during which providers can modify their arrangements to ensure they are in compliance with Stark, as well as tweaking the requirement that arrangements be set in advance.

"We wanted to give providers as many options as possible," explained Kimberly Brandt, formerly principal deputy administrator for policy and operations at the **Centers for Medicare and Medicaid Services** (CMS). Now an attorney with **Tarplin, Downs, and Young LLC**, Brandt explained how CMS "said that providers can modify the compensation agreement at any time during the arrangement and still satisfy the requirement that it be set in advance. It gives more flexibility and allows providers to adapt agreements as things change." CMS also stated that electronic signatures are valid for purposes of the signature requirement.

Defining 'Commercially Reasonable'

CMS, for the first time, has defined the term "commercially reasonable," which is used in many Stark exceptions. Under the new definition, an arrangement can be commercially reasonable if it makes good business sense, even if it does not turn a profit (for example, if a new clinical laboratory opens a patient service center in a physician office building, but does not make a profit in the first year).

"The term 'commercially reasonable' was never defined in the statute, which is very disconcerting when you have a strict liability statute," Lovitch commented. "CMS now defines a 'commercially reasonable' arrangement as one that furthers the legitimate business interest of a party even if it does not result in a profit. Examples include improvement of health outcomes, community need, timely access to health services, fulfillment of licensure obligations and charity care." The key element for compliance with this requirement is to document the legitimate business rationale, Wood added.

Defining Volume or Value of Referrals

CMS provides a bright-line rule as to when compensation would be deemed to vary directly or indirectly with the volume or value of referrals for designated health services.

"Only when the mathematical formula used to calculate the amount of compensation includes referrals or other business generated as a variable, and the amount of compensation correlates with the number or value of the physician's referrals to or for the physician's generation of other business for the entity," would the volume or value standard be violated, states CMS in the final rule. The formula applies both to an increase, as well as a decrease in the physician's compensation. This test does not apply under the AKS.

Rental of Office Space or Equipment

Clarifies that multiple lessees can use the same space or the same equipment. The limited remuneration exception above can also be used to cover lease payments.

Isolated Transactions

This exception says a provider can have a single isolated transaction that is commercially reasonable—typically used for sale of a practice—once per year.

CMS has more clearly defined this as a one-time financial transaction with a single payment or integrally-related installment payments. This can be used to

cover a single instance of forgiveness in an amount used to settle a bonafide dispute.

➤Personal Services Safe Harbor

While the changes to Stark are more significant because of the strict nature of the law, there is one important revision to the AKS about which clinical laboratories should be aware. The personal services safe harbor typically is used when a health system contracts with an individual physician, such as a pathologist, as an independent contractor.

Historically, the personal services safe harbor required aggregate compensation to be set in advance. If an entity paid someone by the hour, that was not considered to be set in advance.

CMS has modified the requirement so that the compensation methodology has to be set in advance. CMS has also eliminated the requirement that if the services are to be provided on a periodic or part-time basis, the agreement must specify the schedule, length, and the exact charge for such intervals.

This change reflects CMS' position that existing safeguards are sufficient to protect against fraud and abuse. This change aligns the personal services safe harbor more closely with the Stark law.

➤Cybersecurity Donation Safe Harbor

There are a few other instances where CMS and the OIG revised the Stark and AKS regulations to make them more closely aligned so that the exception under Stark and the safe harbor under the AKS are the same.

One of the most important of these exceptions for clinical laboratories is a new exception and safe harbor that allows healthcare providers to donate cybersecurity technology and services to physicians and other providers who may not be able to afford sufficient protection.

Covered technology and services must be "necessary and used predominantly to implement, maintain, or re-establish cybersecurity," which is the same standard applied under the safe harbor and exception for EHR donations, noted HHS.

Donors have wide discretion in choosing the technology to be donated. When determining eligibility or the amount or nature of a donation, donors cannot directly take into account the volume or value of referrals or other business generated between the parties.

The most important difference between the exception and safe harbor is the writing requirement. Under the safe harbor, the arrangement must be set forth in writing and signed by the parties, and it must include a general description of the donation and the contribution amount. In contrast, CMS merely requires that the arrangement be documented in writing.

Both agencies considered whether to restrict the scope of potential donors but ultimately declined to do so, noted Lovitch. Various laboratory industry organizations recommended the exclusion of laboratories based on the fact that many physicians reportedly conditioned referrals on EHR donations before laboratories became excluded donors in 2013 under the exception and safe harbor for EHR donations.

According to the agencies, there is no need to exclude laboratories because recipients cannot make the receipt of cybersecurity technology or services, or the amount or nature of such technology of services, a condition of doing business with the donor.

Regardless of these changes, clinical labs that contemplate business relationships with physician practices and other healthcare providers should ensure that all arrangements comply with both the Stark Law and the Anti-Kickback Statute. Clinical laboratories should consult with inside or outside counsel before entering into any arrangements that could potentially be perceived as problematic. TDR

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IVD & IT Update

Roche to Acquire GenMark, Ovation.io Raises $21.5M

Roche to Pay $1.8 Bil. for GenMark

THERE'S MORE CONSOLIDATION in the *in vitro* diagnostics (IVD) industry. It was announced on Mar. 15 that **Roche Diagnostics** would acquire **GenMark Diagnostics** of Carlsbad, Calif., for a purchase price of $1.8 billion.

With access to GenMark's technology, which enables rapid testing of many pathogens from one sample, Roche will expand its capabilities in infectious disease testing, including respiratory and bloodstream infections.

Barron's wrote that "it's a deal that makes sense, said a team of analysts at **UBS** [Union Bank of Switzerland], led by Michael Leuchten. 'The acquisition adds testing menu (multiplex tests) and also broadens Roche's reach into hospitals when at the moment the majority of its diagnostics business is focused on centralized labs.'"

With the acquisition of Genmark, Roche sees an opportunity to "challenge rivals like France's **bioMérieux**," reported *Reuters*, which also said the merger may make it possible for Roche to expand its diagnostics services in hospitals and to departments beyond the core laboratory.

Founded in 2010, GenMark developed the ePlex system, a proprietary eSensor detection technology that enables performance of molecular tests detecting multiple pathogens from one sample, *BioSpace* wrote. The tests run on a compact workstation using disposable test cartridges.

"Acquiring GenMark Diagnostics will broaden our molecular diagnostics portfolio to include solutions that can provide life-saving information quickly to patients and their healthcare providers in the fight against infectious diseases," said Thomas Schinecker, PhD, CEO, Roche Diagnostics, in a news release.

LIMS Firm Ovation Gains Access to Capital

One of the newest competitors offering a laboratory information management system (LIMS) just raised $21.5 million. The closing of the series B funding round was announced last December by **Ovation.io** co-founder and CEO Barry Wark, PhD.

Established in 2017, Ovation.io has enjoyed rapid growth. Revenue doubled during 2020 as the growth of COVID-19 increased demand for its LIMS platform.

"Ovation is entirely cloud-based. Being cloud-based enables us to deploy up to twelve times faster than legacy solutions and better support a rapidly changing diagnostic landscape," Wark said. "The benefit to labs is that there is zero on-premise software or hardware that needs to be installed and maintained."

One of the five key funders called attention to Ovation.io's focus on molecular genomics labs and precision medicine. "These labs need specialized software, and the real value is being able to stitch the data together to create a solution to go after targeted therapeutics," said Chris Scoggins, Venture Partner, **SignalFire**, in *Crunchbase News*. **TDR**

Some public lab companies have good insights

What Comes Next? Predictions on COVID-19 Test Volumes in 2021-22

CEO SUMMARY: Incoming data show that the number of referrals for both COVID-19 tests and routine tests is in a decline that started in October and is continuing. This complicates the strategic planning for hospital/health system labs, independent labs, and pathology groups. They need to make accurate predictions about the demand for tests in coming months, so that they can manage their supply chains and schedule lab staff. The financial consequences of guessing wrong about lab test volumes can be substantial.

WHAT WILL THE COVID-19 PANDEMIC BRING NEXT to clinical laboratories and anatomic pathology groups? Will COVID-19 test volumes increase or decrease through 2021 and 2022? Will demand for SARS-CoV-2 serology tests increase in the coming 12 months?

These are some of the most important questions now driving both short-term and long-term strategic planning at the nation's labs. Every lab's strategic planning must address the clinical and financial consequences in response to the evolving nature of this pandemic, along with unexpected changes in how patients access care.

Lab administrators and pathologists walk a daily tight rope as they attempt to balance their purchases of SARS-CoV-2 test kits, collection supplies, transport media, and other lab consumables with the incoming flow of patient specimens.

Similarly, clinical laboratory managers must align lab staffing schedules to the incoming volume of samples so as to maintain the desired turnaround times. This goal is particularly important now that the Medicare program pays a higher price per test for COVID-19 molecular tests reported within 48 hours. *(See TDR, "Medicare to Cut Payment for COVID Tests Jan. 1," Oct. 26, 2020.)*

Unfortunately, it is the nature of this pandemic to be entirely unpredictable. Since the first surge of cases in March, there have been three separate surges in daily test volumes. Each wave had a peak in the number of daily new COVID-19 cases, followed by a decline.

One example is the third wave, which started in early October. From a baseline of 50,000 new cases per day, it grew to a peak of 314,000 daily new cases on Jan. 8, 2021. That was a 419% increase in new infections over the second wave's peak of 75,100 cases, recorded on July 24, 2020.

The good news is that, since Jan. 8, daily new cases of COVID-19 have fallen to as low as 50,013 on Monday of last week, according to data published by the federal **Centers for Medicare and Medicaid Services** (CMS).

Just as the first two waves of new COVID-19 case crested, then declined, only to yield to an even bigger wave of daily new cases, one cannot rule out the potential for a fourth wave of daily new COVID-19 cases to hit in coming months.

However, there are strong reasons to predict that the worst of the pandemic in the United States may have passed. A number of epidemiologists believe this current decline in daily new cases might continue downwards because of two factors.

First, the number of people with at least one dose of COVID-19 vaccine is now greater than 115 million and is increasing by about two million people per day in this country, according to CDC data. So more than one-third of the U.S. population already have some protection against a SARS-CoV-2 infection.

30 Million Cases in the U.S.

Second, the total number of COVID-19 cases reported in the United States since the onset of the pandemic is now about 30 million, which is almost 10% of the population. These individuals have some level of immunity to a new infection.

Together, these two factors would argue that the worst of the pandemic has passed. But it is the nature of pandemics to be unpredictable and new variations of SARS-CoV-2 are popping up all over the world.

Further, there is the unanswered question as to whether SARS-CoV-2 will become endemic in the United States. In this scenario, new COVID-19 infections show up regularly—and just as with the common cold and influenza—cases of COVID-19 might increase in a pattern associated with the seasons.

Thus, lab managers and pathologists have vexing questions to answer as they develop a strategy to respond to the pandemic, supported by operational tactics to handle the required volume of testing.

The data above provide a starting point for labs as they do their business planning. But more information about the ongoing demand for molecular SARS-CoV-2 testing and COVID-19 serological testing is needed to help labs with their strategic planning.

There is a credible source of insight about how the demand for COVID-19 testing may play out during 2021 and into 2022. It comes from the nation's billion-dollar public laboratory companies.

Both **LabCorp** and **Quest Diagnostics** have access to all that is happening with efforts to manage the pandemic. Their executives speak daily with the federal and state officials in charge of the pandemic response. This has been true since the earliest days of the pandemic, when the federal government was under great pressure to help clinical labs increase the number of molecular SARS-CoV-2 tests they could perform daily.

Unique Access to Information

This means that the executives at the two blood brothers have unique access to information about the latest regional hot spots for infections and the actions federal and state officials are taking to control the pandemic and ensure an adequate number of COVID-19 tests across the nation.

LabCorp and Quest executives—along with administrators at such big organizations as **ARUP Laboratories**, **Mayo Clinic Labs**, and **Sonic Healthcare**, which each have a national network of labs—also know more about the daily changes in the supply chain of collection supplies, transport media, COVID-19 test kits, and primers than the administrators of other labs in the United States.

Given the engagement of the executives at these two laboratory companies with government officials at the federal, state, and local levels, it can be assumed that their strategic planning incorporates this knowledge and information.

During their respective fourth quarter and full year 2020 conference calls, the leadership at LabCorp and Quest did provide opinions on the demand for molecular and serological tests for SARS-CoV-2 during the balance of 2020 and into 2021. Their comments can be useful for lab managers and pathologists to use when developing forecasts and strategic plans for their own labs.

On Feb. 4, Quest Diagnostics was first to issue its Q4-2020 earnings report and hold its conference call with financial analysts. LabCorp issued its Q4-2020 earnings report on on Feb. 11 and held its conference call the same day. Highlights of the financial performance for each public lab company are shown in the sidebar on page 13.

During their respective earnings calls, executives at both companies discussed the following topics that can help inform strategic planning activities at other clinical labs and pathology groups. They include:

- falling demand for COVID-19 tests in recent months;
- decrease in daily number test referrals for routine and reference testing since fall of 2020;
- speculation about a more important role for SARS-CoV-2 serology tests.

The following statements were made during the Q4-2020 earnings calls conducted by Quest Diagnostics and LabCorp. The Dark Report presents below their statements about each of the three points shown above.

Dropping Demand for COVID-19 tests

During the Quest earnings call, the COVID-19 test demand was mentioned early. "... demand for COVID testing is likely to decline throughout 2021 as more people become vaccinated and fewer new cases are reported," stated Steve Rusckowski, Chairman, President, and CEO at Quest. "We believe that COVID-19 testing will continue into 2022."

"The demand for and duration of COVID-19 testing—as well as the continued recovery in the base business—are significant swing factors that remain challenging to forecast," commented Mark J. Guinan, Quest's Chief Financial Officer.

LabCorp, Quest Diagnostics Report Earnings for Q4 and Full Year 2020, the Year of COVID

BECAUSE OF THE COVID-19 PANDEMIC, 2020 was a year like no other in the history of the clinical laboratory industry. The shutdown of the nation in March, 2020, caused a precipitous decline in both the volume of routine lab test specimens referred daily to the nation's labs, along with a corresponding crash in cash flow. The fourth quarter and full-year 2020 earnings reports of both Quest Diagnostics and LabCorp reflect all of the disruptive consequences of the pandemic. Here are some of the financial highlights for both public lab companies.

Quest Diagnostics™

Quest Diagnostics released its Q4 and full-year 2020 earnings report on Feb. 4. For the full year, revenue was $9.1 billion, a 23.4% increase over 2019's revenue of $7.4 billion. Comparing 2020 to 2019:

- revenue per requisition was up 16.2%
- number of requisitions grew by 6.6%
- organic requisition growth was 4.5%

For the fourth quarter, revenue was $2.9 billion, a 58% increase over Q4-2019. Because COVID-19 test capacity had expanded over the year, Q4 performance was much greater compared to the same quarter in 2019:

- revenue per requisition was up 25.2%
- number of requisitions grew 26.8%

labcorp

On Feb. 11, LabCorp released its Q4 and full-year 2020 earnings report. For its diagnostics division (the clinical laboratory business), revenue for the full year 2020 was $9.3 billion compared to revenue of $7.0 billion in 2019, an increase of 32.2%.

For the fourth quarter, diagnostics revenue was $2.9 billion, a 58% increase over Q4-2019.

Comparing Q4-2020 to Q4-2019:

- revenue per requisition was up 34.0%
- number of requisitions grew by 33.9%
- organic requisition growth was 22.3%.

LabCorp's other major division is **Covance**, its clinical trials business. When adding together all its businesses, LabCorp reported total revenue of $14.0 billion in 2020, compared to $11.6 billion in 2019, an increase of 21.0%

"COVID-19 molecular testing volumes averaged roughly 100,000 tests per day in the first half of the year. However, we expect average daily volumes [of molecular COVID-19 tests] to decline throughout the first half of 2021 as more people become vaccinated. Therefore, we assume COVID-19 molecular volumes will be lower in the second quarter compared to Q1-2021."

During LabCorp's earnings call, the following statements addressed demand for COVID-19 testing. LabCorp provided guidance to financial analysts, with Glenn A. Eisenberg, LabCorp's Chief Financial Officer, stating, "... COVID testing revenue [at LabCorp] will decline 35% to 50%" during 2021, compared to 2020.

"If the country vaccinates a significant portion of the population by the summer, we would expect a continued decline in COVID-19 molecular testing volumes in the second half of 2021 compared to our expectations for the first half," added Eisenberg. "Similarly, demand for COVID-19 serology testing is likely to wane in the back half of the year."

"And I assume that the [molecular COVID-19 test] volume is going to continue to decline," commented Adam H. Schechter, Chairman, President, and CEO of LabCorp. "... then for the second half of the year [2021], the [COVID-19 molecular test volume will] be significantly less than the first half of this year. That's our base-case assumption."

Decrease in Routine and Reference Testing

Recent declines in testing volume for routine clinical lab test referrals was discussed during each conference call. Both lab companies reported that this decline began last fall and continues into the first months of 2021.

During the Quest earnings call, CFO Guinan explained, "As we highlighted in our 2020 outlook update in mid-December, organic [routine] testing volumes ordered in our base business were down mid- to high-single digits versus the prior year in October and November. The recovery stalled in late November with organic testing volume trends down high single digits versus the prior year in December due to the surge in new infections across the country.

"Our first half outlook generally assumes a gradual improvement in base [routine] testing volumes, but we expect the base business to remain below our prepandemic 2019 baseline throughout the first half of the year," added Guinan.

LabCorp's Schecter explained that "... we saw lower [routine test] volumes down 7.7%, but still, that's an improvement [from our routine lab volume] trend through the earlier parts of the year [2020, during the lockdown months of March and April], and it was more than offset by favorable price and test mix."

Even as LabCorp experiences an overall decline in the number of routine test orders, it spotted an increase in the average number of tests per requisition. "We continue to see an unusually high level of favorable [test] mix, primarily driven by higher tests per accession," explained LabCorp's Schecter. "The feeling is because there are fewer visits by patients to their physicians, physicians are conducting more [lab] tests per visit ... going forward and [that is] reflected in the guidance."

Speculation about Role for SARS-CoV-2 Serology Tests

Uncertainty continues about the demand for COVID-19 serology tests. Each lab offered perspectives on this subject.

At Quest, "we do believe there'll be increasing role of serology throughout 2021," stated Rusckowski. "We see some early interest in understanding whether an individual has the antibodies or not, which might inform patients and physicians around their urgency of getting vaccinated.

"At the same time, we're bringing out a new capability called quantitative serology testing," continued Rusckowski. "This will allow physicians and patients to see if, in fact, they do get the spike protein from the vaccines. We'll be bringing that assay [to market] on two platforms in the next few weeks.

"So, we do believe that there will be some increased demands for serology. And this is on top of what we already do," concluded Rusckowski.

Serology testing for SARS-CoV-2 is also under development at LabCorp. "We are very specific to say COVID-19 testing and not break apart PCR and serology because it could go in multiple different directions," observed LabCorp's Schechter. "I think if you end up having to have a vaccination every year, serology might not be that important. If you need a vaccination every several years, then I believe serology will be very important."

Schechter continued, saying "the real question is going to be what level? What's the quantitative analysis that you need for a certain level of antibodies to feel like you're protected. If there is a quantitative number that allows people to feel comfortable that they can fly, they can go to events, they can do many other things—then it will be very important [for COVID-19 serology testing]." TDR

IVD Update

Truvian Sciences Raises $105M for Near-Patient Lab Test System

San Diego company hopes to obtain FDA clearance for its multi-analyte analyzer that uses drops of blood

DESPITE THE PANDEMIC, investors continue to support emerging *in vitro* diagnostics (IVD) companies. This is particularly true of start-up companies that want to develop clinical lab testing systems that can be used at the point of care, that require small amounts of blood, and that deliver accurate results in just minutes.

That would describe the testing analyzer under development at San Diego-based **Truvian Sciences**. Just last month, the company raised $105 million in a series C funding. Truvian said the money will be used to apply for 510(k) clearance and a CLIA waiver from the federal **Food and Drug Administration** and it hopes to make that regulatory submission before the end of the year.

Disrupt Core Lab Model

The company's founders state their objective is to disrupt the existing model of the central clinical laboratory by delivering a self-contained instrument system that is:

- small enough for point-of-care and near-patient settings,
- performs CLIA-waived tests so anyone can operate it,
- produces tests results in just minutes,
- has a competitive cost per test, and,
- is consumer-friendly, because only small quantities of blood are required to run the tests.

As a start-up IVD company, Truvian has ambitious goals. In statements provided to THE DARK REPORT, Dena Marrinucci, founder and Senior Vice President of Corporate Development and Business Operations, said, "Truvian's automated benchtop system combines clinical chemistry, immunoassays, and hematology assays in one device. The first panel will offer 40 of the most commonly ordered diagnostic tests—including a lipid panel, metabolic panel, and complete blood cell count—to be completed in a single run, from just five drops of blood, and with results in 20 minutes.

Broader Test Access

"Currently, such a panel needs multiple vials of blood and results can take days," she continued. "And at a fraction of the cost of traditional lab tests, Truvian's solution won't be cost prohibitive, thus allowing broader access to more individuals."

During the past three decades, many start-up IVD companies have pursued the goal of a low-cost, accurate, fast point-of-care (POC) multi-analyte analyzer capable of running most of the routine tests ordered daily in doctors' offices. But no front runner has emerged in that race.

Truvian predicts it can succeed, arguing there are two new sources of demand for near-patient and POC testing. The first source are consumers. The second source are the national pharmacy companies such as **CVS** and **Walgreens**, and the national retailers, including **Walmart** and **Target**, that are now establishing primary care clinics in their retail stores.

Clinical lab administrators and pathologists should step back for a moment and consider what is different in healthcare in the United States today, versus, say, 15 years ago. In 2006, the first "convenience clinics" began to appear in retail chains, usually next to the pharmacy. Typically, for a modest fee a registered nurse or nurse practitioner was available to diagnose about 40 to 50 simple conditions, many of which needed a prescription that could be filled by the patient before leaving the store.

2,000 In-Store Medical Clinics

Now, a decade and a half later, there are approximately 2,000 in-store clinics. CVS operates almost 1,000 such clinics. Significantly, most retail chains have plans to expand these convenience clinics into full-service primary care clinics. For example, Walmart already has 20 standalone primary care centers and plans to increase that number to 4,000 by 2029.

The executives at these national chains recognize that their primary care clinics will be more productive, and can handle more patients and generate more revenue, if clinical laboratory test results can be produced within minutes of a patient's arrival at the clinic. Truvian Sciences recognizes that these retail chains are new buyers of speedy diagnostic tests. Moreover, these retail chains will want to purchase millions of near-patient and POC tests each year.

New Demand for Testing

This demand for near-patient testing did not exist until a few years ago. Thus, the trend of more consumer interest in their healthcare, combined with the trend of national retailers wanting to deliver primary care medical services, is what drives a new and substantial demand for clinical laboratory tests that are accurate, fast, cheap, and can be performed where patients see physicians.

Truvian CEO Jeff Hawkins described these twin trends in a *MedCity* interview. "The idea that has always been at the center of our vision is that our healthcare industry needs to evolve, and as part of that, blood testing needs innovation," he noted. "Routine testing needs to move closer to the consumer, away from the lengthy process and cost-constricting centralized lab model.

"Consumers need a more convenient solution for health and wellness management that provides them with insights into their own health, at their fingertips, affordably, and rapidly," explained Hawkins. "Point-of-care solutions with retailers such as CVS and Walmart, are becoming a driving force in bringing routine healthcare to the masses and enabling easier access in a variety of ways.

"But [clinical laboratory] testing continues to be a bottleneck," he emphasized. "Truvian is driven to disrupt the centralized lab model, making routine health testing convenient, affordable, and actionable for today's connected consumers."

Overnight Specimen Delivery

The two Truvian executives are direct and clear about their plans to be disruptive and why the current model of clinical laboratory testing—dominated by the overnight delivery of specimens to central labs, with results reported the next day or later—will cease to meet the needs of both consumers and operators of clinics in retail stories.

"As healthcare continues moving to meet people where they are, Truvian will focus on both retailers and corporate on-site and near-site clinics to enable more convenient testing for today's connected consumers," stated Hawkins in the *MedCity* interview. "We also know that primary care physicians value the rapid insights our platform will deliver to help take some of the guesswork out of their initial diagnosis."

"With consumers demanding control of their life at their fingertips, health data shouldn't be any different," added Marrinucci in the same interview.

(Story continues on page 18.)

San Diego-based Truvian Sciences Wants to Deliver a Lab Test Solution to Pharmacies, Retail Stores

SOON TO ENTER THE MARKET FOR NEAR-PATIENT AND POINT-OF-CARE TESTING is Truvian Sciences, based in San Diego. Founded in 2015, the company is developing a multiplex desk-top analyzer (shown at right).

Truvian believes that there will be robust demand from non-traditional buyers of clinical laboratory tests. This demand will come from national pharmacy chains and retailers with primary care clinics in their stores.

Truvian believes they will want a clinical lab testing solution that requires a small quantity of blood, can return results in minutes, is cost-effective compared to core lab test results, and allows patients and doctors to have the test results needed to make decisions during a single patient visit.

truvian™

Truvian's multiplex system is designed to perform 40 most-commonly ordered diagnostic tests

ON ITS WEBSITE, TRUVIAN SCIENCES SHOWS THE PHOTO BELOW of how samples are loaded into its analyzer. In news reports, the company says it will launch with a panel that offers 40 of the most commonly ordered diagnostic tests that can be performed on a single run with just five drops of blood and deliver results within 20 minutes. The first tests will include a metabolic panel, a complete blood cell count (CBC), and a lipid panel.

(Continued from page 16.)

"Truvian will also provide results directly to the consumer via an easy-to-use mobile app. This will provide timely access to test results that might otherwise be challenging to get and allow for trend tracking over time."

Truvian Sciences was founded in 2015. It has raised a total of $150 million in capital, including last month's offering. Truvian's diagnostic device resembles a desktop computer. It uses optical sensing systems to deliver clinical chemistries, immunoassays, and hematology all in one instrument. As part of its platform, Truvian can deliver blood test results to mobile phones.Its initial panel would target standard wellness markers such as cholesterol and glucose levels, complete blood cell count (CBC), as well as thyroid, kidney, and liver functions.

Platform and Consumables

"We have innovated in many different ways in terms of the platform and our consumables, and we have captured this in 12 pending patents in the U.S. and internationally across consumables, optical systems, and novel methods of processing blood samples," Marinnucci told TDR.

She said the company also has a "trade secret technology and manufacturing method" to make storage of reagents at room temperature possible. "And we have implemented a wide range of algorithms for data analysis, including deep learning models for cell counting and differentiation," Marinnucci said.

"While we have not made the pricing for our instruments and assays public yet, we think that, at scale, these types of routine tests should be available for about one dollar per analyte. At this price, we believe testing can be conducted in many more settings, making access to routine blood testing information more widely available to consumers and their clinicians," Marinnucci added.

Truvian plans to publish data on its technology in at least one medical journal this year, the *San Diego Union Tribune* reported. Also, in 2020, Truvian received FDA Emergency Use Authorization for the Easy Check COVID-19 IgM/lgGTM test. Easy Check is a SARS-CoV-2 antibody test with sensitivity of 98.4% and specificity of 98.9%, Truvian said in a separate news release.

There Are Competitors

Truvian may face some competition—at least for CBC testing—from another young diagnostics company: **Sight Diagnostics**, based in Tel Aviv, Israel, with a newly opened New York office.

In January, THE DARK REPORT published a newsmaker interview with the CEO of SightDx, describing its five-part OLO CBC analyzer. About the size of a toaster oven, OLO has FDA clearance for moderately complex testing in CLIA-compliant facilities. SightDx, founded in 2011, has raised about $124 million in venture capital funds from international and U.S. corporations. *(See TDR Newsmaker Interview: "Two-Drop 'Digital CBC' Enters U.S. Market with FDA Clearance," Jan. 19, 2021.)*

Useful in Clinical Settings

Lab administrators and pathologists working in hospital and health system labs will recognize that the functions and features of the analyzer Truvian is developing could be useful in emergency departments and in the physicians' offices that are owned and operated by the parent hospital and health system.

Thus, as the Truvian instrument system eventually reaches the clinical laboratory market, on one hand it could be a threat to the central/core lab model. On the other hand, it could be an opportunity for a core lab to develop a clinically-valuable distributed lab testing network that serves all care settings within an integrated healthcare system. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

This may be the nation's first federal case of fraud and abuse involving a clinical laboratory company specializing in microbiome testing. In San Francisco last week, federal prosecutors filed multiple criminal charges against bankrupt **uBiome**, formerly based in San Francisco, Jessica Richman, uBiome's former CEO, and Zachary Apte, its former chief scientific officer. The company was founded in 2012. Its first test was "Gut Explorer" and was a direct-to-consumer service. Consumers submitted fecal samples to uBiome, which compared them to other samples sent by other consumers. The lab company provided the test and analysis for less than $100.

MORE ON: *uBiome Lab*

In court documents, federal prosecutors lay out the alleged scheme to defraud investors out of $60 million, stating "uBiome's purported success in generating revenue, however, was a sham. It depended on duping doctors into ordering unnecessary tests and other improper practices that Richman and Apte directed and which, once discovered, led insurers to claw back their previous reimbursement payments to uBiome." Court papers also say that, between 2015 and 2019, uBiome sent $300 million in claims to government and private health programs and was paid $35 million from those claims. The federal charges center around a conspiracy to commit securities fraud, healthcare fraud, and money laundering.

TRANSITIONS

• Paul Marr was appointed Chief Commercial Officer by **Ontera**, based in Carlsbad, Calif. In his career, Marr worked at **Hologic**, **Beckman Coulter**, **Gen-Probe**, **Leica Biosystems**, and **Siemens Healthcare Diagnostics**.

• **PierianDx** of St. Louis, Mo., announced that Lindsay Mateo was its new Chief Business Officer. She previously held executive positions at **Tempus Labs**, **NAVICAN**, and **Genoptix**.

• **Prometheus Biosciences** of San Diego selected Mark Stenhouse to be Chief Operating Officer. Previously, Stenhouse served in positions at **Exact Sciences**, **AbbVie**, and **Abbott Laboratories**.

• **Precipio** of New Haven, Conn., anounced that Ron Andrews had joined its Board of Directors. Andrews is currently CEO of **Oncocyte** of Irvine, Calif., and was formerly President of the Genetic Sciences Division at **Thermo Fisher Scientific**, President of **Life Technologies**, CEO of **GE's Clarient**, and before that, held executive positions at **Roche Diagnostics**, and **Abbott Laboratories**.

• Vince Wong is the new Chief Commercial Officer at **Geneoscopy**, based in St. Louis, Mo. His career includes positions with **Roche Diagnostics**, **Ventana Medical Systems**, and **Telemon Corporation**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 12, 2021.

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