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2021's List of Top 10 Lab Stories

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Congress Votes: No PAMA Price Cuts for 2022

It's welcome news that Congress voted earlier this month to defer the PAMA price cuts to the Clinical Laboratory Fee Schedule (CLFS) that were scheduled to take place in 2022. This is a positive development for the finances of the nation's clinical labs, particularly the smaller, independent labs that are often the only local labs for the communities they serve. *(See pages 10-11.)*

Yet, given the reticence of members of Congress to address the fundamental flaws and biases in how officials at the **Centers for Medicare and Medicaid Services** are implementing the Protecting Access to Medicare Act of 2014 (PAMA) in recent years, why did Congress act now? The pandemic is the main factor. Since the outbreak started in the winter of 2020, the federal government has now twice postponed implementing the next round of PAMA price cuts, which cannot exceed a 15% reduction for any specific test. The first postponement delayed the Jan. 1, 2021, implementation. This new legislation now postpones these lab test price cuts until Jan. 1, 2023.

Deferring this next round of PAMA price cuts to the CLFS is the least the lawmakers in Congress can do for the nation's clinical labs. Since the outbreak of the COVID-19 pandemic, the nation's clinical laboratories and anatomic pathology groups did yoeman's work to speedily ramp up SARS-CoV-2 testing to handle more than two million COVID-19 tests per day at peak demand, while at the same time collaborating with government health officials to set up and staff drive-through specimen collection sites throughout the United States. Lab administrators, pathologists, and staff worked 7-day/15-hour work weeks from the onset of the pandemic in early 2020 through the winter of 2021. It was a superhuman effort by lab professionals that benefited the American public.

Those walking the halls of Congress and speaking to elected officials and their staffs tell our editorial team that there is now great recognition about the vital role that medical laboratory testing plays in keeping the population healthy and fighting infectious disease outbreaks like SARS-CoV-2. It seems timely for the entire laboratory profession to come together, strike while the proverbial iron is hot, and educate Congress about the need to reform the existing PAMA statute as written and permanently fix the flaws that financially starved numerous community labs, causing their closure or sale, thus depriving Medicare beneficiaries of local access to quality lab testing services. TDR

2021's Top 10 Lab Stories Confirm Important Trends

Yes! COVID-19 remains top issue, but other important trends portend changes for all labs

CEO SUMMARY: Much like 2020, the pandemic dominated our new list of the top 10 lab industry stories for 2021. Beyond COVID-19 testing, the virus creeped its way into long-term trends, such as pathology jobs and technology innovation. New ways of delivering healthcare will need responses by clinical laboratories, as will significant developments in the regulatory environment and related reimbursement. The biggest message emerging for our list of 2021's top 10 lab stories is that changes far beyond the clinical lab's walls are wielding large influence on the future of day-to-day operations.

FOR THE SECOND YEAR IN A ROW, the public health emergency caused by the SARS-CoV-2 pandemic takes the top spot among the 10 most influential stories in 2021 that affected clinical laboratories and pathology groups.

Life with COVID-19 will be a defining period for generations of Americans and the healthcare system upon which they rely. The clinical lab profession continued to play an oversized role in the pandemic, performing and analyzing hundreds of millions of SARS-CoV-2 tests administered since this coronavirus arrived in the U.S. almost two years ago.

Looking at the full list of top 10 lab stories this year, COVID-19 stretched its grip into at least four of them, making the pandemic an overlapping topic. But this year also saw major developments that will need immediate responses by all labs, particularly changes involving government regulation and new managed care contracting practices, as noted below:

- A busy regulatory year, with important new or revised laws coming into play.
- Technology's ever-growing presence in the day-to-day life of lab directors and pathologists—for both good and criminal purposes.
- The continued shift in healthcare delivery that is driven by the patients themselves and how they want to receive their tests and treatments.

One big unknown hanging over the future of healthcare and the profession of laboratory medicine is whether COVID-19 becomes endemic even with mass vaccinations occurring. Also unknown is whether a future variant will emerge that

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proves resistant to vaccines and therapies currently used to treat infected patients.

For clinical laboratories, that means continued, long-term testing will be required to monitor COVID-19, much like influenza. *(See story 1, page 5.)*

The pandemic also influenced pathology jobs, which are in high demand as an older generation retires and fewer new doctors come forward to replace them. This trend is related to a new term that is linked to the pandemic: the Great Resignation, also often described as the Big Quit. As *The Atlantic* noted, "The term Great Resignation was likely coined by Anthony Klotz, a professor at **Texas A&M**, in May [2021]; at the time, he framed a mass exodus from the workforce as a prediction for this year."

In a paper released last month, the **World Economic Forum** pointed out two dynamics of the Great Resignation that must be dealt with by clinical laboratories and anatomic pathology groups. One is that "resignation rates are highest among mid-career employees," and the other is that "resignation rates are highest in the technology and healthcare industries."

➤Regulatory: Good and Bad

But 2021 has not been a year dominated by bad news or negative developments. In fact, 2021 started with good news (for once) from two federal agencies as revised new final rule versions of the Stark Rule and Anti-kickback Statute went into effect on Jan. 1, 2021. *(See story 2, page 5.)*

The move cleared up confusion between the two regulations for laboratory directors and their compliance teams.

Yet throughout the year, another regulatory effort grew that—like other laws—threatens reimbursements to laboratories for testing services. The No Surprises Act, which goes into effect on Jan. 1, 2022, generally bans copayments for certain services such that a patient's cost cannot be higher than what they would pay in-network. This is a legislative and regulatory response to the practice—conducted by many providers including anatomic pathologists and some labs—of submitting high-priced bills in order to be paid at out-of-network rates.

The No Surprises Act aims to protect consumers caught off guard by unanticipated, higher out-of-network bills and cost sharing. From the patients' perspective, added protection is welcome because it keeps more money in their pockets. But the opposite will happen for labs that do not have in-network status with most health plans. *(See story 4, page 6.)*

➤Innovation Shines

Fueled by technology advancements and nudged further by the pandemic, new testing and analysis methods found fertile ground in the clinical laboratory industry.

Artificial intelligence (AI) seemed to finally stake its ground in aiding billing, operations, and diagnosis. Digital pathology in particular enjoyed a surge thanks to AI and the pandemic. Additionally, the federal **Food and Drug Administration** warmed up to AI as a tool to diagnose prostate cancer. *(See stories 4 and 6 on pages 6 and 7, respectively.)*

For more than 20 years, The Dark Report has published its pick of the 10 biggest lab stories for the year about to end. Because our picks and our analyses are on the record, it demonstrates to clients and careful readers that we tend to be on the money at highlighting those developments that should get priority attention from clinical lab administrators and pathologists.

For that reason, we consistently recommend that every lab should incorporate the current year's 10 biggest lab stories into their strategic planning. These lab stories typically represent important new developments that are in the process of establishing deep roots. Such timely strategic planning can help astute lab leaders position their laboratories to deliver a high level of clinical testing and other services, while doing it in a financially-sustainable manner. TDR

2021 1 COVID-19 Is Big Story of 2021, Will It Become an Endemic Disease?

We're guilty—along with many others—of assuming the pandemic was on its way out this year after being the top challenge for clinical laboratories in 2020.

What shouldn't be lost on laboratory directors and pathologists is that SARS-CoV-2 has a bad habit of rising back up again. The resulting burdens placed on clinical labs may not be going away for a long time, especially if COVID-19 becomes endemic or a seasonal challenge like influenza. *(See TDR, Nov. 8, 2021.)*

Surges of the coronavirus in the winter and of the Delta variant over the summer finally waned, but then came another variant in the fall: Omicron. Once again, testing demand has outstripped the healthcare system's ability to provide the tests in some areas and new emphasis is being placed on at-home rapid testing.

The question of whether SARS-CoV-2 is a pandemic that fades, as did SARS in 2003, or becomes endemic and a respiratory virus that shows up every season like influenza and the common cold, is of major concern to clinical lab administrators. That's because clinical labs and pathology groups must continue to serve physicians and patients with the usual menu of routine, reference, and esoteric testing.

What is true as of today is that most laboratories have mastered the duality of providing timely COVID-19 test results even as they continue to serve the regular, ongoing demand for lab testing by client physicians and their patients.

2021 2 HHS, CMS Issue Revised Rules for Stark Law, Anti-Kickback Statute

In welcome news, revisions to the federal Anti-Kickback Statute (AKS) and the Stark Law went into effect on January 19. The changes clear up confusion for clinical laboratories and pathology groups about conflicting language between the two regulations and how to best comply. *(See TDR, March 22, 2021.)*

Regulators first proposed these changes in 2019, and in December 2020, the revisions were finalized by the **Centers for Medicare and Medicaid Services** (CMS) and the **Department of Health and Human Services** (HHS) **Office of Inspector General** (OIG).

The changes sought to clarify what labs encounter when contracting with insurers and physician groups in care-coordination arrangements. Federal officials recognized that the Stark Law and AKS can impede care coordination.

One of the highlights was CMS, for the first time, defining what "commercially reasonable" means, as that term is often used in many Stark Law exceptions. Now, an arrangement is commercially reasonable if it makes good business sense, even if it does not turn a profit.

It's likely most laboratory and pathology compliance teams have reviewed these changes, but if not, add it to your to-do list for the new year.

In February, a federal appeals court upheld that it is a violation of the Anti-Kickback Statute to pay sales commissions to independent contractors working as sellers for clinical labs and pathology groups. *(see TDR, May 3, 2021.)*

2021 3 Encryption and Ransomware Attacks Threaten All Labs, Pathology Groups

THIS IS THE YEAR THAT ENCRYPTION AND RANSOMWARE ATTACKS became the single biggest risk to the nation's clinical laboratories and anatomic pathology groups. In just minutes, hackers can totally lock out access to the information systems and back-up systems of hospitals and laboratories.

For example, **Scripps Health** in San Diego fell victim to a malware attack in May that prevented patients from accessing their medical records and making appointments online. *(See TDR, May 24, 2021.)* Of the 328 healthcare organizations **Sophos Group plc** surveyed, 34% experienced a ransomware attack in 2020, and 34% of those that encrypted their data paid a ransom to unlock it. *(See TDR, September 7, 2021.)*

Labs and other healthcare settings are hesitant to discuss their experience with ransomware—and for good reason. Such crimes become public relations nightmares that can decrease revenue. And the publicity also may invite further attacks.

Ransomware attacks are costly. The average bill to respond to and rectify an intrusion is $1.27 million, Sophos Group estimated. These attacks shut off a lab's access to its own servers and data, forcing laboratory and pathology directors to make tough decisions about whether to pay the offending party for a de-encryption key to unlock the information.

THE DARK REPORT was first to alert the laboratory profession to the still-growing threat from encryption and ransomware attacks. All labs need to continually harden their software and hardware systems against the attack of hackers.

2021 4 Artificial Intelligence Begins Delivering in Lab Operations, Billing, Diagnosis

ARTIFICIAL INTELLIGENCE (AI) IS A TERM BOLSTERED BY MEDIA HYPE and dubious claims of efficacy, so one can be forgiven for not fully investing in it. However, the technology is real, and in 2021 clinical laboratories started to see true progress in practical areas from AI.

Consider billing and operations. An executive for **Labcorp** detailed to THE DARK REPORT how its large clinical lab network uses AI and machine learning to assist lab workflows and operations, such as ensuring the right test at the right location and minimizing turnaround time. *(See TDR, July 6, 2021.)*

Additionally, in tandem with robotic technology, Labcorp uses AI to visually recognize loaded test tubes and appropriate positioning for them. This combination of robotics, AI, and automation brings increased efficiency.

Other providers have turned to AI to automate the collection of a patient's information for lab-billing purposes and correct inaccurate data in real time. *(See TDR, July 27, 2021.)* Meanwhile, AI has also improved cancer screening and diagnostics. *(See story 7 on page 8.)*

In fact, use of AI-powered tools and products is exploding in labs across the United States. When the next *Executive War College* convenes in the spring, expect to hear many examples of AI in lab operations during the sessions to be presented.

2021 5 New Out-of-Network Billing Law, 'No Surprises Act,' Impacts Labs

LABORATORY DIRECTORS AND PATHOLOGISTS are just a few days away from the Jan. 1, 2022, rollout of the No Surprises Act, which brings significant financial concerns to the nearly 30,000 labs it affects.

The law, which **Congress** passed in December 2020, aims to protect patients from unexpected higher billing for non-emergency services performed by out-of-network laboratories and other providers at in-network healthcare facilities. *(See pages 17-18 of this issue for more information.)* The act also sets up procedures to determine payment amounts for out-of-network services and requires labs to issue good-faith cost estimates to uninsured patients.

The **Centers for Medicare and Medicaid Services** (CMS) issued a host of rules and guidance during 2021 that formally set up provisions within the act. *(See TDR, Sept. 7, 2021.)*

Many clinical laboratories and pathology groups sought out-of-network status to get paid more for services. However, CMS and other federal agencies published data that showed pathologists were among the six medical specialties that issued more surprise bills than other specialists, based on prior research from the **Health Care Cost Institute**. *(See TDR, Oct. 18, 2021.)* The **College of American Pathologists** took issue with some of that data.

Will some labs close due to lower reimbursements caused by the No Surprises Act? Possibly. Has reimbursement for testing gotten more complicated? Absolutely!

2021 6 More Pathology Jobs than Pathologists: Path Groups Scramble to Fill Positions

GROWING DEMAND FOR PATHOLOGISTS may be good news for jobseekers but bad news for pathology groups and health systems needing people to handle increased volumes of tests.

THE DARK REPORT revealed in August that there were 600 open pathologist jobs in the U.S. alone. *(See TDR, Aug. 16, 2021.)* One lab industry recruiter noted there were more openings for sub-specialist pathologists than at any time in the past 20 years. *(See TDR, Nov. 8, 2021.)*

Among the biggest reasons for this gap: older pathologists are retiring, and fewer new pathologists are graduating from residency programs to replace them.

This situation poses a challenge for private practice pathology groups across the nation. Even as the number of biopsies for cancer and other diseases is increasing—and the complexity of diagnosing cancer increases—there are fewer pathologists in the pipeline to meet demand.

In the short term, it means pathology groups will need to pay more in salary and benefits to recruit qualified pathologists. In the long term, the gap in the supply of pathologists versus the demand for these physicians will motivate companies to develop tools that automate the analysis of tissue. *(See trend #7 on page 8.)* When labor is scarce and/or expensive, automation is almost always the final market solution.

2021 7 FDA Clears First AI-Powered Tool for Primary Diagnosis of Prostate Cancer

In September, the federal **Food and Drug Administration** (FDA) for the first time cleared the use of an artificial intelligence (AI)-powered solution to diagnose prostate cancer. It marked a milestone for AI in healthcare and anatomic pathology. *(See TDR, Sept. 27, 2021.)*

Created by **Paige**, a New York vendor, the software increases the diagnostic accuracy for prostate cancer from digital images of biopsy specimens. Paige's tool improved detection of cancer by 7.3% compared with pathologists not using the software, the FDA concluded. An AI tool for prostate cancer could lead to earlier diagnoses and help pathologists limit the number of false positives as a companion to visual reviews of images.

Anatomic pathologists will want to explore the performance of the Paige Prostate system, now that it can be used to make a primary diagnosis of cancer on digitized images of prostate specimens collected via biopsy. Data submitted by the company to the FDA also demonstrated that the algorithm can discern high grade and low grade areas of cancer from the digital pathology image. That capability was a factor in the assessment that the accuracy of Paige Prostate is comparable to a trained pathologist.

Interest in AI-powered digital pathology image analysis tools is at an all time high. Paige and at least three other digital pathology firms collectively raised $326 million this year from investors.

2021 8 More Genetic Test Payment Barriers, Patients Want 'Benefit Investigation'

The growing interest from patients in genetic testing hit a hard wall from **Medicare** and private insurers, who remained resistant to paying for the tests.

Moreover, growing numbers of patients have joined the game. Recognizing that the genetic test suggested by their physician could cost them thousands of dollars out-of-pocket, they are holding up the genetic test order while they go out and search for a better test at a more attractive price.

This trend is called "benefit investigation" and most lab coding, billing, and collections companies have organized service reps who specialize in helping patients find a genetic test at a price they will accept. This increases the length of time from when a physician orders a test to when the lab may actually get the specimen and perform the test. *(See TDR, July 6, 2021.)*

Meanwhile, payers are still reluctant to cover genetic tests. Savvy lab executives are learning that a faster path to positive coverage and reimbursement decisions is to provide the payer with complete data on the analytical and clinical validity of the test before the payer makes a coverage decision. *(See TDR, June 14, 2021.)*

These twin trends make it advisable for clinical labs to put a program in place that helps patients with their benefit investigation, and another program that delivers comprehensive data on the lab's genetic test's analytical and clinical validity to speed coverage decisions.

2021 9 Pharmacy Chains Want Primary Care in Retail Stores, Will Be Lab Test Buyers

THIS IS THE YEAR THAT RETAIL CHAINS indicated they want to go "all-in" in building full-service primary care clinics in their retail pharmacies. This has major implications for the existing business model of clinical laboratory services.

The retail chains see a big opportunity to capture market share and generate new revenue. Convenience is the motivator here, as patients often live or work closer to a retail store with a pharmacy than their doctor's office. For clinical laboratories, this change means pharmacies have an opportunity to become new partners to provide lab tests to this new class of buyer. *(See TDR, Oct. 18, 2021.)*

Walgreens Boots Alliance, **CVS Health**, and **Walmart** are leading this expansion into retail primary care, even as COVID kept people home and Millennial and Generation Z patients showed their preference for new care models.

In October, Walgreens announced it would spend $5.2 billion to acquire a majority interest in **Village MD**, which operates primary care clinics in certain Walgreens. Walgreens' goal is to build 1,000 clinics at its stores by 2027. CVS has already opened 1,100 **HealthHUBs** in its retail pharmacies. Walmart continues to open retail clinics in its stores.

As these national chains push into primary care, they could become the nation's biggest buyers of lab analyzers and tests. *(See TDR, June 14, 2021.)*

10 Ex-Theranos CEO Elizabeth Holmes Trial Puts Lab Director on Witness Stand

THREE YEARS AFTER BEING INDICTED on wire fraud and conspiracy charges, the trial of disgraced former **Theranos** CEO Elizabeth Holmes began in August 2021. Closing arguments were scheduled for Dec. 16 and 17, just as this issue of THE DARK REPORT went to press.

Many in the clinical laboratory profession are closely watching the trial as it unfolds because when Theranos became a high-profile company back in 2013, they recognized the lab company could not deliver on its promise of: 1) dozens of tests from a capillary blood sample; 2) results in two hours; and, 3) a price that was 50% of Medicare reimbursement.

The interesting twist in the trial is how attorneys raised questions about the role and responsibility of the laboratory directors at Theranos who were on the lab's CLIA license. For example, former Theranos lab director Adam Rosendorff, MD, spent days on the witness stand being grilled by prosecutors and defense attorneys. *(See TDR, Oct. 18, 2021.)*

Prosecutors said Holmes and ex-Theranos Chief Operating Officer Ramesh Balwani lied to investors about the success of the company's Edison blood-testing technology. Balwani goes on federal trial next year.

Holmes countered that she relied on her lab directors to stay on top of CLIA and equipment operation. However, Rosendorff testified that when he pointed out problems with test results, Holmes shrugged them off. If convicted, Holmes—a new mother—faces up to 20 years in prison. TDR

Labs, Pathology Groups Face Reduced Revenue

➤Law to protect patients from expensive bills will cause added scrutiny to out-of-network claims

➤➤CEO SUMMARY: In recent years, certain clinical laboratories and pathology groups found they can generate more revenue by remaining out of network whenever possible. But when the No Surprises Act goes into effect Jan. 1, labs and pathologists may find advantages in being in network. The law bans certain out-of-network payments if they are higher than in-network charges. For revenue teams at labs and pathology groups, it's time to review in-network statuses.

Come Jan. 1, the No Surprises Act ironically may bring a few shocks to those clinical laboratories and pathology groups that are unprepared for the law's new out-of-network (OON) billing restrictions.

Laboratory and pathology revenue teams that haven't developed strategies to address the consequences of submitting out-of-network claims need to do so quickly. Beginning New Year's Day, all clinical laboratories and pathology groups will want to be in as many health insurers' networks as possible to avoid facing penalties from the No Surprises Act, a lab revenue cycle adviser warned.

Congress wrote the No Surprises Act to protect patients from unexpected bills and excessive cost sharing if they receive services outside of their health insurers' networks. The federal **Centers for Medicare and Medicaid Services** (CMS) says the bill:

- Bans out-of-network co-insurance or copayments for services that cause a patient's cost to be higher than what an in-network provider would charge.
- Prohibits certain out-of-network charges without advance notice.
- Requires providers to give good-faith estimates for lab tests for patients without insurance.
- Establishes an independent dispute resolution process for patients.

Labs need to decide whether the benefits of being in-network for health plans outweigh the lower prices they may be paid for their lab tests.

"Being in-network means lower prices, but also could protect lab providers from the most onerous requirements of the Act," says Heather Agostinelli, VP of Strategic Revenue Operations at **XIFIN**, a technology company in San Diego that helps labs manage revenue cycles.

➤End of OON Advantages

Some pathology groups have found that being out of network can boost their revenue when compared with what insurers pay labs for being in network. But the No Surprises Act will penalize providers who choose to be out of network.

"Up until now, being out of network meant that labs and pathology groups were getting higher payments from some payers," Agostinelli said. "That helped offset instances when payers either pushed payment responsibility to the patient via deductibles, or paid the patient directly. Either way, this makes it harder for the lab to get paid. Those higher OON payments helped offset labs when patients didn't pay their bills."

The difference between in-network and out-of-network payments can be big. "For pathology groups that are out of network, payment for certain specimen reviews can be two, three, or four times the physician fee schedule," she added.

Clinical labs also can get a higher rate from being out of network, but not as high as pathology groups can get, she added.

Unusual Tests Are Vulnerable

Laboratories and pathology groups that aren't affiliated with a hospital or healthcare system could struggle financially under the No Surprises Act.

"For example, labs that are doing a lot of exome or other kinds of genetic sequencing may find that Medicare and Medicaid plans will not pay for those tests," she warned. "Any tests that payers consider to be exotic in any way could be a problem because there is a lot of payer policy surrounding these tests.

"Some of those unusual tests don't even exist on the traditional state Medicaid fee schedules," she added. "If such tests don't exist on a state Medicaid fee schedule, that means that those tests are not likely to be on the fee schedules of Medicaid managed care plans either."

Some Labs Could Close

Out-of-network billing has become common among small and regional clinical laboratories, anatomic pathology groups, and other provider organizations that are not part of a hospital or health system, Agostinelli said.

Some of these laboratories could close because of the financial ramifications of either being forced into lower in-network prices or into billing as patient responsibility, which has a lower collection rate, according to Agostinelli and other clinical laboratory experts. "I don't expect that it will affect the national labs, but for all labs, contracting and being in-network is the key to success," she added. TDR

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Large Pathology Group Will Stay In-Network

ONE OF THE NATION'S LARGEST PATHOLOGY GROUPS aims to stay in all health plan networks rather than risk offending patients or running afoul of the No Surprises Act in 2021.

Cory A. Roberts, MD, the President, Chairman, and CEO of the pathology group ProPath, said the group's aim is to operate exclusively as an in-network provider.

"That is our goal, and it's also one of our foundational core values because it shows that we are patient centered," Roberts said in an interview with THE DARK REPORT. "In my view and in the view of everyone here, being patient centered means doing the right thing for every patient diagnostically, of course. But also, that involves doing everything else right for the patient, including billing.

ProPath is headquartered in Dallas with 550 employees, including sales and support staff in 11 states. Its 50 pathologists serve as medical directors in 26 Texas hospitals.

"We don't want any patient to get an exorbitant bill," he added. "That's why we've always had an in-network strategy. That means we must stay in network here in Texas and in all the other 45 states where we operate. That's just all part of being patient centered."

IVD Update

IVD Companies Report Record Sales as 2021 Draws to Close

For in vitro diagnostics companies, 2021 will go down as a successful, albeit challenging, year

JUDGING BY THE THIRD QUARTER FINANCIAL PERFORMANCE of the major *in vitro* diagnostics (IVD) manufacturers, the demand for COVID-19 testing continues to generate a substantial stream of revenue.

During their respective conference calls with investors and financial analysts, IVD company leaders associated revenue growth with increased sales of tests and supplies while noting the gradual return to business as usual. But the global makers of lab analyzers and tests said supply chain disruptions are putting a pinch on their robust offerings and services. Some IVD leaders suggested rising inflation was pushing prices up and a factor in sustaining manufacturing at desired levels.

Three insights about the clinical lab marketplace emerged from these conference calls. Clinical laboratory administrators and pathologists may want to update their strategic plans with the following developments:

- COVID-19 is proving to be a lucrative business for the IVD companies, and should the virus become endemic, related SARS-CoV-2 testing could continue to boost long-term earnings.
- Supply chain woes have squeezed IVD manufacturers. Despite that fact, the growth in profits suggests the firms are successfully saving money in other areas or passing off the costs of material and transit to suppliers and customers.
- Rapid COVID-19 testing—particularly at home—is becoming routine as social events, travel, and other activities require the ability for people to quickly produce a negative result.

Here is a summary of information released by the top 11 IVD companies in their Q3-2021 earnings reports. *(See TDR, 2020 Rankings of the World's Largest IVD Corporations, Sept. 7, 2021.)*

ThermoFisher SCIENTIFIC

THERMO FISHER: Strong Growth in All But One Division

For Q3-2021, **Thermo Fisher Scientific, Inc.**, in Waltham, Mass., reported a revenue increase of 9% to $9.3 billion, as compared to $8.5 billion in 2020. Thermo Fisher also shared data on Q3 revenue for its business segments:

- Laboratory products and services segment grew 12% to $3.4 billion, compared to $3.1 billion in Q3 2020.
- Analytical instruments segment was up 11% to $1.4 billion, compared to $1.3 billion in Q3 2020.
- Life sciences segment grew 9% to $3.7 billion, compared to $3.4 billion in Q3 2020.
- Specialty diagnostics segment was $1.3 billion in Q3, down from $1.4 billion in Q3 2020.

During an earnings call, Marc Casper, CEO, responded to an investor's request for his thoughts about supply chain woes. "The world is clearly experiencing supply chain disruptions," he said. "We all see

that, and the duration of the impact of that still is to be determined. I think [that] we are well-positioned to navigate these environments better than the smaller, less capable companies.

"You have certain things you have to manage through, including freight, logistics, and slower delivery times," continued Casper. "I have high confidence in our team's ability to navigate it, and I think we'll be talking about this in some fashion across the world and across the Pacific probably into 2022."

Roche

ROCHE: Diagnostics Division Grew 39% in First Nine Months of 2021

The world's largest IVD company, **Roche**, based in Basel, Switzerland, reported strong growth in the first nine months of 2021:

- Group sales increased 8% to 46.6 billion Swiss francs (CHF) (US$50.4 billion).
- Diagnostics division sales grew 18% in Q3 and 39% in the first nine months.
- Diagnostics generated 13.3 billion CHF (US$14.4 billion) of Roche's total sales.

Roche attributed the quarterly growth to continued high demand for COVID-19 tests, a strong recovery in its base business, and new diagnostic platform offerings.

"Demand for coronavirus tests remained high in the third quarter due to the Delta variant," said CEO Severin Schwan. "Together with recently launched medicines and diagnostics platforms, they contributed to the strong sales growth."

During the conference call, Thomas Schinecker, PhD, CEO at Roche Diagnostics, released these details on diagnostics growth year-over-year for the nine months ending Sept. 30, 2021:

- Core lab increased 26% to 5.6 billion CHF (US$6.1 billion)—immunodiagnostics up 29%, and clinical chemistry up 21%.
- Molecular lab increased 36% to 3.5 billion CHF (US$3.7 billion)—virology up 34% and point-of-care/molecular up 565%.
- Point-of-care (POC) services up 279% to 2.1 billion CHF (US$2.2 billion)—POC immunodiagnostics up 1,469%.
- Pathology lab grew 14% to 889 million CHF (US$961 million)—advanced staining up 15% and companion diagnostics up 3%.
- Diabetes care increased 4% to 1.3 billion CHF (US$1.4 billion)—blood glucose monitoring up 6%.

Abbott
A Promise for Life

ABBOTT LABORATORIES: Company Can Now Supply 100 Million COVID-19 Tests Per Month

Abbott Laboratories in Abbott Park, Ill., shared data on a stellar Q3-2021, while noting the major contribution its rapid COVID-19 test sales have had on company earnings:

- Total sales of $10.9 billion represented a 23.4% increase, compared to 2020.
- COVID-19 test-related sales were $1.9 billion.
- Excluding COVID-19 earnings, sales were up 11.7% over 2019.

Robert Ford, Abbott's new CEO, shared details on growth in the company's major business areas during an earnings call with investors. "Turning to diagnostics, sales increased more than 45% overall and 12.5% excluding COVID-19-testing-related sales," Ford said.

"During the quarter, as the Delta variant spread and COVID-19 cases surged, particularly in the U.S., demand for testing increased significantly—most notably for rapid tests," he explained. "In total, during the quarter, we sold more than 225 million COVID-19 tests globally and have now shipped over one billion tests since the start of the pandemic.

"COVID-19 testing—particularly rapid testing which is fast, affordable, and easy to use—is an important companion to vaccines and therapeutics," Ford added.

In rapid testing, Abbott has a "supply capacity of more than 100 million [COVID-19] tests per month," he stated.

During the call's Q&A session, an investor inquired about implications of inflation and supply chain issues on Abbott. Robert Funck, CFO, responded, "I think inflation and supply chain are really linked together. The global supply chains have not been able to keep up with strong demand out there. Like others, we're seeing some increased input cost across areas of our business. We're experiencing some higher shipping costs and, in some cases, higher commodity costs.

"In some areas, we have flexibility to adjust pricing a bit, and we plan to do that," he continued. "In other areas, that flexibility doesn't exist. And so, we're working to mitigate the impacts we're seeing, such as looking at other manufacturing costs."

BECTON, DICKINSON AND COMPANY: CEO Says Many Hospitals Are Treating More Non-COVID Patients

For **Becton, Dickinson and Company** (BD) in Franklin Lakes, N.J., the period ending Sept. 30, 2021, marked the end of the company's Q4 and fiscal year. The multinational medical technology company released this data:

- Q4 revenue of $5.1 billion grew 7.3% compared to the same quarter in 2020.
- Q4 revenue in the life sciences division, which includes diagnostics services, grew 2.9% quarter over quarter.
- Full-year revenue of $20.2 billion grew 18.3%.

During the BD earnings call, CEO Tom Polen said BD revenues got a boost as hospitals started to experience increased non-COVID-19 patient volumes, as compared to how hospitals emphasized caring for COVID-19 cases during 2020.

"Revenues grew over 15% to more than $20 billion in fiscal 2021 with $2 billion in COVID-19 testing revenues and strong 8.1% growth in our base business," Polen said. "As hospitals have returned to serving both COVID-19 and non-COVID-19 patients and the overall healthcare utilization levels increased, we saw strong demand for our broad portfolio of products."

BD leaders anticipate more pressures from COVID-19 variants and inflation in the economy. "We expect the greater resiliency exhibited by healthcare systems during Delta will continue, along with continued recovery in patient demand post-Delta," he predicted.

"While there are inflationary pressures occurring across most every industry, we have been very active in addressing those challenges. We have put specific, defined, actionable plans in place to help mitigate these pressures. And in this environment, it's also required to initiate pricing actions, which we have begun," Polen added.

BIO-RAD LABORATORIES: Robust Revenue Increases in 2021

Bio-Rad Laboratories in Hercules, Calif., shared these Q3-2021 and year-to-date results:

- Sales of $747 million, up 15.4% in Q3, compared to $647.3 million in Q3 2020.
- Clinical diagnostics segment sales of $372.2 million grew 15.5% in Q3, compared to Q3 2020.
- Life science segment sales of $373.5 million were up 15.3%, compared to Q3 2020.
- Sales for the first nine months increased 24.7% to $2.1 billion, compared to $1.7 billion in 2020.

"During the quarter, demand continued for products associated with COVID-19 testing and research, though at a more moderate level," said Norman Schwartz, Bio-Rad's CEO.

SIEMENS HEALTHINEERS: Company on Track to Have Record Year of Revenue Growth

The period ending Sept. 30, 2021, also marked the end of the fiscal year for **Siemens Healthineers**, in Erlangen, Bavaria, Germany. It reported a record year for earnings:

- Annual revenue of €18 billion (US$20.3 billion) represented a growth of 19.3% year over year.
- Diagnostics division annual revenue grew 42.3%, excluding rapid COVID-19 antigen tests.
- In Q4, diagnostics revenue grew 22.3% year over year to €1.2 billion (US$1.7 billion), excluding revenue from rapid COVID-19 antigen tests of €160 million (US$181 million).

"This momentum will continue in fiscal 2022," said Roland Busch, CEO of Siemens. "We're ideally positioned to support our customers and benefit from major growth drivers of digitalization and sustainability."

BIOMÉRIEUX: Solid Growth Follows Increased Demand in U.S.

For **bioMérieux** in Marcy-l'Étoile, France, Q3-2021 and nine-month period data included these highlights:

- €2.4 billion (US$2.7 billion) in sales over the first nine months, which represented an 8.2% increase, as compared to first nine months of 2020.
- Q3 sales were up more than 11%, as compared to Q3-2020.

Here are reports on business segments sales for Q3 and the first nine months, respectively:

- Clinical applications sales, generating 85% of company sales, rose by 11.8% and 11.7%.
- Molecular biology sales increased 7.8% and 4.9%.
- Microbiology sales went up 14.1% and 13%.
- Immunoassays sales rose 7.3% and 20.7%.

The company's BIOFIRE reagents sales grew 19% during Q3-2021, largely due to demand in the U.S. for respiratory panels related to testing for the Delta variant. "All other business lines—namely microbiology, immunoassays, and industrial applications—kept on maintaining solid growth," said CEO Alexandre Mérieux.

SYSMEX CORPORATION: Sales Climbed 27.8% during 2021

Sysmex Corporation, in Hyōgo, Japan, reported financial results for the first six months of its fiscal year, which ends March 31, 2022. Highlights included:

- Sales of ¥168.75 billion (US$1.5 billion) were up 27.8%, as compared to 2020.
- Sales in North America grew 31.2% to ¥35.67 billion (US$314 million).

Sales in North America of instruments, reagents, and maintenance services increased due to "resurgence in testing demand in hematology and sales increase of instruments," Sysmex said. In partnership with Siemens, Sysmex said its urinalysis instruments and reagents sales grew, too.

HOLOGIC: Diagnostics Performance Did Not Meet Expectations

Quarterly earnings at **Hologic, Inc.**, in Marlborough, Mass., weren't as rosy compared to other IVD manufacturers. Hologic shared financial results for the company's Q4, which ended Sept. 25. Included was this quarterly data:

- Revenue of $1.3 billion, a decrease of 2.3% in the quarter, compared to the prior year period.
- Revenue for breast health and gynecologic surgical divisions grew 15.6% and 21.8%, respectively, compared to 2020 when the company said sales were affected by the COVID-19 pandemic.
- Diagnostics revenue was $836.8 million, a decrease of 10.9% due to slowdown in COVID-19 assay sales.
- Molecular diagnostics revenue was $704.5 million, a decline of 14% from Q4 2020.

The company's annual revenue growth was 47% or $5.6 billion, driven by women's health and COVID-19 testing needs, according to Steve MacMillan, CEO.

Ortho Clinical Diagnostics

ORTHO CLINICAL DIAGNOSTICS: Company Sales Increased 13.2%

Ortho Clinical Diagnostics, Inc., in Raritan, N.J., released Q3-2021 financial indicators:

- Revenue increased to $508.9 million, up from $443.3 million in Q3 2020, a 13.2% increase.
- Net income for Q3-2021 was $50.9 million, compared with $21 million in Q3-2020.

"Both our clinical laboratories and transfusion medicine businesses grew double digits, supported by our strong recurring revenue base," said CEO Chris Smith.

DANAHER CORPORATION: Lab Activity Back to Pre-Pandemic Level

At **Danaher Corporation** in Washington, D.C., financial performance data for Q3 and year-to-date included:

- Net earnings grew to $1.2 billion in Q3, which represented a 33% year-over-year increase from Q3 2020.
- Revenues were $7.2 billion, up 23% year-over-year.

During an earnings call with investors, Rainer Blair, CEO, said the company has recently regained its access to medical laboratories.

"Across life sciences, we're seeing robust customer activity and demand across all major end markets," Blair said. "Lab and other site access is largely back to pre-COVID levels, and we're seeing this through more normalized productivity levels, installations, and project initiations, driven by a strong funding environment."

Like other IVD leaders, Blair also informed investors of supply chain impact on the company. "While we see some global supply chain constraints … [we are] actively working with our customers and suppliers to help mitigate any impact," he said.

➤Pandemic Test Volumes

Overall, Q3-2021 performance of the large *in vitro* diagnostics companies points to continued strength in the market as the COVID-19 pandemic enters its third calendar year and need for COVID-related testing continues.

Although the effect of the new Omicron variant on the IVD testing market remains to be seen, should that variant prove to be on par with the Delta variant, testing demand may grow in 2022.

Also, the current administration's national plan to provide more at-home COVID-19 rapid clinical laboratory testing options for Americans is likely to spur further revenue growth for some IVD manufacturers.

As with many options in healthcare, a shift towards local-based preventive care in place of hospital and physician clinic visits seems to be occurring with COVID-19 testing as well. TDR

TDR sources: Company presentations to investors, news releases, and earnings call transcripts.

Regulatory Update

PAMA Test Price Cuts Deferred: It's a 'Huge Win' for Labs

Congress votes a one-year delay in implementation of the next round of fee reductions to Medicare CLFS

Two bipartisan votes in the U.S. House of Representatives and Senate will save clinical laboratories from another year of deep payment cuts imposed under the Protecting Access to Medicare Act of 2014 (PAMA).

"This is a huge win for clinical labs," said Erin Will Morton, Senior Vice President for Washington, D.C.-based **CRD Associates**. Morton represents the **National Independent Laboratory Association** (NILA) in matters pending before **Congress**.

On Dec. 7, the House passed the Protecting Medicare and American Farmers from Sequester Cuts Act, which included the payment-cuts delay. The Senate approved the bill on Dec. 9, and President Joe Biden signed the act into law the next day.

Cuts Delayed for One Year

The move delays until 2023 cuts that were scheduled to go into effect on Jan. 1, 2022. Under PAMA, Medicare was scheduled to put in place the next round of phased-in cuts, which could have been as much as 15% on some 600 clinical lab tests. Also, under the Budget Control Act of 2011, **Medicare** would have imposed a cut of 2% due to what's called sequestration, which Medicare has included in its budgets since 2013, according to published reports.

In the House, 221 Democrats and one Republican voted in favor of the bill, while 211 Republicans voted no. In the Senate, 59 Democrats and Republicans voted in favor, 35 Republicans voted no, and six members did not vote.

"What Congress passed, and Biden signed, was a standalone bill that included a series of Medicare fixes to address PAMA, the sequestration cuts, an increase in payment under Medicare's physician fee schedule, and other measures affecting Medicare," Morton explained.

"In addition to the delay in the cuts under PAMA, there's also a delay in the reporting requirements under PAMA for 2022," she added.

The Congressional votes, however, do not eliminate PAMA's requirements. "Right now, the delay is for one year," Morton noted. "While this is a huge relief, our focus now is on long-term reform of PAMA.

"NILA and other organizations are working on a more permanent legislative solution that needs to pass next year," she explained. "Doing long-term PAMA reform will continue to be an uphill battle, but for 2022, clinical laboratories get a reprieve, and that's great news for now."

Through PAMA, Medicare has cut deep into what it paid clinical labs. Under the Clinical Laboratory Fee Schedule, Medicare paid labs 10% less in each of three years (2018, 2019, and 2020) than it would have originally paid, for a cumulative total cut of 27.1% to date, according to the **American Clinical Laboratory Association**. The federal **Centers for Medicare and Medicaid Services** did not

implement a cut of 15% under PAMA that was scheduled to take effect on Jan. 1, 2021. Instead, that 15% cut was scheduled to take effect on Jan. 1, 2022.

Since the first days of the novel coronavirus early in 2020, the value and necessity of rapid and high-quality clinical laboratory testing have been on display nationwide. Never in the history of the clinical laboratory industry has testing been such a necessary component of the healthcare system.

"Over the past two years, policymakers and the American public have learned that having a robust clinical laboratory infrastructure in every state is a critically important part of the nation's healthcare system," Morton noted.

"We've seen a renewed understanding among policymakers of the value that clinical laboratories contribute to patient care," she said.

"Certainly, the role that labs played during the pandemic has been instrumental in battling the coronavirus. That created a renewed understanding among members of Congress that cutting what Medicare pays for clinical lab testing is not appropriate during the pandemic.

"Even before the pandemic, NILA focused on improving access to lab services," she added. "Yet a number of labs were forced to close when the payment reductions under PAMA went into effect in 2018."

Labs Serving Rural Areas

NILA Executive Director Mark Birenbaum noted that payment cuts under PAMA have already weakened the nation's clinical laboratory infrastructure. "Any additional cuts will severely damage the ability of laboratories to continue their COVID-19 response, especially for those laboratories that service rural and underserved communities," he said.

NILA and 27 other organizations sent a letter to Congress in November urging them to delay the PAMA cuts. Representing clinical laboratories, hospitals, healthcare systems, diagnostic-test manufacturers, and patients, those organizations urged Congress to delay Medicare payment cuts on the most common clinical laboratory tests.

"As our nation's community and regional laboratories continue to respond to the ever-evolving COVID-19 pandemic and brace for the onset of the newest variant, Omicron, they cannot afford drastic cuts to their Medicare reimbursement," Birenbaum stated.

Actions to Take

While the news about the PAMA delay is promising, full attention to the future is needed from clinical laboratory executives and pathologists.

The Dark Report will cover developments with PAMA as they unfold. Meanwhile, lab directors may want to take some or all of the following actions in the new year:

- Keep tabs on the progress of NILA, the ACLA, and other industry organizations regarding PAMA reform efforts. These groups will let members know of any changes.
- Reach out directly to your representative or senator in Congress to discuss the importance of lab testing during the pandemic, related reimbursement difficulties, and why permanent reform on PAMA may be necessary.
- Review PAMA cuts with your revenue teams and analyze data about how the cuts affected the organization. This type of information may help push the cause for reform if presented to industry groups and lawmakers.

With more PAMA cuts averted for a year, there is relief, but also realization that the battle is not over. TDR

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Managed Care Update

Payers Continue to Increase Coverage of Liquid Biopsies

Research team expects greater reimbursement as clinicians expand their use of ctDNA tests

Since the first blood-based, circulating-tumor DNA (ctDNA) sequencing test for cancer became available in 2014, federal and private payer coverage of these so-called "liquid biopsy" tests has increased substantially. Now, clinical laboratory and pathology directors can expect additional coverage as the clinical utility of these assays becomes more widely accepted.

The lead author of a 2020 study on ctDNA policies told The Dark Report that he and his colleagues have received a grant from the **National Institutes of Health** to continue researching payer coverage of ctDNA, including for genes beyond epidermal growth factor receptor (EGFR).

"What we are expecting to find is a greater increase in coverage, probably expanding to more genes than traditional EGFR," said Michael Douglas, Program Manager for the **Center for Translational and Policy Research on Precision Medicine** at the **University of California, San Francisco**. "We also expect to see the addition of other cancers."

As of mid-2019, a total of 65 private payers and four **Medicare** Administrative Contractors (MACs) had published policies on ctDNA, according to a study published in the July 2020 issue of the *Journal of the National Comprehensive Cancer Network* (*JNCCN*) which Douglas led.

He and the other authors found a shift in private payers from no coverage in 2016 to 38% coverage in 2019. It was a similar story with government health plans. Douglas' team also noted a shift in Medicare policies from no local coverage determinations (LCDs) for use of ctDNA-based panel tests in cancer indications in 2017 to nine final LCDs and three drafts LCDs by mid-2019. During this same time, insurer policies increased in scope regarding the number of different cancers included, and from a single gene to 73 genes.

Reimbursement Varies

The *JNCCN* study, which examined Medicare policies—as well as those from more than 200 payers covering 75% of private U.S. policies—found that reimbursement varies widely. Some payers specified the type of technology used in the test, others the cancer type, and some only cover a certain test.

Specifically, the study found that 38% of private payer policies provided coverage of ctDNA-based panel testing for some clinical indications as of July 1, 2019, with most of the policies covering use of these tests for determining treatment for non-small-cell lung cancer (NSCLC).

The first instance of a positive coverage policy was by **Blue Cross Blue Shield Massachusetts** in September 2017 for Guardant360, a ctDNA-based panel test for NSCLC.

Others have also noted improved payments. Kyle Fetter, Chief Operating Officer with **XIFIN** in San Diego, said this increase in payer coverage for liquid biopsies is consistent with the experience of his revenue cycle management firm.

"In general, our lab customers are getting covered more and more for the circulating-tumor-cell tests that they perform," he said. "There is more general acceptance of this type of testing in the marketplace. For example, we've experienced a 25% increase in the claims paid on the front end. Similarly, we see a significant increase of 30% in claims paid on the back end with appeals."

Still, payment policies are lagging behind clinical guidelines, Fetter said, noting that ctDNA testing is becoming more broadly accepted as a useful diagnostic tool. Although Medicare does not have an explicit national coverage determination (NCD) for ctDNA-based tests, there is one for advanced cancer sequencing. NCD 90.2, issued in 2018, governs the use of FDA-approved or -cleared, next-generation sequencing tests in cancer, both for CDx tests and hereditary risk management.

This NCD covers the use of next-generation sequencing tests as companion diagnostics—including liquid biopsy tests—on a rolling basis as they are approved by the FDA. Currently, the FDA CDx liquid biopsy tests covered under this NCD are the FoundationOne Liquid CDx and the Guardiant360 CDx.

Several Medicare administrative contractors (MACs) use LCDs to cover liquid biopsies. For example, L38290, effective Oct. 18, 2020, covers liquid biopsy screening tests for colorectal cancer in individuals with a personal history of this disease. The Signatera molecular residual disease assessment test, developed by **Natera, Inc.**, classifies recurrence risk for patients with nonmetastatic colorectal cancer after treatment.

Medicare coverage policies are evolving rapidly, noted the *JNCCN* study. The policy framework for Medicare LCDs is evolving from coverage of specific cancers to policies providing coverage of pan-cancer scenarios, which marks a significant change from early LCDs, wrote the study authors.

For example, four MACs issued final LCD policies in 2018 for the Guardant360 ctDNA-based panel test in NSCLC, and the same four issued draft LCD policies that would provide pan-cancer coverage in 12 solid tumors. One MAC issued a final LCD effective Feb. 3, 2020, that covers Guardant360, but also includes a provision that "other liquid biopsies will be covered for the same indications."

More recently, in September 2020, **National Government Services**, a MAC, proposed an LCD (DL37810) covering genomic sequence analysis panels in the treatment of solid organ neoplasms. However, the proposed LCD specifically excludes coverage of ctDNA. Still, it is a step in the right direction, Fetter said.

➤ Medicare Coverage

"What is positive for this space is that National Government Services, which has been a hold out in terms of covering most types of genetic testing, has proposed much more broad coverage for next-gen sequencing tumor testing," he said. "This MAC still considers circulating tumor cells to be experimental, so it has no coverage for that specimen type. However, I think it shows growing progress in expanding coverage for NGS testing when the less progressive Medicare contractors finally issue coverage policies that benefit cancer patients."

➤➤➤ Glossary of Clinical Terms

Circulating tumor DNA (ctDNA) *refers to cancer cells whose DNA fragments enter the bloodstream.*

Epidermal growth factor receptor (EGFR) *is a protein on cells that helps them grow. A mutation in the EGFR gene may lead to abnormal growth, which can cause cancer.*

Non-small-cell lung cancer (NSCLC) *is the most common type of lung cancer, so named because of the larger appearance of the tumor cells.*

Sources: American Lung Association; MD Anderson Cancer Center; Yale Medicine.

According to the *JNCCN* study, the overall trend in both private payer and Medicare coverage for ctDNA-based panel testing is an increase in the number of coverage policies and scope of coverage. The majority of private payer coverage policies are written with defined clinical scenarios. By contrast, Medicare policies are evolving to pan-cancer uses and these developments signify a significant shift in coverage frameworks of private and government payers, wrote the study authors.

"Private payers tend to look at these tests and issue coverage policies faster than Medicare, but Medicare tends to be a little more open to covering multi-cancer tests," Douglas said.

The study determined that the majority (87%) of policies were on NSCLS, and nearly half (47%) were for EGFR gene analysis. Further, of those policies on NSCLS, the majority (79%) only covered specifically named tests.

One of the most interesting findings, according to the study, was in the case of EGFR analysis, in which 43% of payers stated that multigene panel tests (Guardant360 and OncoBEAM) would be a covered benefit for EGFR gene analysis only. Given that tests such as Guardant360 and OncoBEAM are panel tests that evaluate multiple genes, the "limited" coverage decision may actually result in testing that is far more comprehensive than intended.

Future Research

The *JNCCN* study suggests that there is a conundrum between what a test evaluates, what a payer is willing to cover, and the information that a clinician receives and can use to guide clinical decisions.

As noted above, several payers provide coverage for multigene tests but only allow the analysis of a single gene from those tests. For example, a clinician can order a particular test that looks at dozens of genes, but the payer will cover that test only for analysis of the single EGFR gene. This may lead to test results not covered by the payer but which can be used by the clinician to manage a patient's cancer.

As part of the next phase of the study, Douglas and his colleagues will further investigate payer coverage of ctDNA since 2019. Meanwhile, both Douglas and Fetter said that they expect private payers and Medicare to continue to increased coverage for ctDNA as liquid biopsies become more widely accepted in clinical practice.

Clinical laboratories that offer ctDNA testing would do well to keep up on payer developments, as trends point to greater reimbursement for these services. TDR

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More Growth Expected for Liquid Biopsies

IN RECENT YEARS, use of liquid biopsy tests to inform treatments for cancer has exploded. The most potent driver for this acceptance is clinical trial data showing the benefits of using these biopsies for patient treatment.

According to clinicaltrials.gov, a registry of U.S. clinical trials, there are currently 447 planned or ongoing clinical trials mentioning liquid biopsies, 10 of which have been completed, and 851 mentioning ctDNA, 17 of which have been completed.

In June 2016, the FDA approved the first liquid biopsy genetic test, a blood-based companion diagnostic (CDx) for the cancer drug Tarceva called the cobas EGFR Mutation Test v2, developed by **Roche Molecular Diagnostics**.

Another milestone for liquid biopsies occurred in 2018 when the **National Comprehensive Cancer Network** updated its guidelines on NSCLC to include the use of "plasma biopsies," another name for liquid biopsies. This inclusion highlights the acceptance of the liquid biopsy into mainstream cancer care and expectation for its use as standard practice.

Legal Update

Theranos Lost $585 Mil. in 2015, Had Revenue of Just $500,000

Not only was Theranos one of the biggest scams in Wall Street history, but its losses were off the scale

by Robert L. Michel

AMONG THE BEST-KEPT SECRETS at **Theranos** during its glory days of 2013, 2014, and 2015—when the news media hailed now-disgraced founder and ex-CEO Elizabeth Holmes as a business genius to match **Apple** founder Steve Jobs—was the actual revenue the company was generating from its clinical laboratory testing activities.

No less a respected business magazine than *Fortune* was happy to put Holmes on its front cover in June 2015 and tell readers that her laboratory testing company was valued at $9 billion and that her personal net worth was $4.5 billion, making her one of the richest women on the planet.

In recent weeks, however, during the federal criminal trial of Holmes now unfolding in San Jose, Calif., details about the company's true revenue in 2015 were presented in documents and testimony.

Theranos Lost $585 Million!

"Evidence presented at the trial also revealed that Holmes had distributed financial projections calling for privatey-held Theranos to generate $140 million in revenue in 2014 and $990 million in revenue in 2015 while also turning a profit," the *Associated Press* reported, adding that "a copy of Theranos' 2015 tax return presented as part of the trial evidence showed the company had revenues of less than $500,000 that year while reporting accumulated losses of $585 million."

As it reported to the government on its tax return for 2015, Theranos lost more than half a billion dollars while failing to generate even $1 million in revenue!

I have some insight to add to this fact. During 2014 and 2015, I went to multiple **Walgreens** retail pharmacies in Palo Alto, Calif., and Phoenix where Theranos operated patient service centers. On each of these visits, multiple tests were ordered and two things were consistent:

- Not once was my blood sample collected by the use of Theranos' much-ballyhood "finger stick" (capillary) procedure. Instead, during each visit, all of my blood samples were collected by standard venous blood collection in multiple, full-sized vacutainer tubes.
- On multiple visits, I used my health insurance card to pay for the tests ordered on that visit, thus avoiding an up-front cash payment. My health insurer plan was never billed by Theranos for these tests. Effectively, Theranos tested me at no charge.

Moreover, on one visit in 2014, I ordered a qualitative RNA test as a challenge and paid $9.43 for this test. When the results were reported, it was **ARUP Laboratories** that performed that test. An ARUP manager told me that Theranos probably paid about $75 to ARUP for that test, although Theranos charged me less than $10.

For some of you who remember radio broadcaster Paul Harvey, sharing my Theranos lab testing experience with you allows me to say, "And now you know ... the rest of the story!" TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In Europe, Switzerland-based Unilabs will be acquired by a Danish Company. **Unilabs** owns laboratories in at least 11 European countries and posted revenue of €2 billion euros (US $2.26 billion) in the financial year ending September. The seller is **Apax Partners**, a private equity company in the United Kingdom. The buyer is **A.P. Moller Holding,** which is owned by the same family that owns Denmark-based global shipping giant **Maersk**. Unilabs operates 200 laboratory sites, 180 imaging centers, and employs 12,600 people.

MORE ON: *Unilabs Sale*

News sources indicate that the value of Unilabs was in the range of US$5 billion. It was reported that **Sonic Healthcare, Ltd.**, of Sydney, Australia, and **Biogroup-LCD** of Wittelsheim, France, submitted bids. It is notable that neither company—each a major operator of clinical laboratories in Europe—lost the sale to a private investment firm. Unilabs is a major international lab company, with operations in 15 countries worldwide.

CLMA MERGES WITH ASCP

On Dec. 1, it was announced that the **Clinical Laboratory Management Association** (CLMA) would join the **American Society of Clinical Pathology** (ASCP). CLMA will operate as a division of ASCP. This arrangement follows successful collaborative activities between the two groups. CLMA membership ratified this change in a vote earlier this year. One factor in this development was the COVID-19 pandemic and the CDC directive prohibiting live events during 2020 and much of 2021. That reduced the revenue CLMA needed to sustain services at pre-pandemic levels. More generally, many lab associations report that Millennials are not joining at rates comparable to the Baby Boomer generation.

TRANSITIONS

• **Abbott Laboratories** announced that Miles White is retiring after 38 years with the company. Upon starting his career at **McKinsey & Company**, White later joined Abbott in 1984, rising to CEO in 1998. White stepped down as CEO in March 2020 and will now leave his position as Executive Chairman on the company's board.

• Modena Henderson is the new Vice President of Clinical Operations for **Allina Health** of Minneapolis. Her prior positions were with **Atrium Health**, **Carolinas Healthcare System**, **Solstas Lab Partners**, **West Penn Allegheny Health System**, and **Humility of Mary Health Partners**.

• Keith Gligorich, PhD, is the new Vice President of Laborator Operations at **Bionano Genomics**, of San Diego. Previously, he worked at **Cradle Genomics**, **NAVICAN**, **ARUP Laboratories**, and **Huntsman Cancer Institute**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 10, 2022.

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