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New class of IVD firms to serve new test buyers for near-patient, POC settings
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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...

R. Lewis Dark
Founder & Publisher

Artificial Intelligence: Coming at Light Speed!

You have probably noticed that the term "artificial intelligence" is now part of the description for a growing proportion of the new products and services being offered to your clinical laboratory or anatomic pathology group. Regardless of whether it is automation, analyzers, or software, the claim is that artificial intelligence (AI) is integral to the product's improved performance.

But most of us are challenged to define what AI is and is not. In reality, what I call the "AI engines" in these products are algorithms that were developed using technologies such as machine learning, neural networks, deep learning, and similar. Moreover, these algorithms need computer chips with special computational capabilities to run the algorithms.

The algorithms comprising an AI solution also must be trained. That requires large quantities of data. As you will read on pages 3-6, last week the federal **Food and Drug Administration** (FDA) cleared for clinical use the **Paige** Prostate system. This is the first-ever AI-powered digital pathology image analysis system the FDA has cleared for diagnostic use. What enabled Paige to develop and refine the algorithm within Paige Prostate was access to decades of data about the prostate cases, PSA test results, biopsy slides, and prostate patient outcomes from a major academic center and other sites. This was the data used to train the algorithm powering Paige Prostate.

I can predict that your lab is about to encounter a tsunami of products and software that each vendor claims use artificial intelligence. Evidence in support of this statement is the content of the sessions we have confirmed for the *Executive War College,* which takes place in San Antonio on Nov. 2-3, 2021. Speakers who are hands-on with different applications of AI will discuss the state of this technology in general session presentations.

However, it will be in the breakout sessions where attendees will see, hear, and learn about how AI is powering process design, improving client service, and—of special interest to labs wanting to increase revenue—helping to automate much of the coding, billing, and collection processes. Of course, progress on AI-powered digital pathology image analysis will be presented. For these reasons, we may look back on 2021 and describe it as the year that artificial intelligence came of age. TDR

First Digital Path AI Tool Cleared for Market by FDA

FDA's action marks start of a new era in pathology where artificial intelligence helps with diagnosis

CEO SUMMARY: In a first for the anatomic pathology profession, the Food and Drug Administration (FDA) has cleared for market a digital pathology image analysis product intended to aid pathologists in the diagnosis of prostate cancer. Developed by New York City-based Paige, the Paige Prostate system was determined by the FDA to improve diagnostic accuracy of pathologists using the tool by 7.3% when compared to the diagnoses of pathologists not using the tool.

It's a major milestone on the road to the digitization of anatomic pathology! Last week, it was announced that the federal **Food and Drug Administration** (FDA) granted its first-ever clearance to allow the sale and use of an artificial intelligence-powered software solution to diagnose cancer.

The clearance was issued for Paige Prostate, described as "a clinical-grade AI solution for prostate cancer detection." This product was developed by **Paige**, a company in New York developing artificial intelligence (AI) software to aid pathologists in diagnosing cancer. *(See next story on pages 5-6.)*

Obtaining the first FDA clearance for a digital pathology image analysis products is widely-recognized as an essential milestone on the path to the wider adoption of whole-slide images (WSI) and digital pathology (DP) by pathology groups throughout the United States. For the first time, pathologists can use an FDA-cleared artificial intelligence software tool to aid the diagnosis of cancer when working with digital pathology images.

Multiple companies were racing to be first to get an artificial intelligence-powered digital pathology image analysis product reviewed and cleared by the FDA. Paige was first to reach this goal.

It was earlier this year in The Dark Report that Ajit Singh, PhD, an expert in digital pathology and artificial intelligence at **Artiman Ventures**, predicted that digital pathology image analysis solutions for prostate cancer would be first to market with regulatory clearance. Now Paige has made his prediction come true. (*See TDR, Is Artificial Intelligence Ready for First Use in Anatomic Pathology?" Apr. 12, 2021.)*

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There are a significant number of companies known to be developing digital image analysis products intended to aid in the diagnosis of cancer and other health conditions. At the upcoming conference of the **Digital Pathology Association** scheduled to take place in Las Vegas on Oct. 17-19, 2021, at least 14 companies developing pathology image analysis solutions will be sponsoring and exhibiting.

AI-Powered Image Analysis

Investors are equally enthused about the potential of digital image analysis to transform anatomic pathology. Digital pathology companies are attracting substantial capital investments, as these examples demonstrate:

- **Proscia, Inc.**, of Philadelphia raised $23 million in a Series B funding round in Dec. 2020.
- **Paige** of New York City raised $100 million in a Series C funding round in Jan. 2021.
- **Ibex Medical Analytics** of Tel Aviv, Israel, raised $38 million in a Series B funding round in March 2021.
- **PathAI** of Boston raised $165 million in a Series B funding round in May 2021.

Pathologists and pathology practice administrators should consider the implications of heightened investor interest. The investment rounds shown above represent $326 million of capital flowing into just four companies developing digital pathology image analysis solutions. In only six months, investors poured one-third of a billion dollars into the development of solutions to automate the analysis of pathology images.

Digital Pathology Predictions

Visionaries in the anatomic pathology profession have long predicted that the profession will move to a fully-digital clinical service. These visionaries noted that two components would form the foundation of a fully-digital pathology practice. But it was the third component that would be the disruptive and revolutionary force.

Component One would be scanners to create whole-slide images from glass slides.

Component Two would be a digital pathology system that includes a viewer and pathologist workflow solution.

Component Three would be automated analysis of whole-slide images. In its first iteration, it will be pathologist-directed image analysis. But eventually the technology will improve so that digital pathology image analysis tools can make a primary diagnosis with accuracy comparable to a human.

It has always been recognized that it would be difficult to achieve component three. It would also take longer than the other two components because of the complexity of developing an artificial intelligence product capable of replicating how the human mind analyzes a pathology image.

FDA Is Ready to Act

That is why the decision by the FDA to clear the first-ever digital pathology image analysis product for clinical use is a watershed moment for the entire profession of pathology. It means that regulators accept the study data that indicates the performance of AI-powered digital analysis tools can perform reliably and contribute to improved accuracy and better patient care.

THE DARK REPORT expects this action by the FDA to trigger two developments. First, other companies will study Paige's study data and the FDA's review of that data. Using those insights, they will prepare and submit pre-market review applications for their own pathology image analysis products. Second, and equally significant, expect Paige to build upon this first FDA review and begin submitting algorithm products trained to analyze other types of cancer.

Collectively, this activity may mean that pathologists will have a steadily-growing number of FDA-cleared image analysis solutions they can incorporate into their daily practice. TDR

Paige's Digital AI Tool Aids in Prostate Cancer Diagnosis

FDA's action marks start of a new era in pathology in which artificial intelligence helps with diagnosis

CEO SUMMARY: Study data provided to the FDA "demonstrated increased diagnostic accuracy" when pathologists used the Paige Prostate system, said Paige's Medical Director. The artificial intelligence-powered pathology image analysis tool is trained to help pathologists detect even small areas of cancer in biopsied prostatic tissue on digital images thus improving accuracy, a significant development given the high prevalence of prostatic cancer and its heterogeneous nature.

PATHOLOGISTS HAVE A NEW TOOL for diagnosing digital images of prostate cancer.

Last week, the federal **Food and Drug Administration** (FDA) approved an application from New York-based **Paige** to market Paige Prostate, the first artificial intelligence (AI)-based software to identify areas that could be cancerous on digitized images of prostate specimens collected via biopsy. FDA clearance of this system allows its use in clinical practice.

FDA officials noted that the prevalence of prostate cancer was one factor in its decision to clear Paige Prostate for clinical use. "The authorization of this AI-based software can help increase the number of identified prostate biopsy samples with cancerous tissue, which can ultimately save lives," said Tim Stenzel, MD, PhD, Director of the Office of *In Vitro* Diagnostics and Radiological Health in the federal agency's **Center for Devices and Radiological Health**.

As most pathologists know, prostate cancer is the second most common form of tumor among U.S. men and is one of the leading causes of cancer death among men, according to the federal **Centers for Disease Control and Prevention**.

The potential risks for pathologists include the usual false negative and false positive results, but pathologists could limit the number of false results by using the software as an adjunct to their visual review of slide images, the FDA noted.

In effect, the software assists qualified pathologists reviewing slide images, and those clinicians also would consider the patient's medical history and other clinical information and may do additional laboratory studies on patients' specimens before issuing a diagnosis, the FDA said.

Diagnostic Accuracy

"The FDA reviewed data from studies Paige completed on what effect the AI software would have on how pathologists diagnose cancer from digitized images of prostate biopsy specimens," explained Paige Medical Director Juan Retamero, MD. "Essentially, we demonstrated increased diagnostic accuracy using Paige Prostate. In other words, pathologists may have fewer errors when aided by artificial intelligence.

"The problem for pathologists reviewing digital images is that prostate cancer is a heterogeneous disease," Retamero commented during an interview with THE DARK REPORT. "What that means is that the same patient may have different cancerous cells with different biological behavior.

"Some of these areas may be low grade, which is a less-aggressive tumor, but also some of the areas may correspond to a high-grade tumor, which would have a very different prognosis," he noted. "Even within the same patient, there could be regions of cancer cells that are less aggressive, and there could be regions with more aggressive cancer cells.

Clinical Significance

"The possibility that a patient could have different regions with each type of cancer is why an accurate diagnosis is essential," Retamero noted. "Pathologists want to be sure that they identify clinically significant cancer, meaning a tumor that will become aggressive, potentially metastasize, and go on to kill the patient.

"Such heterogeneity means it is important to help pathologists identify any areas harboring cancer in a prostatic biopsy specimen," he added.

Therefore, an AI-powered image analysis tool can assist pathologists in achieving a higher level of diagnostic accuracy. "According to some studies, about 1% to 3% of prostate cancer cases are diagnosed incorrectly," he explained. "But that means that—out of 100 patients—three might end up with a false negative diagnosis.

"That 3% rate may not sound like a lot, but the incidence of prostate cancer is substantial enough that even a small percentage of incorrect diagnoses can equal a large number of patients when that percentage is applied to the entire population," Retamero observed. "That means inaccurate diagnoses may affect a significant number of prostate cancer patients.

"This is where artificial intelligence—such as in the form of the Paige Prostate software—can be useful in helping pathologists to do a better job," he noted.

In its review of the Paige Prostate device, the FDA reported that it evaluated data from a clinical study in which 16 pathologists examined 527 slide images of prostate biopsies that were digitized using a slide scanner. Of the 527 images, 171 contained cancerous cells and 356 were benign. Each pathologist did two assessments of each slide, one was an unassisted read without the software followed by an assisted read using the Paige Prostate software.

For the clinical study, researchers did not evaluate the effect of the software on a final patient diagnosis, which is typically based on multiple biopsies, the FDA added.

Instead, the researchers in this study found that Paige Prostate improved detection of cancer on individual slide images by 7.3% on average when compared with pathologists' unassisted reads, the agency noted. No effect was reported in the study on the reads pathologists did on benign slide images, the FDA added.

The Benefits of AI

While a 7.3% rate may appear to be relatively low, Retamero explained that researchers in this study reported the average sensitivity level among 16 readers who had different levels of clinical skill. "The data comes from some pathologists who were urological specialist pathologists and from some who were not such specialists," he noted.

"If you're a urological specialist in pathology and that's what you do day in and day out, you have a significant amount of experience assessing prostatic biopsies," he added. "The AI software will help you, but not as much as it would help pathologists who are not urological specialists. These are the pathologists who end up reporting most prostatic biopsies, and they are the group in the study in which we saw the greatest amount of impact from using artificial intelligence." **TDR**

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Pathology Update

Digital Pathology Image Service Delivers AI via the Internet

Germany's Mindpeak allows pathologists to upload digital images for analysis

In Germany, an emerging digital pathology (DP) company has introduced a novel feature that could be a low-cost way for pathology groups to access artificial intelligence (AI) for digital image analysis. This would appeal to pathologists who may be reluctant to invest the substantial cost and time required to acquire and implement image scanners and digital pathology systems.

This novel approach uses the cloud to allow a pathologist anywhere in the world to upload an image for the DP company's image analysis tools to analyze. Then, the system provides the pathologist with the results of the analysis.

Simple Access to AI Tools

This development is a strikingly simple way to access sophisticated pathology image analysis tools. Independent of how the German company, **Mindpeak**, charges for access to its digital-image analysis system, the referring pathologist needs only a digital image, a computer, and access to the internet to submit a digital pathology image for analysis.

Currently, Mindpeak focuses on the most common cancers, such as breast and lung cancer, and has a limited but growing number of digital image analysis algorithms that pathologists anywhere can access. Therefore, this DP company does not yet offer the full menu of tests that a busy pathology group would need every day. But the more important point is that a digital pathology company is willing to make its digital image analysis tools widely available to any interested pathologists.

Another insight that pathologists can take from this development is that when pathologists submit digital images for analysis online, such a system can help end the debate over whether it is better to use an open system or a closed system for such analysis. That choice is one pathology groups currently must make when preparing to purchase scanners and digital pathology systems.

At least one other company is using a system similar to the one Mindpeak uses to make pathology image analysis tools available via the cloud. That means, it could soon be possible for Mindpeak or other companies to offer best-of-class systems that provide digital image algorithms for each of the anatomic pathology subspecialties.

Mindpeak CEO and founder Felix Faber has said that offering AI-powered tools over the internet will allow anatomic pathologists to shorten the time required for diagnosis, while also improving the quality of care and diagnostic accuracy.

Deep Learning Tools

Founded in Hamburg in 2018, Mindpeak says it automates time-consuming visual tasks in clinical laboratories and pathology groups with state-of-the-art artificial intelligence (AI) and deep learning (DL) tools. Deep learning is defined as a subset of machine learning in which algorithms learn from analyzing large amounts of data.

Mindpeak's strategy of allowing access to its AI and deep learning tools via the internet is a new development. Thus, it is still early for THE DARK REPORT to identify and interview surgical pathologists who have established relationships with Mindpeak and have begun submitting images via the web for analysis.

Digital Workflow in Pathology

Pathologists can realize the full benefit of AI-utilization in a digital workflow where the AI algorithms are integrated into an image management system (IMS). An executive at **Gestalt Diagnostics**, a software company in Spokane, Wash., that has partnered with Mindpeak, is familiar with how Mindpeak has organized this service. Gestalt provides digital pathology solutions for pathologists.

In an interview, Gestalt's COO Lisa-Jean Clifford clarified that the Mindpeak algorithm does not provide the diagnosis. "The algorithm provides the information that the pathologist then uses to make a diagnosis," she said. "That's called a pathologist-aided interpretation.

"One of the interesting features of the Mindpeak system is that anatomic pathologists or AP groups can have whole-slide images (WSI) or just a specific section from a whole-slide image analyzed when the AI algorithms are deeply integrated into IMS platforms, such as our PathFlow," she added. "If the submission is just a section of a whole-slide image, that's called a region of interest.

"When a pathologist submits a region of interest, the pathologist can use annotation tools to add a circle, a square, or other line drawing to a specific area," Clifford noted. "Basically, the pathologist can then do a review of the AI-algorithms' analysis and return the analysis quickly."

In May, Mindpeak gained the European Union's CE-IVD Mark for its BreastIHC AI software's ability to detect and quantify breast-cancer cells for primary diagnosis. CE-IVD means the software has met the requirements of the European Parliament to sell its software to pathology practices as an *in vitro* diagnostic medical device.

In the coming months, Mindpeak plans to submit an application to the federal **Food and Drug Administration** for approval to market its BreastIHC AI software to pathologists in the United States, Faber said. BreastIHC AI can distinguish between tumorous and non-tumorous structures at the cellular level and is the first deep-learning software of its kind to get the CE-IVD mark, he noted. In the meantime, interested U.S. laboratories can follow the approach of introducing lab-developed tests, Faber noted.

The increased throughput that AI provides creates an opportunity for anatomic pathology groups that have invested heavily in digital scanners and imaging systems in recent years to reduce how much they spend on these systems, Faber said in an interview with THE DARK REPORT.

Shift in Spending to AI

"Right now, pathology group budgets are usually allocated for scanners and image management systems," he commented. "But in the next couple of years, they will shift that spending toward artificial intelligence because AI is the part of the process that—in the end—creates the value that pathologists seek from digital systems because it speeds up the process and it increases accuracy."

During the same interview, Anil Berger, PhD, Mindpeak's Vice President for Sales and Marketing, explained how Mindpeak's product works. "The BreastIHC product includes three algorithms: one is for Ki-67, a protein used widely as an indication for proliferation for human tumor cells," he said. "And the other is for the quantification of estrogen receptors (ER) and progesterone receptors (PR), and human epidermal growth factor receptor 2 (HER2, not yet CE-marked), which are markers for breast cancer.

"For BreastIHC, we have completed a study that's not yet published about the variability of breast cancer diagnosis from different laboratories," Berger added. "In that study, we showed that our product, BreastIHC, can work on different scanners and different stainers. In fact, we determined that BreastIHC works with six scanners and three stainers.

"What that means is that a wide range of pathology labs using different scanners and stainers could use the BreastIHC software almost right off the shelf," he explained. "It's a plug-and-play application that works without the need for any retraining and without the need to set up new parameters in the laboratory."

Boosting Throughput with AI

During the interview with THE DARK REPORT, Faber explained the role of artificial intelligence. "The AI software classifies cells in different ways, depending on whether they are tumorous or non-tumorous and whether they are positively stained or not," he said. "On digital images, the software can identify where there might be a membrane staining, for example, and whether the membrane has been positively stained.

"At the same time, the AI software counts the number of cells that it identifies as tumorous and provides a clinical score. It then suggests that clinical score to the pathologist," Faber added. "So, instead of having to classify and count, let's say, 2,000 cells manually one by one, the AI software does the counting for the pathologist."

By counting cells and providing a clinical score, such systems can save pathologists a significant amount of time each day. Therefore, AI software incorporated into digital imaging systems allows pathologists to review more cases per hour, thus improving throughput. Increased throughput means pathologists can provide faster results to referring physicians and better care to patients, Faber commented.

Executive Explains AI Software Pricing

IN THE UNITED STATES, Mindpeak works with several partners in anatomic pathology, including Gestalt Diagnostics, **PathPresenter** and **Augmentiqs**, among others.

Gestalt COO and Chief Strategy Officer Lisa-Jean Clifford explained that Mindpeak has adopted flexible terms for pricing its products to anatomic pathology groups. "Your lab can pay a fee for a one-year term based on the number of pathologists who would use the AI tools, which amounts to a yearly subscription for unlimited use," she noted, adding, "Or, your lab can choose an enterprise license. These are options that we resell for Mindpeak with our larger reference laboratory customers.

"An enterprise license works on a sliding scale as a per-month-per-use subscription fee, based on case volumes," she commented. "In this pricing model, the number of whole-slide images doesn't matter because it's one set fee based on the number of cases.

"If a lab uses the Mindpeak software on, let's say, zero to 600 cases, then the group would pay one set fee," she noted. "But, if the pathology group used the software for 601 to 1,000 cases, then the set fee would be a higher per-month-per-use fee."

It was just last week when the federal **Food and Drug Administration** (FDA) issued its first-ever clearance allowing a pathology image analysis system to be used in clinical settings *(See pages 3-6 in this issue).* Pathologists and pathology practice administrators can expect to see more AI-powered image analysis solutions submitted to the FDA for review. TDR

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Exec. War College to Show New Opportunities for Labs

➤As of now, all systems are 'go' for live conference, 75 speakers and 400 attendees expected on Nov. 2-3

➤➤CEO SUMMARY: Yes, the pandemic continues and hospitals are running short of beds in many communities. At the same time, 225 million Americans are either vaccinated or have some immunity to COVID-19. Based on the early registrations to attend the 27th annual Executive War College, it appears vaccinated individuals are ready to travel to a live conference and network with their peers. When they gather, they will have access to a full slate of powerful speakers and topics.

CLINICAL LAB AND PATHOLOGY GROUP LEADERS looking for what's coming next in healthcare and laboratory medicine will get plenty of insights, predictions, and answers at the upcoming 27th *Executive War College,* which takes place in San Antonio on Nov. 2-3, 2021.

Speakers and sessions will deal the current dichotomy facing all lab managers. On one hand, hospitals in many regions are again filled with COVID-19 patients. The difference in this wave is that they are 20- and 30-somethings and mostly unvaccinated. This resurgence in hospital admissions continues to stress hospital and health system labs.

➤Daily Lab Test Referrals

On the other hand, currently 182 million are fully vaccinated and another 43 million have tested positive and thus have some immunity to SARS-CoV-2. These individuals are now visiting their doctors and medical providers seeking routine care. The nation's labs are again handling about the same number of daily lab test referrals as in the months before the March 2020 onset of the pandemic.

Simply said, it is necessary for labs to move forward and be innovative in the testing services they provide to their clients, while at the same time continuing to provide COVID-19 testing.

How labs can succeed and prosper in the midst of this dichotomy will be a major theme at the *Executive War College*. For example, there will be multiple sessions that show lab administrators how to add value with their lab test results in ways that generate new sources of revenue.

Case in point is how a lab can collaborate with payers and providers to identify care gaps and improve patient outcomes in arrangements that generate new streams of revenue for the lab. That is one theme in the session to be presented by Monique Dodd, MT, PharmD, Manager, Enterprise Clinical Services at **TriCore Laboratories** in Albuquerque, N.M.

Another important trend is data portability and data aggregation. Because of the large volumes of patient test data that labs create and archive, labs have the opportunity to be major contributors in regional health information exchanges (HIEs). Tim Pletcher, CEO of the

Michigan Health Information Network (MiHIN), will describe the progress of what is recognized as one of the nation's more innovative HIEs.

Artificial Intelligence

There will be multiple presentations on artificial intelligence (AI) across the span of healthcare, clinical laboratory, and anatomic pathology. Technologies used in artificial intelligence are improving at a rapid rate. Sessions about AI include:

- Stan Letovsky, PhD, Associate Vice-President for Clinical Bioinformatics at **Labcorp**, talking about Labcorp's use of AI in daily lab operations, interpreting data, and digital pathology.
- Ajit Singh, PhD, Founder and Principal of **Artiman Ventures**, on the strategic directions for AI in healthcare and diagnostics.
- Michael Tarwater, CIO at **Gravity Diagnostics**, on using data integration and AI to automate processes and generate more clean claims.

FDA Approval of AI Tool

Of special interest for those lab administrators closely following the developments with artificial intelligence, the *Executive War College* will feature a presentation by **Paige** on its experience working with the federal **Food and Drug Administration** (FDA) to obtain clearance for its AI-powered Paige Prostate.

This marks the agency's first-ever clearance for a digital pathology AI-powered tool to be used for diagnosis in clinical settings. Paige CEO Leo Grady, PhD, will deliver this presentation *(See pages 3-6 in this issue).*

For clinical lab executives looking for new sources of revenue, the opportunity exists to take the automated molecular systems used for SARS-CoV-2 testing and redirect that testing capacity to other types of lab tests in ways that generate more revenue. Several sessions involving lab leaders who are doing this successfully will be featured.

COVID-19 Protocols at Exec. War College

IT'S SAFETY FIRST FOR EVERYONE attending the upcoming *Executive War College on Laboratory and Pathology Management* event, which takes place on Nov. 2-3 at the Hyatt Regency Riverwalk-San Antonio. Even as the vaccination rate continues to climb in the United States, it remains important to follow the directives and recommended protocols intended to prevent the spread of COVID-19.

The Hyatt Riverwalk Hotel in San Antonio has implemented strict safety and cleaning procedures and returned to hosting live conferences several months ago.

The *Executive War College* is dedicated to everyone's safety and follows the **Centers for Disease Control and Prevention** (CDC) Guidelines for Organizing Large Events and Gatherings, updated May 20, 2021. At the conference this will include screening questions and temperature checks in conformance with the CDC's guidelines.

For pathologists in smaller private practice groups, a new model of private practice pathology is emerging. To share the lessons and successes with this model, **TruCore Pathology** Founder and Chief Science Officer Adam Cole, MD, and Chief Operations Officer Stephanie Evans, will provide a business case study of TruCore and its collaborators in the **PathNet Labs** network.

Business Intelligence Needs

Despite the ongoing pandemic, many senior clinical laboratory administrators and pathologists are ready to gather in person to learn what's working, what's coming next, and network with industry vendors and consultants. The need for business intelligence remains constant, even more so because of the uncertainties triggered by the pandemic. TDR

Innovators in Near-Patient, Point-of-Care Testing Systems

New Class of IVD Firms Want to Serve POCT in Near-Patient Settings


Robert L. Michel

➤➤ CEO SUMMARY: Our second installment in this series describes an emerging new class of in vitro diagnostics (IVD) companies. These companies have analyzers and tests designed specifically to be simple to run, generate results in minutes, use small sample sizes, and cost less than even high-volume routine tests run in core labs. These new IVD competitors expect to sell their diagnostic products to national chains opening primary care clinics in pharmacies and retail stores.

SECOND IN A SERIES
by Robert L. Michel

Looming over the horizon is a new class of *in vitro* diagnostic (IVD) companies developing lab testing systems and assays that will deliver very different performance characteristics compared to existing clinical laboratory analyzers and tests.

These are new players in the diagnostics space and they are off the radar screens of most clinical lab administrators and pathologists. One reason for their low visibility is because most of these firms are still in the development mode and they continue to refine their testing systems and assays. In a few cases, certain pioneering IVD companies in this sector have gained EU marks or FDA clearance for their first products, but they are still in the early stages of marketing these products.

➤Second of Three Trends

This new class of IVD companies represent the second of three significant trends that lie at the heart of this special series presented here by The Dark Report. The three trends are:

- Emergence of a new class of buyers for clinical laboratory tests that will quickly become dominant.
- Arrival of a continuous flow of ever-smaller, faster lab analyzers and test kits that incorporate new and transformative diagnostic, digital, and AI technologies, and are specifically engineered for use in near-patient settings while also producing low-cost, speedy results at a competitive price per test.
- The new preferences of Millennials who—as patients—demand access to medical services and health information in radically different ways than earlier generations.

The first installment of this series described the different type of buyers for clinical laboratory tests and was published on June 14, 2020. *(See TDR, "New Players May Alter Who Buys and Who Orders Lab Tests.")* Included in this new class of clinical lab test buyers will be large national and regional corporations that operate primary care clinics and medical care "hubs" in their retail stores.

Three types of chain store companies fit this description. First are the pharmacy chains, including **CVS**, **Walgreens**, **RiteAid**, and others. Second are national retailers, particularly **Walmart** and **Target**. Third are national and regional grocery stores that include pharmacies. The biggest of these supermarket chains include **Kroger**, **Albertsons**, and **Publix**.

As noted earlier, this installment describes the second trend that centers around the arrival of new types of IVD companies and how they are expected to disrupt the status quo in both the way clinical lab tests are ordered and used, as well as, the supply chain that delivers lab test systems and assays to end users.

➤Generations Y and Z

The next installment will describe our third trend involving the transformative impact of Millennials and Gen Y on healthcare generally and as users of clinical lab testing.

Odds are great that a fourth disruptive factor may develop in the new future. That disruptive factor is **Amazon**. It currently operates a network of clinical lab facilities originally built and scaled last year to provide COVID-19 testing to its almost one million employees.

The Dark Report expects that Amazon will repurpose its existing lab test facilities to provide the usual menu of clinical lab tests ordered by physicians on behalf of their patients. Amazon's potential to be disruptive to the clinical laboratory industry will be the fourth installment in this series.

It is helpful to describe the IVD industry as it exists today so that key differences in this new class of IVD companies become visible. At this time, the IVD market is dominated by 11 global IVD corporations.

In 2020, global IVD revenue was estimated to be $74.1 billion. (Remember, IVD firms sell their products at "wholesale prices" to labs, who then use them to produce test results they sell at "retail prices.")

Biggest Global IVD Firms

During 2020, the top 11 biggest global IVD firms had cumulative revenue estimated at $61.3 billion. That represents 82.7% of all global IVD sales in 2020 and shows how these 11 huge corporations dominate the IVD market. *(See TDR, "2020 Rankings of the World's Largest IVD Corporations," Sept. 7, 2021.)*

The biggest customers of these IVD firms are clinical laboratory organizations that operate large core lab facilities. Think of this segment of the lab profession as the relatively small number of lab buyers who regularly make substantial purchases of automation, analyzers, and test kits.

Robert L. Michel

➤"These three characteristics are relevant in our prediction that a new class of IVD companies is soon to emerge..."

In the independent lab sector, **Labcorp**, **Quest Diagnostics**, and **Sonic Healthcare Ltd.** are among the world's largest buyers of IVD instruments, tests, and supplies. Lab companies doing molecular and genetic tests are a fast-growing component of the independent lab sector.

In this country's hospital and health system sector, integrated delivery networks (IDNs) such as Texas-based **Baylor Scott and White Health** (52 hospitals), **Advocate Aurora Health** of Wisconsin and Illinois (27 hospitals), and North Carolina-based **Atrium Health** (36 hospitals) are representative examples of IVD customers who buy large volumes of automation, instruments, and tests for use in their core labs and satellite facilities.

The other important sector of today's IVD market is made up of physician office laboratories (POLs). Think of this sector as a relatively large number of buyers who each purchase small quantities of analyzers and clinical laboratory tests.

Historically, the largest IVD players have organized their products and their marketing and sales programs to serve the two biggest types of buyers of lab test equipment and assays: independent lab companies and hospital labs. Economies of scale drives everything for both the IVD sellers and their biggest lab buyers.

Central and core laboratories performing substantial volumes of lab testing daily can buy analyzers, automation, and tests at lower prices. They also can produce lab test results at a lower cost-per-test because of the high volume of procedures.

Price Is Based on Volume

Clinical lab administrators and pathologists understand these fundamentals. It is standard IVD industry practice to price analyzers and test kits based on volume. IVD vendors will offer lower prices to a lab with a sizeable daily volume of tests. The greater the daily volume, the lower the prices for lab analyzers, automated systems, and test kits.

There are three more characteristics to the current IVD market that are relevant to our analysis and to what will be different about the emerging new class of IVD companies. These characteristics include:

- Choosing one of several methods available to test for the same biomarker.
- Using one of multiple methods for establishing reference or normal ranges for a diagnostic test.
- Selecting a name for a specific test to use in the test catalog and with physicians, payers, and patients.

These characteristics are relevant in our prediction that a new class of IVD companies is soon to emerge because each characteristic (or accepted lab industry practice) creates some level of ongoing

Truvian Sciences Building Multi-Analyte Platform

THE PHOTO BELOW FROM TRUVIAN SCIENCES' WEBSITE SHOWS how samples are loaded into the analyzer. In news reports, the company said it would 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, with results delivered within 20 minutes. The first tests will include a metabolic panel, a complete blood cell count (CBC) and a lipid panel. Truvian's initial panel will target standard wellness markers, such as cholesterol and glucose levels, complete blood cell count (CBC), as well as thyroid, kidney and liver functions.

confusion with physicians, payers, and patients.

In the first case, users of lab test results can be confused when different clinical labs select a different methodology for a specific biomarker, as noted above. Many diagnostic biomarkers can be measured by the use of two or more different methodologies.

Three TSH Test Methods

One good example is thyroid-stimulating hormone (TSH). At least three different methods are available. They are chemiluminescent assay (CLA), radioimmunoassay (RIA), and enzyme-linked immunosorbent assay (ELISA).

In the second case, the different approaches individual labs can take to establish the reference or normal ranges for the tests they perform can be a source of confusion among physicians, payers, and patients. Different methodologies generate different reference ranges. A lab also can develop its reference ranges based on testing the regional patient population it serves.

The third case centers upon the test names different labs give to the same assay. It is widely recognized that there is little uniformity in how individual laboratories name their tests. For decades, this has been a source of confusion for labs, physicians, patients, and payers.

The LOINC (Logical Observation Identifiers Names and Codes) system is one effort to help add clarity to this situation. LOINC is designed to help labs and healthcare providers share lab test data that was produced by different labs, given their choices of methodology, reference ranges, and names.

As noted above, each of the three characteristics involving test methodologies, test reference ranges, and test names often prove perplexing. This happens when physicians, payers, and patients want to understand how to interpret the same patient's test results from different clinical labs that reported the same biomarker, but used different methodologies, reference ranges, and/or test names for that same biomarker. Pathologists and clinical lab managers deal daily with this problem.

The three characteristics described above are widely-recognized to be a source of confusion among providers. It is reducing or eliminating that element of confusion that is an opportunity for any IVD company that wants to be innovative.

New Type of IVD Firm

Further, The Dark Report believes that the coming class of new IVD companies will recognize this opportunity. They will design their tests and analyzers in ways that eliminate the problems caused by the same biomarker having multiple methodologies, different reference ranges, and different test names.

The timing of this development will coincide with the ongoing efforts of multi-hospital health systems to further integrate their operations, achieve standardization in methods and workflows across all hospitals, labs, and doctors' offices, and deliver a unified electronic health record (EHR) system accessible to all providers within the integrated delivery network.

To sum up, today's IVD marketplace has these attributes:

- Dominated by 11 global IVD giants.
- Biggest IVD buyers are the central labs of independent lab companies, hospital labs, and health system labs.
- Smaller IVD buyers are tens of thousands of physician office labs.
- IVD sales and prices are closely associated with volume. Larger volume equals lower price.
- Different labs use different methodologies for the same biomarker.
- Different labs develop different reference ranges for the same biomarker.
- Different labs use different names for the same biomarker and/or the same assay.

Pathologists and clinical laboratory administrators should use the baseline established above to understand how and why the coming new class of IVD companies has a solid opportunity to win market share and even transform the fundamentals of how lab analyzers and test kits are sold and used.

Robert L. Michel

➤"...the coming class of new IVD companies will recognize this opportunity. They will design their tests and analyzers in ways that eliminate the problems caused by the same biomarker having multiple methodologies, different reference ranges, and different test names."

Over the past 12 to 18 months, The Dark Report has tracked progress of multiple young IVD companies that have several things in common.

Near-Patient Test Benefits

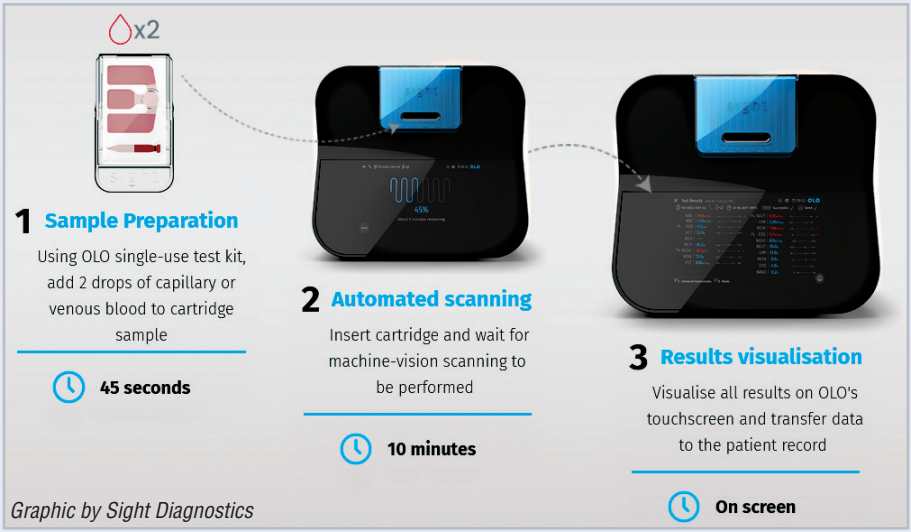
First, they share the primary goal of delivering an instrument and a test kit that provides a test result as close to the patient and patient care encounter as possible. This means creating a testing system that functions in near-patient and point-of-care settings.

Second, they are working to combine multiple new technologies developed outside the diagnostics field that:

- Simplify the test methodology used to produce a result;
- Reduce by a substantial magnitude the volume of specimen required to perform the test;

Sight Diagnostics Now Sells 'Digital' CBC Test

Sight Diagnostics OLO CBC Analyzer utilizes machine imaging and artificial intelligence to deliver a five-part CBC result in about 10 minutes, using two drops of blood. One point of competitive differentiation between the design and function of the OLO CBC analyzer and most existing hematology instruments is the absence of complex tubing, pumps, and moving parts. This diagnostic test utilizes different technology from conventional hematology instruments, including artificial intelligence developed for self-driving automobiles.



Graphic by Sight Diagnostics

- Shrink the size of the analyzer used to perform the analysis down to a bench-top instrument or a hand-held device;
- Are cheaper to buy than core lab testing, even with lower volumes of tests daily;
- Make users of analyzers and tests more productive.

Third, their common goal is to develop a diagnostic test that can be performed by any individual in the doctor's office or hospital. They want a CLIA-waived assay because it provides two benefits: a reduction in the cost of labor to perform the test, and it allows any individual within a provider's office to run the test.

Fourth, these young companies want to develop a testing system and assay that require just minutes to produce an accurate, reproducible result. This is the linchpin in the strategy of the new class of IVD companies we are tracking.

As buyers, office-based physicians and hospitals will welcome an instrument and test kit that deliver test results in minutes, with accuracy comparable to the same biomarker tested in CLIA-certified labs that do complex testing.

Major Buying Point

However, for the emerging new class of lab test buyers described in the first installment of this series, a fast time-to-answer while the patient is present and waiting to see the physician will be the single most important attribute. This will be a major buying point when buyers for national retail chains shop for lab analyzers and tests to put into their national networks of primary care clinics located in retail pharmacies and other retail stores.

It takes a bit of digging to identify the emerging IVD companies that are devel-

oping instrument systems and diagnostic test kits that fit most of the attributes described above. That's because they are either still under the radar during their development mode or their first diagnostics products and regulatory approvals with the European Union and the FDA did not get much news coverage.

In the past year, clients and regular readers of The Dark Report have read profiles about a few of these companies that in some cases included interviews with their CEOs or other key executives.

The companies described below illustrate what we consider to be new members of this emerging new class of IVD companies. This is a small sampling of a much larger number of IVD companies racing to develop disruptive diagnostic tests and bring them to market. The companies below have raised significant amounts of capital in the past 24 months and have issued public statements about plans to obtain regulatory clearance in the EU and with the FDA. The companies below are presented in alphabetical order.

CUE HEALTH

Founded in 2010 as a response to the swine flu epidemic which created consumer interest in a home test for this virus, San Diego-based Cue Health has a diagnostic device that connects to a smartphone and can deliver results in minutes.

In 2018, Cue Health entered into what turned out to be a timely collaboration with the federal **Biomedical Advanced Research and Development Authority** (BARDA), a division of the federal department of **Health and Human Services** (HHS).

The contract award was for $30 million. In a press release at that time, Cue Health said the project's goal was to "accelerate the development and regulatory validation of an over-the-counter and professional-use Influenza and Multiplex Respiratory Pathogen diagnostic cartridge for the Cue Health Monitoring System."

Following the onset of the COVID-19 pandemic, Cue Health obtained an FDA EUA for its SARS-CoV-2 molecular test. Then, in October 2020, HHS announced a $481 million investment intended to help Cue Health expand manufacturing capacity of its molecular COVID-19 test kits. *(See TDR, "$481 Million Federal COVID Contract Awarded to Young IVD Company," Oct. 26, 2020.)*

COVID-19 Tests for NBA

At the time of that announcement, news stories reported that the **National Basketball Association** (NBA) used Cue's test cartridge and smartphone-based diagnostic testing system during the summer and fall of 2020 for COVID-19 testing of its players and staff.

These developments provide evidence that Cue Health has a credible diagnostic testing solution which can be used in point-of-care settings or by consumers at home to produce accurate test results. When the pandemic subsides and routine clinical care resumes, Cue Health can be expected to begin marketing its diagnostic system to healthcare providers, retail chains, and consumers.

GENALYTE

Even the Silicon Valley behemoths want a piece of the clinical diagnostics market. In January, **Genalyte** of San Diego raised $50 million. **Verily**, the life sciences division of Google's parent company, **Alphabet**, led that round of financing.

Genalyte says its Maverick Diagnostic System (MDS) is a benchtop analyzer that "uses silicon chip-based photonic

Cue Health's Diagnostic Test Uses Smartphone

THIS IS THE DIAGNOSTIC TESTING SYSTEM developed by Cue Health and now in use for COVID-19 testing. The federal **Department of Health and Human Services** sent $481 million in funding to Cue Health last year to ramp up production of this test. It is a rapid molecular test for SARS-CoV-2 that was granted an emergency use authorization (EUA). It uses a nasal swab to collect specimens from the lower part of the nose, feeds data from the test unit to a smartphone, and delivers results within 20 minutes.

ring resonance technology to perform multiple, simultaneous, rapid tests on a small volume of whole blood or serum in twenty minutes."

In 2020, Genalyte's SARS-CoV-2 Multi-Antigen Serology Panel received Emergency Use Authorization (EUA) from the FDA. The panel uses the company's Maverick analyzer to test for an autoimmune disorder and for SARS-CoV-2 antibodies. The company says it is on track to submit more tests for FDA review by year's end. Genalyte's board includes Andy Conrad, PhD, currently CEO of Verily, and at one time a Chief Scientific Officer of **Labcorp**.

sight

SIGHT DIAGNOSTICS

A new player in hematology testing is **Sight Diagnostics**, founded in 2012 and-based in Tel Aviv, Israel. Its flagship analyzer and test already has FDA clearance for clinical testing and is available for purchase in the United States and the European Union.

Sight Diagnostics obtained 510(k) clearance from the federal Food and Drug Administration (FDA) for its its hematology testing system in November, 2019. The Sight OLO CBC analyzer is cleared for moderately-complex testing in CLIA-compliant facilities.

This test produces a five-part CBC results with 19 parameters and signature flagging capabilities. What differentiates the Sight CBC testing system is that—compared to most hematology systems used in clinical laboratories today—it is engineered around a radically different mix of technologies.

To run the test, one drop of blood is placed in each of the two wells on the cartridge, which uses lateral flow technology to move the specimen through the

required steps to create a monolayer of cells within a self-contained cartridge.

Next, the specimen cartridge is inserted into the analyzer which captures more than 1,000 images. Within 10 minutes, the instrument analyzes the images to produce the CBC results. *(See TDR, "Two-Drop 'Digital CBC' Enters U.S. Market with FDA Clearance," Jan. 19, 2021.)*

truvian™

TRUVIAN SCIENCES

San Diego is the home of another innovative young *in vitro* diagnostics company. **Truvian Sciences,** launched in 2015, wants to deliver a fully-automated benchtop blood testing system.

Investors seem impressed with Truvian's technology. Last winter, the company raised $105 million to fund further development of its analyzer and tests. *(See TDR, "Truvian Sciences Raises $105 Million for Near-Patient Lab Test System, Mar. 22, 2021.)*

In a press release, Truvian declared that it was "developing a compact and fully-automated benchtop system that combines chemistries, immunoassays, and hematology assays in one device. There is no other single on-site diagnostic platform that covers the breadth of analytes that Truvian can address, with accuracy that rivals central labs."

The company also stated that its goal was to combine "multiple testing modalities into one system [so that] clinics can perform all standard blood tests ordered during a routine check-up onsite, helping their patients realize significant cost and time savings." Truvian's comprehensive wellness panel will cover the most commonly ordered diagnostic tests, including a lipid panel, metabolic panel, and complete blood cell count.

More specifically, Glen Tullman, Managing Partner at **7wireVentures** who co-led Truvian's $105 million funding round in February, identified primary care clinics in retail chain stores as the major target for Truvian's diagnostic products. "As we move to a more consumer-directed system of healthcare, providing easy, convenient access to a full suite of high-quality blood tests at a local pharmacy, an on-site clinic at work, or a physician office will be a game changer," Tullman declared.

Robert L. Michel

➤"The emerging *in vitro* diagnostics firms described here illustrate the rich and diverse range of companies that want to revolutionize clinical lab testing. Investors are betting they can succeed."

"New rapid diagnostic tools are essential to provide health consumers with more information earlier in the process and equip clinicians with the information they need to provide high-quality care," Tullman added.

amazon

AMAZON

There are numerous published reports, some dating back to 2018, that describe how teams within **Amazon** are developing diagnostic tests and analyzers. Amazon already operates several CLIA-accredited clinical laboratory facilities designed to provide COVID-19 tests for its one million employees. The company even has an EUA for its own COVID-19 test, which it sells to consumers on its website.

The emerging *in vitro* diagnostics companies described above illustrate the rich and diverse range of companies that want to revolutionize clinical laboratory testing. Investors are betting they can succeed. TDR

Regulatory Update

MedPAC Reports to Congress on Issues in Lab Test Price Survey

Yes, CMS' collection of private payer lab price data fails to collect prices paid to hospital labs, POLs

In the halls of Congress, a good news/bad news story is unfolding around the multi-year cuts to the prices Medicare pays for clinical laboratory tests. First the good news.

In its latest semi-annual report to Congress, the **Medicare Payment Advisory Commission** (MedPAC) confirms much of what the clinical laboratory industry has been saying about Medicare's new lab test payment rates being skewed and suggests that a sampling of private-payer rates would provide a more accurate picture of actual rates than the methodology currently being used by the **Centers for Medicare and Medicaid Services** (CMS).

The clinical laboratory industry has long complained that the methodology used to set payment rates for laboratory testing under the **Protecting Access to Medicare Act** (PAMA) was flawed and that hospital outpatient laboratories and physician office laboratories were under-represented in the data, resulting in Medicare payment rates being artificially lowered.

Report's Positive Points

The good news is that MedPAC concurred with this conclusion. It noted that Medicare's new methodology reflects 85% of the Medicare payments made to independent labs, but only 22% of the payments made to hospital labs and physician-office laboratories. The report states that by the time PAMA is fully implemented in 2025, fees on the Medicare Clinical Laboratory Fee Schedule (CLFS) will have been reduced a total of 24% overall.

MedPAC looked into whether using a survey approach to gathering private payer data would address some of the concerns raised by clinical laboratories. The group concluded that such an approach would reduce the overall regulatory burden on laboratories and permit the CMS to gather more data on the lab test prices that private health insurers pay from a larger number of hospitals and POLs.

Report's Negative Points

However, the bad news is that what MedPAC gave the lab industry with one hand, it took away with the other hand. In its report, MedPAC pointed out that using the price survey methology it described would result in an increase of Medicare spending for laboratory testing in the range of 15% to 24% and may be undesirable in certain circumstances.

Should Medicare officials use such a survey methodology, MedPAC recommends excluding higher lab payments made to hospitals and POLs (which it says are the result of "enhanced" negotiating leverage from the non-laboratory services they perform) as well as new high-cost molecular tests that are often sole proprietary tests not subject to competition.

"For most routine tests, policymakers should consider setting laboratory payment rates based on private-payer data from certain types of laboratories (e.g.,

independent laboratories), while excluding the data from the others (e.g., hospital outpatient laboratories)," the report says.

"Through the first two years of setting Medicare rates based on private-payer data, lower Medicare payments appear to have had little impact on the use of routine laboratory tests among Medicare fee-for-service beneficiaries, suggesting that access to services can be maintained with lower rates," MedPAC wrote in the report. "However, if access issues did arise, policymakers could consider implementing targeted payment adjustments instead of incorporating private-payer data from laboratories that receive private-payer rates. Targeted payment adjustments could help ensure access in particular circumstances without overpaying for all laboratory tests."

Lab Groups Support Sampling

Mark Birenbaum, PhD, Administrator of the **National Independent Laboratory Association** (NILA), says that NILA supports conducting a survey that would better represent the clinical laboratory market than that which was implemented originally under PAMA.

"The original implementation of PAMA left out large segments of the clinical laboratory market, leading to artificially low Medicare reimbursement rates that underestimate the cost of delivering laboratory services to patients," he said. "NILA advocates for legislative changes that would require a more accurate sampling of private payer rates to rectify the flawed implementation of PAMA.

"Without legislative action, additional devastating rate cuts to Medicare lab test prices will go into effect in January 2022," Birenbaum noted. "These rate cuts will undermine the country's response to the ongoing COVID-19 public health emergency. Fixing PAMA, avoiding these cuts, and implementing a sustainable laboratory reimbursement structure should be a public health priority."

Julie Khani, President of the **American Clinical Laboratory Association** (ACLA), concurred. MedPAC, she noted, found that a sampling of private payer rates from independent labs, hospital labs, and POLs is feasible and would produce accurate, representative data while reducing burden, and would correct below-market Medicare rates.

'Unsustainable Rates'

"This finding [in the MedPAC report to Congress] validates concerns long expressed by the clinical laboratory community that reimbursement reduction imposed as a result of a flawed data collection process are too extreme and have resulted in unsustainable below-market rates," she stated. "Importantly, this finding also refutes CMS' assertion that the inclusion of hospital rates would not materially change Medicare rates."

ACLA also supports a legislative change and has called on Congress to establish a payment system that is representative of the market and that supports continued innovation and access to clinical laboratory services.

This would require Congress to take up this issue and enact legislation that would address and correct the flaws and biases identified in the MedPAC report. Such legislation would need to clearly describe and define how CMS would gather the private payer lab test price data it uses to determine fees for the Medicare Clinical Laboratory Fee Schedule.

Represents All Lab Sectors

The clinical laboratory industry has consistently called on CMS to use a fair, unbiased process for collecting the lab test prices paid by private health plans—a process that accurately represents all the major segments of the clinical laboratory profession.

The June 2021 MedPAC report is available at www.medpac.gov. TDR

Contact Mark Birenbaum at 314-241-1445 or birenbaumm@birenbaum.org; Julie Khani at 202-637-9466 or jkhani@acla.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Following the opening of her criminal trial in a Silicon Valley courtroom in recent weeks, Elizabeth Holmes—the disgraced ex-Founder and CEO of **Theranos**—continues to be the subject of news headlines. Federal prosecutors are calling witnesses to testify. Much of this testimony includes anecodotes and facts about her personal life and the way she made business decisions. Our sister publication, *Dark Daily*, issues regular e-briefings that cover the disclosures that would be of greatest interest to clinical lab managers and pathologists.

MORE ON: *Holmes*

Last week, pathologist Adam Rosendorff, MD, testified for the prosecution. He was the CLIA laboratory director for Theranos from April 2013 until December 2014. He stated that he resigned after repeatedly notifying Holmes and ex-COO Ramesh "Sunny" Balwani about inaccurate lab test results and other serious problems with many of the lab's testing operations that would have negative consequences for patients.

11 PSCs CLOSING IN ROCHESTER, NY

WXXI News reported that the **University of Rochester (N.Y.) Medical Center** would temporarily close 11 patient service centers (PSCs) on Sept. 28 due to its inability to fill necessary positions. Health system officials stated that the open positions were not because of COVID-19 vaccination requirements for the health system's staff.

TRANSITIONS

- **Sysmex America** announced the retirement of CEO Ralph Taylor, effective Sept. 30, ending 14-years of service. Taylor previously held positions with **Beckman Coulter** and **Coulter Electronics.**

- Andy Hay was selected to be the new CEO of **Sysmex America**, of Lincolnshire, Ill., and he served with the company for 32 years.

- Julie Khani will join **Hologic**, of Marlborough, Mass., as Vice President of Government Affairs. Her prior positions were at the **American Clinical Laboratory Association**, **National Association of Chain Drug Stores**, and **Ford Motor Company**.

CORRECTION

In the July 26 issue of THE DARK REPORT we wrote that **Compass Group** leaders had "sent a letter to the **College of American Pathologists** (CAP) expressing concerns about the College's CLIA accreditation process and service." This was incorrect. TDR has confirmed that it was one individual lab member of the Compass Group who contacted CAP directly with concerns about the CLIA accreditation program during the time originally referenced. We regret the error.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 18, 2021.

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