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CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS VERSUS The Joint Commission Accreditation Laboratory

Why do 372 hospitals want to switch?
Major Health Systems Are Changing CLIA Accreditors
(see pages 2-11)

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

2021 Opens with a Major Story … and It's Not COVID!

ON THE PAGES THAT FOLLOW, YOU WILL LEARN ABOUT A MAJOR STORY in the clinical laboratory industry that has gone unreported and publicly unremarked by the lab profession at large. This story is how three large health systems that own 372 hospitals have switched to a different CLIA (Clinical Laboratory Improvement Amendments) accreditation organization over the past 18 months.

In simplest terms, the **Veterans Administration** (170 hospitals), **Ascension Health** (151 hospitals), and **Providence Health** (51 hospitals) made **The Joint Commission** (TJC) their preferred CLIA accrediting body over the **College of American Pathologists** (CAP). Given the two-year cycle for CLIA lab inspections, it will take several years for these hospital labs to switch to TJC. CAP is expected to continue accrediting certain hospitals within these three health systems.

On pages 3-6, you will learn important details about these developments, along with a statement from CAP. Following on pages 7-8 is an analysis of why this huge shift in market share of CLIA hospital lab accreditations is happening. Next, on pages 9-11, you will read a lab director describing the experience of his hospitals during the first CLIA lab inspections conducted by TJC.

Each story draws open a curtain on this highly-significant development within the clinical laboratory profession. Every clinical laboratory in the United States must comply with CLIA 1988 requirements. Thus, if owners of 372 hospitals are choosing to use a different CLIA accrediting body, owners and administrators of other labs will want to know why these hospital owners decided to move away from one accreditor and use a different one.

THE DARK REPORT is doing its job of delivering timely, actionable intelligence on this major development in the clinical lab industry. The College of American Pathologists was first to organize lab quality activities dating back to the 1930s. It has been in the forefront of most advances in lab quality programs and is justifiably proud of this 80-year-long leadership.

As to THE DARK REPORT's coverage of these developments, it is important for CAP members to remember Sophocles, who was first to be credited with the statement, "Don't shoot the messenger. Don't blame the person who brings bad news." Instead, CAP and its membership would be best served by understanding these decisions, addressing the reasons why health systems are switching, and deliver an even better, more competitive CLIA accreditation service to the clinical laboratory profession. TDR

CAP Loses Accreditation Clients to Joint Commission

Several large health systems are moving their clinical laboratories' CLIA accreditation services

CEO SUMMARY: Over the past 18 months, several prominent national health systems decided to shift their CLIA laboratory accreditation services away from the College of American Pathologists and to The Joint Commission. These shifts from one accrediting body to another will involve hundreds of hospital laboratories. Such a shift in the market for CLIA accreditation services has not happened since the Clinical Laboratory Amendments Act was enacted in 1988.

WITH LITTLE FANFARE OR NOTICE to the clinical laboratory profession, three large health systems—representing hundreds of hospitals—recently decided to use a different accrediting body to certify their laboratories to the requirements of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

In September, **The Joint Commission** (TJC) issued a press release announcing that the **U.S. Department of Veterans Affairs** (VA) had selected the accrediting agency in Oakbrook Terrace, Ill., to provide laboratory accreditation services for the hospital laboratories of the **Veterans Health Administration**.

The Joint Commission is considered to be the nation's largest standards-setting and accrediting body in healthcare and has evaluated and accredited hospital-based laboratory services since 1979 and freestanding clinical laboratories since 1995.

Since that announcement on Sept. 14, THE DARK REPORT has learned that at least two other large health systems have decided to switch to The Joint Commission for CLIA laboratory accreditation services. One is **Ascension Health**, in St. Louis, and the other is **Providence Health and Services**, in Renton, Wash.

In the market for CLIA laboratory certification, this development is significant for two reasons. First, the **College of American Pathologists** (CAP) has enjoyed the largest share of the market for clinical laboratory accreditation services for decades.

Second, the shift in CLIA accreditation business away from CAP and to TJC involves at least 372 hospitals: the VA has 170 hospitals, Ascension Health has 151, and Providence Health has 51.

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Under the CLIA accreditors' two-year inspection cycle, it will take several years to determine how many hospital labs actually have completed the move to have TJC do the next CLIA assessment at these clinical labs.

Veterans Administration

As the largest integrated healthcare system in the United States, the Veterans Health Administration serves more than nine million veterans annually at 1,243 healthcare facilities, including 170 VA Medical Centers and 1,063 outpatient sites of care of varying complexity.

In its Sept. 14 announcement, TJC said that, effective Sept. 15, it would provide laboratory accreditation services for the VA's moderate- and high-complexity clinical laboratories at VA Medical Centers and community-based outpatient clinics. Those accreditation services would include education on the process, on-site and post-survey reviews, monitoring, and data and measurement activities. Left out of the announcement was the fact that CAP was the losing accrediting body after accrediting VA hospitals for many years.

The VA never issued a statement about the change and did not respond to repeated phone and email requests from THE DARK REPORT for comment on why the agency shifted from CAP to TJC. When asked for its comments, CAP officials provided a statement that is reproduced in full on the sidebar at right.

Changes in Lab Accreditation

While the VA's decision was announced publicly, other hospitals that have switched from CAP to TJC did not make such announcements. Despite that, THE DARK REPORT has learned that at least two other large health systems decided to make similar changes in how their laboratories are accredited.

Ascension Health will stop using CAP for accreditation and instead is contracting with The Joint Commission to accredit its laboratories.

Although no start date has been announced by Ascension, THE DARK REPORT has learned that this change was discussed at the highest levels of management and could be announced publicly at any time. Ascension did not respond to requests for comment.

Ascension Health operates 145 hospitals and more than 40 senior-care facilities and provides healthcare services in 19 states and the District of Columbia.

Providence Health and Services (PHS) is the third large health system to switch its accreditation services from CAP to TJC. PHS operates 51 hospitals in six states: Alaska, California, Montana, Oregon, Texas, and Washington. Before this change, CAP was the primary organization providing accreditation services to Providence Health's laboratories.

Using Both Accreditors

Under a new arrangement, CAP and TJC will provide accreditation services to PHS laboratories, sources said. The addition of The Joint Commission as a lab-accrediting body for PHS was not announced but was referenced on the website of the **Providence Portland Hospital** in recent weeks.

In a comment to THE DARK REPORT, a spokesperson for **Providence St. Joseph Health** said, "Our labs across the six states we serve have different accreditations. Many are Joint Commission accredited. Others are maintaining CAP or **COLA**, and still others are CMS inspected. This isn't new. In Oregon, for example, many of our labs transitioned to The Joint Commission five years ago, while one maintained CAP. Our lab operations in our different states are at different stages and have various reasons for the decisions they have made or are contemplating."

The Providence healthcare network includes:

- **St. Joseph Health** in Northern Calif.,

College of American Pathologists Provides Statement on Changes in CLIA Accreditation

IN RESPONSE TO THE DECISIONS BY SEVERAL LARGE HEALTH SYSTEMS to have their CLIA laboratory accreditation services provided by The Joint Commission (TJC), THE DARK REPORT asked the College of American Pathologists to comment. CAP provided the following statement from Richard M. Scanlan, MD, Chair of the CAP Council on Accreditation. Scanlan's statement is reproduced in its entirety.

For nearly 60 years, the College of American Pathologists (CAP) has maintained its market-leading position as the most comprehensive provider of laboratory improvement and accreditation programs. In strong partnership with our laboratories and member pathologists, we continue to lead and define laboratory quality standards, bolstering patient care and safety.

During the last year, two health systems have indicated their decision to move their CLIA laboratory accreditation services. While it might be tempting to evaluate alternative accreditors, we know that those providers lack the CAP's specialization to meet the needs of today's high complexity laboratories.

Our accreditation program is unlike any other. Beginning with our annually updated checklists infused with best practices, offering a blueprint for running a high-quality laboratory coupled with our peer-to-peer review and strong collaboration in the field, we provide laboratories with a more thorough and up-to-date review process.

Many top-ranked hospitals prefer the CAP's program because of its rigor and because we continually help them manage the changes in laboratory medicine, technology, and the evolving regulatory environment.

Through discipline-specific requirements, year-round education, and an adaptable peer inspection process, CAP-accredited laboratories keep current with the changes on the front lines of laboratory medicine.

Our priority is always to ensure seamless laboratory support and continuing access to the CAP's broad range of resources. Chief among these are proficiency testing, education, cancer protocols, clinical guidelines, as well as advocacy for essential regulatory relief during this pandemic.

In a year when COVID-19 has underscored the critical importance of high-quality laboratory performance for global public health, the CAP's commitment to our laboratories has never been more vital. Again, while some health systems may be enticed to evaluate alternate accreditation providers, the CAP continues to support them in many areas, and we stand ready to renew their accreditation when they wish to return.

- **Covenant Health** in West Texas,
- **Facey Medical Foundation**, Los Angeles,
- **Hoag Memorial Hospital Presbyterian,** Orange County, Calif.,
- **Kadlec** in Southeast Washington,
- **Pacific Medical Centers** in Seattle,
- **Swedish Health Services** in Seattle.

In addition to these three health systems—for which there is public information about their decisions to move hospital laboratory CLIA accreditation services away from CAP and to TJC—several parties have told THE DARK REPORT that one of the nation's largest for-profit hospital operators is considering switching from

CAP and could contract with The Joint Commission.

When contacted by THE DARK REPORT, none of the parties involved (the for-profit hospital operator, CAP, and The Joint Commission) would confirm this change or provide a comment.

Implications for Other Labs

It is unusual for any large, multihospital health system to decide to change its long-standing CLIA accreditation relations with its existing accrediting body. The fact that—during a period of just 18 to 24 months—three large health systems made a similar decision to switch away from CAP to begin using TJC is significant.

As noted earlier, these three large health systems operate 362 hospitals, which represents a large shift in accreditation business away from an existing accrediting body, and all three health systems decided to use the same accrediting body as their new provider.

Important Questions

Questions lab directors are likely to ask is whether these decisions were based, all or in part, on:

- obtaining a better price from the new accrediting body?
- because of poor service by one accrediting body?
- the perception that another accrediting body would provide better service?
- hospital owner's desire to use one accrediting body for the entire hospital?

The answers to these questions are important to the clinical laboratory profession, because meeting the requirements of CLIA 1988 is integral to the ability of each laboratory to continue operating and to bill federal healthcare programs. The intelligence briefing that follows on pages 7-8 takes up these questions. It is followed on pages 9-11 by an interview with a lab administrator about the reasons why his parent health system decided to use a new new organization to meet its CLIA accreditation requirements. TDR

VA's Accreditation Decision Was Appealed

PATHOLOGISTS FAMILIAR with the steps the Veterans Administration (VA) took to review CLIA lab accreditation services and to engage The Joint Commission (TJC) have told THE DARK REPORT that the deliberations over this decision were lengthy.

These sources told THE DARK REPORT that the VA had conducted a first review in 2018 that continued into 2019. Based on that review, the VA awarded its CLIA accreditation services to TJC. At that point, the College of American Pathologists (CAP) successfully appealed that decision, allowing CAP to retain the accreditation business with the VA hospitals until recently, sources said.

In 2019, the VA issued a new request for proposal (RFP) for CLIA hospital lab accreditation services. Following its review of the RFPs, it selected TJC to be its CLIA-accreditation provider.

When the VA awarded the accreditation contract to TJC, the decision was made at the highest levels of VA management, sources said. In making these decisions, the VA's top executives did not seek the opinions of staff in the clinical laboratories—including pathologists who direct the operations of these labs—the sources added.

Other sources stated that the Veterans Administration decided to let individual hospital labs in the VA system continue to use CAP for its accreditation services, with one caveat: If a VA hospital lab chose to stay with CAP for its CLIA accreditation, that hospital would need to pay for those services from its own budget, sources said.

Some VA hospitals in New England, are considering paying CAP under this arrangement, sources added.

Why Are Health Systems Changing CLIA Accreditors?

Health systems representing 372 hospital labs are changing their CLIA lab accreditation provider

CEO SUMMARY: It is uncommon for a major health system to switch its CLIA lab accreditation business from one accrediting body to another. Yet, just in the past 18 months, that decision was made by the Veterans Administration, Ascension Health, and Providence Health. This is an important development for the entire clinical laboratory profession, because these decisions may reflect significant changes in how hospitals want to operate their clinical laboratories.

IT IS A MAJOR EVENT WHEN A MULTI-HOSPITAL HEALTH SYSTEM decides to move its CLIA lab accreditation business from one accrediting body to another. The fact that at least three health systems—representing 372 hospital labs—have made this same decision in the past 18 months is noteworthy.

As explained on pages 3-6, three health systems are known to have switched the CLIA accreditation of their respective labs away from the **College of American Pathologists** (CAP) and to **The Joint Commission** (TJC). These health systems and the number of hospitals they own are:

- **Veterans Administration** (170 hospitals),
- **Ascension Health** (151 hospitals),
- **Providence Health** (51 hospitals).

Swing in Market Share

This shift away from one CLIA accrediting body to another by three major health systems in an 18-month period represents a huge swing in market share of CLIA accrediting services. The magnitude of the market share swing can be calculated in two ways.

One way to calculate market share of CLIA accreditors is to calculate the number of hospital labs switching their CLIA provider as a percentage of all community, acute care hospitals. Data from the **American Hospital Association** (AHA) show that, in 2020, there were 5,198 community hospitals. Thus, the 372 hospitals involved in the switch represent 7.2% of all community hospitals in the U.S.

A second—and more relevant—way is to calculate this same market share number by subtracting out the 1,821 rural hospitals reported by the AHA. The 372 hospitals switching their CLIA accrediting bodies represent 11% of 3,377 non-rural community hospitals.

However, that 11% number might increase if a story on the lab industry grapevine proves to be true in the near future. Credible rumors are circulating that one of the nation's largest for-profit hospital corporations is studying how to handle its CLIA accreditation needs going forward.

The largest for-profit hospital corporation is **Community Health Systems** with 188 hospitals. The second largest

for-profit hospital company is **HCA** with 166 hospitals.

By using the hospital count from the smaller of the two big for-profit hospital operators, that would potentially add another 166 hospitals switching their CLIA accreditor to the 372 hospitals known to be in the process of changing, for a total of 538 hospitals, or 15.9% of the nation's 3,377 community hospitals.

This produces a useful estimate of the market share swing in hospital lab accreditations now occurring between two of the largest organizations with CLIA accreditation authority. At a minimum, The Joint Commission has gained a 7% market share by adding the three health systems that have stated their decision to switch. And if TJC were to gain one of the largest for-profit hospital corporations as a client, it will have gained a sizeable 15.9% chunk of the CLIA hospital lab accreditation market.

Significant Trend

These statistics demonstrate why THE DARK REPORT believes a highly significant trend is unfolding in how hospitals and health systems handle the CLIA accreditation of their clinical laboratories.

It is a major decision anytime an organization switches its CLIA accreditation business to a different accrediting body. The fact that three large health systems made this same decision over the past 18 months is evidence that important changes are happening behind the scenes in the nation's hospitals and their clinical labs.

Lab administrators and clinical pathologists with years of experience know that the CLIA accreditation debate involving CAP and TJC has always centered upon one key difference in how each organization handles a lab's accreditation inspections. The College of American Pathologists uses a team of peer assessors to conduct the on-site inspection. By contrast, The Joint Commission uses professional assessors who are trained and paid by TJC.

Since the advantages and drawbacks of each organization's inspection model have been argued since the implementation of CLIA regulations in 1992, what might have changed in recent years to cause the parent organizations of 372 hospitals to leave one CLIA accreditor and move to another?

Advantages, Disadvantages

Many clients and regular readers of THE DARK REPORT know the pro and con arguments put forth by advocates of each approach to CLIA lab accreditation. They include the following:

- Cost savings from using a CLIA accreditor that is less expensive.
- Standardization of Medicare accreditation within a single hospital and health system by using the same accrediting body for the entire hospital, including the clinical lab.
- Avoiding the disruption caused by an inspection involving a large team of peers roaming throughout the laboratory for several days.
- The benefit of a lab being inspected by peers who can share best practices.
- More consistency in CLIA inspections because professional assessors work from a common standard.
- The benefit of not having to send a reciprocal inspection team of key lab staff to another hospital lab and have them gone for several days.
- Alternatively, the benefit of having one lab's assessment team learn useful knowledge from the clinical lab they are inspecting that they can take back to their laboratory.

Healthcare's Transformation

The ongoing transformation of the U.S. healthcare system may cause hospitals and health systems to revisit every aspect of their operations and compliance with federal and state laws. THE DARK REPORT will provide additional intelligence briefings on lab accreditation in upcoming issues. TDR

CLIA Update

Understanding Differences Between 2 CLIA Accreditors

Use of peer assessors vs. professional assessors is a factor when selecting CLIA accrediting bodies

MAJOR CHANGES ARE HAPPENING IN THE COMPETITIVE MARKET for CLIA accreditation of hospital laboratories. Some health systems representing hundreds of hospitals have shifted from using the **College of American Pathologists** (CAP) to using **The Joint Commission** (TJC) to meet the accreditation requirements of the federal Clinical Laboratory Improvement Amendment (CLIA) statute.

Such a movement of hospital labs from one CLIA-accrediting body to another has not happened since the CLIA regulations became effective in 1992. To learn more about the differences in how CAP accredits labs versus how TJC conducts lab accreditations, THE DARK REPORT interviewed William Remillard, MT(ASCP), Laboratory Director of the **Providence Health Care** (PHC) hospital labs in Eastern Washington.

Remillard has extensive lab management experience at **TriCore Reference Laboratories**; **PAML** of Spokane, Wash.; and **ARUP Laboratories**, and has worked with CLIA lab accreditors from CAP, TJC, **COLA**, **AABB**, and others over more than three decades in the clinical laboratory industry.

In an interview with THE DARK REPORT, he said, "I feel strongly that CAP needs to re-evaluate how they do their CLIA inspections. There are fundamental differences in how the two larger organizations handle the inspection process.

"Lab professionals perform CAP's inspections and work as volunteers when they visit peer labs. While CAP requires their volunteer inspectors to complete CAP online training modules, the process can result in variability among inspectors," explained Remillard. "By comparison, The Joint Commission's processes generally require fewer on-site inspectors who follow a checklist and serve as employed professional inspectors."

Since **Providence St. Joseph Health System** engaged The Joint Commission for CLIA accreditation of some of its hospital labs at the beginning of last year, two of the system's hospital labs in Remillard's area have had a TJC assessment. TJC inspects labs on a two-year cycle.

"The **Providence St. Joseph's Hospital System** operates 51 hospitals in six states: Alaska, California, Montana, Oregon, Texas, and Washington," he noted. "We're split into six regions, and PHC is the Washington-Montana region.

System-wide Standardization

"Since my return here in 2018, we've continued with many system-driven standardization initiatives in our hospitals and in our labs," he added. "Not all of our hospital labs are accredited through The Joint Commission because we are a large complex system and local decisions may steer each lab in a different direction. That said, some of them have already moved to TJC and some are just considering the move."

In a comment to THE DARK REPORT, a spokesperson for Providence St. Joseph Health said, "Our labs in the six states we serve have different accreditations. Many are Joint Commission accredited.

Others are maintaining CAP or COLA, and still others are CMS inspected. This isn't new. In Oregon, for example, many of our labs transitioned to TJC five years ago, while one maintained CAP. Our lab operations in our different states are at different stages and have various reasons for the decisions they have made or are contemplating."

In the Washington-Montana region, Remillard is responsible for lab operations at four hospitals. Previously, two of those hospitals were with CAP before switching to The Joint Commission last year. The other two are smaller critical access hospitals that the **Washington State Department of Health** inspects. "We're sticking with that for now," he noted.

Seeking Improvements

Seeking improvements in efficiency and lower costs, the two larger hospitals switched from CAP to The Joint Commission, Remillard explained.

"One important factor was that The Joint Commission accredits the entire hospital, which gives it oversight over just about everything," he noted. "That means we now have complete alignment with one regulatory body for much of the hospital, including the laboratory.

"In many hospitals, the laboratory is a bit of an outlier," he explained. "It's almost as if we speak a different language, and in many ways we do. To get alignment within our hospitals, it made a lot of sense to go with The Joint Commission because CAP doesn't inspect hospitals. It does laboratory CLIA inspections.

"Previously, when we would talk about being inspected by CAP, hospital leaders would sometimes say, 'Remind me again of what CAP does,'" he recounted. "That doesn't happen anymore.

"Now that we're with The Joint Commission, we're working with one regulatory body, which levels the playing field by simplifying the language everyone speaks when talking about accreditation," Remillard said.

"In that way it improves communication within the hospital," he added.

"The Joint Commission uses different assessors who inspect the laboratory from those who inspect the hospital itself," he said. "But the process is smooth and more efficient for all concerned.

"Another way that TJC inspection is different is that it has fewer people do the inspections," he reported. "CAP sends a team to inspect your lab and that team is sized in a way that's appropriate to your operation. Generally, that's more than one person, and it could be as many as 25 people inspecting your facility.

"In my experience, the CAP inspectors try to get their inspections done in one to three days," he said. "For most of my career, I've worked with larger labs, and I've found CAP will generally bring an entire army of people into those laboratories.

"Basically, that army is comprised of colleagues and peers from within the lab industry," Remillard explained. "CAP has said that having peers doing inspections is a big advantage, and in some cases this is true. Unfortunately, CAP has gone in a direction in which its process can be a burden on the laboratory that's being inspected—in part because they bring this small army of people to your lab.

"Many times, CAP inspectors in one department request the same documentation that other CAP inspectors are requesting in another department," he warned. "That kind of overlap is redundant and stressful for the staff, supervisors, and the management team.

Reciprocal CLIA Inspections

"To execute its inspection strategy, CAP expects your medical director to assemble and send a team to do a reciprocal CLIA inspection at another facility of a similar size," he noted. "While this is often an exciting process to do, it's also a burden because it's a big commitment for your lab to fulfill. You must assemble a team and send them on the road to do a CLIA inspection in another city or another state for multiple days.

"CAP has said that sending out peers to inspect other labs is an advantage because your team sees how other labs operate and potentially your team can learn best practices," he noted. "But my experience from a number of CAP inspections is that it can be hit or miss as to how much peer inspectors learn or share best practices when they assess your lab.

"There are times when a team of peers has extensive experience and does a thorough inspection. But then you might get the opposite too," he cautioned. "The team may be confused about the questions they're asking, or they may not fully understand the intent of the questions in the inspection process. Also, the team might interpret what your staff says about your lab operations in a way that's different from the way your staff interprets those same operations. When that happens, there's a potential for a difference of interpretation.

Resolving Issues

"To be fair, CAP has a way to resolve those issues, but that process often creates more work, and if those questions are not resolved, then the process can go off in a wrong direction quickly," he noted. "At least that's been my experience."

Remillard's experience with TJC is much different. "The Joint Commission's professional inspectors use a checklist and have a lot of experience using that checklist," he noted. "They know exactly what they're looking for, and there's not much interpretation in how they use the checklist.

"When we had our TJC inspection at one hospital in this region, it was thorough and went smoothly," he added. "This was one of our larger hospitals with 750 beds. In that facility, we had one inspector who stayed for about four days total. With a single inspector we could quickly establish a good, professional rapport and we found this inspector to be quite knowledgeable.

"Preparation for the change to the Joint Commission was extensive," he reported. "In July 2019, we presented the idea for the change to key lab stakeholders. Once we had their buy-in, we sent two content experts to an off-site TJC training in November. Preparation then continued with significant effort to update our standard operating procedures and to train to TJC checklist. Our on-site inspection was in February 2020, which was just prior to the pandemic travel freeze.

Feedback from Staff

"The feedback from our staff was that if they had known what The Joint Commission CLIA inspection would be like, they would have moved to TJC many years ago," he recalled. "I say that because the lab team considered it, overall, to be a great experience. Not only was it a more efficient inspection, but we were not required to send out a team of inspectors to go to another lab.

"CAP might say that with The Joint Commission, we would not get the peer-to-peer experience or learn best practices," he added. "I would challenge that thinking because the inspectors from TJC have been in many dozens of labs over the years. That experience means they can guide us to meet regulatory requirements using their wealth of knowledge. In that way, we don't lose out on the opportunity for TJC's CLIA assessor to share best practices with us."

In closing, Remillard added that having one accrediting body for the hospital and lab is an important point that lab directors and hospital administrators should not overlook. "Being aligned with the rest of the hospital is very important for labs," he said. "As laboratorians, we're separated enough as it is from the rest of the hospital staff. Having one accrediting organization both for the hospital and the lab helps to bring both entities into more of an alliance than they would be otherwise." TDR

Contact William Remillard at William.remillard@providence.org.

NOTE: THE DARK REPORT invites those who would like to explain the pros and cons of CAP vs. TJC accreditations to respond to: *rmichel@darkreport.com*

NEWSMAKER INTERVIEW

Two-Drop 'Digital CBC' Enters U.S. Market with FDA Clearance

"We believe the ability to work with just two drops of blood, plus the fast time-to-results and the reduction in operator overhead provided by our FDA-cleared moderate-complexity analyzer, will be highly attractive to providers."
—**Yossi Pollak, CEO Sight Diagnostics, Ltd.**

CEO SUMMARY: For 70 years, the Coulter Principle has been a bedrock technology in hematology. Now this seven-decades-old technology has a challenger. An Israeli company obtained clearance from the Food and Drug Administration (FDA) to market a new CBC instrument as a moderately-complex CLIA device. The system needs only two drops of blood placed on a specially-designed cartridge. The cartridge is inserted in a small analyzer, which uses machine imaging and artificial intelligence to produce a five-part CBC with 19 parameters and signature flagging capabilities.

EDITOR'S NOTE: Digital imaging, digital image analysis, and artificial intelligence/machine learning are technologies expected to disrupt anatomic pathology and its centry-long reliance on the light microscope. Now **Sight Diagnostics, Ltd.**, a young diagnostic company headquartered in Tel Aviv, Israel, is adapting these technologies to clinical laboratory testing—specifically hematology and complete blood counts (CBC). The company manufactures a diagnostic solution that has the potential to be disruptive in multiple ways. The following interview with Yossi Pollack, Co-Founder and CEO of SightDx, was conducted by Robert L. Michel and Donna Marie Pocius of The Dark Report.

EDITOR: Yossi, let's set the scene for our readers by explaining that, in November, 2019, the federal **Food and Drug Administration** (FDA) issued a 501(k) clearance to your Sight OLO CBC analyzer for moderately-complex testing in CLIA-compliant facilities. This test produces five-part CBC results with 19 parameters and signature flagging capabilities. What differentiates the Sight CBC testing system is that it is engineered around a radically different mix of technologies, compared to most hematology systems used in clinical laboratories today. Could you explain more about why your OLO system is different from most hematology systems used by clinical laboratories today?

POLLAK: In simplest terms, the system takes two drops of blood—collected either by fingerstick or venipuncture—and turns that sample into a set of high-resolution digital images. The images are analyzed automatically using our algorithms to accurately perform a complete blood count (CBC)—to count the patient's red and white blood cells, platelets, etc., including a white blood cell differential. Our OLO system can analyze 19 different blood parameters in minutes.

EDITOR: How large is your OLO system?

POLLAK: The system is about the size of a toaster oven—less than one foot per side—weighs 22 pounds, and can be placed on a bench, as well as in many other near-patient settings.

EDITOR: It is important for lab administrators and clinical pathologists to also understand that it is not just the small size that sets your CBC instrument apart from existing hematology systems. It does not count blood cells as they move through a gate, for example. Rather, it uses digital imaging and artificial intelligence (AI) in novel ways, correct?

POLLAK: Yes. Our OLO CBC analyzer essentially digitizes blood samples. We have a sample preparation method that allows us to automatically create a monolayer of cells within a self-contained cartridge. Next, this specimen cartridge is inserted into the analyzer and over 1,000 images are captured within 10 minutes. Then, in real time, the instrument analyzes these 1,000 images to produce the CBC results.

EDITOR: It this the first diagnostic for clinical purposes that you created?

POLLAK: Sight previously developed a test for malaria, which we launched in 2015. As laboratory scientists know, there is no malaria testing solution that is sufficiently inexpensive, rapid, and highly accurate. Yet it is a huge market globally: data from the **World Health Organization** (WHO) shows

that about 500 million malaria tests are performed each year. These diagnostic tests are primarily microscopy and rapid diagnostic tests (RDTs). Our team saw this as an opportunity to apply new AI technologies that were being developed in domains such as self-driving cars and put them to use in clinical diagnostics.

EDITOR: That would seem to be quite a leap—from self-driving cars to a diagnostic test for malaria. How did this happen?

POLLAK: It started back in 2010. Some of us had worked at **Mobileye**, an Israeli-based company using digital images, digital image analysis, and artificial intelligence to guide self-driving cars. We looked outside this field to see how these same technologies could be used in novel ways. We saw a way to use machine vision—already capable of recognizing pedestrians, crosswalks, and traffic signals—and train it to recognize biomarkers in the blood.

EDITOR: What caused you to see a way to link technology that supports self-driving cars with some type of diagnostic test for use in patient care?

POLLAK: Imagine, for a moment, how much training a human needs to drive a car. Typically, an individual can become an expert after maybe 20 hours of actual driving. By contrast, it requires years of training for someone to achieve the skills needed for clinical-grade microscopy. That caused us to think that we might be able to adapt these technologies in malaria testing specifically to replace the human eye for the analyses. There was the potential to greatly reduce the cost of a malaria test while at the same time producing a fast time-to-result that would enable treatment to begin immediately at remote clinics in developing nations. With this type of solution, even I could be "behind the microscope" and use this system to produce an accurate answer.

EDITOR: When did you introduce this malaria test?

POLLAK: That happened in 2015, after five years of development. The test is marketed as the Parasight Malaria Detection Platform.

EDITOR: In researching your company for this interview, I noticed that just one year later, in 2016, your company entered into an agreement with **Becton Dickinson** for BD to distribute this test system in India.

POLLAK: Yes. The market numbers in India are huge, because almost 900,000 cases of malaria are diagnosed in India each year and 128 million tests are performed. BD's interest in distributing this test system in India was an important confirmation of our malaria test's accuracy and reliability at that time. In fact, we've now sold over one million of our Parasite malaria tests worldwide.

EDITOR: This is a credible track record for your digital imaging and artificial intelligence (AI) technologies in their use to test for malaria.

POLLAK: All this work also helped us better appreciate diagnostic accuracy because the sensitivity and specificity of a malaria test needs to be at very high levels to avoid the cost of following up on false positives, as well as the negative impact on patient outcomes from false negatives.

EDITOR: What came next after the introduction of the malaria test?

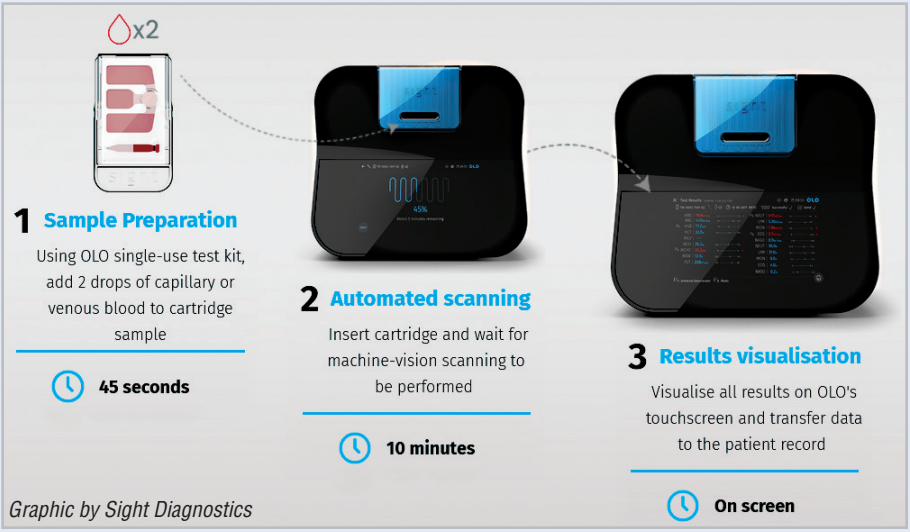
POLLAK: In 2016, we started to consider other types of blood tests. Our technology is a platform technology—meaning it can be adapted for a wide range of clinical and biological testing. And remember, for malaria, we were already creating a monolayer of human blood cells, digitizing the images, and analyzing those images with AI technologies.

EDITOR: So, you looked at the types of clinical laboratory tests that use whole blood and microscopy. Is that a good guess?

POLLAK: That's on target. Before the days of Coulter counters, labs would perform blood counts by creating a slide that presents the blood cells for microscopy,

Sight Diagnostics' OLO 5-Part CBC Test Needs Just Two Drops of Blood to Produce Results

ONE WAY TO LOOK AT THE NEW INSTRUMENT SYSTEM MANUFACTURED by Sight Diagnostics of Tel Aviv, Israel, is that it brings new value to clinical laboratory testing by combining several rapidly-changing technologies to create a novel diagnostic testing solution. Sight's OLO CBC analyzer utilizes machine imaging and artificial intelligence to deliver a 5-part CBC result in about 10 minutes, using two drops of blood.



Graphic by Sight Diagnostics

Shown above are the three steps that Sight Diagnostics says are needed to produce a CBC test result using its OLO analyzer in moderately-complex CLIA labs. 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. After inserting the cartridge into the instrument, results are available within 10 minutes.

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. The manufacturer expects the OLO CBC analyzer to be simpler to operate and to require less maintenance when compared to existing, high-throughput hematology systems. At the same time, the OLO CBC analyzer's cost per test will not be as low as the high-volume CBC analyzers used in the large central laboratories around the United States.

and even today, 5% to 20% of CBC samples are sent to reflex testing that is based on microscopy. Our technology platform was already doing all of these actions for the malaria test.

EDITOR: However, in hematology, there are many reputable, highly-automated systems already delivering speedy, accurate CBC results at a low cost. Why did Sight Diagnostics believe it could successfully compete in this market?

POLLAK: Certainly there are many robust hematology systems in use globally. These systems have something in common. The highest-throughput instruments are generally large, complex, and most either utilize resistive pulse sensing—the Coulter Principle—or flow cytometry to

assess the blood specimen. The Coulter Principle dates back to the early 1950s and is now 70 years old. We saw the opportunity to bring new technology to this market and also to address an underserved segment of the clinical market for blood testing.

EDITOR: Please explain, particularly about what you see as the underserved segment of the clinical market.

POLLAK: These hematology systems are commonly used in larger clinical laboratories. If your lab runs hundreds or thousands of CBC tests per day, then these hematology systems are efficient and cost-effective. But this model of CBC testing comes with delays in reporting results because specimens must be transported to the large central laboratories that operate big hematology systems. We saw the opportunity to move CBC testing closer to the patient to produce faster results.

EDITOR: Does this mean tailoring your OSO CBC analyzer to meet the needs of smaller labs?

POLLAK: Yes. We identified a huge gap in small and medium test volume settings—a need for on-site CBC testing that was closer to the patients and where the specimens didn't need to be sent to one central lab.

EDITOR: How did you identify this unmet need?

POLLAK: We conducted interviews with doctors. We recognized that if technology was available that provided them with critical information during the patient visit, or otherwise within minutes of ordering the test, treatment could start faster. Armed with those insights, we worked from 2015 to 2019 to modify our platform to perform complete blood counts. It was in December, 2019, that the FDA issued clearance for this device for moderately-complex settings.

EDITOR: What you are talking about is point-of-care testing done in the doctor's office and other near-patient settings.

POLLAK: We are targeting various near-patient settings today, and we plan to enter the point-of-care and doctors' offices down the road, subject to additional regulatory approval. It is our strong belief that the key to these settings is to avoid any compromise in the quality of the result of running the CBC on OLO locally—as compared to sending it to a large laboratory. From day one we said, "we are going to replicate the best in class." This is reflected in OLO's design and in our choice of predicate device for the studies that we submitted to the FDA.

EDITOR: Could you explain your strategy for use of a two-blood-drop specimen to perform a CBC?

POLLAK: Not only is the Sight OLO both robust and compact, but it also allows—for the first time—a CBC test directly from a fingerpick of blood (as well as from a venipuncture). We expect this to prove to be an easier and more welcomed collection process for the patients.

EDITOR: Can the option of using either a finger-stick specimen or a venipuncture specimen be a benefit to the provider?

POLLAK: We think so. The ability to use fingerprick samples can avoid the time needed for scheduling and performing phlebotomy, permitting the process to be faster and more convenient. This can be of value, for example, in various hospital departments, including in the emergency department where speed is of the essence. Similarly, a fast CBC result would benefit patients showing up at an oncology center for treatment. We believe that the ability to work with just two drops of blood, plus the faster time-to-results and the reduction in operator overhead provided by our FDA-cleared moderate-complexity analyzer, will be highly attractive to providers.

EDITOR: Yossi, your platform has the potential to disrupt hematology testing in several ways. But let's stay with near-patient settings and physicians' offices capable of doing moderately-complex CLIA

testing, which you've identified as the market segment you want to serve with the OLO CBC analyzer. Why are you confident this solution will gain traction?

POLLAK: The advantages offered by the speed of results and the ability to use finger-stick samples seem to be resonating across a number of moderately-complex settings, including hospital satellite facilities, oncology centers, and urgent-care centers. However, a less obvious advantage stems from OLO's impact on operational efficiency and cost structure in low- and medium-volume settings: analyzers designed for large labs require a good deal of overhead in the form of washouts, calibrations, and frequent quality control (QC) runs. While these are effectively amortized across the large number of samples in larger facilities, they result in significant impact on test cost and workflow in the low- and medium-volume settings.

Yossi Pollak

"We believe that the ability to work with just two drops of blood, plus the faster time-to-results and the reduction in operator overhead provided by our FDA-cleared moderate-complexity analyzer, will be highly attractive to providers."

EDITOR: Explain these benefits, please.

POLLAK: Some of our customers have been surprised to learn just how much of an impact these factors have on their cost structures with legacy analyzers. In contrast, OLO's use of disposable test kits means it does not require washouts; it is calibrated at the factory, so it does not require repeated calibration, and we enable our users to put in place independent QC plans (IQCPs) to reduce the number and cost of QC runs. We are building a collection of case studies that illustrate the resulting advantages in terms of total cost of ownership.

EDITOR: Finger-stick sampling is a patient-friendly feature, since many patients are uncomfortable with venipunctures. How was this part of your strategy?

POLLAK: Finger-stick collection has several equally important benefits. It eliminates the need for a phlebotomist or nurse to perform the venipuncture. That reduces the cost of collecting a specimen. It also gives the provider more flexibility in staffing, while preserving the ability to collect specimens and perform a CBC test with the moderately-complex device.

EDITOR: What about the benefits of time-to-result?

POLLAK: That is perhaps the most important source of value. The ability to speed up how a patient moves through the process of specimen collection, diagnosis based on test results, and decision on how to treat can have major positive consequences for providers. For example, during the COVID-19 pandemic, we are finding that hospitals are interested in the OLO CBC analyzer because it can help move patients faster through the appropriate care pathways in the emergency department. Hospitals want to triage patients as fast as possible to determine if they are positive for SARS-CoV-2. This moderately-complex testing solution can help cut the time to answer.

EDITOR: The **Sysmex** XN-2000 Hematology Analyzer is your predicate device and this instrument has FDA clearance as a moderate-complexity CLIA system. The Sight OLO CBC Analyzer also has FDA clearance as a moderate-complexity CLIA system. Do you have a timeline with the FDA at this point to obtain clearance as a waived CLIA test? And are you open to sites that might want to be study sites?

POLLAK: Hopefully, we will soon advance OLO by applying for a CLIA Waiver. The COVID-19 pandemic has unfortunately slowed our recruitment of additional clinical study sites, but we are

back on track now. We have had clinical studies with **Columbia University Medical Center**, with **Boston Children's Hospital**, and with **TriCore Reference Laboratories** in Albuquerque, N.M., and we plan to do more studies. We are interested in finding additional sites to take part in studies.

EDITOR: In coming to the United States, who is your perfect buyer and user? And who is an early adopter and user of the system?

Yossi Pollak

➤"We report 19 parameters in total, including red and white blood cells enumerated per microliter of blood as well as absolute and relative counts for the WBC differential."

POLLAK: We provide a lot of value to pediatrics, oncology centers, emergency rooms, hospital satellite facilities, and to urgent-care facilities that need to provide a speedy clinical service. Because of the excitement we see, we've accelerated expanding our sales distribution network. Our U.S headquarters is in Brooklyn, New York. This is where we warehouse devices, as well as recruit and train our U.S. sales professionals.

EDITOR: Some clinical insights are of interest to help our clients and regular readers who tend to be the first-mover types in labs in the U.S. They want to do the right thing for patients and be ahead of the curve with the kind of technology they think is ready for clinical service. How is information provided on the number of different blood cell types? Is it the same as you would obtain with a CBC with the cells enumerated per a given volume?

POLLAK: Yes, we report CBC results in a similar fashion to existing analyzers. We report 19 parameters in total, including red and white blood cells enumerated per microliter of blood as well as absolute and relative counts for the WBC differential. OLO also has a flagging system, which flags blasts, immature granulocytes and nucleated RBCs, and raises a number of messages. Results are displayed right on the instruments, optionally printed by an attached printer and transmitted to the laboratory information system.

EDITOR: Does OLO provide information about the function of the blood cells, most notably platelet function?

POLLAK: At this point, we are not going beyond the original CBC. However, we are collecting image and information to support ongoing research as to how we can adapt our platform for other types of diagnostic tests.

EDITOR: I understand you have six gigabytes of raw data coming out of a single assay. Is that being sent to an LIS?

POLLAK: It's true: our method for "digitizing blood" results in six GB of image data per sample. However, we don't currently store the images on the LIS, only the test results. Of course, when we do store image data, it will be HIPAA compliant and anonymized. We already have an extensive database of blood images—about half a petabyte worth. We are working with it to find trends, specifically with a few studies around stroke.

EDITOR: This is the future of laboratory medicine—to combine lab test results with other relevant clinical and demographic data to provide a more detailed picture of the patient that helps physicians make a more accurate diagnosis and select the most appropriate therapies. Thank you, Yossi, for taking the time to explain how Sight Diagnostics is using new technologies in the field of hematology testing.

POLLAK: As you can see, we are excited about the different ways that this new testing platform can help improve patient care. Thank you for the opportunity to share this information. TDR

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Digital Pathology Launched in the 'Era of COVID-19'

Memphis lab company makes the business case for scanning slides to cut costs, boost productivity

CEO SUMMARY: Is it smart to initiate digital pathology (DP) systems and whole-slide imaging just as a novel coronavirus upends healthcare and society at large? That was the question asked at Poplar Healthcare, a pathology lab in Memphis. Senior management proceeded with the implementation, despite the uncertainty that accompanied the SARS-CoV-2 pandemic. Nine months later, the early experience with digital pathoolgy has been successful and Poplar now enjoys lower costs and new clients.

LIKE TWO TRAINS ON THE SAME TRACK APPROACHING A HEAD-ON COLLISION, a large pathology group's scheduled implementation of digital pathology systems ran directly into the full effect of the COVID-19 pandemic when it hit with force last March and April.

The good news is that this collision of a planned roll-out of a digital pathology (DP) and whole-slide imaging (WSI) solution during the SARS-CoV-2 outbreak turned out well for **Poplar Healthcare**, an anatomic pathology group in Memphis with 25 pathologists. Poplar is beginning to realize the benefits of digital pathology and WSI in its daily workflow.

Poplar's foray into digital pathology began in 2018, when Poplar's managers started on an 18-month process of defining needs, selecting the scanners, and choosing the overall digital pathology management system.

In September, Sweeney spoke at THE DARK REPORT'S *Executive War College* regarding Poplar's entry into digital pathology. His co-presenter was Lisa-Jean Clifford, Chief Operating and Chief Strategy Officer for **Gestalt Diagnostics** in Spokane, Washington.

During their presentation, Sweeney discussed Poplar's pathway to adoption of digital pathology and whole-slide imaging and Clifford discussed Gestalt Diagnostics' PathFlow system. "Late in 2017, right after we merged with **Bostwick Laboratories**, we brought the idea of investing in digital imaging systems to the board of directors," he said. *(See, "Memphis Path Lab Pivots to COVID, Pooled Testing," TDR, Dec. 7, 2020.)*

Evaluating DP Systems

"During that initial phase, we spent about nine months talking to different vendors to understand the steps they were taking to obtain clearances for their systems by the FDA and to develop their hardware systems," he said. "We also wanted to understand how digital pathology systems need to be validated.

In 2013, the **College of American Pathologists** (CAP) issued guidelines for pathologists seeking to self-validate on the digital pathology systems they were using. By giving AP groups the steps needed to self-validate WSI systems, these CAP guidelines could enable pathologists to be agnostic about which imaging systems

they could use to review cases without waiting for FDA clearances.

"In that initial phase, the biggest concern that the board had was the cost of a digital pathology system," Sweeney reported. "They wanted to know how much each scanner would cost, how many scanners we would need, and what other equipment would be required.

Capital Outlay for DP System

"Because our big concern was the capital outlay, we proposed different payment models to use in acquiring the scanners and DP systems," he explained. "Instead of making a big capital investment, we looked at other forms of funding that were more like reagent rental agreements.

"We settled on a per-case cost that reduced our up-front spending while allowing our DP program to pay for itself through savings and revenue growth," noted Sweeney. "We also knew that we needed to be careful when choosing a scanning system. We did not want to choose one that would limit our ability to serve any pathology practice in the United States or potentially any pathologists overseas.

"Our goal was to stay agnostic and use an open system that gives our pathologists the flexibility to interpret images from any other scanning system," he noted. "At that point, we turned to Gestalt. Their system includes that flexibility and it can send and receive images to and from multiple imaging systems and can interface with virtually any artificial intelligence (AI) applications."

Digital Pathology's Benefits

Now, as 2020 comes to an end, Poplar Healthcare has realized five significant benefits from using digital pathology systems. Sweeney says those benefits are:

- "First, it lowers costs by eliminating the need to ship glass slides to remote pathologists.
- "Second, it improves the productivity of remote pathologists, because the whole-slide images can be sent instantaneously to a pathologist along with the case information, and both are viewable at the same time within our case viewer.
- "Third, it allows remote pathologists to share digital images for second opinions, consults, or to refer difficult cases back to our subspecialists for review or for interdepartmental review.
- "Fourth, it provides faster turnaround time for results, which helps us gain new clients.
- "Fifth, it provides a platform to increase revenue by delivering services to customers seeking to reduce their histology costs and to incorporate whole-slide imaging."

Under a model in which Poplar Healthcare works remotely with anatomic pathologists located within physician practices, some of its revenue comes from doing the technical component (TC), some comes from the professional component (PC), and some comes from doing both TC and PC (or global).

TC, PC, Global Opportunities

"Of our daily volume, about 65% is global, and the other 35% is either TC or PC," Sweeney reported. "By that, I mean a hospital or pathologist somewhere asks us to make glass slides and to send those slides out to them, or someone makes glass slides and sends them to us to read.

"Digital pathology lends itself to supporting this model of business," he added. "Slides can be produced efficiently in our 114,000-square-foot CLIA-certified laboratory, scanned, and then transmitted to pathologists anywhere in the country. Special stains and IHCs [immunohistochemistry] can be ordered and performed immediately."

In addition to working with pathologists in physician practices, Poplar Healthcare also works with hospitals in Tennessee and other states in the Mid-South. "We currently provide pathology

Considering Open and Closed Systems When Choosing Digital Pathology Solutions, Scanners

ANATOMIC PATHOLOGISTS SEEKING BEST-IN-CLASS VENDORS for digital pathology systems (DP) or scanners to produce whole-slide images (WSI) should look first for vendors that support a variety of WSI hardware and software, said Lisa-Jean Clifford, Chief Operating and Chief Strategy Officer for Gestalt Diagnostics in Spokane, Washington.

"The best systems will be those that sit on top of whatever infrastructure the anatomic pathology laboratory already has," Clifford explained. "That's the key to deploying digital pathology systems.

"Many vendors support only the workflows and applications that work with their own hardware and those systems are unable to incorporate multiple different applications (such as laboratory information systems and scanners)," she noted.

"That's something that many of the earliest DP and WSI vendors didn't realize," she added. "Or, they didn't think about the fact that the whole premise behind digital pathology is to be able to expand its use to any pathologist working in any location at any time.

Open vs. Closed Systems

"That means pathology groups considering DP and WSI need to be aware of the differences between open versus closed systems," Clifford explained. "If a vendor is one of the large digital imaging system companies, and its system works only with its other systems, then pathology groups using these types of closed DP sysems are limited in how they can expand.

"How does an anatomic pathology group wanting to work with other pathologists in remote locations make that closed system work without a substantial investment each time?" Clifford asked. "What happens if an AP laboratory wants to deploy its choice of a DP system to other pathologists or to hospitals outside of their organization or service area?

"That laboratory would not be able to integrate its systems without buying all new scanners, other hardware, the image analysis and artificial intelligence software, and the operating system," she warned. "Without that, they can't play in that environment.

"With a closed DP system, it's challenging for a pathology group to share different image file formats and data," she noted. "That inability to share files and data defeats the purpose of digital pathology, which ideally includes the ability to streamline workflow, to automate imaging systems, and to make them all interoperable."

When Poplar Healthcare in Memphis implemented a whole-slide imaging system for its pathologists who work remotely, the AP group also deployed Gestalt's PathFlow system, Clifford said.

"Our solution to the problem that many AP groups have is a digital pathology platform called PathFlow that includes an image management system, a viewer, and an integrated workflow," Clifford explained. "In this open system, the pathologist works in a cockpit from a worklist that includes the slides that need to be reviewed that day or that shift. It also has an integrated reporting system, voice recognition, artificial intelligence, and image analysis.

"The key to our system is that it is completely vendor agnostic," she added. "That's been our premise from the beginning and that means our open system can work with any scanner from any scanner vendor."

services for a number of small hospitals," Sweeney noted. "That means we can now discuss the possibility of managing the histology departments that exist in many of the hospitals in our region.

"If we do that, we could help them save costs by making the glass slides, scanning those slides, and sending the images back to the pathologists in those hospitals," he explained. "The pathologist in that hospital could be an employee of Poplar Healthcare or could be a hospital employee, or that pathologist might work for another pathology group practice."

While working remotely with pathologists in hospitals and physician groups outside of Memphis, Poplar Healthcare also could add international pathology clients. "By some estimates, about 75% of the world's pathologists reside in the United States," Sweeney reported. "So, when we talk about the future of pathology, there is a significant opportunity for AP groups in the United States to read cases from anywhere in the world.

➤Overseas Opportunities

"Doing that would allow us to provide care to patients in many different countries," he commented. "To date, we have not begun selling outside the United States, but we are talking about how we might do so."

For Poplar Healthcare, dermatologists also are an area of interest to grow its digital pathology business. "During their residency training, dermatologists get experience in pathology by reading their own cases," he said. "We are working with companies developing AI applications that will assist with digital triaging of cases, allowing dermatologists to do their own case reviews.

"We simply need to confirm that they have high-resolution monitors and that the dermatologists have been validated through CAP's validation process for primary diagnosis," he added.

"We are very excited about the future of AI in anatomic pathology," commented Sweeney. "There are numerous companies developing algorithms for quality assurance, primary review, and digital triaging, to name a few.

"Each of these applications will have a place in the future," he concluded. "Although there is much work to be done before those applications are ready for prime time, we plan to be on the front of that curve." TDR

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Gestalt Diagnostics Wins Workflow Award

IN TODAY'S INCREASINGLY COMPETITIVE MARKET FOR ANATOMIC PATHOLOGY SERVICES, pathologists need a world-class productivity and workflow solution that supports digital pathology and allows them to protect existing clients and expand market share. That's why a recent award may be of interest to many pathology groups.

In recent months, *CIO Applications* magazine published its current list of the "Top 10 Workflow Solutions Companies." One of the companies recognized was Gestalt Diagnostics, based in Spokane, Wash., which developed and sells its pathology workflow solution PathFlow.

CIO Applications recognized Gestalt for its solution to convert conventional anatomic pathology manual processes and workflow to an "electronic digital workflow."

Gestalt says its PathFlow solution "provides a full image management system, robust case routing, a universal viewer, integrated artificial intelligence, image analysis algorithms, and reporting."

Gestalt's Pathologist's Cockpit provides a single, streamlined, fully interoperable workflow that enables pathologists to interpret and sign out their cases.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Just days ago, the federal **Food and Drug Administration** (FDA) issued updated information about the COVID-19 tests it has authorized since early in the pandemic. As of Jan. 15, 2021, the agency had authorized a total of 317 tests for the SARS-CoV-2 coronavirus. Included in this total are 236 molecular tests, 68 antibody tests, and 13 antigen tests. Of the 236 molecular tests, 32 are authorized for use with home-collected samples. There is one molecular prescription at-home test, one antigen prescription at-home test, and one over-the-counter at-home antigen test.

23ANDME RAISES $82.5 MILLION IN NEW CAPITAL

23andMe of Sunnyvale, Calif., disclosed that it raised $82.5 million in new funding in a Series F round led by **Sequoia Capital** and **NewView Capital**. News reports indicated that it wanted to raise $85 million, but lack of investor interest caused it to close the funding round with $82.5 million. Now that the tidal wave of consumers wanting to do genetic tests to learn about their ancestry and family trees is subsiding, companies like 23andMe and **Ancestry** are looking for other products and services to sell. In the case of 23andMe, the company hopes to use the genetic data it says it has on 12 million people to collaborate with the development of therapeutic drugs. It entered into one such deal in 2018 with **GlaxoSmithKline**.

CHANGE HEALTH TO BE ACQUIRED BY UNITEDHEALTH

On Jan. 6, it was announced that **Change Healthcare** would be acquired by **Optum**, a division of **UnitedHealth**. The purchase price is $8 billion and the press release issued by the two companies described the transaction as "combining" the two businesses. The two companies also said, "Change Healthcare will join with OptumInsight to provide software and data analytics, technology-enabled services and research, advisory, and revenue cycle management offerings to help make healthcare work better for everyone." Many clinical laboratories use services from Change Healthcare, including lab test billing and collection services.

UNITEDHEALTHCARE AGAIN DELAYS TEST LAB TEST REGISTRY

Last month, **UnitedHealthcare** (UHC) announced that it would delay implementation of its Laboratory Test Registry Protocol until January 1, 2022. This is the third time that UHC has moved back the start date for the cumbersome program. UnitedHealthcare is requiring nearly all tests and panels used by in-network medical laboratories to be registered. After January 1, 2022, UHC will not pay for claims for clinical laboratory tests and panels that are not registered.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 8, 2021.

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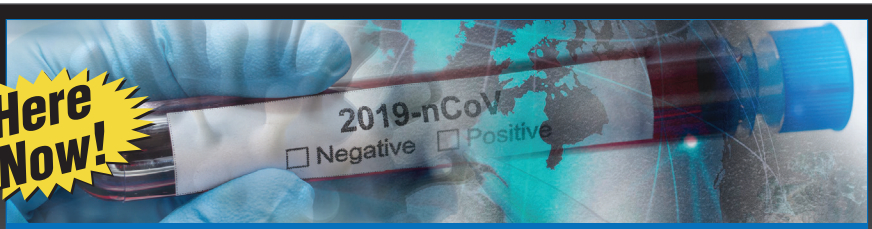

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- ***Converting a histopathology lab to SARS-CoV-2: One million tests later, important lessons learned.***
- ***Is it time to declare an end to the era of baby-boomers and welcome the up-and-coming X and Y generations?***
- ***More consolidation among major healthcare players: Implications of UnitedHealth's acquisition of Change Healthcare.***

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