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Exclusive!
Lab Accreditors Find It Tougher to Field More CLIA Inspectors
(See pages 3-6.)

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

Building Collaborations to Deliver More Value

INNOVATIVE CLINICAL LABORATORY LEADERS CLOSELY MONITORING THE FINANCIAL HEALTH of their labs or hospitals will find plenty to chew on in this issue of THE DARK REPORT.

The laboratory team at **Atrium Health** in Charlotte, North Carolina sets the stage with a case study about how the lab team's interaction with health system administrators and clinical leaders during the COVID-19 pandemic generated increased respect for the role of the laboratory, particularly in its ability to be a valuable collaborator with different service lines within the health system. *(See pages 12-15.)*

This new-found respect and interest in cooperation led to the Atrium Health laboratory's participation in a growing number of initiatives with different service lines designed to improve patient care and better manage the overall cost of care. By raising the laboratory's profile, projects arose that squarely took aim at boosting patient care while saving money.

One endeavor spearheaded by the lab resulted in $2 million in savings by reducing blood culture collection contamination. Another saved thousands of dollars by working with physicians in the health system to substantially reduce the number of reference labs they used for send-out tests.

These successful projects involving Atrium Health's laboratory can be easily replicated in other health systems. They demonstrate how a clinical laboratory team can collaborate with other clinical service lines and participate in projects designed to boost patient outcomes while better managing the costs of care.

Meanwhile, this issue of THE DARK REPORT opens with exclusive coverage of an important story about how several of the organizations with CLIA deeming authority are finding it difficult to put enough skilled assessors in the field to do CLIA inspections. *(See pages 3-6.)* These organizations are experiencing the same acute staffing shortage of clinical laboratory scientists, pathologists, and other laboratory professionals encountered by the nation's labs.

Reports from the field indicate that this is not yet a problem for labs that undergo a CLIA inspection every two years. At the same time, when skilled professionals are in short supply, quality can often suffer. Thus, the ability of CLIA accrediting bodies to maintain a consistent, high-performance lab inspection service going forward should be monitored. TDR

CAP, TJC Under Pressure to Add More Inspectors

Sources say CAP and Joint Commission short on CLIA surveyors, but CAP says its roster is 'not in crisis'

CEO SUMMARY: Like the clinical laboratories they accredit to the requirements of CLIA, The Joint Commission and College of American Pathologist (CAP) face recruitment and hiring pressures when it comes to their surveyors and inspectors. Labs involved with CAP's peer inspections may be finding it difficult to send out staff members for days at a time, leading the accreditor to ask other inspectors to step up for extra duty.

THERE ARE GROWING SIGNS THAT ACCREDITATION ORGANIZATIONS are facing a common challenge: having an adequate number of assessors to conduct CLIA lab inspections.

This is a development that can have ramifications for every clinical laboratory in the United States, particularly those accredited as high complexity under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The federal government grants deeming authority to certain organizations to inspect medical labs. Those organizations include **The Joint Commission** (TJC) and the **College of American Pathologists** (CAP).

Job openings on The Joint Commission's online careers page show several open posts for pathology and medical technologist surveyors. Also, several sources tell THE DARK REPORT that both groups have run into difficulty finding enough surveyors and inspectors to perform CLIA evaluations.

Meanwhile, two CAP inspectors we contacted said they are performing more inspections than they have in the past.

"I can tell you anecdotally that I get a lot more requests now to help with CAP inspections," said Barbara Day, MS, MT(ASCP)SBB, a volunteer inspector for CAP. Day spent 36 years in the medical laboratory industry before joining a biopharmaceutical strategy company in 2020.

"I think I get more requests because of the staffing crisis in labs. It would be difficult to send an entire team from a lab to do a CAP inspection," added Day, who continues to participate in inspections to stay involved in the clinical laboratory industry.

CAP generally uses peer inspectors from other labs to conduct accredita-

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tion visits, while TJC hires professional surveyors. *(See the sidebar on page five for more details about the differences in surveyors and inspectors from the two groups.)*

Although CAP has felt pressure to ensure it has enough inspectors, the organization has been able to fill any gaps, said Mick Scanlan, MD, FCAP, a member of CAP's Board of Governors. "We're not in crisis at the CAP for inspectors," Scanlan told The Dark Report.

However, the SARS-CoV-2 pandemic and the lab industry's staffing shortage have created problems at times, he acknowledged. "We did get a little behind during the COVID crisis, and we've been trying to complete as many inspections as we can," he noted. "We're in a pretty good spot right now. Based on what we've accomplished, we're not seeing a lot of difficulty in staffing our inspections."

Volunteers Step Up to Help

Among the moves CAP has made is to solicit inspectors to voluntarily conduct more inspections. "We have a robust network of trained inspectors, including both pathologists and other laboratory professionals," Scanlan said. "We have been able to get a huge response from our inspectors. People are doing extra inspections to help out."

Among the people seeking out more CAP inspections is Angela Lauster, MBA, ASCP(DLM), AMT(MT), Senior Administrative Laboratory Director at **Tampa General Hospital** in Florida.

"It has been difficult, but we actually volunteer to do extra surveys to help with the situation," she said. "I performed three surveys last year, my quality manager did at least four surveys, my director of esoteric testing did two surveys, and my chemistry manager did two surveys. We truly find it to be a great learning opportunity."

She also viewed her team's extra efforts as a way to give back to the lab community. "I feel a commitment to support the peer-to-peer opportunities," she said.

Required to Send Team

CAP's peer inspection approach means that participating laboratories must in theory send multiple people out to another lab for the inspection.

Day, who has participated in dozens of CAP inspections during her career, completed her most recent inspection in early February as part of a seven-person peer team. That inspection took place over three days. She was there one day inspecting for CAP's point-of-care checklist.

"If your lab gets CAP-inspected, that lab is required to send a team to do a CAP peer inspection at another lab," Day explained. "In the past, I have sent eight or more inspectors out of my prior lab to perform an inspection."

That type of obligation is difficult for labs to meet these days because of the overall staffing shortage in pathologists and bench workers. *(See TDR, "Insights and Advice about the Lab Staffing Crisis," Oct. 10, 2022.)*

Day used personal time off when she participated in her most recent laboratory inspection. At Tampa General, Lauster juggles the CAP inspection commitments with her managers' schedules. She has eight managers under her, who are all salaried employees, so they fit CAP inspection work into their regular duties.

Labs Have Staffing Issues

"We recognize that there are a lot of staffing issues at the local laboratories, and it's challenging situation to deal with," Scanlan explained.

"Sometimes a lab can't get everybody on the team to go out to a CLIA inspection, so CAP will supplement the team, often with these people who are willing to do more inspections," he continued. "We have goodwill with our laboratories. CAP is understanding of their staffing challenges and tries to help out as best it can

with other people who have the time and the inclination to inspect."

In response to questions from THE DARK REPORT about its surveyor roster, a spokesperson for TJC stated that the accreditor faces surveyor recruitment and hiring pressures similar to clinical laboratories and pathology practices.

The Joint Commission's full response is as follows:

The Joint Commission faces the same labor market dynamics as other healthcare organizations. We are always looking for top talent, especially in today's environment. We are currently recruiting for a variety of field surveyor and reviewer openings. Please follow The Joint Commission's careers page for the latest openings, as well as The Joint Commission on social media for information on upcoming virtual career fairs and more.

The spokesperson pointed THE DARK REPORT to TJC's career page, which as of mid-February showed openings for a pathologist surveyor, two laboratory medical technologist surveyors, and an international pathologist surveyor.

Featured Job Opening

The first pathologist surveyor opening was highlighted on the careers page as a featured job. Among the qualifications for that job: "Five years of recent clinical experience, including at least two years in management, preferably lab, and two years demonstrated responsibility for oversight, decision-making, management, and improvement in histopathology and cytology."

Those qualifications are likely being sought by dozens of hiring laboratories in search of their own full-time clinical laboratory scientists and pathologists, which further highlights the difficulties The Joint Commission may have in securing more surveyors.

It's not just TJC's clinical laboratory accreditation program that faces challenges. On Feb. 16, The Joint Commission planned to hold a virtual Life Safety Surveyor Career Fair to address an "immediate need" for these surveyors.

More Lab Clients, Fewer Surveyors

ANY SHORTAGE OF SURVEYORS MAY BE COMPOUNDED by two developments at The Joint Commission (TJC) that have brought more business to the organization, sources noted to THE DARK REPORT.

In December, TJC announced it will no longer recognize COLA accreditation at clinical labs that operate within TJC-accredited hospitals and healthcare systems. *(See TDR, "Joint Commission Will Not Accept Cola Accreditation," Jan. 23, 2023.)*

An estimated 300 affected laboratories have until Dec. 31, 2024, to switch their COLA accreditation to either TJC accreditation or that of another approved partner, such as CAP. The decision potentially adds hundreds of new labs to The Joint Commission surveyor schedule over the next two years.

Meanwhile, during a period from 2019 to 2020, CAP lost CLIA accreditation clients to TJC from several prominent health systems, including the federal **U.S. Department of Veterans Affairs**, **Ascension Health** in St. Louis, and **Providence Health and Services** in Renton, Washington. *(See TDR, "CAP Loses Accreditation Clients to Joint Commission," Jan. 19, 2021.)*

That shift in business involved labs at 372 hospitals, which meant many, if not all, of those laboratories needed to be evaluated by TJC surveyors.

Taken in total, by the end of 2024, TJC possibly could have more than 650 new labs as accreditation customers compared to five years earlier, while also simultaneously facing CLIA surveyor hiring challenges.

CAP and The Joint Commission Staff Their CLIA Inspector and Surveyor Teams Differently

Deemed authorities The Joint Commission (TJC) and College of American Pathologists (CAP) both accredit clinical laboratories and pathology practices on behalf of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

However, the two groups take different approaches to the accreditation visits. Among the big differentiators is how they use surveyors and inspectors to conduct evaluations of clinical labs.

The Joint Commission hires full-time professional surveyors for its accreditation assessments. Usually one surveyor will visit a clinical laboratory or anatomic pathology department.

By contrast, CAP sends a team of peer inspectors to accredit sites. These teams comprise members of other labs in the country who agree to send members to the CLIA inspection. Occasionally, some CAP inspectors also include a professional surveyor.

"The CAP's unique peer-inspection model benefits both the laboratories being inspected and the laboratories providing the inspection teams," CAP states on its website.

"Our inspection teams are trained, practicing laboratory professionals who understand the workflows and challenges [clinical laboratories] face because they face them every day as well. In addition, only CAP offers specialty inspectors for key, high-complexity disciplines."

On its website, TJC points out that it does not use the peer-inspection approach; instead it uses professional surveyors.

"The Joint Commission does not require that each accredited laboratory complete an inspection of a peer laboratory, as our surveyors are trained professionals employed by The Joint Commission," TJC states.

"All surveyors have a master's degree at minimum and have worked in at least three technical specialty areas of laboratory medicine with hands-on laboratory management experience.

"Our smaller accredited laboratories without a large number of staff appreciate this as it is difficult to send multiple staff members to perform peer surveys and still be able to staff the laboratory," TJC continues.

Clinical laboratory and pathology leaders whose organizations participate in CAP or Joint Commission accreditation programs should consider how these developments may influence the timing and length of their CLIA surveys and any peer inspection obligations. It's reasonable to assume that inspection and survey scheduling will continue to be affected by the availability of existing surveyors and inspectors.

Much like clinical labs that are strained by a limited pool of new job candidates, The Joint Commission and CAP do not have a brigade of new CLSs and pathologists waiting to join accreditation teams.

This is one factor in why The Dark Report named the pathologist shortage one of the key industry trends for clinical laboratories to monitor in 2023. *(See TDR, "Eight Macro Trends for Clinical Labs in 2023," Jan. 3, 2023.)*

Further, clinical labs involved in CAP's CLIA peer inspection program may continue to find it difficult meeting commitments to send lab staff to other labs to conduct CLIA inspections. How that dilemma will affect future CAP inspections is not certain. Although CAP says it has had success encouraging its CLIA inspectors to take on more work, that may not be a long-term solution. **TDR**

Legal Update

Labcorp to Pay $19m to Settle Whistleblower Allegations

Allegations involved collection of lab specimens on behalf of other labs accused of Medicare fraud

Last week, **Labcorp** agreed to settle whistleblower allegations that it violated the False Claims Act by allowing its phlebotomists to draw blood from patients when the company allegedly knew kickbacks were behind the test orders for other lab firms.

As part of the settlement, Labcorp in Burlington, North Carolina, will pay the federal government $19 million, the **U.S. Attorney's Office for the District of South Carolina** announced on Feb. 7.

Clinical laboratory leaders and compliance officers should note that the resolution comes after years of legal wrangling. It is the latest legal settlement that highlights the perils of whistleblower lawsuits centering on alleged illegal inducements.

More significantly, the willingness of the two parties to settle may have created a new compliance risk for those clinical laboratories and anatomic pathology groups that have their employees collect lab specimens that are intended to be forwarded to a different lab company that will perform the tests and submit claims to the Medicare program. For that reason, lab executives and pathologists may want to review the court documents in this *qui tam* case and update their lab's compliance practices to address the issues at the heart of this lawsuit.

Whistleblower Journey

There is a noteworthy twist in this case. The two whistleblowers alleged that employed phlebotomists of Labcorp collected lab specimens intended to be tested by other lab companies, although Labcorp knew that those other lab companies were using marketing practices that were in violation of the federal False Claims Act.

Labcorp's phlebotomists drew blood from patients whose healthcare providers ordered laboratory tests from Labcorp, **Health Diagnostic Laboratory** (HDL), and **Singulex**. The whistleblowers contended in their lawsuit that Labcorp allegedly knew HDL and Singulex were paying the providers "process and handling fees" as an inducement to refer patients to the labs, according to the U.S. Attorney's Office.

Labcorp did not admit to any wrongdoing as part of the settlement, according to the government.

HDL, Singulex Settlements

HDL and Singulex previously settled their related civil cases for a combined $48.5 million. Both companies denied the allegations. *(See TDR, "Will Federal Prosecutors Pursue HDL Lab Execs and Physicians?" April 20, 2015.)*

For reference, this lawsuit is titled *United States of America, et al., ex rel. Scarlett Lutz and Kayla Webster v. Laboratory Corporation of America Holdings*, Case No. 9:14-cv-3699-RMG (D.S.C.).

The two whistleblowers involved in the Labcorp case, Scarlett Lutz and Kayla Webster, will receive $5.6 million of the settlement amount for their *qui tam* action.

As The Dark Report has noted previously, laboratory employees, physicians, and other insiders have access to docu-

ments that may illustrate questionable compliance practices by laboratories and trigger antikickback laws.

A lawyer for Lutz and Webster said in a statement posted online that the pair undertook a 10-year battle to get to the settlement, which occurred three weeks before a jury trial was to begin.

Small Town Whistleblowers

"These whistleblowers are hard-working people from a small town in South Carolina, not highly-paid laboratory industry executives," stated their attorney, Pamela Coyle Brecht, partner at **Pietragallo Gordon Alfano Bosick & Raspanti, LLP**, in Philadelphia.

"Webster—a nurse working for a Florence, South Carolina, family practitioner who was receiving HDL and Singulex [processing and handling] payments while Labcorp's in-office phlebotomist drew the blood samples exchanged for kickbacks—knew that what was happening was wrong," Brecht added. "Lutz, a small business owner who did some work for the same, now-deceased doctor, saw checks from HDL and Singulex with patient names attached and questioned why a doctor was being paid by a lab."

Singulex went out of business, while HDL's assets remain in bankruptcy proceedings, according to the law firm. HDL was well known in lab circles for allegations of False Claims Act violations. *(For example, see TDR, "In HDL Case, Judge Imposes Damages, Penalties of $114 Million," May 29, 2018.)*

New Legal Issue for Labs?

The fact that Labcorp was willing to settle this lawsuit for $19 million is a sign that attorneys for both parties believed there was merit in the whistleblower's claims. The legal liability probably stems from the allegations that Labcorp and its employees were aware that they were collecting and forwarding lab specimens to lab companies viewed as paying illegal inducements to referring physicians or reference labs, yet they neither reported this situation to federal authorities nor stopped collecting specimens on behalf of these labs.

If this is an accurate interpretation of the facts as presented in court documents, then the outcome of this *qui tam* case is a timely warning to all other clinical laboratories. It puts lab executives and pathologists on notice that there can be legal consequences if they are providing certain services to lab testing companies that are later accused of violating federal fraud and abuse statutes. TDR

Health Diagnostic Lab, Singulex *Qui Tam* Cases

FRAUD AND ABUSE WAS RAMPANT DURING THE 2010s among two classes of lab companies. One group of labs specialized in pain management, drugs of abuse, and therapeutic drug monitoring. The other group of labs offered cardiology and cholesterol tests.

The second group included Health Diagnostic Laboratories (HDL) of Richmond, Virginia, Singulex of Alameda, California, and **Berkeley Heart Labs** of Berkeley, California. Federal whistleblower lawsuits were filed against all three lab companies. All three defendents denied the allegations and entered into settlement agreements to resolve their respective *qui tam* law suits.

The magnitude of the alleged lab testing fraud was substantial. In the HDL case, federal prosecutors filed documents stating that, in just the 60 months of 2010 through 2014, federal health programs had paid the lab company more than $500 million. During this time, court documents say HDL had made payments of as much as $80 million to referring doctors. Those payments were for "packaging fees" and for consulting services, among other things. *(See TDR, "Feds Show How Labs Took $500 Million from Medicare," Sept. 14, 2015.)*

Fujifilm Buys Inspirata's Digital Pathology Assets

Fujifilm execs see similarities between digital path adoption and early implementation of PACS and EHRs

Mark Lloyd, PhD

***CEO SUMMARY:** Fujifilm's acquisition of the digital pathology technologies and clients of Inspirata marks the departure of one early entrant into the digital pathology market. At the same time, executives from Fujifilm Healthcare Americas Corporation discuss why the company is increasing its offerings in digital pathology.*

Bill Lacy

At the end of 2022, **Fujifilm** announced its acquisition of the technology and clients of **Inspirata**, the digital pathology company based in Tampa, Florida. The deal marked the exit of Inspirata as provider of digital pathology workflow systems while boosting the digital pathology product offerings of Fujifilm.

This transaction is significant because it shows that one early player in digital pathology was unable to make the technology work financially, while another global firm is ready to take Inspirata's assets and move forward to advance the acceptance of digital pathology.

The following interviews will help pathologists and lab executives better understand how and why, going forward, Fujifilm sees a robust business opportunity in digital pathology.

"Vendor-neutral software and cloud storage will be very important to digital pathology adoption moving forward," said Bill Lacy, Senior Vice President of Medical Informatics at **Fujifilm Healthcare Americas Corporation**. "They will break down the last barriers and accelerate the adoption of digital pathology."

In January, Tokyo-based Fujifilm finalized its purchase of the Dynamyx digital pathology technology of Inspirata. The move made Fujifilm a significant contender in the digital pathology market given the company's existing imaging products. Dynamyx offers a vendor-agnostic pathology suite, essentially allowing clinical laboratories to use it with any image scanner. *(See the sidebar on page 11 for more details about the acquisition.)*

Hub of Digital Pathology

Precision medicine consulting firm **DeciBio** in Los Angeles noted in an August blog that vendor-agnostic platforms are an important aspect of the digital pathology market.

"These platforms serve as the central hub of digital pathology within a lab, ensuring slides can be viewed remotely, analyzed, and archived for future clinical care or training," DeciBio wrote. "This software needs to be interoperable with slide scanners upstream and [artificial intelligence] tools, data storage, and [lab information systems] downstream."

Pathology Journal Offers Project Recommendations

Challenges of integrating digital pathology into laboratory information systems (LIS) and other IT setups were outlined in an article in the Jan. 17 issue of the journal *Pathology and Laboratory Medicine International*.

Such limitations include a wide range of image management systems from vendors, complexity of the anatomical pathology reporting process, and possible need to re-engineer an LIS to achieve integration.

Based on a case study discussed in the article, the authors recommended the following steps for clinical laboratories and hospitals if they are considering a digital pathology rollout:

- Organizations should set up a contractual obligation with digital pathology vendors that requires successful integration to an LIS.
- Extensive and early involvement in integration projects from as many medical staff members as possible.
- Identifying changes that will be required in the LIS to achieve integration with digital pathology platforms.
- A budgeted increase in IT resources after a digital pathology implementation goes live for users.
- Establishing quality assurance measures ahead of the project, such as how to centrally document errors and what software test scripts will be used to gauge digital pathology platform installation.

A path forward for many clinical laboratories and hospitals will be an ability to tie in vendor-neutral archives (VNA), cloud storage of whole-slide images, and digital pathology software, Lacy said.

"We need to break down that barrier of storage and how storage is managed," he noted.

VNAs are systems that store medical images in a standard format, making them accessible to pathologists regardless of what proprietary software created the images, according to *TechTarget*.

Fujifilm points to numbers from U.K.-based **Signify Research** that estimate the global digital pathology market will be worth $640 million by 2025, doubling the 2021 estimate of $320 million.

"We're bullish on those numbers," said Mark Lloyd, PhD, Vice President of Pathology at Fujifilm Healthcare Americas. Lloyd founded Inspirata, where he was lead scientist. He came to Fujifilm as part of the Dynamyx deal.

"Fujifilm has extensive experience in digital transformation that helps to alleviate industry concerns, whether they're large files or how those files move," Lloyd said. "And that is usually one of the main considerations from a return-on-investment perspective."

The Dark Report previously identified digital pathology adoption as a significant trend to watch this year. *(See TDR, "Eight Macro Trends for Clinical Labs in 2023," Jan. 3, 2023.)*

➤ PACS Adoption Lessons

The cost to purchase and maintain new systems often delays widespread installations in clinical laboratories.

Digital pathology adoption faces challenges that are similar to what electronic health record (EHR) systems encountered in early 2010s—and even before that, what picture archiving and communication systems (PACS) met in the 1990s. PACS enable providers to view and share medical images created on a scanner.

"In the 1990s, most radiology departments were film-based," Lacy said. "Today, I see pictures of pathology areas where there are glass-based slides everywhere. It reminds me of when I used to look at file rooms with jackets of x-ray film piled up. The barriers back then were similar to what they are now in pathology.

Fujifilm's Deal to Buy Inspirata's Digital Path Business

FUJIFILM HAS EXPANDED ITS PRESENCE IN THE GLOBAL DIGITAL PATHOLOGY MARKET with its move to acquire the technology of Inspirata. The deal, announced in December, features two main elements:

- Inspirata's Dynamyx digital pathology technology, employees, and customers have become part of Fujifilm.
- Fujifilm's Synapse Enterprise Imaging product will incorporate Dynamyx to integrate pathology images and data into electronic health records.

Dynamyx is a vendor-agnostic, end-to-end digital pathology suite that has been cleared by the **U.S. Food and Drug Administration**. It can use whole-slide images from various manufacturers' scanners to create centralized imaging records.

"This is a part of enterprise imaging that Fujifilm did not yet have a solution for in our portfolio," said Bill Lacy, Senior Vice President of Medical Informatics at Fujifilm Healthcare Americas Corporation. "We cover all of enterprise imaging, and digital pathology was that next big area. It's a logical synergy for us to look at that technology. What we liked about Dynamyx was that they were the choice of many of our really large strategic customers."

Lacy did not disclose the price of the deal with Inspirata or how many Dynamyx customers came over to Fujifilm as part of the deal. However, he said Fujifilm's existing healthcare imaging customer base provides many new prospects for Dynamyx.

"From an enterprise imaging perspective in the U.S., we have over 1,000 customers," Lacy noted. "Most of those customers will be interested in digital pathology to compliment other enterprise imaging products they already use."

A possible factor in the deal is whether it was time to pay back any early-stage funding from when Inspirata was founded in 2014. Typically, venture capital firms offer funding for five to seven years, during which time investors hope for growth. The late 2022 deal with Fujifilm fits into that timeline.

Fujifilm and Inspirata are not strangers, as the two companies partnered together for the last three years in Europe.

Inspirata will continue as its own company, with plans to focus more on its automated cancer informatics and clinical trials lines.

In the announcement of the deal, Fujifilm described a "largely unpenetrated digital pathology market." It said 85% of U.S. and 86% of European healthcare organizations continue to run on analog systems as opposed to digital.

Inspirata formed in 2014, focusing on digital pathology and cancer diagnostics. In 2018, it purchased **Omnyx** from **GE Healthcare**. Omnyx created the Dynamyx digital pathology software suite. *(See TDR, "GE Healthcare Sells Omnyx to Inspirata," Feb. 12, 2018.)*

"Radiology customers saw a big expense. They had to transition from film to digital storage. But there was a realization that seemed to hit the radiology market, which was that everyone needed to go digital.

"That trend accelerated and everyone started moving towards radiology PACS, leaving film behind. I see a similar trajectory with digital pathology," he noted.

Other elements also are pushing digital pathology. For example, public health restrictions during the SARS-CoV-2 pandemic promoted digital viewing of pathology samples from remote locations.

"Remote working—and the need to be able to access cases and not be tethered to the glass slides—became a tangible way to see how digital pathology enabled hospitals to work and how that can become the pathology of the future," Lloyd told THE DARK REPORT. TDR

Contact Mark Lloyd at mark.lloyd@Fujifilm.com.

Pandemic Helped Lab with Hospital Leaders

Atrium Health's clinical labs spearheaded changes for reference lab testing and blood culture collection

Karen Atkinson

CEO SUMMARY: Growth at Atrium Health during the COVID-19 pandemic elevated its clinical laboratory's profile with medical leaders and health system administrators. What followed was a new spirit of collaboration that led to lab involvement in cost savings efforts, such as improved blood culture collection and better utilization of expensive reference lab testing.

ATRIUM HEALTH IS NO STRANGER TO GROWTH—AND WITH THAT EXPANSION COMES PRESSURE to reduce costs and redundancies, including in its clinical laboratories.

Yet Atrium's clinical lab team was able to take that situation and recast their relationship with hospital administrators and clinical leaders to good advantage.

Atrium Health in Charlotte, North Carolina—part of the **Advocate Health** system—faced a financial mandate in 2021 to cut $275 million over a three-year period, based on prior acquisitions.

Karen Atkinson, MBA, MT(ASCP), Assistant Vice President of Hospital Operations at Atrium Health, credited cost-savings to laboratory leaders' efforts to establish new connections with providers and service lines, particularly during the SARS-CoV-2 pandemic.

"Our recipe for success is that we forge true relationships and partnerships through listening, empowering our teams, and then communicating," Atkinson explained. "Our laboratories are looking for synergies and best practices to lower costs and still keep high quality."

Among the successful efforts were:

- Rolling out a blood culture collection device at 15 sites that reduced contamination risks.
- Reducing the number of reference labs used by the health system, which saved hundreds of thousands of dollars.

Atkinson spoke at the 2021 *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management*. Her session was titled, "How Demonstrating Our Lab's Value During the COVID-19 Pandemic Evolved into Tight, Ongoing Collaborations within Our Health System."

Using Pandemic Goodwill

As with many labs, the pandemic opened immediate doors for collaboration among various departments within hospitals and health systems.

Awareness and appreciation of the work performed by clinical laboratories rose during COVID-19 responses, not only with the public, but among peers.

Atrium's laboratory leadership took advantage of this goodwill to make those relationships more permanent.

"The pandemic brought us all closer together. That's because the lab held incident command meetings to work through supply chain barriers, assess antigen testing versus antibody testing, and boost molecular PCR analyzers," Atkinson recalled. "The lab worked through those challenges with the various service lines. The lab reported out to the service lines, and they were there beside us at the table."

The laboratories' leaders decided to keep moving forward with these relationships, even as COVID-19 response activities waned. "The lab is still using the relationships established during those reporting meetings with every service line," Atkinson observed.

Trust with Administrators

"Now the service lines [throughout the health system] trust us because we were able to navigate every barrier with them for their COVID-19 needs," she added. "The lab began to invite multidisciplinary service leaders and their executives to our table to gain laboratory perspective. Suddenly, we were no longer just that lab result. Several significant collaborations have emerged to enable our lab to deliver safer, more efficient, higher quality care at lower cost, both to our patients and to our hospitals."

One of those collaborations involved blood culture contamination. In 2020, Atrium began a three-site pilot program using Steripath blood culture collection systems. Steripath, manufactured by **Magnolia Medical Technologies** in Seattle, features an add-on diversion chamber that captures the initial 1.5 mL to 2.0 mL of blood from a sample.

This amount typically includes contaminants that could cause false positives, such as skin fragments introduced by a needle during a draw, according to the December 2010 *Journal of Clinical Microbiology*.

"False positive blood cultures due to sample contamination continue to curse our healthcare providers," Atkinson noted. "Of a laboratory's positive results, 35% to 50% are usually false. These false positives lead to unnecessary antibiotic treatments, patients staying on those treatments too long, increased length of stay, and increased hospital costs. On the low side, it's $4,300 per patient per false positive."

Steripath has been cleared by the **U.S Food and Drug Administration**, and according to Magnolia, reduces false positives by up to 88%.

Thanks to initial successes from the pilot program—and the relationships among the lab and services lines established during COVID-19 planning—a wider Steripath effort commenced.

During a three-month period in late 2021, 15 emergency departments and ICUs within the Atrium system began using Steripath.

Standardizing Technology after Hospital Mergers

ONE ADVANTAGE OF MERGERS AND ACQUISITIONS is the ability for a clinical laboratory to use technology that another lab already owns.

Such a situation arose when Atrium Health combined with **Wake Forest Baptist Health** in Winston-Salem, North Carolina, in 2020.

"Wake Forest Baptist has a mass spectrometer, so that system is able to do its own urine drug screen testing," said Karen Atkinson, MBA, MT(ASCP), Assistant Vice President of Hospital Operations at Atrium Health.

"Other Atrium labs had been sending those tests out, so we were excited to be able to utilize that technology and start sending drug screening samples to Wake Forest Baptist," Atkinson added.

Also, several organizations that Atrium acquired used the same blood management system, which has since been implemented at other Atrium sites.

"We were able to reduce blood culture contamination rates to 1.38% from a baseline of 3.23%," Atkinson said. "We prevented 475 patients from having false positives, and the estimated savings was $2,042,500."

Multi-Department Discussions

When introducing new devices such as Steripath, Atrium found that a multidisciplinary approach before the rollout helped move adoption.

That team included the lab, infection prevention, emergency department leaders, materials management, and trainers from Magnolia. Staff using the device received instruction on use and a clear explanation of how Steripath could help the health system reach its goals of zero blood culture contaminations.

A simple point that Atkinson noted was that lack of adoption is not always because of staff members being resistant.

"We found in some cases that the device wasn't near the blood culture supplies, and that's why people didn't use it," she said. "So, just making device availability as streamlined and standard as possible for the teammates is helpful."

Reference Lab Evaluation

Another initiative made possible by expanded communication during COVID-19 involved reining in the amount of reference laboratories being used by providers at Atrium.

Atrium's primary reference provider is **Labcorp** in Burlington, North Carolina. However, due to various acquisitions and mergers, physicians were initially allowed to continue to use their own preferred reference labs, Atkinson said. At one point, more than 80 reference labs interacted with Atrium's physicians.

"Providers like having that choice. This sounded like a good idea at the time," she recalled. "But it turned into the wild west—there were paper results for delivery, there were paper requisitions, and we were not interfacing with these various laboratories. So, providers were having a heck of a time trying to find results that could be delayed or lost for months at a time."

An assessment followed via Atrium's appropriate care committee, which was overseen by a physician provider and whose members included the vice president of laboratory operations.

"They started looking at where the money was going and where the most commonly ordered tests were coming from," Atkinson said. "They talked to providers and found out their stories."

Initial efforts to reel in reference lab options started with two areas: pediatrics and neurosciences.

Pediatric Test Examined

Two pediatrics specialists who had come into Atrium from an acquisition were using a laboratory-developed test for complement 50, which measures protein abnormalities.

"Pediatrics is not a typical use for complement testing," Atkinson noted. "And Labcorp used a different method that had a different reference range. It was hard to compare looking at the two reports side by side."

At the invitation of the clinical lab, Labcorp sent in a tech specialist to discuss the matter with the pediatric specialists. Both sides agreed to send split samples to the original reference lab and Labcorp. After comparing the results, Labcorp was able to develop a formula that produced a similar reference range compared to the other reference lab.

"Their two pediatricians were able to use this assay from Labcorp at a much lower cost," Atkinson observed. "Their patients can save a hundred thousand dollars annually."

Neurosciences faced a similar situation regarding cytogenetic testing panels. Once again, a Labcorp tech specialist was the starting point for

conversations on why neuroscience providers were using another lab. Based on those conversations, Labcorp came up with a solution. "We chipped away at this opportunity," Atkinson explained. "We estimated $600,000 in savings annually."

Working with Reference Labs

It's not practical in a large health system to think that a single reference lab can serve all providers.

"We won't be able to have one reference laboratory for the whole enterprise, but we're shooting for 90% of the system to use Labcorp," Atkinson noted.

She reiterated that establishing relationships and open communication proved key points to nudging along discussions about where to draw the line with provider choice versus medical laboratory-driven economics in regard to reference testing.

"This is something that before the pandemic we could get no traction and no leverage on, but now we're succeeding," Atkinson concluded.

Key Takeaways

Clinical laboratory managers and pathologists can take away two key lessons from Atrium's experiences:

- Using laboratory goodwill built up during the pandemic can give the lab a greater voice in system-wide issues.
- Open communication between medical laboratory leaders, physicians, and hospital executives can uncover problems and lead to common ground about solutions.

"Laboratories usually aren't front and center," Atkinson said. "But during COVID, all labs ended up there. By listening to people and empowering people, we thankfully made it to the 'cool kids' table. Now we're so excited to see what the future will bring." TDR

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Advantage of Labs Streamlining Services

ATRIUM HEALTH'S SUCCESS IN COST SAVINGS illustrates how clinical laboratories can raise their profiles after mergers and acquisitions (M&A) within a healthcare system.

In 2022, there were 55 M&A transactions among hospital and health systems, according to healthcare financial planning firm **Kaufman Hall** in Chicago.

That number was up from 49 in the prior year, but much lower than the recent high of 117 transactions in 2017. Two-thirds of 2022's activity involved a not-for-profit system acquiring another not-for-profit entity.

"Hospitals and health systems are facing competition from highly capitalized (albeit specialized) tech companies, national health plans, and retail giants," Kaufman Hall noted. "A clear and present challenge to all in the industry is the scarcity (and resulting supply/demand realities) of human resources."

Atrium Health's efforts showed the usefulness and pragmatism of streamlining services across laboratories and clinical service lines.

"The pandemic demonstrated the resiliency of certain large systems, in which operational risk was distributed across multiple markets and resources could be moved to where they were needed most," Kaufman Hall noted.

Kaufman Hall anticipates that 2023 will see more healthcare M&A activity than 2022 as hospitals across the country attempt to deal with strained finances, higher interest rates, and increased costs of labor.

"Smaller organizations and organizations that did not have balance sheet strength may soon have to look for alternatives, including stronger partners that can help them stabilize financially," Kaufman Hall wrote.

IVD Update

Public IVD Companies Report Q4, Full-Year 2022 Earnings

In 2022/Q4, IVD companies see base business rise even as COVID-19 test revenue continues to drop

YEAR-END AND Q4 2022 EARNINGS REPORTS FROM MAJOR *IN VITRO* DIAGNOSTICS (IVD) COMPANIES pointed to a welcome sign of core diagnostic business rebounding.

That's the good news for IVD firms. The bad news? All of the SARS-CoV-2 testing revenue that these companies brought in over the last three years—as clinical laboratories and the general public demanded nonstop access to COVID-19 tests—has waned.

In fact, one company (**Danaher**) announced that for 2023 it would remove COVID-19 testing completely from its core business financial reporting.

COVID-19 testing revenue has not evaporated totally, as it proved a significant line item to some IVD companies in 2022. But it is not the golden goose it once was, and perhaps more significantly, it is becoming an unreliable barometer for future sales success.

Reading recent earning reports for fiscal year 2022 and listening to IVD executives, it is clear that they recognize the need to capitalize on new markets COVID-19 testing opened up, such as retail pharmacy testing and consumer demand for at-home self testing for a variety of conditions.

Those goals will be on the minds of IVD leaders during 2023 as SARS-CoV-2 heads into endemic territory and the federal public health emergency related to the pandemic ceases on May 11.

Here's a look at Q4 and 2022 financial results from some of the world's largest IVD companies with a fiscal year ending Dec. 31, 2022.

Roche

ROCHE: 'Good Results' in 2022, Diagnostics Sales Grow 3%

For **Roche** in Basel, Switzerland, decreased demand for COVID-19 tests and treatment is estimated to cost the company sales of up to five billion Swiss francs (CHF) (US$5.3 billion) in 2023.

That said, in 2022, the company's overall and diagnostic revenue increased, which CEO Serin Schwan characterized as a positive development.

Roche's sales overall and Diagnostics Division sales grew slightly in 2022 amid COVID-19 testing revenue decreases in Q4. Roche shared the following:

- 2022 revenue grew 2% to 63 billion CHF (US$67.8 billion).
- 2022 Diagnostics Division sales grew 3% to 17.7 billion CHF (US$19 billion).
- 2022 COVID-19 test sales decreased 13.6% to 4.1 billion CHF (US$4.4 billion).

"We achieved good results in 2022, even though the demand for COVID-19 products declined, as expected. The diagnostics base business and our newer medicines continued their strong growth," Schwan said in a statement. "For [2023], we expect solid underlying growth in both divisions, which will largely compensate for the further significant drop in sales of roughly CHF five billion in COVID-19 products."

Matt Sause, new Roche Diagnostics CEO, said the diagnostics sales increase over 2021 was "driven by base business offsetting COVID-19 testing decline." He shared these 2022 year-over-year details:

- Core lab sales increased 6% to 7.7 billion CHF (US$8.2 billion).
- Point-of-care sales went up 17% to 3.5 billion CHF (US$3.7 billion).
- Molecular lab sales decreased 15% to 3.4 billion CHF (US$3.6 billion).
- Pathology lab sales increased 11% to 1.3 billion CHF (US$1.39 billion).
- Diabetes care sales fell 2% to 1.5 billion CHF (US$1.6 billion).

Roche received **U.S. Food and Drug Administration** approval in December for its cerebral spinal fluid test for Alzheimer's disease, which will run on the company's Cobas automated analyzers.

Roche also plans to launch these instrument, test, and software products, among others, in 2023, according to Sause:

- In the molecular lab category, the LightCycler Pro real-time PCR instrument.
- For pathology lab, a glioma neuropathology immunohistochemistry (IHC) test to detect tumor cells.
- For clinical lab, an update to Cobas Infinity Laboratory Solution, which is software that manages specimen tracking and diagnostic data.

Abbott
A Promise for Life

ABBOTT LABORATORIES: Q4 Slump Occurs Despite Full-Year Growth

Of all the IVD companies, **Abbott Laboratories** in Abbott Park, Illinois, may be the one showing the most downside of the decreased demand in COVID-19 tests. Its Q4 diagnostic sales dropped 26.1% compared to a year earlier.

Despite these challenges—and a shutdown of its infant formula plant in 2022 due to contamination concerns—Abbott still reported 2022 revenue growth. Here are full-year and Q4 details:

- 2022 revenue rose 1.3% to $43.7 billion.
- 2022 diagnostics sales went up 6% to $16.5 billion.
- Q4 2022 sales were down 12% to $10 billion.
- Q4 2022 diagnostics sales were down 26.1% to $3.3 billion.
- Q4 core laboratory sales were down 6.3% to $1.2 billion.
- Q4 molecular sales plunged 47.9% to $180 million.
- Q4 point-of-care sales decreased 3.3% to $131 million.
- Q4 rapid diagnostics sales plummeted 34.5% to $1.7 billion.

During an earnings call on Jan. 25, CEO Robert Ford said that the testing business during the pandemic pushed the company into new markets, such as physician offices and at-home testing, which will serve as a long-term benefit to the company. Abbott has sold nearly three billion COVID-19 tests worldwide since the pandemic started.

"Going forward, we expect COVID-19 to transition to more of an endemic, seasonal type of respiratory virus," Ford told investors. "We expect variants will continue to emerge, and therefore our tests will remain an important part of our leading respiratory testing portfolio, along with flu, RSV [respiratory syncytial virus], and strep."

Abbott still envisions billions of dollars in sales for COVID-19 testing 2023.

"We forecast about $2 billion," Ford said. "Obviously, we see society transitioning here. We've got a strong installed base. We've got manufacturing capacity. We haven't factored in any kind of real surge, but if that happens, we do have the capacity to be able to do that."

ThermoFisher
SCIENTIFIC

THERMO FISHER: Impressive Revenue Growth in 2022 and Q4

Thermo Fisher Scientific in Waltham, Massachusetts, impressively grew its 2022

revenue by 15% to $44.9 billion and its Q4 revenue by 7% to $11.5 billion. The company also reported:

- Q4 laboratory products and biopharmaceutical services segment revenue was up 41.7% to $5.9 billion.
- Q4 analytical instrument segment revenue grew 8.9% to $1.8 billion.
- Q4 specialty diagnostics segment revenue fell 22.9% to $1.1 billion.

During an earnings call on Feb. 1, CEO Marc Casper responded to a financial analyst's question about 2022 growth in analytical instruments and what demand the company sees.

"There has been a stream of launches in our chromatography, mass spectrometry, and electron microscopy businesses," Casper said. "Those products have been well adopted. We're clearly growing well."

In Q4, Thermo Fisher earned $370 million in COVID-19 testing revenue, with $3.1 billion for the full year. Because that amount was lower than in 2021, it offset core business gains.

Lower COVID-19 testing demand has also resulted in the layoffs of 230 workers from three Thermo Fisher manufacturing plants in California, *Fierce Biotech* reported on Feb. 9.

DANAHER Corp.: Strong Non-COVID Diagnostics Business Seen in 2022

Danaher in Washington, D.C., noted positive developments in non-COVID respiratory business and digital pathology. The company shared these results:

- 2022 revenue increased 7% over 2021 to $31.5 billion.
- 2022 diagnostics revenue was up 10.2% to $10.8 billion.
- 2022 life sciences revenue increased 10% to $7 billion.
- Q4 diagnostics revenue was up 2.9% to $2.9 billion.
- Q4 life sciences was up 7.9% to $1.9 billion.

In a Jan. 24 earnings call, CEO Rainer Blair said the company remains uncertain about future COVID-19 testing demand. "Based on discussions with our customers, we believe COVID-19 will enter an endemic disease state in 2023, and as a result we expect to ship 30 million respiratory tests and generate $1.2 billion of revenue for the full year," Blair said.

Blair called out the growing presence in digital pathology by one of its companies, **Leica Microsystems**.

"In our digital pathology business, we saw record placements of the GT 450, [Leica's] digital pathology slide scanner, as customers are increasingly realizing the operational and clinical benefits of digitization," he told investors.

Another of its firms, **Cepheid**, was boosted in 2022 by strong respiratory testing demand. Further, its non-respiratory test menu grew by more than 20%, led by tests for infectious disease, sexual health, and hospital-acquired infections. Blair said growth of non-respiratory tests was across nearly 50,000 instruments, a base which has doubled since 2020.

BIOMÉRIEUX: Preliminary Results Show Sales Flat in 2022

bioMérieux, in Marcy-l'Étoile, France, released these preliminary results for full year and Q4 2022:

- 2022 sales are expected to be stable at an estimated €3.3 billion (US$3.5 billion). The company reported sales of €3.3 billion in 2021.
- Q4 respiratory panel sales were higher than usual due to an increase in influenza and high incidence of respiratory syncytial virus, and they are expected to grow 8% to 10% in 2023. TDR

Editor's note: A few large IVD firms will report year-end revenue after press time. We will cover the performance of those companies in our next issue.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Laboratory leaders should prepare now for the end of the federal public health emergency (PHE) for SARS-CoV-2. The White House announced the PHE would cease on May 11. One big change is that patients covered by **Medicare**, **Medicaid**, or private insurance may pay higher costs for COVID-19 treatment, including some diagnostic laboratory tests. If patients cannot pay these costs, hospitals and other providers will absorb the resulting loss of revenue.

MORE ON: *COVID-19 Public Health Emergency*

Under the PHE, the **Centers for Medicare and Medicaid Services** (CMS) allowed remote pathology work as long as the emergency remained in effect. On Feb. 1, CMS clarified this aspect, noting that remote case reviews will continue after the PHE expires. "CMS will continue to exercise enforcement discretion that allows pathologists to examine digital images and laboratory data at remote locations," the agency stated.

HOSPITAL TURNS TO PAPER TEST ORDERS AFTER INCIDENT

Tallahassee Memorial HealthCare in Florida responded to an "IT security issue" on Feb. 2 by shutting down its IT systems, including at its clinical laboratory. The hospital needed to switch to paper documentation as a result of the incident. "Staff have been unable to access digital patient records and lab results because of the shutdown," a source told *CNN*, as reported on Feb. 3. The hospital said it had contacted law enforcement, which suggests a cyberattack occurred.

CLIAC PONDERS AT-HOME TESTING RULES

In vitro diagnostic (IVD) companies may be interested to learn that the Clinical Laboratory Improvement Advisory Committee (CLIAC) is considering regulatory recommendations that could affect at-home diagnostic testing kits. Currently, at-home tests are not regulated. Some of CLIAC's discussions include the potential to require built-in adequacy controls for specimens as part of at-home IVD tests and the need to monitor that an adequate specimen was collected.

TRANSITIONS

- **Myriad Genetics** in Salt Lake City named Lisa Olson-Coombe as VP of Laboratory Transformation. She previously served in vice president roles at **Exact Sciences**, **Sonic Healthcare USA**, and **Aurora Diagnostics**.
- Vicki DiFrancesco retired as **XIFIN**'s Chief Strategy Officer. DiFrancesco will continue as a strategic advisor to the San Diego-based company. She was previously President and CEO at the former **Pathology Inc**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 6, 2023.

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Niall Lennon, PhD

Senior Director of Translational Genomics,
Broad Institute of MIT, Cambridge, Mass.

How Local Labs and Hospitals Can Scale Genome Sequencing Modalities to Utilize Capacity and Advance Patient Care

Ongoing advances in precision medicine are creating opportunities for clinical laboratories to do whole genome and genetic sequencing onsite, and then send the data to partners for analysis, annotation, interpretation and diagnosis. Labs are using this approach to add to their clinical service menu, win market share, and generate new streams of revenue.

During this session, attendees will learn proven ways to scale different genome sequencing modalities to fully utilize sequencers while lowering sequencing costs across all types of work, whether it's research, clinical studies, or for patient care. Information technology needs for handling data and working with partners who use genomic data to provide diagnoses will be discussed.

If establishing or expanding genome sequencing is on your lab's radar, then this is a must-attend session for you and your team.

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UPCOMING...

- ***Consolidation among health systems continues: What does this mean for their hospital labs?***
- ***How solutions powered by AI and machine learning are allowing labs to automate manual processes.***
- ***Retaining staff during the 'Great Resignation': Proven ways to build med tech commitment.***