Volume XXIX, Number 14 Monday, October 10, 2022

Get More of Your Lab's Genetic Test Claims Paid!

Four Experts Explain Proven Ways to Improve Payer Relationships

See pages 10-14.

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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Getting the Jump on Solving Major Lab Issues

OBSERVANT LABORATORY MANAGERS AND PATHOLOGISTS will note a recurring theme among the business intelligence briefings in this issue of THE DARK REPORT: Solutions to major challenges require proactive steps.

A case in point comes with our lead story about how to recruit and retain medical technologists (MTs), medical laboratory scientists (MLSs), and medical laboratory technicians (MLTs) in the lab. We went to **American Medical Technologists** (AMT)—one of the industry leaders in the accreditation of MTs/MLSs/MLTs—to get their insights and advice on how labs can help increase the supply of skilled scientists. *(See pages 3-5.)*

Speaking of the staffing shortage among clinical labs, you may not think of digital pathology and artificial intelligence (AI) as solutions to the demand for surgical pathologists, which currently outstrips supply. But at **Mayo Clinic**, far-sighted pathology leaders established the Division of Computational Pathology and AI not just to achieve faster, more accurate diagnoses, but also to develop working tools that help pathologists be more productive. *(See pages 6-9.)*

Our theme of being proactive continues with the story that follows on pages 10-14, which addresses the fact that it is difficult to get reimbursed for genetic tests. A panel of experts at the latest *Executive War College Conference on Laboratory and Pathology Management* recommended that genomic labs take purposeful steps to establish trust with payers before seeking reimbursement for new tests. Health plans need to see the value of a novel genetic test and how it benefits patient care. Clinical laboratories should be thinking ahead on how to collect data to support those two aspects and present it accordingly to payers to win favorable coverage and reimbursement decisions.

Savvy lab administrators and pathologists know the importance of anticipating how healthcare and laboratory medicine is changing so they can guide their lab teams to develop effective strategies designed to keep their lab organizations at the front edge of clinical excellence in a financially-sustainable manner. Achieving that is a win for both labs and their staff, as well as for the doctors and patients served by their labs. **TDR**

Insights & Advice about the Lab Staffing Crisis

Labs have several paths forward to help address the shortage of MTs, MLSs, MLTs, other lab positions

Kathy Cilia

CEO SUMMARY: For the past decade, it's been recognized that the supply of skilled laboratory professionals is inadequate to meet the needs of the nation's clinical laboratories and anatomic pathology groups. Leadership at American Medical Technologists recommends steps that labs can take to encourage more individuals to opt for a career in the lab profession.

By now, it's a well-established fact that the shortage of medical technologists (MTs), medical laboratory scientists (MLSs), and medical laboratory technicians (MLTs) is acute in most major cities across the nation. The inability to fully staff clinical labs may be the single most pressing issue for lab leaders today.

Someone with valuable insights on the current state of lab personnel and the training pipeline for incoming MTs, MLSs, and MLTs is Kathy Cilia, CAE, MLS(AMT), MLS(ASCP), Executive Director at **American Medical Technologists** (AMT) in Rosemont, Ill.

The widening gap between available laboratory workers and open lab jobs has multiple facets. For example, even before the SARS-CoV-2 pandemic, burnout among overworked lab staff was a problem in U.S. labs. COVID-19 exacerbated the issue, as lab workers put in long hours with constant pressure to turn tests around.

The pandemic also created a phenomenon known as the "Great Resignation," in which workers completely exited the industries they worked in, searching for more rewarding careers and better work/life balance. *(See TDR, "Lab Workforce Crisis Takes Top Spot, Says CAP Today," April 25, 2022.)*

In an exclusive interview with The Dark Report, Cilia confirmed the current lab staffing crisis. "We often hear from our members how short staffed they are in the lab and how stressed they are."

AMT certifies professionals for a dozen roles in healthcare, including MLSs and MLTs. The organization has about 100,000 members, a quarter of which are in the medical laboratory industry.

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

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Cilia suggested that clinical laboratories look at the following options as they seek to successfully attract, hire, and retain staff while staying ahead of competitors:

- Establish relationships with high school math and science students who could serve as lab workers in the future.
- Explore non-traditional education options for would-be lab workers.
- Change the nomenclature of the MT job title to raise the visibility of the scientific aspect of the work.
- Audit workflows to allow lab scientists to work at the top of their potential.

High School Relationships

Cilia provided detailed thoughts about each of these areas. She started by suggesting labs should contact students early who have interest in science. This early outreach should be a high priority for clinical lab certification programs and for labs and pathology practices that worry about their future workforce.

AMT partners with the **National Consortium for Health Science Education** (NCHSE), which represents teachers and state education agency leaders responsible for middle school, high school, and post-secondary health science learning programs.

"As a member of their Executive Council, we are in contact with high school teachers to let them know that the lab profession is an option," she explained. "At the high school level, and probably even middle school, you really want to get students interested in looking beyond just a nurse or a physician career."

Laboratory administrators and pathologists interested in promoting career options to students should look for high schools in their communities that offer "career technical education" programs.

"We're starting to see more career technical education programs pop up in high schools," Cilia noted. "Students are leaving high school with professional credentials, like that of a lab assistant or phlebotomy technician, which allow them to start careers or work in the field while they continue their education."

Non-Traditional Paths

Cilia has also witnessed a trend in non-traditional education of future lab scientists and workers, which comes at a time when college- or university-based options for lab training are limited.

"A lot of MT/MLS/MLT training programs are either closing or they're not attracting the right talent," she added. "Because of that, we see a trend in which lab employers start to conduct their own training through apprenticeship programs and workforce development programs."

A good example of this trend is **Scripps Health** in San Diego, which offers its own 12-month, clinical laboratory scientist training program with free tuition for enrolled applicants.

AMT has also created an apprenticeship eligibility route to certification. "This is a valid option for somebody who is trained through an apprenticeship program. They can complete the program and obtain a professional credential," Cilia noted.

'Scientist' over 'Technologist'

There is movement among laboratory industry groups and certification boards—including the AMT, **American Society of Clinical Pathology (ASCP) Board of Certification**, **American Society for Clinical Laboratory Science**, and other groups—to change the nomenclature of "medical technologist" to "medical laboratory scientist."

Cilia suggested that by focusing on the science of the job, more people who have scientific backgrounds may be nudged into the lab profession. She also said there is an outdated connotation to the term MT. "There's so much more behind an MLS than just running instruments," she noted.

"It's the science behind it and the theory of knowing what to do if a result is not within range," she added. "You're discussing diagnoses with physicians, so you

really have to know the science behind what you're running. I think 'scientist' is a more appropriate term. It will do the laboratory profession well to have this new terminology introduced."

In a position paper on the topic, the ASCP dissuaded further use of the terms "med tech" or "bench tech." "These phrases denote outdated terminology, as 'medical technology' has come to commonly mean any use of technology in medicine," the paper stated.

Workflows and Duties

Cilia suggested that, while COVID-19 raised the profile of laboratory workers to the general public, the workload also created staffing shortages leading to longer shifts, a greater emphasis on efficiency, and a heavier workload. Burnout was a natural result from this combination of factors.

Moving forward, if labs want to retain existing MTs, MLSs, and MLTs, there must be greater efforts to make scheduling more reasonable.

"Employers will need to figure out how to creatively schedule their laboratory staff so that they can have that balance and have time off," she observed. "The goal is to avoid them working long hours and without breaks."

She has also heard of labs taking the initiative to restructure workflows in a way that frees up time for lab scientists to focus on the important parts of their jobs while jettisoning more routine tasks.

"Laboratories are starting to consider different staffing models," she said. "They are rearranging their work so that the bulk of the duties may be done by someone who's an MLT or even a lab assistant, thus leaving the higher-level work to the medical lab scientist."

Doing so may improve morale and retention among MLSs by letting them work to the top of their scope of practice.

As THE DARK REPORT recently noted, one way to achieve a better distribution of work tasks versus skills is for labs to use Lean Six Sigma to eliminate waste and inefficiencies in workflows. *(See TDR, "Lean is Smart Approach to Major Lab Cost Savings," Sept. 19, 2022.)*

Employee Retention

Using Lean Six Sigma can improve employee retention through quality measures that streamline work processes at a time when clinical laboratory managers are under extreme pressure to cut costs, even as they deal with understaffing.

Further, as recommended by Cilia, forward-thinking clinical laboratory leaders must reach into younger populations to fill their future workforce needs, while also taking steps to bring added value to their current workers' careers.

Failure to do so has implications beyond staff levels, as a lab's ability to meet testing demands and generate new revenue hinges upon having enough staff to accomplish these business objectives. **TDR**

Contact Kathy Cilia at kcilia@americanmedtech.org.

In-House Locum Tenens Offer Innovative Approach

ONE PROGRESSIVE APPROACH to staffing shortages Kathy Cilia, CAE, MLS(AMT), MLS(ASCP) heard about was a health system that created its own internal locum tenens team.

The team travels among the various labs in the system, focusing on locations that have staffing shortages on any given week or even day, said Cilia, Executive Director at American Medical Technologists.

"The health system identified medical lab scientists who might want to travel to different hospitals, and they pay the scientists a little bit more to be able to plug them in where the system needs them staffing wise," she added.

"That's an innovative solution within their own system. It's not bringing contractors from out of the system, which can be costly."

AI Fuels New Efforts in Computational Pathology

Labs can draw inspiration from Mayo Clinic on how to modernize clinical pathology workflows

Jason Hipp, MD, PhD

CEO SUMMARY: *Computational pathology combines technology and data science to improve laboratory medicine. Mayo Clinic is exploring how this new model can improve productivity and diagnostic accuracy in ways that even labs at smaller hospitals can put into practice. Success will stem from interdisciplinary cooperation between pathologists and data scientists.*

MAYO CLINIC IS CURRENTLY SETTING THE STAGE for application of artificial intelligence (AI) and computational pathology to patient care within two years.

Mayo Clinic's new Division of Computational Pathology and AI is set to reimagine pathology and the laboratory through multidisciplinary teams of pathologists and data scientists. These teams will accomplish this by using technology, longitudinal information, and strategic partnerships.

The new division has a head start on this goal because it will build upon the Rochester, Minn.-based integrated health system's earlier investments in digital pathology equipment, software, and vendor relationships.

Clinical labs and anatomic pathology groups looking to take advantage of digital pathology will note that—while Mayo Clinic's efforts benefit from the size of the institution—its approach to the new technology can be replicated by other organizations regardless of size.

"Computational pathology is the use of data science, information, and digital technologies for lab medicine," stated Jason Hipp, MD, PhD, Chair of Computational Pathology and AI at Mayo Clinic's Department of Laboratory Medicine and Pathology, and Director of Digital Innovation for Mayo Clinic Laboratories. He identified three factors that make these goals feasible:

- Cloud storage of abundant information;
- Big datasets; and
- AI, which has always needed large amounts of data and storage to be practical.

Digital Opportunity for Labs

"We have a once-in-a-lifetime opportunity in this field," he noted. "There are new opportunities to be generated with this new discipline—novel ways to generate revenue, conduct pathology, and rethink data." Hipp, a pathologist and data scientist, spoke during a keynote at April's *Executive War College Conference on Laboratory and Pathology Management*. The session was titled, "Building the Future of Computational Pathology and Artificial Intelligence at Mayo Clinic."

"Clinical laboratories need to redefine the practice of pathology digitally," Hipp continued. "They must develop and

integrate new tools to extract and analyze pathology and laboratory medicine data to bring new insights that do not exist right now. Doing so will bring value and operational efficiency to workflows and allow labs to offer more prognostic theory to clinicians."

Artificial intelligence and machine learning will be transformative technologies in clinical labs and pathology practices. Forward-looking lab managers and pathologists will note that AI's potential reaches beyond just large organizations such as Mayo Clinic. *(See TDR, "Artificial Intelligence is Ready to Deliver for Labs," July 26, 2021.)*

For example, consider the following takeaways from AI experiences at Mayo Clinic, which even labs and pathology groups with limited budgets can explore:

- Bring pathologists and data scientists together in multidisciplinary teams to learn from each other and collaborate to more effectively advance new initiatives in clinical settings.
- Improve an organization's use of digital image analysis beyond the medical laboratory by working in collaboration with radiology and other departments.

Computational Pathology?

Hipp observed that, amid a tight pathologist labor market and significant healthcare cost cutting, there is a need to enhance the productivity and responsibilities of individual pathologists.

One approach to achieve this is to remove tedious tasks, like counting items, and elevate contributions to clinical assessment of patient cases. This is possible, Hipp said, through a combination of pathology, genomics, AI, and radiology.

Computational pathology makes visible what is not apparent to the human eye, Hipp added. It is data driven, as compared to the subjective nature of traditional pathology. *(See the sidebar on page 8.)*

"Computational pathology enables digital analysis of every pixel in an image. These are smaller than cells," he noted. "It enables a pathologist to see differences between cells and inflammatory cells. These are very novel features that cannot be quantified by pathologists working without these tools."

Boost Lab Workflows

Computational pathology advances digital pathology by integrating with machine learning for image analysis and precision medicine. Machine learning is a subset of AI.

"We can take tissue, put it on a glass slide, image it, and make a diagnosis of cancer," Hipp said. "Why don't we insert an intermediary step? This is a step that would suggest medical patterns within the image that hold the keys to understanding therapeutic response to a prognosis. It is also the step we are working to achieve with the use of AI and related technologies."

Before arriving at Mayo Clinic, Hipp worked in pharma and technology companies. While at **AstraZeneca**, he and other colleagues wrote an article in 2020, titled, "The Revival of the H&E with Artificial Intelligence" for the *Journal of Clinical and Anatomic Pathology*.

The article spotlighted the following ways that computational pathology and AI can aid diagnostics workflow:

- Directing the pathologist to a region of the slide.
- Determining cancer presence or absence.
- Providing tumor grading.
- Searching for and identifying diagnostically similar cases.
- Predicting mutational status from hematoxylin and eosin (H&E) stains.

"I consider computational pathology to be a new frontier for our profession," Hipp observed. "I think of this as a revival of the H&E, which is so vital to pathology."

As THE DARK REPORT previously noted, Mayo Clinic is bridging the work of pathologists and data science engineers who develop AI algorithms. *(See TDR,*

Step-by-Step Plan for Computational Pathology Guides Team at Mayo Clinic Laboratories

WITHIN THE NEW DIVISION OF COMPUTATIONAL PATHOLOGY AND ARTIFICIAL INTELLIGENCE AT THE MAYO CLINIC, the goal is to pull together a host of technologies and integrate them to boost the productivity of pathologists while also improving the accuracy of diagnostic and therapeutic services. During his presentation at last April's *Executive War College*, Jason Hipp, MD, PhD, Chair of Computational Pathology and AI at Mayo Clinic's Department of Laboratory Medicine and Pathology, and Director of Digital Innovation for Mayo Clinic Laboratories, described how computational pathology is expected to change the workflow for anatomic pathologists.

Benefits of Computational Pathology and AI

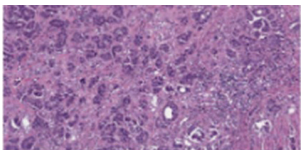
- To aid the pathologist in the diagnostic workflow
- Directing the pathologist to a region of the slide
- Determine the presence/absence of cancer
- Provide the tumor's grading
- To quantify biomarker (IHC) expression
- To search and identify diagnostically similar cases
- To predict mutational status from H&E
- To predict protein (IHC) expression from H&E
- To predict risk category as determined by gene expression from H&E
- To predict survival

SOURCE: The revival of the H&E with AI; Burlutskiy et al. Journal of Clinical & Anatomic Pathology (2020)

Traditional Pathology vs Computational Pathology

Traditional pathology is limited and subjective

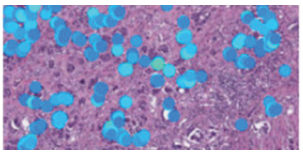
- Tissues and cells are examined under a microscope
- Subjective, qualitative, and semi-quantitative assessments are made about the tissue
- Pathology report contains both qualitative and semi-quantitative interpretations
- Human brain looks for specific patterns and ignores non-confirmatory data



Significant amount of data from tissue remains unutilized or underutilized

Computational pathology is robust and data driven

- Tissues and cells are examined by computer algorithms
- Robust, highly quantitative and complex spatial measurements generated for every pixel/feature
- Numerical results are integrated with disparate datasets and analyzed by secondary analytic tools
- Computer brain 'looks' at everything and can identify novel features



Most data from tissue is utilized

"Innovation Showcased at Executive War College," May 16, 2022.)

"We want to embed both sets of skills into the pathology workflow," Hipp explained. "We need the data scientists working side by side with the pathologists. That practical part is missing today." Hipp experienced a similar workflow when he worked previously as a pathologist at **Google Health** alongside engineers.

Hipp explained that pathologists look at things differently than data scientists,

so it benefits computational pathology projects to have both disciplines collaborating. "There's a lot of discovery that requires data scientists and pathologists to work very closely together," Hipp noted.

Digitizing Millions of Slides

One ambitious project now unfolding within three years at Mayo Clinic's Department of Laboratory Medicine and Pathology is the goal of digitizing five million of its 25 million archived tissue glass slides. This digital data—stored in a cloud-based image repository—will be accessible for use in clinical pathology, as well as for research and education.

"We don't want to create data silos," Hipp declared. "Rather, we look at this as a 'data tumor board,' where all the data is available for evaluation. Because it's integrated, it's expected to produce novel insights and better patient care."

There is another rich source of data that Hipp's team wants to incorporate into the diagnostic/therapeutic process. Currently, Mayo Clinic stores three billion paper pathology reports going back more than 100 years. They, too, will be digitized to support the pathology slides.

Longitudinal Information

Such longitudinal information and history of patient care has value to the creation of algorithms. "What we want to do with all this longitudinal data—pathology data, radiology data, genomics data—is determine what information we can identify for algorithms," Hipp said.

Integrating algorithms with the data will be a critical part of the work ahead. The efforts fall into three buckets:

- Detection and triage;
- Quantification; and
- Prediction.

"The algorithmic tools will be leveraged for enlightenment of detection, but more so for workflow decision-making," Hipp said. "What is most exciting to me is predictive value: How do we know whether a patient will respond to an immmunotherapy drug? And what is the risk and reward?"

It's not just pathology that will be a primary focus for Mayo Clinic's Division of Computational Pathology and AI. The division aims to advance medical imaging throughout the institution starting with Mayo Clinic Laboratories, the Department of Laboratory Medicine, the Mayo Clinic Platform, and Biopharma.

"We are going to first empower these divisions to leverage this technology and then work in other layers of radiology, digital health, and informatics," Hipp said. "We are trying to implement a matrix approach that is currently not being done in traditional patient care settings."

Hospital-based pathologists should consider this broad approach to digital and computational pathology and reach out to peers in other areas of the organization for assistance, including data scientists. TDR

Contact Jason Hipp, MD, PhD, at Hipp.Jason@mayo.edu.

External Partners Aid in Pathology Transformation

MAYO CLINIC IS WORKING WITH VENDORS to digitize and analyze its clinical pathology data.

Pramana, an AI company in Cambridge, Mass., that focuses on the pathology sector, is helping Mayo Clinic digitize an initial five million glass pathology slides. Pramana sells a whole-slide imaging system—fed by a robot and analyzed by AI algorithms—to make automated quality assessment of slides possible. Technology from Pramana can scan more than 1,000 slides per day, according to the company.

Meanwhile, as part of a partnership between **Google** and Mayo Clinic, Google Cloud is storing the health system's data and applying AI to it. Google, headquartered in Mountain View, Calif., opened an office in Rochester, Minn., in 2021 so that its engineers can work closely with Mayo Clinic researchers.

Useful Approaches for Prior Authorization a

How Genetic Test Labs Can Improve Relationships wit

James Almas, MD

Trish Brown

➤➤ ***CEO SUMMARY: For payers and hea be a matter of trust that initially curta bursement of new and novel genomic tes of experts at the Executive War College on effective ways that genetic testing establish that trust early on with payers. ical labs must then navigate obstacles demonstrating the value to patients of ge ensuring that these genetic tests are prop***

GETTING PAID FOR GENETIC TEST CLAIMS IS A MAJOR CHALLENGE for many clinical laboratories and anatomic pathology groups. Yet there are ways labs can work with health plans to increase the number of genetic test claims that are reimbursed.

Payers may challenge a new genetic test's clinical utility, ask whether an effective alternative already exists, or even wonder if the laboratory is a legitimate business—the latter factor a side effect of the **Theranos** fraud saga.

To evaluate the reimbursement landscape for genomic testing, a panel of experts gathered at April's *Executive War College Conference on Laboratory and Pathology Management* in New Orleans last spring. The panel included:

- James Almas, MD, Vice President and National Medical Director for Clinical Effectiveness at **Labcorp** based in Burlington, N.C.
- Trish Brown, Genomics and Precision Medicine Program Director at **Aetna** in Hartford, Conn.
- Brent Gibbs, Senior Vice President of Market Access at **Scipher Medicine**, a precision medicine company in Waltham, Mass.
- Karen McFadden, former Senior Vice President of Managed Care at Labcorp

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lth plans, it may ils speedy reim- t claims. A panel offered insights laboratories can From there, clin- while effectively enomic tests and erly coded.

Brent Gibbs

Karen McFadden

and now a consultant for the company, who served as moderator for the panel.

Reimbursement Roadblocks

During the session, titled, "Genomic Testing: How Labs and Payers Can Work Together to Achieve Better Outcomes and Health Equity," the panelists cited the following litany of roadblocks to genomic test reimbursement:

- Prior authorization (PA) requirements imposed by some payers.
- Challenges in demonstrating the value of new and novel tests.
- Inconsistent test coding practices among genetic testing lab companies, in addition to inconsistencies among payers regarding which codes they recognize.

"Nothing is ever clear when dealing with a payer and the different health plans in the market," McFadden said. "When I'm asked if a certain genetic test is a covered benefit, my typical answer is, 'It depends.'"

Establishing Trust Early On

The four panelists agreed that one overriding issue for genomic testing companies is a lack of trust from payers. When approaching insurance carriers and health plans, genetic testing laboratories "have to realize first what payers are thinking," Almas observed. "There are bad actors in the lab community. Labs have to tell payers, 'We're not Theranos.'"

The conviction of Theranos founder Elizabeth Holmes in 2022 looms in the lab industry as payers fear a test or technology that may not work as touted. *(See TDR, "Jury Finds Elizabeth Holmes Guilty in Four of 11 Criminal Counts," Jan. 10, 2022.)*

'Bad Coding is Out There'

Beyond fraud, payers worry about coding troubles from clinical laboratories and pathology groups. "Labs have to admit up front that bad coding is out there," added Almas. "Thus, they should be prepared to explain to payers that they don't play coding games, such as improperly billing CPT code 81408." *(See TDR, "One Genetic Test CPT Code Earns 'Fraudomatic' Title," Dec. 7, 2020.)*

Demonstrating the value of a genomic test can go a long way with payers. Almas gave the example of a specific molecular genomic test. The policy at one health plan was that the test was medically unnecessary because an ob/gyn could use microscopy instead. Furthermore, "Labs were billing the test in crazy ways, with 'zillions' of CPT codes," he said.

In this case, Labcorp's response was that the payer's policy harmed marginalized patients. Half of the counties in the U.S., he noted, don't have board-certified ob/gyns.

"These patients are going to urgent care centers and to primary care doctors for obstetrics," Almas explained. "And only 10% of U.S. ob/gyns have a CLIA certificate to do microscopy. So, now, in conversations with that payer, we can rule out that the ob/gyn using a microscope is the appropriate way to assess these patients."

James Almas, MD

➤"The payer wants to know a genomic test is effective, it's going to work, and it's going to improve outcomes."

Labcorp presented the molecular test as an effective alternative. "We've made some headway," he said. "That's been a payer-lab provider collaboration to try to do the best thing and it includes equity because these are marginalized patients."

The key to finding successful solutions in these situations is explain why the status quo isn't effective and provide a tangible approach involving a genetic test that the payer feels good about. "The payer wants to know a genomic test is effective, it's going to work, and it's going to improve outcomes," Almas noted.

➤Prior Authorization Hurdle

Prior authorization (PA) requirements for many genetic and molecular tests has long been a major hurdle in obtaining reimbursement. Providers believe the tests they order are in the best interests of patients. But long ago the price of these tests caught the attention of managed care companies, who instituted prior authorization mandates.

Prior authorizations and their associated administrative burdens are cumbersome, Brown said. "They are complicated. They add to the administrative system."

In theory, prior authorization is supposed to happen in advance of a test. "But in practice, it's sought after the doctor has drawn the sample," Gibbs noted. "The lab has a sample, then the genetic testing lab says, 'Oh, we need a PA,' and it's too late once a draw has happened."

He pointed to logistical challenges that make prior authorization for some genomic tests impractical. "Yes, the sample was drawn, but there's a short window in the life of that specimen before labs have to test it," Gibbs observed. "That specimen probably flies across the country. It has to stay at a certain temperature. Labs cannot hold the specimen until that PA is obtained."

➤Real-Time Claim Adjudication

Brown pointed to pharmacy benefit management (PBM) as a possible model that could ease prior authorization for genomic tests. "While pharmacy benefit manager models have their own issues, one thing with which they don't have an issue is real-time claim adjudication and transparency," Brown explained. "Typically, the clinician at the point of care gets a quick answer from the PBM on whether a drug is covered.

"This works because every individual pill and dose on the market has its own unique code," she noted. But in the medical laboratory space, "We have the AMA CPT codes, we have PLA codes, we have Z codes."

In addition, **Concert Genetics** in Nashville, Tenn.—which maintains a database of 175,000 genetic tests—has "genetic testing units" available to the industry to identify tests more clearly.

"Further, we have payers that require genetic test registry," Brown said. "And everybody's supposed to put that genetic test in the electronic equivalent of Box 19," a catchall for additional information about a medical claim.

"I know that the genetic testing companies are really frustrated by that requirement because it puts them into a position where they must change how they submit a claim," she added. "However, that prob-

Pandemic Changes Made by Laboratories and Payers Will Stretch Beyond COVID-19

PANELISTS AT AN *EXECUTIVE WAR COLLEGE* SESSION ABOUT GENOMIC TESTS discussed the impact of SARS-CoV-2 on the testing landscape. They noted some changes made due to COVID-19 may be useful beyond the pandemic, but there were also negative situations that continue to make doing business more difficult.

Wins included labs supporting non-traditional testing sites, such as homes. "Labs truly rose to the occasion, and payers helped support them," said Trish Brown, Genomics and Precision Medicine Program Director at Aetna.

At-Home Phlebotomy

For example, Brown recalled that some clinical laboratories implemented at-home phlebotomy for non-invasive prenatal testing to help reduce patients' possible COVID-19 exposure at blood draw centers. As a result, some payers, including Aetna, changed their reimbursement policies to cover this type of at-home testing.

The pandemic also spurred innovation in how specimens are collected, such as in retail locations, pharmacies, and at home, she said. This compelled payers to determine how the payment process would work given these new situations.

Negatives Also Noted

There were challenges for payers from the pandemic as well. "A claim comes with required information, but the payer doesn't get that when the patient has a receipt from a retail location where the person purchased the SARS-CoV-2 test or from **Amazon**," she said. "Those were all things that had to be sorted out at the last minute."

Payers also had to navigate a new regulatory environment where the **Food and Drug Administration** (FDA) was routinely granting Emergency Use Authorizations (EUA).

Differences with LDTs

"It helped shine a light on the differences between laboratory-developed tests, FDA-approved tests, and Emergency Use Authorizations," Brown said. "Previously, some payers didn't fully comprehend the difference between laboratory-developed tests and FDA-approved tests."

As a result, labs ran into some payer policies that mandated FDA approval even if a test was available via an EUA.

Meanwhile, COVID-19 restrictions made it more difficult for laboratories developing novel genomic tests to demonstrate the clinical utility of their work, said Brent Gibbs, Senior Vice President of Market Access at Scipher Medicine.

"With a lot of patients not going to the physician's office, it was hard to enroll them in trials to get the clinical utility for novel genetic tests," Gibbs noted.

As consumers seek more of their medical care at retail clinics rather than hospitals or doctor's offices, genomic testing labs will need to figure out how to reach new trial participants who now may gravitate to community healthcare settings.

lem would go away if we all came up with a system that had great transparency while allowing real-time claim adjudication."

One solution suggested by panelists was "gold carding," in which payers relax prior authorization requirements for healthcare providers with high prior authorization approval rates.

Gibbs next discussed some special challenges facing startup genetic testing companies offering new and novel genomic tests. Beyond demonstrating that

they're not the next Theranos, these start-ups must also show they're producing a valid test.

"The problem that new, innovative genetic testing lab companies face is the ability for the technology assessors and the payers to review and keep up with all the new genetic tests," he said. "Payers can't keep up with the advancement. This stifles creativity and reimbursement for a laboratory. Many startup labs won't make it because they can't get reimbursed for their genetic test claims."

For genetic testing companies seeking coverage for their proprietary assays, "the first few payer contracts are the hardest ones to obtain," Gibbs noted. "The biggest opportunity for such labs is to find one or two payers that see the value of the test and partner with them.

Brent Gibbs

➤"The biggest opportunity for a genetic testing laboratory is to find one or two payers that see the value of the test and partner with them."

"One approach is to do a pilot or demonstration project," he explained. "Another path forward is to seek coverage with evidence development in which the **Centers for Medicare and Medicaid Services** agrees to cover a test or procedure while data about its effectiveness is collected."

➤Test Effectiveness

The lab can then show data developed during the time Medicare covered the genetic test that demonstrates the assay's effectiveness to other payers, though Gibbs added that payers will want to see positive results that apply specifically to their patient populations.

"Every payer thinks their patients are unique, and these payers believe that what works with one payer won't work in their patient population," Gibbs observed. "One way to overcome this hurdle is to obtain approval from Medicare for that specific genetic test. We know that once a novel test gets Medicare coverage, it helps validate the test and allow for additional reimbursement."

Brown added that there are some examples where payers will agree to cover a genomic test if the developer can demonstrate that it works in a certain population. "We are moving into a precision medicine era and a novel genetic test really should be tailored to give better outcomes," she explained.

Another path for genetic test coverage involves use of value-based contracts. "In this scenario, either the genetic test delivers a certain amount of savings and improved member outcomes, or there is no reimbursement because that test did not work for patients as intended," Brown added.

➤Issues Go Beyond Genomics

Beyond communicating with payers, clinical labs and pathology practices affiliated with an academic medical center or an integrated delivery network may want to involve the clinical and scientific expertise within the broader institution. "Many of these issues go beyond genomics and genetic testing," McFadden said. "These are common issues we have in the healthcare industry."

As genomic testing continues to grow in importance, the panelists predicted that payers will likely need to streamline how they reimburse for these tests. At the same, panelists emphasized that forward-thinking clinical labs have an opportunity now to educate health plans on how these tests benefit patient care and why rapid reimbursement benefits both sides. TDR

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IVD Update

Thermo Fisher Expands Menu to Offset COVID-19 Decreases

It's not just clinical laboratories seeking ways to repurpose the analyzers and automation they used to perform SARS-CoV-2 testing. As the pandemic continues to ease, some *in vitro* diagnostics (IVD) companies want to help their lab customers by expanding the types of diagnostic tests than can be run on these instrument systems.

This is true at **Thermo Fisher Scientific**. Faced with diminishing returns for SARS-CoV-2 testing revenue, the company is working to expand its diagnostic test menu so that clinical laboratory and pathology customers can continue full use of the vendor's instruments.

Given that other IVD companies must also deal with less demand for COVID-19 testing, the coming months present a good opportunity for lab and pathology leaders to review their vendor contracts and perhaps negotiate more favorable agreements.

Thermo Fisher expects to earn $2.6 billion in testing revenue in 2022, but that amount will fall in 2023, said Marc Casper, CEO, President, and Chairman of the company based in Waltham, Mass. Casper spoke during **Morgan Stanley's** *2022 Global Healthcare Conference* on Sept. 12.

"We're assuming an endemic level next year, and about $400 million [in testing revenue]," Casper said. "We'll know that better as the pandemic plays out."

Thermo Fisher is the third largest IVD company in the world. Its Laboratory Products Division earned $14.8 billion in 2021 and the company holds an estimated 12.6% of the IVD market. *(See TDR, "2021 Rankings of the World's Top 12 IVD Companies," Aug. 29, 2022.)*

Casper outlined expansion plans for the following three product areas:

- **Rapid systems** (i.e., generating results within 30 minutes): Thermo Fisher has already added influenza testing to the menu for these systems. This will largely benefit physician's offices and retail clinics. Other tests will be added.
- **Sample preparation**: These instruments will support other molecular testing beyond respiratory diagnostics.
- **Quantitative polymerase chain reaction (qPCR)**: The company has already launched new panels for infectious disease testing, primarily with respiratory illnesses. It plans to add panels for sexually-transmitted diseases.

New qPCR Instruments

Casper said qPCR technology found new buyers during the pandemic, which led to more clinical lab customers.

"Pre-pandemic, we were a smaller player in molecular diagnostics," he noted. "We had all the technologies in sample preparation as well as our qPCR instruments, but they were primarily used in research applications. So, you'd find them in every research lab around the world, every public health lab, but less of a presence in the clinical space."

In 2019, Thermo Fisher had 5.4% of the IVD market. The company has more than doubled its market share since then.

According to Casper, as COVID-19 spread, Thermo Fisher increased its production of molecular diagnostics tests while also working with regulators to streamline approval processes. "We wound up with a very large share of the qPCR base for COVID testing around the world," he said. "That led to a huge install base increase of lab-based qPCR instruments and lab-based sample preparation instruments." TDR

Labs Must Audit Their Cybersecurity Measures

During 2022, five labs reported data breaches, two cases involved more than 300,000 patients

Ben Denkers

CEO SUMMARY: While clinical laboratory managers and pathologists are aware of the risks of a data breach, they often assume that related protection measures are working as needed. That is a mistake. With the cost of healthcare data breaches on the rise, it is vitally important for labs and hospitals to ensure that their defenses are operating properly.

SINCE THE BEGINNING OF THE YEAR, the **Department of Health and Human Services' Office of Civil Rights** has posted five lab data breaches. Each affected more than 500 lab customers, and two of them impacted more than 300,000 patients each. Those numbers alone should capture the attention of laboratory managers and pathologists.

All five of the breaches involved a network intrusion, according to the government. But it is likely they all started with missteps by an employee within the lab, said Ben Denkers, Chief Innovation Officer at **CynergisTek**, a cybersecurity firm based in Austin, Texas.

"The way that computer network environments work today, users are acknowledged as the weakest link and offer the most potential for access to a hacker," Denkers told THE DARK REPORT.

Denkers advised clinical lab leaders to ask their IT colleagues about how the organization's security measures are tested because lapses in this regard can lead to a false sense of protection.

Data breaches can cost labs not only money to fix security holes and pay for credit bureau protection for victims, but also be harmful in terms of lost reputation and business.

A network attack is an attempt by a cybercriminal to gain unauthorized access to computing devices that contain and exchange data within a company. The information may be on individual devices or on servers. However, network attacks are often only possible after a hacker enters a system through an endpoint, such as an employee's email inbox.

Network Attack Explained

"It's important to understand that while the network server itself might have ultimately been the target, that doesn't necessarily mean that it was compromised first," Denkers explained. "Phishing is a perfect example of a way an attacker could first gain access to a workstation, and then from there move laterally to a server."

Phishing refers to attempts by a cybercriminal to convince a user to give the intruder access, such as by providing a link that the user clicks. Once opened, the link executes a program that seeks ways into the network.

It is possible for an attacker to initially target a network without going through email, Denkers added. For example, if a

server is on a public network or isn't configured properly, a cybercriminal may be able to directly enter the server.

While training employees is important for cybersecurity because it aims at changing human behavior, laboratories and other healthcare organizations also need to audit the technological measures they have in place to protect data. Too often, that latter step is not taken, perhaps because labs and other healthcare entities are overconfident, Denkers said.

"What we find is that organizations have security technology or processes in place that are either not effective or not working as designed," he commented.

"They've installed a firewall or antivirus software at an endpoint. But how do they know it's effective? Sometimes software isn't installed correctly. Other problems can be due to lack of monitoring technology," he added.

"For example, maybe a short-staffed lab doesn't have a designated person to monitor whether a software vendor has recommended installing a security patch," he continued. "At that point, organizations have an even bigger risk, because they think they've handled those issues by implementing technologies, but in reality, they haven't handled the issues."

Complete Blindside

"So, it's a complete blindside for a lot of organizations that think they have protections in place because they bought a product, or they developed a policy," he added.

Regardless of whether a clinical laboratory or an anatomic pathology practice has suffered a data breach, clinical and operations leaders should work with their IT counterparts to verify that technology and processes are actually protecting patient data.

"Testing, validating, and auditing whether measures are working as designed is a change of mentality for a lot of organizations," Denkers said. "I would recommend taking those steps."

HIPAA Governs PHI Breach Reporting

STATES HAVE VARIOUS REQUIREMENTS FOR DATA BREACHES, but when those security lapses involve personal health information the federal Health Insurance Portability and Accountability Act (HIPAA) comes into play.

Under HIPAA, covered entities—defined as healthcare providers that transmit data electronically—must take certain steps following a breach involving personal health information. Those steps include:

- Notify affected individuals by postal mail or email within 60 days of the breach's discovery.
- In incidents affecting more than 500 people in a state or jurisdiction, notify prominent media outlets in that state or jurisdiction within 60 days of the breach's discovery. The notification will likely be through a press release.
- In incidents affecting more than 500 people, notify the U.S. Secretary of Health and Human Services within 60 days.

The costs of not doing so are significant. **IBM** revealed in its "Cost of a Data Breach Report 2022" that an average data breach sets a healthcare organization back by $10.1 million. That's up $1 million from IBM's 2021 report—a worrisome number given how financially strapped many labs and hospitals are. Those costs can include forensic work, audits, crisis management activities, lost business, and notification efforts, IBM noted.

Security Problem

Additionally, ransomware attacks can also cost organizations tens of thousands of dollars if they choose to pay off criminals to unlock the files that have been taken hostage. *(See TDR, "All Labs Are Threatened by Encryption, Ransomware," Sept. 7, 2021.)*

A report published in August by **Comparitech** indicated that medical data breaches accounted for 342 million

Laboratory Data Breaches Reported in 2022

HEALTHCARE DATA BREACHES ARE TRACKED by the **Health and Human Services' Office of Civil Rights.** It maintains a list of healthcare data breaches that it is investigating.

The list is fairly general, offering the names of hospitals, labs, and other healthcare entities that suffered breaches and the type of incidents that occurred. The following lab entries are on the list for 2022:

- **Bako Diagnostics** in Alpharetta, Ga. (25,745 individuals affected.)
- **CSI Laboratories** in Alpharetta, Ga. (312,000 individuals affected.)
- **Laboratorio Clínico Toleda**, Arecibo, P.R. (500 individuals affected.)
- **Laboratorio Clínico Caparros**, Utuado, P.R. (500 individuals affected.)
- **Molecular Pathology Laboratory Network** (MPLN), Maryville, Tenn. (339,741 individuals affected.)

Details about the two largest cases, CSI and MPLN, showed that sensitive patient data was accessed in the cyberattacks.

"CSI determined that an unauthorized intruder acquired certain files from CSI's systems, including documents that may have contained patient information," the company wrote in a March 25 press release.

"Some of the impacted files contained very limited patient information," CSI noted. "Some impacted files contained more information, including patient name, date of birth, address, medical record number, and health insurance information. None of the files contained Social Security numbers or financial account information."

On July 6, MPLN concluded a review into its breach and noted the vast array of information that was accessed in some instances. That information included financial data, Social Security and driver's license numbers, diagnostic test and treatment records, and prescriptions.

A public relations firm hired by CSI in the wake of the breach did not provide further information when asked by THE DARK REPORT. The CEOs of Bako Diagnostics and Molecular Pathology Laboratory Network did not return requests for comment. Contact information for executives at the two labs in Puerto Rico could not be found.

leaked patient records in the U.S. from 2009 through June 2022. Comparitech is a cybersecurity research and product testing company in Kent, U.K. Among the top five patient data breaches noted by Comparitech were incidents at **Optum360** and **Labcorp**.

Optum360's breach occurred from August 2018 to March 2019, during which hackers accessed personal and financial information from 11.5 million lab records. Also in 2019, Labcorp had 10.2 million records hacked during an attack.

In both cases, the companies contracted certain billing activities to outside vendor **American Medical Collection Agency** (AMCA) in Elmhurst, N.Y. Labcorp and Optum360 terminated their contracts after the breaches. *(See TDR, "BRLI, Labcorp, Quest Disclose Data Breaches of 20 Million Patients," June 10, 2019.)*

AMCA eventually sought bankruptcy protection. In March 2021, AMCA settled with Attorneys General in 42 states over investigations into the data breaches. The states contended AMCA had been warned about flaws in its data security systems but did not take steps to fix them.

➤ Possible $21 Million Penalty

As part of the settlement, AMCA agreed to create a more comprehensive information security program and hire a chief information security officer. The states held back on penalizing the company $21 million due to its financial woes at the time. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Future regulation of laboratory-developed tests (LDTs) may not be as clear as it once appeared. On Sept. 30, Congress passed a short-term resolution to keep the federal government funded. As part of the move, a proposed bill to increase oversight of LDTs has been sidelined, at least for now, according to law firm **Ropes & Gray** based in Boston. The Verifying Accurate Leading-edge IVCT Development Act of 2022 (VALID Act) seeks to move approval of LDTs to the **Food and Drug Administration**. Currently, LDTs are regulated under the Clinical Laboratory Improvement Amendments Act of 1988. Federal lawmakers have discussed versions of the VALID Act since 2021. At one point the legislation seemed a sure bet to pass.

MORE ON: *VALID Act*

The congressional spending resolution expires on Dec. 16, but it remains to be seen whether the VALID Act will be part of any subsequent add-ons to future funding activity, Ropes & Gray reported. The Act and other policy proposals "will likely receive renewed attention as members of Congress come back to the negotiating table in an attempt to move forward with further legislation later this year," the law firm noted.

GOOGLE CLOUD LAUNCHES DIGITAL SUITE FOR MEDICAL IMAGING

Google Imaging is making a foray into digital imaging for medical diagnostics. *Fierce Healthcare* wrote "Google Cloud's Medical Imaging Suite will include cloud-based file storage using international imaging standards and secure data exchanges." This will be a "web-based picture archiving system for radiologists." It is known that Google is working to apply imaging solutions to pathology specimens.

TRANSITIONS

• **Beckman Coulter Diagnostics** named Karan Arora as Senior VP of Marketing, Strategy, and Product Insights. He previously served in high-level roles at **AstraZeneca**, **Abbott**, **Pfizer**, and **Novartis**.

• Dominic Weilbaecher is the new Vice President of Payer Relations at **Babson Diagnostics**. He worked in reimbursement roles for AI biomarker firm **Mindera** and genomic testing company **Agendia**. He previously spent 14 years at **Quest Diagnostics**.

• David Vinson is the new Senior Vice President for Diagnostic Laboratory Services at **Vanderbilt University Medical Center**. He had been serving as Interim Vice President on a contract basis for the past 15 months. Previously he worked in pathology operations for **Med Fusion** and **Specialty Laboratories**.

• Peter Manes is now Area Sales Manager at **CompuGroup Medical US**. He previously served at **Ortho Clinical Diagnostics, Cerner**, **Labotix**, and **Abbott Laboratories**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 31, 2022.

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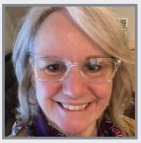


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