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Eric Feinstein on...

Using Microtomy Automation to Boost Productivity & Quality

Improving workflow in histology

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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

Is It Time for Clinical Labs to Embrace Consumers?

HEALTHCARE IN THIS COUNTRY HAS A WELL-DESERVED REPUTATION for being slow to incorporate new clinical knowledge, technologies, and management models into daily practice. Adoption of these innovations by hospitals, physicians, and clinical laboratories often lags behind other industries by several years.

Seen in this context, today's "new consumer" is one of those powerful developments that is disrupting many industries and is poised to reshape traditional modes of clinical care delivery. For the leaders of clinical labs and pathology groups, the warning signs are easily visible. There is a regular flow of news stories about how these new consumers are willing to bypass physicians and medical professionals to go to the internet, digital media, and social networks to research their health conditions, and then purchase products and services (think clinical laboratory tests) they think will enhance their health and well-being.

One of the goals of THE DARK REPORT is to alert you and your management team to important developments as they emerge and mature. This rapid growth in the number of consumers wanting to order their own clinical lab tests without a visit to a doctor's office is in part due to the increased availability of direct-to-consumer (DTC) testing and consumer self-testing.

Steady growth in DTC testing motivated **Quest Diagnostics** and **Labcorp** to each establish a business unit specifically designed to reach consumers, educate them about lab tests, and enable them to order tests from the companies' websites as appropriate without their own doctor's order. Growth in this business line is so significant that, during their respective quarterly earnings calls, the two blood brothers regularly update their investors and financial analysts about the increased volume of tests and growing revenue produced by these DTC programs.

Of course, every hot new trend can have an upside and a downside. That is true of consumer self-testing. As you will read on pages 3-6, a new crop of investor-funded DTC lab companies now eagerly fills this consumer demand. What's notable about them for lab leaders is two things: First, they cut the doctor out of the loop. Second, they market their products using social media and influencers.

DTC testing can generate a new stream of revenue for clinical laboratories. That's important today as payers cut reimbursement. Of equal significance, those clinical labs serving physicians have a reputation for clinical expertise that many of these investor-funded DTC consumer testing companies will probably never achieve. TDR

New Type of Competition from Investor-Owned Labs

Washington Post investigates "shadow system" of do-it-yourself tests offered directly to consumers

CEO SUMMARY: More investor-funded lab companies see robust future growth in serving what The Washington Post calls "a booming online wellness market that aims to leave the doctor's office behind." This is a new market driven by younger health-care-minded consumers who turn to the web for information and resources without first speaking with their own doctors. Clinical labs will want to understand and respond to this new trend.

by Robert L. Michel

THERE IS A NEW CLASS OF CLINICAL LABORATORIES THAT ARE BUILDING MOMENTUM in the United States today. These are labs serving what *The Washington Post* described as a "new world of DIY [do-it-yourself] testing."

According to a June 9, 2024, investigative report by *The Post*, "A new world of DIY testing is changing the relationship between physicians and patients, allowing people ... to *bypass the doctor's office* and take medical tests on their own." *[Italics added by THE DARK REPORT.]*

The key development, according to *The Post*, is not that consumers are bypassing physicians and ordering their own clinical laboratory tests. Rather, it is that, by their own efforts, consumers are finding a new class of clinical laboratory companies that maintain a high profile on the Internet.

These are lab testing companies organized specifically to:

- Offer tests directly to consumers, thus bypassing the traditional role of physicians,
- Use the Internet and social media to aggressively promote their lab testing services, and to
- Pay social media influencers to endorse these lab tests to consumers.

Another trait common to this new class of lab testing companies is that they go farther in giving advice to consumers than has been the long-established role of CLIA-certified clinical laboratories.

Experts quoted in *The Post* article predict that direct-to-consumer (DTC) and DIY lab testing will boom in coming years. As this happens, conventional clinical labs can expect these consumer-focused testing companies to bring about important changes in how both patients

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(seeking care for a medical condition) and consumers (wanting to improve their wellness) get information about lab tests.

➤'Shadow System' of Labs

Because this "shadow system" of investor-funded labs wants to encourage consumers to buy their own laboratory tests, these companies are different from conventional CLIA-certified clinical labs in two ways. First, they provide clinical advice on their websites and when speaking to consumers.

Second, these lab firms then recommend specific lab tests they assert will help the consumer better understand their clinical issue. As noted in *The Post's* reporting, the "shadow system" lab companies enable consumers to cut their physicians out of the conventional diagnostic loop.

This new class of DIY testing companies also wants to fill the gap that exists when informed consumers are frustrated because their physicians have yet to make correct diagnoses or provide treatments that halt the progression of the disease.

Seen from this perspective, these lab companies can be differentiated by their willingness to act as clinical advisors in direct communication with a consumer. Again, this bypasses consumers' physicians, who typically provide diagnoses, identify appropriate therapies, and monitor the progress of their patients.

The headline for *The Washington Post's* story was "Doctors Couldn't Help. They Turned to a Shadow System of DIY Medical Tests." The subhead was equally provocative: "Buoyed by regulatory vacuums, Silicon Valley is building a booming online wellness market that aims to leave the doctor's office behind."

To illustrate the new ability of a consumer to "work around" his or her physician, *The Post* provided the example of a mother with a six-year old daughter who, by the age of three, was not tolerating common first foods, leading in one case to hospitalization for dehydration. *The Post's* reporting team—Elizabeth Dwoskin, Daniel Gilbert, and Tatum Hunter—then wrote:

> *Half a dozen pediatric specialists largely dismissed her daughter's ailments, said the mother, forcing her to leave her job as a hospitality executive, because "you can't just have any babysitter looking after a child" with such serious reactions to food.*
>
> *After a year and a half, an answer came finally in the form of a **Facebook** ad for **Tiny Health**, a Silicon Valley start-up that could test her baby's gut microbiome. Using a bead of stool swabbed from a diaper, the company diagnosed the problem: Annika's gut was overcrowded with* P. vulgatus*, a common bacteria. A company nutritionist recommended a probiotic, sauerkraut, and exposure to animal microbes through daily visits to the petting zoo. Within months, Annika's food reactions were normal. More tests showed a gut transformed.*

➤Three Notable Elements

Three elements in the above reporting are notable. First, this mother saw information about Tiny Health's tests on Facebook, a social media website. Second, it was the mother who collected the sample from her child and sent it to Tiny Health. Third, it was the company's nutritionist who interpreted the test results and made recommendations to the mother.

Each of these three elements is not the conventional step taken by consumers or patients when they have a health issue. Traditionally the consumer visits the physician, the physician orders clinical lab tests to confirm the diagnosis, then identifies and starts the appropriate therapies.

Experts told *The Post* that the consumer DIY approach to clinical laboratory testing is an exploding market. Described as a "parallel medical ecosys-

tem," the market for "home diagnostics was described as currently at $5 billion annually," according to a report by **Precedence Research**.

Pathologists and clinical lab managers should recognize some additional significant differences in how these consumer-focused test companies conduct their business.

Grabbing Data from Internet

One, these test companies are proactive about grabbing data from the Internet on the diseases and health conditions getting the greatest number of searches. They then feature tests for these conditions on their websites using outbound marketing, and posts on social media sites.

Two, related to the study of **Google** searches for different diseases, these labs are organized to maintain a high-profile digital presence. *The Post* described this attribute, stating, "On **TikTok** and **Instagram**, the shadow ecosystem of self-testing is fueled by algorithms and influencers—and feeds off lost trust in 'Big Health.'"

Three, these DIY consumer test companies pay social media influencers to tout their lab tests. One example is Crystal Jung of Nashville. She is described by *The Post* as someone with autoimmune disorders who stopped going to doctors, "relying instead on at-home blood tests from the company **LetsGetChecked** to monitor thyroid stimulating hormones, a metric her doctors refused to check, she said."

Jung was described as an advertising partner of LetsGetChecked, and told *The Post* that she estimates "she has earned $20,000 from promoting blood tests from the company for thyroid health, micronutrients, and female hormones."

Regardless of surging fortunes, this new class of consumer DIY testing companies does have critics from within the healthcare industry. There are physicians speaking out about the unreliability of many of these DIY test offerings.

Remember Theranos? It Was a DIY Lab!

ANY CLINICAL LABORATORY PROFESSIONAL who was around in 2014 remembers **Theranos**, the once high-flying and now-defunct lab company organized to market tests to consumers.

That year, Theranos launched with a message directed at consumers that they could: 1) get lab test results in two hours; 2) priced at 50%of Medicare test fees; and 3) using only a finger-stick specimen of blood. Founder and former CEO Elizabeth Holmes was convicted of criminal charges and is now in federal prison serving out her 11-year sentence.

Her direct-to-consumer marketing of lab tests triggered a very public debate over whether it was a good or bad thing to cut physicians out of the diagnostic loop.

NPR reported on this issue, noting that Norman A. Paradis, MD, an emergency medicine physician and professor of medicine at **Dartmouth School of Medicine** called "the model of offering a wide assortment of tests—as Theranos did—a recipe for disaster." He told *NPR,* "If you simply run medical tests on large numbers of people who don't have the signs and symptoms of a certain disease, then many of the results you get will be false positives."

These concerns were detailed in a story published in the *The British Medical Journal (BMJ 2023;382:p1895).* The authors wrote "speaking at the 'Preventing Overdiagnosis Conference 2023' in Copenhagen, Denmark, researchers from around the world expressed apprehension over the growing prominence of poorly evidenced direct-to-consumer tests and the questionable ways they are promoted."

The story continued, "'This is a regulatory Wild West at the moment,' said Patti Shih, research fellow at the **Australian Centre for Health Engagement Evidence**

and Values. 'There are multiple players in a very large, unregulated market and there's very little transparency.'"

Setting aside the issue of a "shadow network of labs," the deeper significance of these events is that the long-established way that clinical laboratories served patients was with a physician as the gatekeeper. Since World War II, the accepted model for clinical care in the United States has been to train physicians to recognize a patient's symptoms, determine which clinical laboratory tests are appropriate, make an accurate diagnosis, and select the appropriate therapies.

It is important to recognize that a major attribute of the post-WWII healthcare system in the United States is that it is reactive and organized to respond whenever a sick patient goes to a doctor's office or shows up in a hospital emergency department.

Era of 'Reactive Medicine'

This means that physicians, until now, have been the front line of diagnosing health conditions and then delivering care appropriate to a patient's symptoms and medical conditions. This is "reactive medicine" and the United States is a recognized world leader for its healthcare system's ability to diagnose and treat patients suffering from a wide range of diseases and health conditions.

In this type of healthcare system, putting physicians on the front lines of ordering clinical laboratory tests in response to sick patients has been appropriate. State laws requiring a physician's signature on most types of clinical laboratory tests validated this approach to diagnostic medicine.

Today, however, that long-standing model of clinical care centered around a physician as the gatekeeper of clinical laboratory tests is being upended. Blame it on informed healthcare consumers who want to be proactive about maintaining their health and wellbeing.

In recent years, healthcare policymakers and the news media have heralded the arrival of the "informed consumer and patient" as a significant trend. There is growing acceptance by the medical establishment that ever more consumers are actively managing their health.

Consumer Health Monitoring

Baby Boomers, Gen X'ers, Millennials, and Gen Z'ers now watch their personal health in ways that were not true of past generations. Today's informed consumers and patients regularly wear devices like **FitBit**, **AppleWatch**, and **Abbott Laboratories'** Libre Sense that provide them data about their vital signs. They search out news stories about new research findings or clinical services that might benefit them, then visit their caregiver with this information.

Both **Quest Diagnostics** and **Labcorp** discuss the increased revenue from their consumer testing services during their quarterly earnings calls because of growth in DIY lab test orders.

Setting aside what *The Post* describes as a "shadow system of do-it-yourself testing companies" offering testing services of questionable value, it is important for lab executives and pathologists at conventional laboratories to recognize that the consumer lab test trend is here to stay.

Consumer-Facing Services

It would be timely for labs to update their strategic planning to add consumer-facing lab testing services to their menu. That requires features on a lab's website designed to educate and guide consumers interested in lab tests. Labs would also benefit from a larger social media presence that targets consumers exploring DIY test opportunities.

The good news is that a properly designed consumer DIY test program can bring in a new source of revenue for the conventional CLIA-accredited complex clinical laboratory. TDR

Clarapath Automates Slide Prep, Microtomy Workflow

System that automates many microtomy steps is ready to launch, may ease histotech shortage

Eric Feinstein

CEO SUMMARY: Histology is one area of laboratory medicine that utilizes a mostly manual workflow. However, pathology labs will soon have a novel solution designed to automate many of the steps in microtomy that produce glass slides. Reduced variability in the finished glass slides can improve the scanning process, thereby generating better quality whole slide images.

Is the time ripe for the profession of pathology to consider automating microtomy—the mostly manual and very laborious process of slicing tissue samples for placement on slides? One company thinks the answer is "yes" and it plans to soon have a solution on the market.

That company is **Clarapath**, based in White Plains, N.Y., and founded 10 years ago. This summer, the company plans to launch SectionStar, a device that uses robotics not only to slice the tissue samples, but also to transfer them to slides without the need for a water bath. It will be available to clinical labs and pathology groups across the U.S.

Clarapath also announced a collaboration with **Mayo Clinic** to further automate the slide preparation workflow. *(See sidebar on page 9.)*

"We're thinking about a bigger, broader Laboratory 2.0," said Clarapath CEO Eric Feinstein in an interview with The Dark Report. "We think about the laboratory as a Lean Six Sigma manufacturing operation. Whether it's manufacturing a widget or a glass slide, we want to cut out and consolidate the steps, to ultimately drive down the cost of producing that slide."

In SectionStar, "we have a system that takes the existing microtome, water bath, and QC steps in the pathology lab and replaces them with a fully integrated smart piece of hardware," Feinstein said. "Inside that system is something like a little laboratory. It has approximately 30 different substations. The inputs are cassettes of tissue. The output is a glass slide."

Laboratory Opportunities

Developing the technology posed many challenges, he said, requiring personnel with skills in robotics, material science, polymer science, chemistry, mechanical engineering, software engineering, and electrical engineering.

"Everything that people read about in terms of robotics—the **Tesla** self-driving car, the humanoid robot—all those buzzy things pale in comparison to evolutionary biological systems. Translating that to medicine and healthcare is extremely difficult," he said.

One important benefit of Clarapath's technology, Feinstein said, is that it addresses the current shortage of histotechnologists in the workforce, a problem that's likely to get worse because many are nearing retirement age.

"Available data shows there is not even close to enough people to fill the backlog of work in histology labs," Feinstein noted.

Clarapath's automated system won't replace histotechnologists, he added, but it will allow them to work more efficiently. "The current paradigm has one human to one microtome," he said. "But with our technology, one person can operate up to four machines at once."

Much like a drone or the Mars Rover, the SectionStar machines can be operated remotely. Telepathology is already an established field, but SectionStar, Feinstein said, offers a new workflow category he describes as "telehistology."

"A histotech can be in the room next door or can be in our office in India," he said. "He or she can remotely control the device at night while we sleep here in New York. This is an entirely new business opportunity for the anatomic pathology profession."

Manual microtomy is also a physically taxing endeavor, Feinstein noted, adding "there are other things histotechs could be doing, such as grossing or IHC staining. But currently they spend the bulk of their time sectioning tissue. It's a critical step, but given staffing shortages, there are other demands for their time."

Benefits of Standardization

In contrast to current manual techniques, Feinstein also claims that SectionStar creates a "gold standard for quality" with standardized output that makes the technology well suited as a front end to digital pathology systems.

In a typical workflow, the histotechnologist processes tissue samples into paraffin blocks, then uses the microtome to manually cut the blocks into slices that might be four or five microns thick. The slices are placed in a water bath and then transferred to slides.

Errors, Random Variations

This approach is rife with chances for errors and random variations, Feinstein said. "There might be different sources of water that are used for staining, different humans turning the microtome wheel, different humans embedding tissue with different orientations, different ways to alter the tissue-processing parameters. None of that is standardized," he explained.

The use of a water bath can lead to tears, folds, and cross-contamination of samples. In comparison, SectionStar uses a dry tape transfer technique that eliminates all these risks, he noted.

As an automated system that incorporates optics and environmental controls, SectionStar can also record each step in the microtomy process, much like a black box on an airplane, Feinstein said.

"Imagine having all of that information about a patient sample," he observed. "It could be data around a visual image, or what SectionStar is sensing in the environment. All of this makes a difference in the final output of the slide. Today, a human is doing that job. All that information is variable from person to person, day to day, location to location."

Clarapath has already registered the machine with the federal **Food and Drug Administration** (FDA), Feinstein said, and this model will be available to early adopters.

"We have a strong pipeline of customers," he said. "Some have invested in the company, which effectively secured them a spot. We are actively taking purchase orders and deposits to get a spot in the queue."

How much does it cost? "SectionStar is competitively priced to fit within the

Clarapath Enters Collaboration with Mayo Clinic to Identify Ways to Further Standardize Histology

ON APRIL 23, CLARAPATH ANNOUNCED A DEAL WITH MAYO CLINIC in which the two parties will collaborate on automation technology for histopathology labs. Clarapath's SectionStar system is designed to automate microtomy and quality control, but with this new deal, the organizations will explore additional ways to automate and consolidate the slide preparation process, Clarapath CEO Eric Feinstein told THE DARK REPORT.

He referenced similarities to other new process consolidation that has emerged in cytology. "For example the combination of **Hologic's** ThinPrep and Genuis embody how Clarapath thinks about slide prep, imaging, and analysis in histopathology," he said.

Mayo Clinic originally approached Clarapath as a potential customer for the SectionStar system, he said. "The discussion was around the challenges that every institution is facing when they try to go digital," including variations in how the sample is prepared at each stage.

"That has an impact on the slide after it's been digitized," he said. "They came to us with the hope of standardizing that process."

SectionStar is designed to remove much of the variability in current slide preparation processes. But one way to take it further, Feinstein said, would be to account for different kinds of tissue samples, much like an equalizer in a sound system.

"Tissue is heterogeneous," he said. "Bone is very different than breast tissue. There are different biochemical components, like lipids and proteins, and they all have different properties. Every lab has its own protocols, but if they can create equalizer settings for different types of tissue, they can get better outcomes. Part of the collaboration with Mayo Clinic is helping us to think about those equalizer settings."

As part of the deal, Mayo Clinic anatomic pathology chair Joaquín García, M.D. is joining Clarapath's board of directors. García also leads Mayo Clinic's Digital Pathology Program.

"By working with Clarapath, we are building the foundation for a 'lab of the future' that incorporates end-to-end automation, robotics, and AI to the patient tissue lifecycle," García said in a press release announcing the partnership.

budget of small to large labs, and in most cases costs less than other advanced pieces of laboratory equipment," he said. "A lab that uses more SectionStars will see a faster return on investment (ROI) in less than 12 months." Pricing will include consumables, plus other products and services.

SectionStar is manufactured at the company's headquarters in White Plains, he said. "We are an ISO 13485 certified manufacturing, assembly, and service site," he stated, referring to an international standard for fabrication of medical devices. "Everything is done here in New York."

Future upgrades include incorporating artificial intelligence (AI), along with more-advanced hardware to further automate the process "and provide deeper insights," Feinstein said.

"Manufacturing operations are only as fast as their slowest bottleneck," he said. "We are not looking to roll out an AI-enabled workflow today, because, frankly, that's not the bottleneck. The current paradigm has one human to one machine. That's the bottleneck." TDR

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Lab Market Update

UK's MassMutual Offers Free Genetic Testing to Its Members

Such programs give patients data they can use to define their healthcare with a focus on prevention

CONSUMER-DRIVEN HEALTHCARE PAIRED WITH A FOCUS ON PREVENTATIVE MEDICINE has given birth to powerful partnerships that are using genetic testing to encourage patients to make informed decisions for their health and wellbeing.

One such example is **Genomics PLC** (Genomics), a healthcare company out of Oxford, England, which partnered with **Massachusetts Mutual Life Insurance Company** (MassMutual) headquartered in Springfield, Mass., to offer MassMutual's customers free polygenic genetic testing to determine their unique risk for eight major healthcare diseases, MassMutual noted in a news release.

Clinical laboratory executives and pathologists may want to study the details of this program in greater detail. It is a clear sign that businesses believe they can deliver value to consumers by offering access to genetic tests. The MassMutual program also validates the trend of consumers taking a more proactive role in their care.

Clinical labs can see this genetic testing program as the newest evidence that consumer demand for self-testing (meaning bypassing a physician to order lab tests of interest) continues to expand.

This is one reason why THE DARK REPORT recommends that all clinical laboratories would benefit from making their websites more consumer-friendly. This would include posting lab test prices so consumers can easily find them in advance of placing an order.

This genetic testing program is part of MassMutual's Health and Wellness Program, which was created "to help policyowners better understand and protect their health," the company's website notes.

MassMutual hopes that its consumers, armed with newly-acquired genetic test results, will then be empowered to make proactive healthcare decisions and potentially change the trajectory of their lives, the website states.

"While the study of genomics is not new, it now provides an enormous opportunity to help individuals live their longest, healthiest lives," said Sir Peter Donnelly, co-founder and Chief Executive Officer of Genomics, in the news release.

"MassMutual is one of the first to understand the untapped value genomics brings in making proactive and preventative health choices," he added.

Genetic Test Details

Genomics and MassMutual began their mission with a pilot test which was offered to 1,400 MassMutual members. Those who opted into the genetic testing program received a saliva test that assessed unrevealed risk for the following conditions:

- Cancer of the prostate or breast (depending on patient's biological sex),
- High blood pressure,
- Cardiovascular disease,
- Atrial fibrillation,
- Low bone density,

- Type 2 diabetes, and
- High low-density lipoprotein cholesterol, MassMutual said.

"Genomic PLCs' at-home test studies millions of small variations in DNA, generating polygenic risk scores, that can inform the likelihood of certain conditions," MassMutual reported.

The results aim to impact two important groups: First, it may help doctors' decision-making when determining each patient's best course of care, and second, the genetic test results may empower patients' decision making for their own healthcare.

If these two goals are met, an overall improvement in the lifespan of the MassMutual pilot participants may be attainable.

And participant benefits extend beyond the individual's risk assessment results. "Policyowners also receive actionable, tailored health advice and a report they can review with their doctor to reduce the chances of developing the condition," MassMutual stated.

Test Results, Patient Privacy

"About one-fifth of the participants found a gene of concern, and 71% of the participants said the test increased their interest in modifying their lifestyles and getting doctor-recommended diagnostic tests," *ThinkAdvisor* reported.

In April, Genomics and MassMutual expanded the program and offered the free genetic test to all MassMutual members ages 35 to 70. MassMutual has not released how many tests are being offered, *ThinkAdvisor* noted. Patient privacy within this offering is a priority, both outside of MassMutual and within it as well. Test participation was completely voluntary and results of the testing does not impact any of the participants' current personal policies, MassMutual said.

"MassMutual only receives high-level, anonymized data from Genomics PLC that allows the company to better understand aggregate policyowners' health and behaviors and interest in these types of offerings," MassMutual added.

"People who qualify to buy individual, medically underwritten life insurance tend to be healthier and longer-lived than usual," *ThinkAdvisor* noted. However, "Even they may have a tendency to suffer from bad hits that lead to diabetes, heart disease, and other health problems."

Tailoring Treatments

Genomics and MassMutual's efforts follow the current trend toward heavily consumer-focused healthcare, as noted in "Dr. Kumo's Healthcare Trends 2024."

"Genomic medicine is enabling a shift from a one-size-fits-all treatment model to personalized care plans," the report states. "By understanding a patient's genetic makeup, healthcare providers can prescribe medications and treatments that are more likely to be effective and cause fewer side effects. This precision in care not only improves patient outcomes but also contributes to the advancement of medicine."

MassMutual recognizes the increased interest by consumers in ordering their own lab tests. Similarly, this is a response to the precision medicine trend of using genetic and other omics data to assess health risk, of which consumers have become more active.

Clinical lab managers should view MassMutual's service/benefit to members not just as validation of the trend of consumers taking personal ownership of their health conditions, but as an example of how relevant health data is originating outside the traditional doctor's office. Typically, local labs have been keepers of patients' records of test results. That may be less true in the future because of these consumer-focused test offerings. TDR

Virchow

Medicine ➤ Money ➤ Managed Care

This column is named after the famous German pathologist Rudolf Virchow (1821-1903), and it presents opinions and intelligence about managed care companies and their laboratory test contracting practices.

Behind-the-Scenes Audits Often Hide Cause of Test Claim Denials

EDITOR'S NOTE: Our column, Virchow, is written by anonymous insiders working within the managed care world. The column aims to help clients of THE DARK REPORT better understand the decisions, policies, and actions of payers as they manage their laboratory networks, establish coverage guidelines, process lab test claims, and audit labs.

PRIVATE PAYER AUDITS OF LAB TEST CLAIMS ARE HAPPENING MORE FREQUENTLY. This is particularly true for molecular and genetic test claims. It is one reason why your lab may see the regular flow of reimbursement payments from a specific health plan suddenly stop without warning.

But there is another reason why a private payer may abruptly stop paying a lab company's test claims. It's because the payer believes the lab is on a federal government watch list. I know of several lab companies that—after payments for their test claims had ceased—discovered that one of their important payers believed they were on a federal government watch list. *(See sidebar on page 15 for details.)*

Payers conduct claims audits behind the scenes and labs are unaware that their test claims are being audited. In the most common scenario, either the payer's auditing department or an outside auditing service takes a small sampling of claims and runs them through an algorithm. The payer then extrapolates the data into a prediction of all claims filed by that lab. If the audit turns up something amiss, the payer will often begin denying a substantial number of the audited lab's test claims.

It is not uncommon for these audits to trigger large recoupment demands from the payer. Payer's use of random sampling and extrapolation during audits has been around for years. But until recently, most payers did not totally stop reimbursement without notice to the lab that had been audited. *(See TDRs, "What Labs Need to Do as Payers Audit More Claims," May 11, 2015, and "Under Audit, Labs Need Statistics on Their Side," Sept. 10, 2018.)*

It is becoming more common for a lab to get regular checks each week from a payer, then suddenly, the following week, the lab gets no checks. Same thing the week after that.

➤ Payer Flagged Lab Claims

When the clinical laboratory contacts the health plan and asks why their lab is not getting paid, only then does the lab team learn that the payer flagged their lab and is denying their claims. The payer may or may not disclose that it stopped payments for test claims because of the results of the audit.

Of course, the lab urgently wants to restore the flow of reimbursement from this payer. The lab says to the payer's rep-

resentative, "We want to be a good citizen and do the right thing. Can your audit team give us an educational call?"

What I've heard from multiple labs is that after months—sometimes as long as two years—the health plan hasn't bothered to follow through with an educational call.

Then, after repeated queries, the lab gets what appears to be a form letter from the payer. Instead of indicating why specific lab test claims were denied, the notice just lists CPT codes along with excerpts from CMS guidelines about those codes. That lab has no way of knowing how the codes are related to the actual claims it submitted to that payer.

The lab must now jump through additional hoops to learn which test claims caused the problems flagged by the payer's audit. I've heard that some labs eventually succeeded in getting a payer representative on the phone. But even here, the employee simply walks the lab through the CMS guidelines, without giving any indication of which specific claims triggered the flag.

OIG Investigation

In previous Virchow columns, I explained how many payers are shrinking the number of workers on staff. This leaves fewer workers to respond to the calls and questions of clinical laboratories—indeed, of all providers. For some national health insurers, there have been multiple waves of layoffs and staff downsizing over the past 24 months. *(See TDR, "Layoffs at Major Health Plans Slow Processing of Lab Claims," Jan. 16, 2024.)*

Clinical lab executives and pathologists should not underestimate the consequences of these layoffs. Often, these major health insurers—when implementing a workforce reduction—will offer an attractive employee buyout (EBO) package. To generate the biggest reductions in payroll costs, these staff reductions typically target employees with many years of service because they have the highest compensation (and also the most knowledge and experience).

This is why these layoffs and staff cutbacks typically reduce the number of personnel who possess the deep knowledge needed to interact with labs in a more constructive manner. These are exactly the people who had the expertise to discern between minor billing problems and a lab that truly warranted a red flag.

Double Whammy for Labs

This leaves clinical labs and other providers with a double whammy. Not only are the most experienced staffers in claims processing gone, but there are fewer people than before to handle the ever-increasing volume of test claims. It means this task is left to rookies who are told to follow a flow chart.

This is happening concurrently with payers doing more audits of lab test claims. Lab managers should recognize that more audits of test claims means larger caseloads in payers' auditing departments.

Another source of claims denials has started to hit the national news because it directly impacts the ability of insured beneficiaries to receive the medical care their health insurance plans cover. It's the use of automation to evaluate incoming claims.

In a previous column, I noted the connection between claim denials and payers' use of algorithms in claims processing. *(See TDR, "Published Data Show Claim Denials on the Rise, But Why?" Feb. 5, 2024.)*

Payers have good reason to use these algorithms, given the huge volume of claims. Without automation, they would not be able to handle the workload.

But it is also true that claim denials are on the rise and that we've seen well-documented cases of abuses involving some payers' use of AI and automation in the claims review process, most notoriously

from a March 2023 *ProPublica* story about **Cigna**. The story revealed that doctors employed by Cigna signed off on thousands of denials each month, without reviewing the patient records, after the claims had been flagged by an algorithm. *(See ProPublica, "How Cigna Saves Millions by Having Its Doctors Reject Claims without Reading Them," March 25, 2023.)*

ProPublica wrote that "over a period of two months last year, Cigna doctors denied over 300,000 requests for payments using this method, spending an average of 1.2 seconds on each case, the documents show." *ProPublica* also identified Alan Muney, MD, a former pediatrician, who "was involved in helping create the system used at Cigna," adding that "Muney and his team had solved the problem once before. At **UnitedHealthcare**, where Muney was an executive, he said his group built a similar system to let its doctors quickly deny claims in bulk."

➤Reducing Risk of Denial

Is there anything that labs can do to prevent claim denials that arise from audits? Not really, but here are steps they can take to reduce the risk and mitigate the impact:

- **Stay on top of accounts receivable**. Especially in smaller labs, it might take weeks before they realize that a certain insurer is not paying. They need a system in place so they can immediately tell if something is amiss and then try to find out why.
- **Assign staff to monitor health plan policies**. Payers distribute periodic bulletins that include notifications of changes to their policies. By staying on top of these, labs can avoid sending claims that run afoul of the changes.
- **Outsource to a lab test billing service**. These services have expertise dealing with health plans and common billing issues. *(See TDR, "Payer Contracts with Labs: Getting the Contract Is Just the Start," April 29, 2024.)* TDR

Payers Incorrectly Think Labs on Govt. Watchlist

THERE IS ANOTHER DEVELOPMENT WITH PRIVATE PAYERS that can disrupt payments for test claims. This is something new in my experience. In recent weeks I've become aware of at least two labs currently dealing with something far more ominous than a payer's audit of claims submitted by these two labs.

Besides the fact that their test claims were not getting paid, when they called the payer's representative to learn why, the payer told both labs that their companies were on an investigation watchlist from the federal **Health and Human Services Office of Inspector General** (OIG).

The response from the labs was understandable: "What do you mean? We don't know anything about that! Can you send us the list?" However, the payer did not give either lab substantiation that they were on a federal government watchlist.

Why are payers telling these labs they are under investigation by the federal government? It's impossible to say at this point. Both labs insist they have done nothing that would warrant an OIG investigation. I can confirm that they're not listed in any public OIG records. Now their only recourse is to hire legal counsel to get the payer to restart reimbursement for the lab test claims.

I understand there are some bad players in the lab business. There are valid reasons for audits and OIG investigations. But something is wrong when a health plan tells a lab that it's on an OIG watchlist without being able to tell them, "Here's the list, here's the date, here's the link to the government website."

I've not seen private health plans do this until these two examples. Any labs experiencing this same issue should notify THE DARK REPORT in confidence.

IVD Update

Global IVD Companies Report First Quarter 2024 Earnings

IVD companies release first financial reports, market results were uneven across the 12 firms

In their initial financial reporting for 2024, *in vitro* diagnostics (IVD) company leaders shared priorities and progress in the first quarter (Q1) while also acknowledging heightened competition in diagnostics. And, for some of the IVD manufacturers, a need for new leaders and perspective is being addressed.

Here is a summary of recent financials, key accomplishments, and plans from top makers of clinical laboratory tests, instruments, products, and technology solutions.

Abbott
A Promise for Life

ABBOTT LABORATORIES: Boosts Q1 Revenue 2%, Gets FDA OK for TBI Test

Abbott Laboratories in Abbott Park, Illinois, shared these Q1 2024 financial results as compared to Q1 2023:

- Total sales were up 2.2% to $9.9 billion.
- Diagnostics sales, excluding COVID-19 tests, were up 5.4% to $2.2 billion.
- Total diagnostics sales were down 17.3% to $2.2 billion from $2.6 billion.
- COVID-19 testing revenue plunged 72% to $204 million from $730 million.
- Core laboratory sales were up 2% to $1.2 billion from $1.1 billion.
- Molecular sales were down 11.9% to $129 million from $147 million.

During the quarter, Abbott said it received **U.S. Food and Drug Administration** (FDA) clearance for the i-STAT TBI (traumatic brain injury) test, which reportedly offers assessment of a concussion in 15 minutes.

CEO Robert Ford explained to analysts during an earnings call that the test, which requires a capillary draw, runs on Abbott's portable i-STAT Alinity, a portable blood analyzer instrument allowing "concussion testing to move beyond the traditional hospital setting and into urgent care centers, physician offices, and other locations that are closer to the patient."

Abbott's plans include capillary draw for the test, which could enable the technology to be placed at high schools and universities.

Roche

ROCHE: Q1 Sales Down 6%, Declares COVID-19 Sales Impact 'Behind Us'

Roche Group in Basel, Switzerland, in reporting Q1 2024 as compared to Q1 2023, said:

- Group sales fell 6% to $14.4 billion Swiss francs (CHF) (US$15.7 billion) as compared to 15.3 billion CHF (US$16.7 billion).
- Excluding COVID-19 testing products sales were up 7%.
- Diagnostics Division sales fell 6% to 3.4 billion CHF (US$3.7 billion) from 3.7 billion CHF (US$4.0 billion).
- Core lab sales of 1.9 billion CHF (US$2.0 billion) were flat.

- Molecular lab revenue of 620 million CHF (US$678 million) was down 9% from 683 million CHF (US$747 million).
- Pathology lab sales of 363 million CHF (US$397 million) increased 10% from 320 million CHF (US$350 million).

"After this quarter, the COVID-19-related impact on sales is largely behind us," declared Roche CEO Thomas Schinecker, PhD.

As part of Roche's presentation to analysts, Matt Sause, Diagnostics CEO, noted regulatory-related achievements during Q1 as follows:

- FDA clearance for first molecular test to screen blood donors in U.S. for malaria.
- FDA Breakthrough Device Designation for a blood test, the Elecsys pTau217 plasma biomarker test, to support earlier Alzheimer's disease diagnosis.

ThermoFisher SCIENTIFIC

THERMO FISHER: Q1 Revenue Down 3%, Launches New Products

Thermo Fisher Scientific in Waltham, Massachusetts, announced in an earnings call these Q1 2024 financial results as compared to Q1 2023:

- Revenue fell 3% to $10.3 billion as compared to $10.7 billion.
- Laboratory Products and BioPharma Services segment revenue was flat at $5.7 billion.
- Life Sciences Solution segment revenue fell 15.3% to $2.2 billion from $2.6 billion.
- Analytical Instruments segment revenue was down 5.8% to $1.6 billion from $1.7 billion.
- Specialty Diagnostics segment revenue was flat at $1.1 billion.

During the earnings call, CEO Marc Casper informed analysts of work with **Bayer** (U.S. office St. Louis) "to develop a next-generation sequencing-based companion diagnostic that will help identify patients who may benefit from Bayer's growing portfolio of precision cancer therapies."

SIEMENS Healthineers

SIEMENS HEALTHINEERS: Increases Diagnostics Revenue 2%, Says It Is All About Atellica

Siemens Healthineers in Erlangen, Germany, shared these results for Q2 as compared to Q2 2023:

- Revenue up 1.7% to €5.4 billion (US$5.8 billion) from €5.3 billion (US$5.7 billion).
- Diagnostics revenue was up 2.1% to €1.1 billion (US$1.18 billion) from €1.0 billion (US$1.08 billion).
- Diagnostics revenue excluding COVID-19 tests was up 4.1%.

During a presentation to analysts and investors, CEO Bernd Montag, PhD, said company savings of €300 million (US$324 million) until fiscal year 2025 are "well on track" and margins are improving amid "solid revenue growth."

BIO-RAD

BIO-RAD LABORATORIES: Sales Down as New CFO, Head of Life Science Named

Bio-Rad Laboratories, in Hercules, Calif., reported Q1 2024 financial results as compared to Q1 2023:

- Sales were down 9.8% to $610.8 million as compared to $676.8 million.
- Clinical Diagnostics segment sales were up 4.7% to $368.6 million.
- Life Science segment sales fell 25.3% to $241.7 million.

During an earnings call, CEO Norman Schwartz introduced new executives including CFO Roop Lakkaraju and Head of Life Science Jim Berry.

QuidelOrtho

QUIDELORTHO: Revenue Down 16%, New CEO Aims to Improve Profitability

QuidelOrtho in San Diego reported these Q1 2024 as compared to Q1 2023 data:

- Revenue decreased 16% to $711 million from $846 million.
- Labs revenue was down 3.7% to $359.6 million from $370.7 million.
- Point-of-care revenue fell 39.4% to $186.6 million from $308.1 million.
- Molecular diagnostics revenue was down 36.8% to $7.2 million from $11.4 million.

Brian Blaser, the new CEO, said during the earnings call that the company will be focused during the short term on "unwavering attention to customer satisfaction and patient care, improving profitability and cash flow while reducing our debt level, and positioning ourselves to compete effectively in the highly competitive diagnostics market."

BD

BECTON, DICKINSON AND COMPANY: Boosts Overall Revenue and Life Sciences Revenue

Becton, Dickinson and Company (BD) in Franklin Lakes, N.J., shared data for its Q2 as compared to Q2 2023:

- Revenue climbed 4.6% to $5.0 billion from $4.8 billion.
- Life Sciences (including Integrated Diagnostics solutions and Biosciences) was up 2.2% to $1.3 billion from $1.2 billion.

During Q2, BD's Biosciences announced additions to the BD FACSDiscover "to incorporate real-time imaging and spectral cell sorting technology in labs."

BD's Integrated Diagnostics Solutions unit started a partnership with Camtech Health to step up cervical cancer screening in Singapore through use of BD Onclairity HPV assay.

CEO Tom Polen said during an earnings call that this is the "first-ever option in Singapore for women to self-collect a sample for cervical cancer screening in the privacy of their own homes."

HOLOGIC The Science of Sure

HOLOGIC: Revenue for Q2 Flat

Hologic, based in Marlborough, Mass., reported financial results for its Q2 as compared to Q2 2023:

- Revenue was $1.01 million, down 0.8% from $1.02 million.
- Diagnostics revenue fell 3.1% to $450.1 million from $464.7 million.
- Molecular Diagnostics revenue decreased 5.7% to $322.7 million from $342.2 million.

DANAHER BECKMAN COULTER Cepheid A better way. Leica MICROSYSTEMS

DANAHER: Diagnostics Sales Up 6.5%, Gets FDA OK for Digital Pathology Scanner

Danaher Corporation, Washington, D.C., reported for its subsidiaries of **Beckman Coulter Diagnostics**, **Cepheid**, and **Leica Biosystems**. Included were these Q1 results as compared to Q1 2023:

- Revenue decreased 2.5% to $5.8 billion from $5.9 billion.
- Diagnostics sales were up 6.5%.
- Life Sciences revenue was up 2%.

CEO Rainer Blair, during an earnings call, said Beckman Coulter Diagnostics had "solid growth in both instruments and consumables."

And in molecular diagnostics, Blair noted Cepheid had revenue of about $675 million, $100 million more than expected in Q1 "driven by both higher volumes and a favorable mix of our four-in-one

test (the SARS-CoV-2/Flu/RSV test which runs on Xpert Xpress)."

Also in Q1, Cepheid received expanded FDA clearance with a CLIA waiver for the Xpert Xpress multiplex vaginal panel (MVP) test. This will enable providers to do testing (on the GeneXpert System) for women in care settings that include physicians offices and ob-gyn clinics, commented Blair.

He also shared news of FDA clearance for the Aperio GT 450 DX Digital Pathology slide scanner.

"Now with this significant milestone, the GT 450 can be more widely used in pathology labs, moving digital pathology one step closer to becoming the standard of care for clinicians.

BIOMÉRIEUX: Q1 Sales Up in Molecular Biology, Microbiology

At **bioMérieux**, in Marcy-l'Étoile, France, sales grew impressively in most areas during Q1 2024 as compared to Q1 2023:

- Sales were up 6.6% to €965.2 million (US$1.04 billion) as compared to €905.7 million (US$978 million).
- Molecular biology sales climbed 16.1% to €409.6 million (US$442 million) from €352.7 million (US$380 million).
- Microbiology sales increased 4.9% to €314.2 million (US$339 million) from €299.6 million (US$323 million).
- Immunoassays sales were down 12.8% to €83.3 million (US$89 million) from €95.6 million (US$103 million).

The company attributed "remarkable performance" in molecular biology to a 19% boost in BIOFIRE non-respiratory reagents sales. The installed BIOFIRE base grew by 300 new units for a total of 25,700. Also, the new SPOTFIRE solution had sales during the quarter of €20 million (US$21.6 million) and an increase of 400 instruments.

Sales in microbiology were driven by "mid-teens growth" for both VITEK automated ID/AST and BACT/Alert blood culture reagent sales.

SYSMEX CORPORATION: Ends Fiscal Year with Sales Up 12%

Sysmex, with headquarters in Hyōgo, Japan, shared financial results for its fiscal year ending March 31, 2024, as compared to fiscal year 2023:

- Sales increased 12.4% to ¥461,510 million (US$2.9 billion), from ¥410,502 million (US$2.6 billion).
- Sales in the Americas were up 12% to ¥118,782 million (US$753 million) as compared to ¥105,905 million (US$671 million).

The uptick in North America sales was associated with hematology reagents, urinalysis reagents, and maintenance services, according to Sysmex.

QIAGEN: Reports Sales Decrease, Respiratory Testing "Robust"

Qiagen, headquartered in Venlo, Netherlands, reported on Q1 2024 as compared to Q1 2023:

- Sales were down 5% to $459 million from $485 million.
- Instrument sales were down 10% to $50 million from $55 million.
- Molecular Diagnostics sales fell 3% to $244 million from $250 million.
- Life Sciences sales decreased 8% to $215 million from $235 million.

"QuantiFERON (for mycobacterium tuberculosis infection) sales continued to grow as we drive conversion of latent TB testing to the modern blood-based test," said CEO Thierry Bernard. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last week, it was announced that **Quest Diagnostics** "would acquire select laboratory assets from 12-hospital **Allina Health**," the Minneapolis-based health System. Quest stated, "Under the terms of the definitive agreement, Quest will offer its laboratory services to Allina Health clinic physicians and outreach provider clients across Minnesota and western Wisconsin." No price was announced and this deal is expected to close in third quarter 2024, following regulatory review.

MORE ON: *Allina-Quest*

Deteriorating finances at Allina Health was probably one spur to sell select laboratory assets to Quest Diagnostics. Last month, *Becker's Hospital CFO Report* stated, "Minneapolis-based Allina Health reported a $352.6 million operating loss in 2023, an 80% drop from the $195.8 million loss reported in 2022, according to financial documents published Feb. 14. *Becker's* further wrote, "Part of Allina's cost reduction efforts include transitioning about 2,000 revenue cycle and IT employees to **Optum**, beginning May 5. Last year, the system laid off around 350 employees—primarily in administrative and leadership roles ... Overall, more than 500 positions have been eliminated."

TRANSITIONS

• Mary Ann Womack joined **Integrated Regional Laboratories** of Deerfield Beach, Fla., as Regional Laboratory Director. She previously held positions as **Advent Health**, **Accumen** and **Florida Hospital**.

• Anil Parwani, MD, PhD, MBA, was named Chair of the Department of Pathology at The **Ohio State University College of Medicine**, effective July 1. Prior to joining OSHU, Parwani was on the faculty at **University of Pittsburgh School of Medicine**.

• **Talkspace** of New York City announced the selection of John Mooney as Chief Product Officer. Mooney's prior positions were with **Neogenomics**, **BioReference Laboratories**, **Misys Healthcare** and **CareEvolve**.

SCC Soft Computer of Clearwater, Fla., selected Peter Manes as Regional Sales Manager. His prior positions were with **CompuGroup Medical US, McKesson Medical-Surgical, Ortho Clinical Diagnostics**, **Cerner Corporation**, **Labotix**, **Abbott Diagnostics**, **Siemens Medical Systems** and **LAB-Interlink**.

• **Illumina Corporation** of San Diego, named Everett Cunningham as Chief Commercial Officer. Cunningham formerly served at **Exact Sciences**, **GE Healthcare**, **Quest Diagnostics** and **Pfizer**.

• **Danaher Corporation** of Washington, DC, announced that Julie Sawyer Montgomery is its new Vice President and Group Executive, Diagnostics. Previously, Montgomery was President of Danaher's **Beckman Coulter** division. Prior to that, she was with **Hospira Infusion Systems** and **Boston Scientific**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 22, 2024.

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