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Robert Tessier on…

Effective Ways Pathologists Can Protect Their Income!

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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

Provider Price Transparency Trend Has New Twist

IT'S NOT JUST PATIENTS WHO ARE TYPICALLY UNABLE TO SEE PRICES FOR THEIR MEDICAL CARE IN ADVANCE OF SERVICE. Guess who else is unhappy that they cannot access the prices charged by hospitals, physicians, and other providers? It is self-insured companies and unions!

Bloomberg recently reported on multiple court cases where a self-insured company or union has sued their health insurer simply to see the exact prices paid by their insurer for services provided to the plaintiff's employees. *(See pages 3-5.)* This development is a harbinger of a wider movement by self-insuring organizations to demand price transparency for the healthcare services they are funding, whether it's the price list available directly from hospitals, physicians, and other providers or the actual prices paid by their health insurers to providers.

According to *Bloomberg*, motivation for self-insured companies and unions to take their health insurer to court over their inability to obtain data about the prices the payer is authorizing is directly related to the continuing year-over-year increase in the cost of medical care. "The annual price of insuring a family, counting employers' and workers' contributions, now exceeds $22,000—up 20% in the past five years alone," wrote *Bloomberg* in its coverage of these court cases filed by employers against health insurers.

Pathologists and clinical lab managers should recognize that self-insured employers have a direct motivation to control the price of healthcare. Unlike the federal Medicare and Medicaid programs, funded by taxpayer dollars, corporations, unions, and other organizations must cover the cost of health benefits from the cash generated by sales of their products and services.

It should be expected that the nation's largest employers will become more strident in their calls for better control of healthcare costs. At the same time, they will become more aggressive in taking direct action to work with those payers and providers—including clinical laboratories and pathology groups—who offer lower prices.

It is clear that self-insured companies will have the motive at some point in the near future to have labs with transparent prices included in their provider networks. Those labs that have price transparency and competitive prices will benefit most from this trend. TDR

Big Employers Sue Payers over Price Transparency

Courts may ultimately decide how much medical claims price data health insurers must provide

CEO SUMMARY: Feeling they've been denied access by insurance companies to price data about medical claim payments, self-funded employer plans and unions are taking their health insurance companies to court. This battle over access to prices may have implications for providers, such as clinical labs, required by federal laws to publicly post prices for their services.

RECENT REPORTING FROM *BLOOMBERG NEWS* ripped the covers off an ongoing battle between private payers and employer-funded health plans regarding what data can be reasonably shared about medical costs. In short, employers aren't getting the data they want and have filed lawsuits.

The federal government has issued rules—including the Hospital Price Transparency Rule and No Surprises Act—to mandate more transparency from hospitals and other providers regarding what they charge patients for procedures. News stories regularly demonstrate that many hospitals and providers have yet to comply with these federal laws by making their prices easily accessible to patients.

Recent developments point to the possibility that any real teeth to price transparency will come from the courts.

Clinical laboratory and pathology group leaders will want to note the connection between more pressure being applied on payers from private employers and how that pressure may manifest itself on providers.

Bloomberg outlined four lawsuits in which employers or worker unions have sued health insurers over data access and pricing disputes.

"The cases reveal an emerging rift between employers that spend $1 trillion a year on health benefits and the insurance firms they hire to operate those plans: Some companies increasingly want to know where their money is going and what prices they pay for care, but insurers say they must keep those details private to stay competitive," *Bloomberg* wrote on Aug. 4.

"It kind of makes you wonder, is there something that they're hiding that they won't release this information?" Michael Thompson, a trustee who represents union contractors in Connecticut, told *Bloomberg*.

In a lawsuit filed in **U.S. District Court for the District of Connecticut**,

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unions representing bricklayers and sheet metal workers in that state have sued **Elevance** (formerly **Anthem**) for allegedly not handing over enough requested information about medical claims.

"Anthem [now Elevance] is refusing to give plaintiffs access to their plan claims data because Anthem is disregarding the contractual provisions governing its claims administration duties performed on behalf of the [health] funds—specifically, it is not uniformly applying its negotiated discount to the claims it processes under the funds' plans," the complaint states. "Instead, Anthem is either unlawfully retaining the improperly discounted amounts for itself, or it is imprudently overpaying providers."

Gap between Billing & Claim

In one example at the heart of the dispute, during a review the unions found that a person covered by one of the health plans received a skin graft that was billed by provider **Hartford HealthCare** at $42,563.

Elevance's negotiated rate with Hartford HealthCare for the procedure was $21,274. "[Elevance], however, repriced this claim with an allowed amount of $43,490, which is $22,216 more than (102% of) the gross charges, and $926.47 more than the amount Hartford HealthCare billed the member for the care received," according to the lawsuit.

The lawsuit also stated that the unions had been stymied by Elevance in their attempts to get hold of more data to review claims, often because the payer claimed such data is proprietary information.

Elevance declined comment to *Bloomberg* about the suit. However, in a motion to dismiss the complaint, the payer stated that the unions and Elevance have operated for years with the current agreement on how data is provided.

"Plaintiffs now contend that the contractual requirements for data reporting and audits that they negotiated are too restrictive," according to the motion to dismiss. "Instead of renegotiating those terms with [Elevance], however, plaintiffs have asked this court to void the terms."

How do such lawsuits tie into transparency regulations? Clinical laboratories, hospitals, and other providers are broadly required to post the prices they charge for procedures, tests, and other clinical services.

For example, according to the **Centers for Medicare and Medicaid Services**, as of Jan. 1, 2021, each hospital operating in the U.S. is required to provide clear, accessible pricing information online about services they provide in two ways:

- As a comprehensive, machine-readable file with all items and services.
- In a display of shoppable services in a consumer-friendly format.

Further, the **American Hospital Association** notes that the No Surprises Act requires hospitals and other providers to share good faith estimates with uninsured and self-paying patients for most scheduled services. That law aims to protect patients from getting unexpected medical bills when they receive most emergency and non-emergency services, such as lab tests, from out-of-network providers at in-network facilities. It allows for arbitration of payment disputes between payers and providers.

Transparency Law Conflicts

"Because of the new transparency laws, employers should in theory be able to compare the rates they pay for medical care to publicly reported prices and determine if they're paying too much," *Bloomberg* reported. "But when companies have invoked the new provisions against gag clauses to compel insurers to hand over the data, some say they've run into resistance. The kinds of conflicts that the lawsuits describe are playing out broadly across the industry, even when they're not winding up in court, according to employer groups."

Posting prices for medical services so that they are easily accessible for patients,

self-insured employers, and other healthcare stakeholders would seem like a common sense requirement. But providers—particularly hospitals—and private health insurers are stubborn in their resistance to more transparency in the prices they charge for medical services.

Clinical laboratory administrators and pathologists will want to watch this growing battle involving access to prices between self-insured employers and the private health insurers administering their health benefits plans.

On one hand, this may be a case of "Don't bite the hand that feeds you!" Self-insured employers pay fees to the health insurance companies. By refusing to provide prices to their customer—the employer—they are giving employers an incentive to switch their business to other payers.

Perverse FFS Incentives

On the other hand, one reason health plans and hospitals don't want to disclose prices is because of the perverse incentives of the current fee-for-service system. If they can hide the excessive prices they are charging from those who pay the bills—self-insured employers and patients with high-deductible health plans—then those outrageous prices continue to push extra profit into their pockets.

Given the two observations above, a natural conclusion is that today's fee-for-service system continues to fuel excessive profits for not only providers, but also for health plans that earn a percentage of the higher medical costs paid when calculating overhead and profit.

Bloomberg found enough self-insuring organizations taking their health plans to court over the failure to disclose prices paid for medical claims to recognize that this is an important story and a new trend within the U.S. healthcare system.

These employers, as *Bloomberg* reported, spend over $1 trillion per year on healthcare. We may be seeing the earliest skirmishes in a new employer campaign to control the year-over-year increase in the costs of health benefits.

If fee-for-service is an original sin for this country's healthcare system, then employers shifting the design of their health benefits programs away from fee-for-service toward value-based payment models is one path to redemption.

Congress has already recognized this fee-for-service sin. Over the past 30 years, it regularly enabled the rapid enrollment growth of Medicare Advantage plans. Medicare Advantage is based on paying the health insurer (and providers) a premium that is risk adjusted for each Medicare beneficiary.

THE DARK REPORT expects that some major self-insuring corporations will decide to recast their health benefits programs to more resemble the Medicare Advantage program in ways that reward providers for keeping their employees healthy. TDR

Federal Arbitration Fees Struck Down by Court

HIGHER FEES CHARGED BY THE FEDERAL GOVERNMENT for arbitration hearings under the No Surprises Act have been struck down by a judge in **U.S. District Court for the Eastern District of Texas**.

In January, the **Texas Medical Association** (TMA) filed a lawsuit against the **U.S. Department of Health and Human Services** (HHS) over increased fees. In late 2022, HHS and other agencies announced that the arbitration fees would increase from $50 to $350 for 2023, citing an increase in the number of disputes filed.

However, in his July ruling, Judge Jeremy Kernodle stated that HHS had improperly bypassed public-notice-and-comment requirements for the fee increases. The TMA also requested an order for refunds on the higher fees, but Kernodle wrote, "Plaintiffs identify no statutory mandate entitling them to a refund."

Actions Pathologists Can Take to Protect Income

➤Pathology groups must determine their fair market value and advocate for beneficial contract changes

Robert Tessier

➤➤CEO SUMMARY: Pathology groups may feel their income is under attack from lower Medicare reimbursement rates and rising practice costs. But steps to protect that income can include carefully determining fair market value under Medicare Part A contracts with hospitals and paying close attention to what constitutes "usual, customary, and reasonable" fees.

GIVEN THAT PATHOLOGY REIMBURSEMENTS ARE ALWAYS ON THE CHOPPING BLOCK and labor costs are at all-time highs, it's understandable that anatomic pathologists today feel a threat to their livelihoods.

However, there are steps creative pathology practices can take to protect their income and strike better third-party deals. "Pathology practices need to think through their business models and plan ahead," said Robert Tessier, Co-Founder of the **Panel of National Pathology Leaders** (PNPL) in Woodbridge, Connecticut. PNPL is a nonprofit group dedicated to advancing best practices in the pathology and laboratory professions.

"Some pathologists generate significant incomes, while others earn much less money for the same amount of work," Tessier added. "How can practices be more efficient? One way is for more pathologists to communicate and share the 'secret sauce' that works for them, which will benefit everyone."

At April's *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management*, Tessier detailed three steps that pathology groups can take to safeguard income and boost practice revenue:

- Determine fair market value for pathology services under **Medicare** Part A contracts with hospitals.
- With fee transparency, aim for "usual, customary, and reasonable" pathology charges.
- Seek extended contracts when feasible for Medicare Part B billing.

His session at the *Executive War College* was titled, "Current State of Private Practice Pathology: Disruptive Trends and Action Steps to Protect Pathologist Income and Boost Practice Revenue."

➤Part A Hospital Negotiations

Before preparing to negotiate a new contract with a hospital, pathology practices should first determine the fair market value compensation for their Part A services.

Citing Medicare's Reasonable Compensation Equivalent (RCE), published by the **Centers for Medicare and Medicaid Services** (CMS) in 2015, Tessier reported that $125 per hour represents the 25th percentile for pathologist rates—a relatively low rank. "It's not difficult to

convince hospital administration that if a practice employs a good group of pathologists, they're worth more than $125 or the 25th percentile," Tessier said.

The RCE has not been updated since 2015, but with updated costs associated with inflation, rising living expenses, continuing education, and malpractice insurance, the current RCE is estimated to be $160 per hour.

Based on data from studies collected by PNPL, the hourly pay rate for pathologists in 2023 should be in the $160 to $274 range. A $240 rate would be in the 50th percentile, and $274 would be in the 75th percentile.

"Determining a pathologist's worth can result in a huge range depending on where you start," Tessier stated. "Many hospital systems have been more than willing to accept hourly rates ranging between $240 and $274, depending on how the information about pathology compensation is presented."

Another important step in preparing for negotiations for Part A hospital contracts is to conduct detailed time studies. These are formal measurements of how long it takes a pathologist or a department to complete work.

Time Studies Measure Output

"PNPL recommends that pathologists do at least two time studies a year for two weeks apiece to document the Part A activities of the pathology practices," Tessier said.

Once the time studies are done, Tessier recommends discussing the findings with department administration and the hospital's finance office before starting Part A negotiations. "Meet ahead of time to discuss the results of the time study," he noted. "Don't wait to share this information during the negotiations."

Tessier also advised adding performance-based incentives to Part A proposals. Such enticements could be used when, for example, a practice or pathologist takes one or more of the following initiatives:

- Reduces the cost of send-out testing.
- Receives a medical director certificate from the **College of American Pathologists**.
- Develops a marketing plan for laboratory services.
- Improves turnaround times.

"Performance-based incentives currently range from about $10,000 to $20,000 per pathologist," Tessier asserted

Tessier believes that fee transparency, which stems from the federal No Surprises Act, also needs to be addressed to improve pathology practice revenue. *(See TDR, "Judge Vacates Provision in No Surprises Act," April 4, 2022.)*

"There are three different sources addressing fee transparency," Tessier said. "First, the hospital system tells the pathologist, 'Your fees have to be usual and customary.' Next, patients—especially those on high-deductible health plans—want to know what they're being charged for pathology services.

"And finally, lab sales representatives want to find out what the competition is doing in the community."

'Usual and Customary'

Hospital-based pathology contracts require fees to be "usual, customary, and reasonable." *Healthcare.gov* defines that term as: "The amount paid for a medical service in a geographic area based on what providers in the area usually charge for the same or similar medical service."

However, pathology service fees can vary immensely. For example, four commonly used Current Procedural Terminology (CPT) codes used by anatomic pathologists—88305, 88307, 88341, and 88342—account for more than two-thirds of Medicare pathology payments for professional services.

Even more extreme, the professional fees charged for the top pathology-re-

lated CPT code (88305) range from $38 to $1,253 nationwide, Tessier explained. That code is used for various biopsies.

He further noted that PNPL performed a study to analyze fees throughout the country for CPT 88305. They discovered that a $175 charge was the 50th percentile and $220 was the 75th percentile.

"There are similar disparities for several of the codes," Tessier said. "If a practice's fees are based on the 25th percentile, that's too low. If the fees are in the 90th percentile, that's too high. So, I recommend practices aim for somewhere between the 50th and 75th percentiles. Those fees would be usual, customary, and reasonable."

Part B for Private Payers

Medicare Part B services can take up a large portion of a pathologist's time.

"I estimate that a hospital-based pathologist spends about 20% of their time doing Part A and about 80% of their time doing Part B," Tessier said.

He suggested that, when possible, pathologists should take advantage of extended contracts with private payers when billing for global services. The reason is because many payers have still not recognized Medicare Part B's 2012 reduction for CPT code 88305's technical component, which covers equipment and supplies used during an case review.

"If a practice has a contract which does not recognize these Medicare cuts, and instead allows the practice to deal with historical reimbursement rates, then the practice should have a long-term strategy to extend that contract over a number of years," Tessier explained.

Negotiating with Payers

Assertive pathologists also can approach payers with a list of five to 10 procedures and request higher fees. That list may eventually get whittled down to three to five procedures that are "carved out" of payers' statewide reimbursement schedule for pathology.

"Payers prefer to have their regular fees accepted but will listen to a practice's argument for carve-outs," Tessier said. "When it comes to third-party negotiations, a multiplier of two times the Medicare rate is okay, although three times Medicare is ideal."

Observant practice owners can view the expert strategies suggested by Tessier as new ways of generating revenue within established operating procedures. TDR

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Pathology, Radiology Can Collaborate

IN 2022, THE PANEL OF NATIONAL PATHOLOGY LEADERS (PNPL) formed a focus group to discuss the concept of hospital pathology and radiology departments practicing together under "diagnostic medicine."

This group is reviewing:

- How pathology and radiology can work together while maintaining separate identities within the same department or institution.
- How to create combined clinical activity that adds value.
- Methods of billing and reimbursement for various services.
- The future role of artificial intelligence for test selection and result interpretation.

"There are seven billion diagnostic tests a year that include imaging as well as laboratory tests," said Tessier. "PNPL advocates collaboration between radiologists and pathologists, sharing information, and trying to work together. We believe that's the way of the future because it will create a significant improvement in patient experiences and outcomes."

Guerrilla Kaizen Events Bring Rapid Change

'Small, incremental improvements can lead to groundbreaking excellence,' says one expert

Rita D'Angelo, PhD

CEO SUMMARY: *Lean Six Sigma principles are familiar to clinical laboratory and pathology leaders. But a lesser-known offshoot called "guerrilla Kaizen" aims to rapidly identify inefficiencies and make improvements—an approach that may appeal to labs interested in independently tackling problems. This briefing outlines the steps behind guerrilla Kaizen events.*

Lean Six Sigma methods are a widely-accepted way to reduce inefficiences and eliminate waste in clinical laboratory workflows. However, "guerrilla Kaizen events" are a lesser known Lean approach that can rapidly produce small changes that lead to lower lab costs and improved staff productivity.

These quick-moving projects often occur without the direct support of leaders and executives. "Guerrilla Kaizen events create changes that happen right now," said Rita D'Angelo, PhD, CEO at **D'Angelo Advantage, LLC** in Rockwood, Michigan. "A clinical lab might not have permission to make the change, but it's going to do it anyway because that change is not going to adversely affect anyone. Instead, it will just improve a process."

D'Angelo tackled the topic of Kaizen at the *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management* in April. Her session was titled, "Guerrilla Lean in Your Lab: Implementing Lean and Kaizen Events without Permission to Achieve Immediate Cost Savings, Improve Quality, and Boost Staff Productivity and Satisfaction."

She previously spent nearly eight years as Manager of Quality Systems for Pathology and Laboratory Medicine at **Henry Ford Health** in Detroit. Henry Ford Health was one of the pioneers of using Lean Six Sigma in clinical laboratory and anatomic pathology settings. *(See TDR, "Using Lean at Henry Ford Transforms Pathology TAT," Aug. 10, 2009.)*

Phases of a Kaizen Event

Kaizen events identify and eliminate waste with an eye towards continuous improvement. Traditional Kaizen events are effective at cutting lab costs swiftly while boosting staff productivity and morale. The "guerrilla" aspect adds a new element to that approach.

"Guerrilla Kaizen is fast moving and independent," D'Angelo said. Formally, Kaizen events have multiple phases and subsets under those phases. D'Angelo gave the four steps that labs should take to host guerrilla Kaizen events:

- Step 1: Establish a team.
- Step 2: Observe the problem.
- Step 3: Analyze root causes of the problem.

Lean Methods Identify Waste in Its Many Forms

QUICKLY REDUCING WASTE IN LAB PROCESSES is the goal of guerrilla Kaizen events. Rita D'Angelo, PhD, suggested the following common areas where waste occurs:

- Operator error using equipment.
- Time wasted waiting for information to perform tasks.
- Transportation activities that don't add value.
- Electronic or physical items taking up valuable space.
- Excess motion, such as bending or walking to other locations to complete tasks.
- Excess processing that involves multiple versions of the same task.

"Labs encounter defects every day, whether they're handed to a lab or whether a lab creates the problem," D'Angelo said. "For instance, if a lab touches something multiple times as part of a process, that's waste."

- Step 4: Brainstorm solutions to the problem.

Let's look at those steps in more detail.

Step 1: Establish a Team

D'Angelo suggested that clinical lab and pathology managers jot down on paper what army they would assemble to quickly tackle an inefficiency. Those people should be on the Kaizen event team.

Frontline workers are important to this effort. "Guerrilla Kaizen experts are the people closest to the work," D'Angelo noted. "They know what needs to be done, and they know where the defects originate. These experts are instrumental for the success of improvements stemming from Kaizen events."

Another key team member? Any staff member who is a natural at influencing change. "These are the individuals who know people, and they know where to get data," she added.

Once the team is formed, it's time to schedule the actual guerrilla Kaizen event. Given that many short-staffed labs may have difficulty breaking away from necessary duties, it is important for leaders to be realistic about how much time they can dedicate to this event.

"Back in the day, I remember doing Kaizen events that lasted eight hours over five days, but I'm not sure that labs can do that anymore," D'Angelo said. "If a lab can spare four hours daily for a few days, great. If they don't have that kind of time, they may have to do it as a lunch event.

"Also, the lab might have people in the room for the event that haven't worked with Lean or Kaizen before," she noted. "Managers need to set the expectations and provide some basic Lean training."

Step 2: Observe the Problem

At the onset of the event, the clinical lab team should discuss a specific challenge or inefficiency. Ideally the desired change ties into the overall goals of the lab or parent organization.

"From there, the team members need to go and see the problem as it's occurring in lab," D'Angelo explained. "Observe the process as a team, collect data, and review standard operating procedures."

A planning form can help the team document observations by date and occurrence, as well as who noted these problems. These entries contribute data to the event.

Step 3: Analyze Root Causes

Guerrilla Kaizen event participants should be cognizant of digging up the actual cause of a waste or inefficiency. "If a Kaizen team makes changes when it does not have the true root cause, it ends up treating just the symptoms of the problem," D'Angelo explained. "And the lab will probably have more problems. The key is to fully identify and understand the root cause. The team can then prioritize solutions."

To determine the root causes of a problem, baseline data is essential. "The same data collected to illustrate the problem prior to the Kaizen event will again be collected later to determine if the outcome was successful," D'Angelo noted.

Test turnaround time and overtime cost per clinical lab scientist are two common metrics to consider for Kaizen events. "Customer complaints are another type of metric," she said. "Many times, customer complaints are helpful because there is a lot of detail in them."

Using visuals during the Kaizen event can also significantly aid in determining the source of a problem. Two diagrams that D'Angelo champions include:

- **Spaghetti diagrams**, which show paths between processes. The metaphor comes when the lines between processes bend and twist like a piece of spaghetti as they get more complicated. "Labs could use a spaghetti diagram to follow a specimen and track steps from start to finish to find bottlenecks," she said. "Or use it to follow a worker, looking for motion versus waste."
- **Fishbone diagrams**, which list a central problem as a "spine" with six branches that resemble a fish's bones. The branches include categories of problems, such as materials, management, staff, methods, environment, and machines. "This is a great problem-solving tool because combined with data, the fishbone diagram shows the current condition of processes," she said.

Step 4: Brainstorm Solutions

The diagrams often point the Kaizen team to the cause of a problem. "For example, on a fishbone diagram, circle the areas that the team thinks are the root causes," D'Angelo said. "This identification is important because from there, the team brainstorms on how to eliminate these non-value-added inefficiencies."

The solutions should be quickly implemented and verified during a guerrilla Kaizen event. "Designated team participants will say to a technologist, 'We have a

Comparing Lean, Six Sigma, and Kaizen

HERE'S A QUICK COMPARISON of Lean, Six Sigma, and Kaizen:

Lean focuses on processes to eliminate waste and operate at top efficiency.

- **Toyota** established Lean principles on its automobile lines to improve productivity by making only what is needed, when it is needed, in the amount that is needed.
- Waste comes in different forms. "Waste can manifest as excess inventory, extraneous processing steps, and defective products, among other instances," according to Toyota.

Six Sigma aims to reduce variations in processes using statistical analysis.

- The "Six" in Six Sigma means that it takes six standard deviations from a mean value for an error to happen. This notion is often visualized as a bell curve chart.
- Six Sigma uses the following steps: Define > Measure > Analyze > Improve > Control (DMAIC). "This process involves identifying the problem you're trying to solve, taking stock of your current processes, identifying and implementing a solution, and maintaining that solution in the future," according to **Purdue University**.

Combining these elements, Lean Six Sigma uses the DMAIC approach to address waste. Meanwhile, **Kaizen** refers to gradual, unending improvement by doing little things better.

- Kaizen events are led by employees who are closest to problem areas.
- Lean Six Sigma tools can be used in Kaizen events.

Examples in Cost-Cutting, Revenue Gains by Guerrilla Kaizen Events at Clinical Labs

RITA D'ANGELO, PHD, PROVIDED TWO REAL-LIFE EXAMPLES of guerrilla Kaizen success at clinical laboratories that she was involved with.

Small Coding Change

A microbiology lab had instances where some medical technologists added a billing code every time a microbiology specimen came through, while others did not add the code. The inconsistency was visible from workflow and billing perspectives. A Kaizen event flagged this issue and the team worked with the IT department to resolve the issue. As part of the solution the lab information system vendor added the billing codes directly into the software.

The payoff was big for a simple solution. "Billing these codes regularly generated millions of dollars from timely reimbursement," she noted. "It's a very small, very simple process for improvement, but the results were significant. Small, incremental improvements can lead to groundbreaking excellence."

Courier Dropoff Overhaul

Another lab examined the process of handling specimens that arrived by courier at the end of the day. The timing caused a backlog of work and a delay getting results to the patients. "As part of a Kaizen event, lab participants observed the process as a team, collected data, reviewed standard operating procedures, and reviewed delivery logs for couriers to understand when they were coming," D'Angelo recalled.

Baseline data indicated a turnaround time of eight hours for these backlogged specimens, which cost the lab overtime because of the off-hours work needed. "The lab spent tens of thousands of dollars in overtime in a year, so that was a wasteful area to cut," D'Angelo noted.

Observation during the Kaizen event showed that nurses were dropping the samples off at stations that had posted outdated pickup schedules. Further, there wasn't a good tracking system in place to monitor if the specimens got delivered to the lab. These were all root causes of waste.

"The organization revised the courier pickup schedule, eliminated drop-offs at stations that weren't convenient for couriers, and color-coded specimens to understand how long they sat in drop-off zones," D'Angelo said.

Staff members were trained on the new process to ensure it was cemented in place with stellar results. "We went from eight hours to four hours in turnaround time and cut med tech overtime by making a few small, incremental improvements," she added.

new process here. Can I show you the new process?'" she explained. "Clinical labs and pathology groups may have to train people on the new process."

The team must circle back on the original data it pulled and begin to collect new data after a solution is carried out to see if the improvement is, in fact, successful.

"After the event, the team should collect the same data at the same time with the same people, under the same conditions," D'Angelo observed. "There must be no question that the data is sound, reliable, and accurate. Make sure to get a second reviewer of the data, too."

Shrewd lab leaders will recognize that a guerrilla Kaizen approach can make a big splash when it comes to rapid improvement. "Kaizen activities can have high impact with low effort," she concluded. "Nobody wants to spend a year on this. Instead, go in, get it done, and move on." TDR

Contact Rita D'Angelo, PhD, at dangeloadvantage@gmail.com.

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.

Smaller Labs Must Verify Z-code Arrangement with Lab Companies

EDITOR'S NOTE: Our new 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.

PLENTY OF HOSPITAL-BASED OR SMALLER CLINICAL LABORATORIES refer their genetic tests to third-party lab companies.

What if those referral laboratories are not based in states where the **Medicare** Administrative Contractor (MAC) participates in the Molecular Diagnostics Services Program (MolDX)? Until now, that was likely not a problem. But it is quickly becoming a concern given **UnitedHealthcare's** (UHC) decision to require Z-codes for genetic test claims under private health plans as of Oct. 1. I'll explain the background of this situation and outline the limited options facing smaller labs that refer genetic tests to outside laboratories.

Dozens of Non-MolDX States

MolDX, which administers Z-codes, is run by **Palmetto GBA**, a MAC based in Columbia, South Carolina. The point of Z-codes is to better identify the components of unique genetic tests, something that Current Procedural Terminology codes have trouble doing. It's an attempt to rein in the tens of thousands of molecular assays on the market, given that the clinical validity of some of these procedures is dubious.

Genetic testing laboratories in the 28 states that participate in MolDX already need to provide Z-codes for claims under Medicare Advantage. That's because the five MACs that cover those 28 states have issued local coverage determinations (LCDs) supporting Z-codes. Those five MACs include **CGS Administrators**, **National Government Services**, **Noridian Healthcare Solutions**, Palmetto GBA, and **Wisconsin Physicians Service Government Health Administrators**.

However, the two remaining MACs—**First Coast Service Options** and **Novitas Solutions**—do not participate in MolDX. Thus, their LCDs do not mandate Z-codes for genetic tests submitted to Medicare Advantage.

Things start to get trickier with UnitedHealthcare's new policy requiring Z-codes for genetic test claims. The payer's policy applies to all states in which it offers private plans, regardless of whether a MAC LCD requires Z-code use. So, genetic testing labs that do business with UHC, and which are located in non-MolDX states—or are referring tests out to lab companies located in non-MolDX states—find themselves in a situation of needing to request Z-codes

Some Lab Companies Stay Away from MolDX

HISTORICALLY, SOME LABORATORY COMPANIES purposely avoided locating their businesses in MolDX states for a variety of reasons, including Z-code use.

Theoretically, if a lab company was founded in California—which is a MolDX state—but did not want to deal with MolDX, it could relocate its headquarters to Florida, Illinois, or Texas, which are non-MolDX states. That means less hoops to jump through for genetic test reimbursement and potentially other local coverage determination policies.

Unfortunately, some unscrupulous laboratory owners have taken advantage of the situation to conduct fraudulent activity with genetic testing. For example, in 2022, 13 defendants were accused of fraudulently billing for tests and paying related kickbacks totaling $562 million. Many of those defendants operated in non-MolDX states. *(See TDR, "Feds Target Genetic Test and Telemedicine Fraud," Sept. 19, 2022.)*

for the first time. That's a lot of pressure to deal with before Oct. 1. *(See TDR, "UnitedHealthcare Delays Z-code Enforcement until Oct.1," July 31, 2022.)*

➤'I Need a Z-code'

In the sidebar on page 15, I show a list of 34 laboratory companies operating in non-MolDX states. This list might not include every lab company in those states, but it has most of them.

Let's discuss **Quest Diagnostics** and **Labcorp**. They have labs in non-MolDX states, but they also have labs in MolDX states. Those companies understand Z-codes. I don't think that they're the concern.

However, there are numerous other laboratory companies in non-MolDX states to which many smaller labs send their genetic tests. If you're a smaller lab utilizing one of these lab companies for reference testing, you might call them and say, "As of Oct. 1, I need a Z-code for my UnitedHealthcare claims."

And they might say to you, "Sorry, we're not going to get Z-codes for you." That's a real problem for the labs that send out those tests and options are limited at that point.

➤Change to a New Reference Lab?

If smaller labs or hospital labs don't run genetic tests in house, they've still got to send those tests out. They may try to send them to their usual reference lab operating in a non-MolDX state that doesn't use Z-codes, but if that claim goes to UnitedHealthcare after Oct. 1, it's going to be denied. If several of those genetic test claims get denied by UHC in a week, smaller labs may conclude that they can't afford to lose that kind of money.

At that point, the smaller labs would have to quickly find another genetic testing company that uses Z-codes to send genetic tests to. That's a horrible position for smaller labs to find themselves in.

And who will those smaller labs go with? As I mentioned earlier, Quest and Labcorp operate in MolDX and non-MolDX states. So, I see smaller labs that can't get Z-codes from their current reference laboratory being forced to use Quest or Labcorp, which may not be a good thing. Doing so increases the already sizable market share for the two big national lab companies.

If I were a sales manager at Quest or Labcorp, I'd be telling my sales reps to find out which smaller labs are using lab companies in non-MolDx states and to ask managers at those smaller labs, "Has your reference lab refused to get Z-codes? We can do the same work for you, and we've got Z-codes."

➤Contacting UHC about Z-codes

Affected laboratories concerned with not meeting the Oct. 1 Z-code deadline might

Lab Companies Operating in Non-MolDX States

THIS LIST, WHICH IS NOT EXHAUSTIVE, shows many of the laboratory companies operating in non-MolDX states:

- Accu Reference Lab
- AccuPath
- Accutox
- Ambry
- AmeriPath
- Any Lab Test Now
- Baylor Miraca Genetics
- BioReference
- Boston Heart
- CAP Diagnostics LLC DBA Pathnostics
- Caris
- CBLPath
- Central Clinical Labs
- Clinical Pathology Laboratories
- Cockerell Dermatopathology
- Diagnostic Laboratory of Oklahoma
- Eurofins Donor & Product Testing
- Exact Science
- Esoterix
- Fulgent Therapeutics LLC
- GeneDx
- HealthTrackRx
- Horizon Laboratory LLC
- Inform Diagnostics
- Labcorp
- Mayo Clinical Laboratories
- MedTech Laboratory Services
- NeoGenomics Laboratories
- Northwell Lab
- ProPath Associates
- Quest Diagnostics
- Sonic
- Tribal Diagnostics
- Veracyte Labs

wonder whether it's worth the time to plead their case to UHC. Those smaller labs may try to reach their UHC representative, however, unless four or five of the labs band together, they're probably not going to get much sympathy from UnitedHealthcare. The enormity of UHC puts smaller labs in jeopardy in this situation, and small labs do not have the ability to make much noise in the market.

Any involvement from a group like the **American Clinical Laboratory Association** (ACLA) could help. ACLA can make enough noise, and UnitedHealthcare will get someone to call ACLA back. But most smaller labs don't belong to ACLA because they can't afford the membership dues.

I feel for the smaller labs that won't be able to adjust their genetic testing send-outs quickly enough to avoid problems with the Oct. 1 deadline set by UnitedHealthcare. They simply don't have enough influence over payers.

In the world of UHC, hospitals are king, followed by large medical groups, accountable care organizations, and then ancillary services. At the bottom of the ancillary are labs. That hierarchy is absurd given how much of a patient's chart is made up of data from diagnostic tests.

Wrapping Up

Here are some takeaway points:

- Even though UHC's deadline for Z-code use for private health plans has been pushed back to Oct. 1, that does not leave a lot of time for hospital-based and smaller labs to verify that any reference labs they use will observe Z-codes.
- There are limited options if a reference lab does not use Z-codes. The obvious move is to do business with a different lab company that is familiar with Z-codes, but those changes take time.

I encourage labs that anticipate problems with UHC reviews of their genetic test claims to act quickly. TDR

Lab News Briefs

Labcorp Buys Tufts' Lab Outreach

In our last issue, we reported **Labcorp** had acquired the lab outreach services of two health systems in Oregon. Then, earlier this month, the Burlington, N.C.-based national lab company inked another laboratory outreach business, this time with **Tufts Medicine** in Burlington, Massachusetts.

In a news release issued on Aug. 3, it was hinted that the laboratory outreach purchase was the first part of a larger relationship between Labcorp and Tufts, which is an integrated academic health system. The lab outreach deal will lead to Tufts eliminating 574 jobs at three of its hospitals, noted *Becker's CFO Hospital Report*. It is expected most of those employees will transition to similar roles at Labcorp, the health system told *Becker's*.

Tufts is struggling financially. In February, **Fitch Ratings** downgraded the health system's issuer default rating—a measure of a company's vulnerability to default on financial obligations. "In FY22, [Tufts] lost $398.6 million on operations, which equated to a negative 17.6% operating margin," Fitch Ratings wrote. Fitch said much of that loss—$217 million—came from staffing costs, including hiring agency nurses. Hospitals and health systems experiencing financial losses are often motivated to sell their clinical laboratory outreach businesses to raise cash.

HIMSS Sells Its Conference to Informa

Informa, a content and live events company based in London, has purchased the **Healthcare Information and Management Systems Society's** (HIMSS) Global Health Conference and Exhibition.

More than 30,000 people attended this year's HIMSS conference. HIMMS will continue to develop the content for the conference, while Informa will take on the logistics of the show, executives from both companies said. Informa's resources in planning events around the world, such as internal technology and hotel partnerships, provided a strong component to the agreement.

"We're going to be able to leverage that for HIMSS to the fullest extent, to make sure that the experience of both the attendee and the exhibitor is enhanced because of the partnership that we have," Ken McAvoy, President of South Florida Ventures at **Informa Markets**, told *HIMSS TV*. Among the changes attendees can expect are new digital features and improved registration. McAvoy added that Informa could quickly expand the HIMSS trade show into other markets globally.

Sanford Bows Out of Fairview Merger

Sanford Health in Sioux Falls, South Dakota, has decided to drop plans to merge with **Fairview Health Services** in Minneapolis. The proposal received stiff opposition from officials at the **University of Minnesota**. Fairview owns the **University of Minnesota Medical Center**.

"Without support for this transaction from certain Minnesota stakeholders, we have determined it is in the best interest of Sanford Health to discontinue the merger process," said Bill Gassen, President and CEO at Sanford, in a statement on July 27.

The Dark Report noted that the proposal may have eventually led to consolidation of clinical laboratory services among the two systems. *(See TDR, "Laboratory Implications of Sanford/Fairview Merger," March 6, 2023.)* TDR

Digital Pathology Update

Digital Path Sales Put Gestalt on Inc. 5000's Fast Growth List

DIGITAL PATHOLOGY WORKFLOW PROVIDER **GESTALT DIAGNOSTICS** earned a place on the *Inc.* 5000 2023 list of the fastest growing private companies in America.

Rarely do companies in the clinical laboratory space grow fast enough to make the *Inc.* 5000 list. The 2023 compilation ranks companies on their growth from 2019 to 2022. Gestalt's sales growth offers a significant indicator about the increasing interest in digital pathology and whole-slide imaging technologies.

Gestalt's rapid revenue growth may surprise many lab professionals. The company seems to be quietly lining up large laboratory organizations as users. Not only does that produce revenue, but it shows that adoption of digital pathology is moving forward.

According to the *Inc.* 5000 ranking, Gestalt came in at No. 3835 after showing 122% growth during the measured three-year period. It was also the 223rd fastest-growing private company in the healthcare services sector, Gestalt stated.

Improved Cancer Diagnostics

Gestalt, based in Spokane, Washington, markets PathFlow, a digital platform that provides anatomic pathologists with automated workflow features, an image-management system, and a vendor-neutral viewer. Its open digital pathology technology integrates with image analysis software and artificial intelligence (AI) algorithms to improve turnaround time and accuracy for cancer diagnostics.

Among the organizations using PathFlow is **ARUP Laboratories** in Salt Lake City, Utah, and **BioReference Laboratories** in Elmwood Park, New Jersey. BioReference is a subsidiary of **OPKO Health**.

The 2022 partnership between BioReference and Gestalt allowed the lab to move to the latest generation of digital scanner and AI image analysis technologies. *(See TDR, "BioReference Labs to Use Gestalt for Digital Pathology," May 3, 2021.)*

Other Lab-Related Rankings

Other companies on the *Inc.* 5000 2023 list that do business in the clinical diagnostics area include:

- **PathologyWatch** in Murray, Utah (rank 386), an AI company focused on diagnostic research for skin cancer. The firm saw 1,500% growth over three years.
- **Mako Medical Laboratories** in Raleigh, North Carolina (rank 1,099), a full-service reference lab that experienced 537% growth over three years.
- **Tasso** in Seattle (rank 4,124) markets at-home blood-collection technology that is less painful than venipuncture or a finger prick. The company enjoyed 109% growth over three years.

The No. 1 fastest growing company on the *Inc.* 5000 list is also in the health services sector. **CareBridge** in Nashville, Tennessee, serves Medicaid patients with physical, intellectual, and developmental disabilities by using tablets to provide them and their families with 24/7 access to interdisciplinary clinical teams. The company grew an incredible 155,144% over three years.

To qualify for the *Inc.* 5000 Fastest Growing Companies list, companies must be based in the U.S., be privately held, and have earned minimum revenue of $100,000 in 2019 and $2 million in 2022. TDR

IVD Update

IVD Companies Launch New Assays, Analyzers, Automation

Quarterly earnings reports show COVID-19 test revenue continues its steep decline for IVD firms

STEEP DECLINES IN SARS-CoV-2 TEST REVENUE were reported by the top *in vitro* diagnostics (IVD) companies in Q2 2023 earnings compared to a year earlier. For some of those firms, the coronavirus testing drops equate to billions of dollars in lost revenue.

In response to the decreasing demand for COVID-19 testing, IVD manufactures are scrambling to emphasize other opportunities, including research and development of assays intended to close gaps in clinical laboratory testing menus. Company leaders want to keep their instruments—which ran full tilt performing COVID-19 tests—to be of continuing value to medical labs by introducing new molecular and point-of-care diagnostics.

"This is an interesting consequence of the pandemic," said Robert Michel, Editor-in-Chief of THE DARK REPORT. "Today, many labs have PCR instruments from three to five vendors, and labs are under pressure to reduce costs by pulling some some brands offline.

"To counter that possibility, IVD manufacturers are adding, for example, tests for a variety of infectious diseases, hoping labs will incorporate these assays to their in-house menu," Michel added.

New business initiatives also include introduction of mass spectrometers, clinical chemistry and immunochemistry systems, compact testing systems, and more. Here is a summary of financial results and recent launches by companies serving clinical laboratories.

ROCHE: Diagnostics Base Business Grows, COVID-19 Sales Drop

Roche Group in Basel, Switzerland, reported on six months of financial results, as compared to half year of 2022:

- Group sales were down 8% to 29.8 billion Swiss francs (CHF) (US$33.6 billion) from 32.3 billion CHF (US$36.5).
- Diagnostics division sales fell 28% to 7.1 billion CHF (US$8 billion) from 9.9 billion CHF (US$11.3 billion). However, excluding declining COVID-19 sales, diagnostics base business rose 6%.
- COVID-19 test product revenue of 400 million CHF (US$460 million) plummeted 87% from 3.1 billion CHF (US$3.5 billion).
- Core lab sales of 3.9 billion CHF ($US 4.4 billion) rose 1.5% from 3.8 billion CHF (US$4.3 billion).
- Molecular lab revenue of 1.1 billion CHF (US$1.2 billion) was down 45% from 2 billion CHF (US$2.1 billion).
- Pathology lab sales of 687 million CHF (US$790 million) increased 5.4% from 652 million CHF (US$750 million).

Regarding base business growth in laboratory diagnostics, the company stated, "The main contributors to growth were immunodiagnostics, particularly cardiac tests, and diagnostics solutions for clinical chemistry." As part of a presentation to financial analysts, Matthew Sause, Roche Diagnostics CEO, explained that the new

Cobas i601 analytical mass spectrometry unit and assay menu is designed to integrate into the Cobas clinical chemistry and immunochemistry system. Roche plans to launch it next year in Europe with 40 of 60 possible assays available. FDA clearance is anticipated in 2025, he added.

HOLOGIC®
The Science of Sure

HOLOGIC: Diagnostics Sales Fall 21%, Overall Company Revenue Stable

Hologic, based in Marlborough, Massachusetts, reported financial results for Q3 2023 as compared to the prior year period:

- Revenue decreased 1.8% to $984.4 million compared to $1 billion.
- Revenue, excluding COVID-19 testing, grew 18% to $918.9 million from $778.3 million.
- Diagnostics revenue declined 21.5% to $439.7 million from $560 million.
- Diagnostics revenue, without COVID-19 testing, was up 11.8% to $374.2 million from $335.7 million.

The company received FDA clearance for its Panther Fusion SARS-CoV-2/Influenza A/B/RSV assay.

Abbott
A Promise for Life

ABBOTT LABORATORIES: 'Good Recovery' as Routine Testing Rebounds

Abbott Laboratories in Abbott Park, Illinois, shared these Q2 2023 financial results as compared to a year earlier:

- Total sales fell 11.4% to $9.9 billion from $11.3 billion.
- Revenue, excluding COVID-19 test sales, was up 11.5%.
- COVID-19 testing revenue nosedived 89% to $263 million from $2.3 billion.
- Diagnostic sales fell 46% to $2.3 billion from $4.2 billion.
- Core laboratory sales were up 5% to $1.3 billion.
- Molecular sales dropped 33.4% to $141 million from $212 million.

"We have had a really, really good recovery as … we are seeing routine testing come back," said CEO Robert Ford during an earnings call with financial analysts and investors on July 20.

Ford shared with analysts Abbott's focus on research and development of assays that may not currently be on customers' test menus. "We've been working on expanding the menu in molecular and point-of-care," he noted. "One of the most exciting assays that the team has developed for point-of-care is a rapid test for traumatic brain injury."

In March, Abbott secured FDA clearance for a brain-injury blood test to run on the company's Alinity clinical laboratory analyzers.

ThermoFisher
SCIENTIFIC

THERMO FISHER: Q2 Revenue Down, Lab Revenue Up 5%

Thermo Fisher Scientific in Waltham, Massachusetts, shared shared these Q2 2023 results versus Q2 2022:

- Revenue declined 3% to $10.7 billion from $11 billion.
- Laboratory products and biopharmaceutical services revenue increased 5% to $5.8 billion from $5.5 billion.
- Life sciences revenue fell 25% to $2.5 billion from $3.3 billion.
- Analytical instruments revenue was up 6% to $1.7 billion from $1.6 billion.
- Specialty diagnostics revenue was flat at $1.1 billion.

THE DARK REPORT recently ranked Thermo Fisher the top IVD company by global revenue for 2022. *(See TDR, "2022 Ranking of the World's Top 12 IVD Corporations," July 31, 2022.)*

Following **U.S. Food and Drug Administration** (FDA) breakthrough designation and clearance, Thermo Fisher launched testing to assess a mother's risk of developing severe preeclampsia during pregnancy, commented CEO Marc Casper during an earnings call on July 26. The immunoassays report gives results in 30 minutes.

Also, Casper called Thermo Fisher Scientific's new Orbitrap Astral mass spectrometer a "significant advancement in mass spectrometry."

During the call's Q&A session, Casper noted the expected effects on business from cautious customers who face financial pressures from an uncertain global economy and higher interest rates.

"We think the customer will be a little bit more muted in spending," Casper continued. "It's really not pinned to one area, but just a spread across the portfolio—probably with instruments feeling the most impact."

QuidelOrtho

QUIDELORTHO: Order Backlog for Lab Instruments Down by 40%

QuidelOrtho in San Diego reported Q2 data as compared to Q2 2022:

- Revenue of $665.1 million increased 8% from $613.4 million.
- Lab revenue of $361.4 million was up 5.7% from $342 million.
- Point-of-care revenue of $134.2 revenue plunged 63.4% from $367 million.
- Molecular diagnostics revenue plummeted 70% to $6.2 million from $20.7 million.

QuidelOrtho was able to put a serious dent in its backlog of orders for lab instruments, said CEO Douglas Bryant during an earnings call on Aug. 9.

"Instrument demand remained healthy across all regions," Bryant noted. "Focused execution by our operations team enabled us to produce nearly 10% more instruments than our record-breaking first quarter and reduced our instrument backlog in our labs business by approximately 40%. These efforts enabled us to ship more instruments than previously anticipated in the quarter."

The launch of the Savanna molecular platform will be a high priority once FDA clearance is received, Bryant said. The initial test menu in the U.S. will include panels for respiratory viruses, herpes simplex virus, and varicella zoster virus.

BD

BECTON, DICKINSON AND COMPANY: Life Sciences Down 6.3%, More Molecular Tests Planned

Becton, Dickinson and Company (BD) in Franklin Lakes, New Jersey, reported these Q3 revenues:

- Revenue increased 5% to $4.9 billion from $4.6 billion year over year.
- Life sciences (including integrated diagnostics and biosciences business units) dropped 6.3% to $1.2 billion from $1.3 billion.
- Revenue from base business grew 6.7% to $4.8 billion from $4.5 billion.

During an earnings call on Aug. 4, CEO Thomas Polen highlighted the opportunity for the company's molecular diagnostic testing system, BD COR. "Overall, BD COR enables entry into the high-volume molecular diagnostics segment, which is expected to grow at a 9% [compound annual growth rate] to a $2.9 billion served marketplace by 2025," Polen said.

"With COVID being a more endemic condition, we continue to expand our offering. We have launched multiple respiratory panels on both BD COR and BD MX for detection of multiple respiratory pathogens from one sample," he added.

Also, in May the company received FDA clearance for the new BD Kiestra

MRSA imaging application, which uses artificial intelligence to interpret bacterial growth from methicillin-resistant Staphylococcus aureus.

QIAGEN: NON-COVID-19 TESTING REVENUE JUMPS 8%

Qiagen, headquartered in Venlo, Netherlands, reported Q2 financial results as compared Q2 2022:

- Sales of $495 million, a decrease of 4% from $516 million.
- Sales, without COVID-19 testing, went up 8% to $457 million.
- Instrument sales of $60 million, a decrease of 4% from $63 million.
- Molecular diagnostics sales of $260 million were up 2% from $255 million.
- Life sciences sales of $235 million were down 10% from $261 million.

Genomics and next-generation sequencing product sales rose by 12% year over year in Q2, the company reported.

SIEMENS HEALTHINEERS: Diagnostics Revenue Falls 23%, More Emphasis on Atellica

Siemens Healthineers in Erlangen, Germany, noted these results for its Q3, as compared to Q3 2022:

- Revenue was flat at €5.2 billion (US$5.6 billion) year over year.
- Revenue, excluding COVID-19 testing, grew 10%.
- Diagnostics revenue dropped 23% to €1 billion (US$1.09 billion) from €1.4 billion (US$1.5 billion).
- Diagnostics revenue, without rapid antigen testing, grew 2%.

COVID-19 testing sales appeared to have bottomed out at Siemens Healthineers, as the company reported that "no appreciable revenues were booked in the third quarter" for rapid antigen testing.

In July, the Atellica CI Analyzer for immunoassay and clinical chemistry received FDA clearance after delays. The new analyzer automates sample preparation and workflows in lower-to-mid-volume labs.

As part of the overall focus on the Atellica brand, Siemens is sunsetting some legacy analyzers. Sharon Bracken, Head of Diagnostics at the company, told *GenomeWeb* in May that the ADVIA Centaur, ADVIA Chemistry, and Dimension lines are reaching end-of-life stage.

DANAHER: Diagnostics Sales Down 13%, New Tests From Cepheid

Danaher in Washington, D.C.—parent company of **Beckman Coulter Diagnostics**, **Cepheid**, and **Leica Biosystems**—announced these Q2 results as compared to the prior year period:

- Revenue was down 7.5% to $7.2 billion from $7.7 billion.
- Base business, without COVID-19 testing declines, grew 2%.
- Diagnostics division sales fell 13% to $2.2 billion from $2.6 billion.
- Life sciences revenue was up 5% to $1.8 billion from $1.7 billion.

Cepheid, which sells molecular diagnostics systems, had $300 million in Q2 respiratory testing revenue—$125 million more than the company projected. The results were due to "high volumes and a preference for our four-in-one test for COVID-19, Flu A, Flu B, and RSV [respiratory syncytial virus]," said Danaher CEO Rainer Blair during an earnings call on July 25.

"With COVID-19 now in endemic state, we believe Cepheid is continuing to take share as many customers look to

consolidate their point-of-care and PCR testing platforms onto the [Cepheid] GeneXpert for both respiratory and non-respiratory testing," Blair said.

Meanwhile, in Q2 Beckman Coulter introduced the Dxl Access 9000 immunoassay analyzer. "The Dxl 9000 will enable Beckman to provide a full menu of blood virus assays over time, closing an important menu gap and further enhancing the breadth and clinical value of our test menu," Blair told analysts.

Blair added that despite the drop quarter over quarter, core diagnostics performance (i.e., non-COVID-19 revenue) was welcome news. "Our clinical diagnostics businesses collectively delivered mid-single-digit core revenue growth," he explained. "Leica Biosystems led the way with high single-digit core growth driven by strength in core histology and advanced staining. Beckman Coulter Diagnostics was up mid-single digits again this quarter, with solid performance across both instruments and consumables and notable strength in immunoassay."

SYSMEX CORPORATION: Sales Up More than 10%, Offers Alzheimer's Test

Sysmex, with headquarters in Hyōgo, Japan, reported financial results for Q1 FY 2024 ending June 30 as compared to the prior year period:

- Sales were up 10.8% to ¥95.3 billion yen (US$660 million).
- Sales in the Americas were up 17% to ¥27 billion (US$187 million) from ¥23 billion (US$160 million).

In Japan, the company recently launched a clinical flow cytometry system, which optically analyzes microscopic particles. Also in Japan, Sysmex now markets an assay kit to identify amyloid beta accumulation in the brain—a cause of Alzheimer's disease—using a small amount of blood.

BIO-RAD LABORATORIES: Clinical Diagnostics Revenue Up 3.3%

Bio-Rad Laboratories, in Hercules, California, shared these Q2 2023 financial results as compared to Q2 2022:

- Sales were down 1.4% to $681.1 million from $691.1 million.
- Clinical diagnostics segment revenue was up 3.3% to $380 million.
- COVID-19 sales were $0.4 million, plunging from $33 million.
- Life science segment revenue of $300.2 million was down 6.9%.

A demand for diabetes testing systems and blood typing drove an increase in clinical diagnostics sales, while Droplet Digital PCR and quantitative PCR products were credited with the non-COVID-19 uptick in life science segment revenue, Bio-Rad reported.

"During the second quarter, we significantly reduced the backlog of customer orders in our life science business, and we remain on track to work down slightly elevated back orders in clinical diagnostics during the remainder of this year," CEO Norman Schwartz said.

In July, Bio-Rad and Qiagen announced that they had settled a patent dispute pending in the **U.S. District Court of Delaware** related to digital PCR technology. The settlement provides for a cross-licensing agreement between the firms, granting each company mutual rights to their respective technologies. No other details were provided. TDR

Editor's note: At press time, bioMérieux in Marcy-l'Étoile, France did not have Q2 financials available.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

New research about ownership of physician practices will be of interest to anatomic pathologists who operate their own businesses. According to an analysis by the **American Medical Association** (AMA), "Physicians are less likely to work in a private practice [today] than 10 years ago due to economic, administrative, and regulatory burdens that have driven physicians to shift traditional business models for medical practices." THE DARK REPORT has previously noted that many private pathology groups, particularly smaller ones, have struggled to stay ahead in the areas of technology and recruitment while also trying to protect pathologists' compensation

MORE ON: *Practice Ownership Changes*

The AMA study pointed out that the proportion of physicians working in larger practice settings continues to expand. From 2012 to 2022, "the percentage of physicians in practices with 10 or fewer physicians fell from 61.4% in 2012 to 51.8% in 2022," according to the AMA research. "In comparison, the percentage in practices with 50 or more physicians grew from 12.2% to 18.3%."

MEAN SALARY FOR PATHOLOGISTS IS ALMOST $253K

Recently updated numbers from the **U.S. Bureau of Labor Statistics** indicated that as of May 2022—the latest data available—the mean salary for anatomic pathologists in the country was $252,850. Labor Department data shows that there is much regional disparity in pathologist compensation. Among the highest paying metropolitan areas for pathologists were Des Moines, Iowa ($452,850 mean); Rochester, Minnesota ($381,890 mean); Little Rock, Arkansas ($381,620); and Milwaukee ($362,730).

TRANSITIONS

- Alastair Dunnett has been named new Senior Director of the Department of Pathology at **Banner Health** in Tucson, Arizona. Previously, he held lab director positions at **Carle Foundation Hospital** in Urbana, Illinois; **Lutheran Hospital** in Fort Wayne, Indiana; and **Seton Family of Hospitals** in Austin, Texas.

- **Caris Life Sciences** has named Gerry Velasco as National Director of Precision Medicine Initiatives at its Philadelphia location. He previously held many roles at **QuidelOrtho** based in San Diego and its predecessor **Ortho Clinical Diagnostics**, mostly recently in the ValuMetrix Services Group.

- **American Oncology Network** in Fort Myers, Florida, announced Ryan Olson, MD, as Medical Director of the Pathology Laboratory. He was previously with **Florida Cancer Specialists & Research Institute** in Fort Myers.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 11, 2023.

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