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Coming on August 1!

UnitedHealthcare to require Z-codes for molecular tests

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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

For Labs, a Little Angel and Devil Sit Behind Z-Codes

MUCH LIES UNDERNEATH THE SURFACE of **UnitedHealthcare's** (UHC) new policy mandating Z-code use for molecular tests covered under its commercial health plans. It's a development that creates headaches for many genetic testing companies.

As we explain in our lead story starting on page 3, as of Aug. 1, UHC will require Z-codes for molecular tests that use one of the 245 CPT codes in Wave 1 of this new policy's implementation. A source close to the situation described to us a scenario where UHC might be viewed as having a little angel and a little devil sitting on its shoulders.

Publicly, UHC—and any other large commercial payers following suit—can highlight the good it does for the diagnostics industry by requiring the use of Z-codes to capture specific biomarkers in molecular tests.

After all, THE DARK REPORT has chronicled over the years how fee-for-service payment can incentivize genetic testing companies to add dozens of medically unnecessary markers to panels, all to increase the price they submit on their test claim. Z-codes consider the clinical utility of a biomarker, and from that perspective, requiring these codes might stave off dishonest labs looking to defraud payers and **Medicare**. That is the angel on one shoulder.

On the other hand, UHC's move to require Z-codes also has an unspoken financial motive. An ever-growing roster of genetic tests—175,000 options at last count—has resulted in associated claims skyrocketing over the last decade. Were UHC to use its Z-code requirement as a hurdle that causes some genetic testing labs to submit fewer valid test claims, it would pay out less in medical expense claims. That is the devil on the other shoulder.

"It's a big cost savings," our source noted. "Take the example of a lab that tests five genes in the same panel, but there's only clinical utility for two genes. The data behind the Z-code for that test can be used by the payer to argue that medical necessity for the patient means the test panel should be reimbursed as a two-gene, $200 test, not a five-gene, $500 test."

Use of Z-code requirements by private payers like UnitedHealthcare can create the conflicting outcomes described above. The angel on a payer's shoulder looks to see that medically unnecessary genetic tests claims are denied, even as the devil on the other shoulder may prod a payer to institute restrictions that cause medically necessary test claims to be rejected and go unpaid. TDR

UHC's Z-Code Requirement to Commence on August 1

'Wave one' of the implementation specifies Z-codes to be required for almost 250 CPT codes

Clarisa Blattner

CEO SUMMARY: In what may be an alarming development for certain clinical laboratories, as of Aug. 1 UnitedHealthcare will require Z-codes for molecular test claims filed under its commercial health plans. Labs unfamiliar with Z-codes have only a short window of time to register for the codes and collect needed clinical data to support accuracy and utility.

ONE OF THE NATION'S LARGEST PRIVATE PAYERS HAS SET AN AUG. 1 DEADLINE for clinical laboratories to begin using Z-codes for patients covered under commercial health plans.

The announcement presents a challenge—and perhaps even a seismic shift—for some clinical laboratories that perform genetic testing.

The move by **UnitedHealthcare** (UHC) in Minnetonka, Minnesota, will greatly expand the need to use Z-codes, as the payer's private commercial and individual plans cover 24.7 million people. In total, UHC covers nearly 46 million people.

For laboratories that are not already using Z-codes as required for certain **Medicare** Advantage claims, UHC's announcement may result in a steady stream of test claim denials.

"There's trouble on the road ahead for those labs," said a source close to the situation who requested anonymity to speak with THE DARK REPORT.

Z-codes are five-digit, alpha-numeric identifiers that are assigned to unique molecular assays that are performed by a particular lab. The codes identify molecular test components, which can vary greatly by lab.

"Beginning Aug. 1, 2023, UnitedHealthcare commercial plans will require DEX Z-codes for molecular diagnostic test services on facility and professional claims for the claims to be considered for reimbursement," UHC stated in an email to providers.

DEX refers to the Diagnostic Exchange, a molecular test identification system established by **Palmetto GBA**, the Medicare Administrative Contractor

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(MAC) based in Columbia, South Carolina. *(See the sidebar on page 6 for more about the origins of Z-codes.)*

DEX's website also noted the UHC announcement. "Providing the Z-code on a claim, with the appropriate CPT code, will clearly identify the test being performed and eliminate some of the administrative burden you may encounter surrounding billing for these services," according to the DEX notice.

Relevance of the Change

Clinical laboratories seeking coverage for genetic tests under UnitedHealthcare commercial plans must apply for Z-codes through DEX. Nearly 250 Current Procedural Terminology (CPT) codes make up the initial "wave one" of Z-code registration.

The source told The Dark Report that without Z-codes after Aug. 1, many genetic tests will be outright denied by UnitedHealthcare.

"After that date, labs will first get what's called a SMART edit, which will say the claim is missing a Z-code," the source explained. "Labs only have 48 hours to clean that up. But if, after August 1, they don't have their Z-code yet and they've been waiting eight weeks, they can't clean up the claim.

"My big concern is for the molecular and genetic testing companies that don't have the staff to keep up with these payer bulletins or that aren't even getting these bulletins," the source continued. "These labs will get flat denials."

Clarisa Blattner, Senior Director of MDx Support Services at **XiFin**, a revenue cycle management company in San Diego, struck a milder tone to the news. In talking recently to an executive at Palmetto GBA's Molecular Diagnostic Services (MolDX) Program, it appears that labs already using Z-codes for Medicare Advantage plans may not need to file a separate request for any new private payer policies.

"It's likely that if your lab already has a Z-code for the MolDX program, you may be able to repurpose that same Z-code for the UnitedHealthcare program as well," Blattner said.

"However, for those molecular lab companies that are not participating in the MolDX program, the UHC announcement is going be something new for them," she added. "They will need to register their molecular tests on the Diagnostic Exchange and go through that Z-code registration process. The registration may be alarming for those labs just because they haven't had to do so before."

Briefly, labs new to the Z-code process can go to *app.dexzcodes.com/login* to create an account and begin registration for a molecular test, Blattner said.

From there, account administrators will be guided through a test worksheet that asks for data about a test, including its use, indications for ordering, limitations, and test methodology. It takes about two weeks to either receive a Z-code assignment or a request back for more information. If more data is needed, that can draw out the time it takes to get a Z-code.

Blattner suggested that labs with questions about the registration process write to this email address: *DEX.Customer.Service@palmettogba.com*.

"Ask questions early on," she advised. "DEX is really good about responding within 24 to 48 hours if a lab has questions about the requirements or the worksheet."

Comparing Genetic Test Panels

There is an overwhelming amount of molecular and genetic tests on the market. The Dark Report has previously noted that **Concert Genetics** in Nashville, Tennessee, tracks about 175,000 genetic tests. *(See TDR, "With 175,000 Genetic Tests Available, Payers Struggle to Manage Utilization," Aug. 8, 2022.)*

At the core of the Z-code requirements is the stance among participating MACs

Might Z-Codes Untangle Payers' Gordian Knot of Increased Number, Volume of Genetic Tests

UNITEDHEALTHCARE'S DECISION TO BEGIN REQUIRING Z-CODES sets the clinical laboratory industry down a new path. As one of the nation's largest health insurers, its coverage and pricing policies are often replicated by other health plans.

For this reason, clinical labs and genetic testing companies will want to monitor how quickly other national and regional health plans implement similar Z-code requirements for molecular tests.

All health plans—from Medicare and Medicaid to private payers—are struggling to cope with an ongoing and ever-growing tsunami of molecular test claims. This tsunami challenges payers in two ways.

First is the incredibly swift growth in the number of unique genetic assays offered by the nation's clinical laboratories. As recently as 2010, there were probably no more than several thousand unique genetic assays. Today, companies tracking this market segment can identify more than 175,000 such tests—with the number climbing monthly. This is one dimension of the genetic test claim tsunami overwhelming health plans today.

Second is the appropriateness of a substantial proportion of these genetic test claims. Payers struggle to understand the answers to these these questions:

- Is this genetic test medically necessary for the patient? (Another factor is if the genetic test includes dozens or hundreds of biomarkers unrelated to the physician's question about the patient.)
- Does this genetic test accurately measure its biomarkers (clinical accuracy)?
- Will the doctor use the genetic test results in ways that benefit the patient (clinical utility)?

There is also another, third dimension that is problematic for payers. Molecular test claims are submitted in large numbers for a range of rare diseases. These are obviously medically unnecessary and probably meet the definition of fraud.

All of these issues were recognized years ago because the CPT coding system was never designed to appropriately classify molecular tests. This problem will intensify as more diagnostic assays come to market that are built on not just genomics and proteomics, but metabolomics and microbiomics, for example.

Birth of Z-Codes

Back in the early 2010s, the need to answer these questions motivated Palmetto GBA, a Medicare Administrative Contractor (MAC), to work with **McKesson Corporation** to develop Z-codes, now administered by Palmetto's Diagnostic Exchange (DEX).

Clinical laboratory executives and pathologists should expect to see UnitedHealthcare use the Z-code requirement in combination with prior-authorization requirements and its preferred laboratory network. The payer will use this combination of tools to better understand which molecular test claims meet clinical accuracy, clinical utility, and medical necessity.

and payers that genetic tests for similar conditions often have varying numbers of biomarkers depending on the lab performing the test.

Popular non-invasive prenatal testing (NIPT) offers a good example of this dilemma. One lab offering NIPT may have 10 biomarkers, while another may have 100. This variation creates confusion and costs for payers trying to wade through the claims and determine both the clinical utility of a molecular test and whether some biomarkers in the test may be medically unnecessary for the patient's health condition.

To that point, experts say it's likely that many biomarkers in NIPT are irrelevant for most pregnant women, thus raising the question of whether a given NIPT panel from a particular lab is truly medically necessary.

Pass Technical Assessment

"Some smaller genetic testing companies—even though they're trying to do the right thing—don't have much data to support accuracy and clinical utility for a molecular test," the source told THE DARK REPORT. "They may not pass their technical assessment with MolDX; therefore, they will not get a Z-code. For smaller labs that don't have the data, the UHC policy change might squeeze them out of the market."

By requiring Z-codes, payers are also trying to avert fraudulent claims, Blattner noted. "A Z-code provides more transparency and clarity for the payer," she observed. "Payers want to determine what's being performed in a test by attaching that Z-code identifier. As part of that effort, payers are trying to weed out certain panels that may be medically unnecessary."

Blattner and the source who spoke to THE DARK REPORT agreed that other large payers will likely follow UnitedHealthcare's lead in eventually requiring Z-codes for genetic tests under commercial health plans.

Medicare Advantage

It should be noted that UnitedHealthcare previously issued policies requiring Z-codes for claims submitted to its Medicare Advantage plans. The decision to expand those policies to its commercial and private health plans creates more uniformity in its policies governing molecular tests.

Given the history of private health insurers at managing utilization and using claims denials as a way to avoid paying for a clinical service, critics will look at UHC's Z-code policy as having elements of that objective. At the same time, these critics should acknowledge that molecular and genetic test claims submitted with multiple CPT codes make it impossible for any health plan to have confidence that the clinical service benefits the patients and is a legitimate test claim. After all, it is the patient who should benefit from any clinical service including a genetic test. TDR

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Z-Code History Reflects Genetic Test Complexity

IN LATE 2011, the **Centers for Medicare and Medicaid Services** (CMS) asked Palmetto GBA to establish a standardized molecular test registration and coverage-determination process for Medicare claims through its Molecular Diagnostic Services (MolDX) Program.

From that directive emerged Z-codes—five-digit, alphanumeric identifiers assigned to individual molecular test components and associated with a Current Procedural Terminology (CPT) code.

Prior to Z-codes, it was difficult for CMS and other payers to determine what an assay actually performed because genetic test complexity and volume had increased rapidly.

The initial years of the program's rollout were bumpy. For example, during the first four months of 2013, few labs reported getting any payments from Medicare for lab test claims involving the new molecular codes. But later that year, payments increased.

By 2015, when the registry was in full swing, THE DARK REPORT noted the benefits to laboratories.

"It seems that the MolDX program and use of the Z-code system has played a role in improving how quickly some health plans pay for genetic and molecular tests," we reported. *(See TDR, "Some Labs Report Faster Pay for Molecular, Genetic Tests via New CPT Code Reimbursement Program," June 1, 2015.)*

Data Analytics Improves Lab Productivity, TAT

MultiCare Health sees $4M in cost reduction after gaining greater access to its diagnostic data

Zac Zahara

Jennifer Maxwell

***CEO SUMMARY:** An increased ability to analyze internal diagnostic data helped MultiCare Health System improve laboratory test turnaround times in real time and more efficiently staff its locations on a day-to-day basis. The data analysis tools also provided insights into the performance of MultiCare's lab outreach sales teams.*

Faced with a growing need to objectively study staffing levels given limited employee numbers—while also fighting a misperception about test turnaround times (TAT)—the clinical laboratory at **MultiCare Health System** in Tacoma, Washington, turned to data analytics for help.

"Labs generally have a lack of accessible, real-time data," said Zac Zahara, Chief Operations Officer for System Lab Services at MultiCare. "Most health systems do an amazing job of finding data or purchasing cool tools that look at productivity. But the problem is these tools typically can't account for the activities of a lab because those activities are so varied."

MultiCare's lab found success in its use of analytics to assess staffing needs—actual versus potential—by taking two broad approaches:

- Partnering with a technology company that understood the lab's challenges.
- Disseminating lab data to a large swath of employees in the health system.

Zahara spoke at the *Executive War College for Diagnostics, Clinical Laboratory, and Pathology Management* in April in New Orleans. His session was titled, "Leveraging Real-Time Operational Lab Data across Multiple Hospitals to Track Workflow, Staff Productivity, and Manage How Physician Clients Benefit from Lab Testing."

Dozens of Testing Sites

MultiCare has 12 hospitals and 240 primary and specialty care clinics across Washington. The not-for-profit system earned $3.8 billion in revenue in 2021.

Its lab services operate under the **Laboratories Northwest** brand. MultiCare performs 12.5 million tests annually at 12 hospital labs, one large physician office lab, six freestanding patient service centers, and 51 in-office phlebotomy sites.

"Three years ago, my work partner and I came in to MultiCare, and we were tasked with several huge endeavors involving our laboratory system," Zahara recalled. "We immediately thought we should put a vision in place to be our guiding North Star as we embarked on some of this work."

The goal was for Laboratories Northwest to be the highest value clinical lab in the Pacific Northwest. This would be based on three tenets: productive people, high test quality, and reasonable costs.

"There's typically a huge opportunity if labs can work with data associated with tests," Zahara said. "It is important to be able to understand what labs bring to the table. The lab needs to know its worth. And that's something I think most health system administrators really don't know."

To accomplish this goal, Zahara worked with laboratory insights company **hc1** in Indianapolis to help aggregate, analyze, and present data to bench staff, lab leaders, and hospital/health system executives. A secure, cloud-based platform from hc1 ingests data from laboratory information systems and evaluates the numbers.

"As a result of our efforts, our clinical laboratory achieved a $4 million year-over-year expense reduction," Zahara said. "Equally important, our lab's use of agency staff across the system was reduced by 75% over the past year."

Data Tracks Turnaround Time

MultiCare's lab employees identified accurate turnaround time (TAT) monitoring as a strong need. "The lab wanted a way to show the hospitals and clients that it was providing service aligned with the agreements in place," Zahara said. "Many labs experience calls from the ED stating that the 'Tests aren't coming back in time.'

"So, the laboratory asks for a preanalytics report, which might take a few days to a week to obtain," he added. "By the time the lab gets the report and analyzes it, nine times out of 10, the problem is with the preanalytics in the ED, not with the lab itself. But by that point, the ED has moved on to the next issue and the perception is already out there that the lab is not meeting the ED's needs."

The preanalytics phase—which includes obtaining a diagnostic specimen, labeling it with the patient's identification, and transporting it to the lab for processing—is prone to errors, according to a study presented in the July 28, 2022, issue of the journal *Medicine*.

"The preanalytical phase has a significant impact on the quality of laboratory results," *Medicine* reported. "The rate of error in the study was high, and the leading causes were nonreceived samples and hemolysis."

Real-Time Information Access

With hc1's platform, MultiCare's laboratory team can see:

- When TAT is high on a given day and how that rate compares to the target TAT.
- Average TAT by location, such as an ED in a specific hospital.
- Average test orders per day and average orders per hour compared to a historical baseline.

"Having turnaround time data at our lab managers' fingertips has been a game changer," Zahara noted. "Our labs are doing well. They meet turnaround time needs overall. Many turnaround time problems are in the preanalytical phase, which is nothing new.

"Data that the laboratory had before we implemented our real-time analytics solution typically looked back a month or more," he continued. "In that situation, when looking at turnaround times a month back, it takes months to make a needed change. However, with real-time data, my team pulls metrics for each campus. Those lab leaders put this information on huddle boards every day. Instead of months, we now implement changes in just a few days."

One example involves the challenge of reducing early morning blood draws of inpatients, while still meeting to goal of increasing blood draws performed before 8 a.m.

"The data shows a reduction in blood draws prior to 5 a.m. and 6 a.m. MultiCare

realized draws during those hours were not useful for patients because clinicians were waking the patients early," noted Jennifer Maxwell, Executive Director of Client Success at hc1. Maxwell also spoke at the *Executive War College*.

Insights into Staffing

The data about TAT and busy days and times for tests has helped MultiCare adjust lab staffing during what is a tough period across the country for employee recruitment and retention in the clinical laboratory industry.

"Our labs have different numbers of people at each location. We have different test menus," Zahara said. "Our CFOs want the labs to look at this in real time. If the labs are not seeing testing volumes today that they saw yesterday or even last week, we're sending staff home. That's where we are financially. So, it's important that the labs have access to this information. The labs can't use the same tools that the MultiCare system uses because it's just not accurate. So, the hc1 tool has been helpful."

Knowing this information allowed MultiCare to place staff more efficiently where it was needed on a day-to-day basis and cut back on contract staff, which saved money.

Lab Outreach Analyses

Another staff productivity concern on which hc1 was able to shine more light was laboratory outreach efforts. By analyzing data, the platform provides insight into different approaches sales teams use to contact lab outreach prospects.

"What are outreach sales teams doing to go out and get business?" Maxwell asked. "Is it emails, in-person meetings, or web meetings? Based on the data, lab leaders might say, 'Hey, emails aren't working, sales reps need to pick up the phone or stop by a prospect's office.' We have a report that gives us a quick snapshot."

For Zahara, lab outreach insight is another niche benefit of the platform.

What's Next for MultiCare's Labs?

COMING ON THE HORIZON for MultiCare Health System's laboratories is the hope to connect lab data to software from **UKG** (formerly known as **Kronos**) for HR and workforce management.

In April, hc1 announced it was seeking beta adopters for a new product called Workforce Optimization that would combine lab-based data with timekeeping data from platforms such as UKG's. The goal is to improve lab staffing efficiency.

"We want to automate our Kronos information so that the lab's productivity report will be that much more powerful," said Zac Zahara, Chief Operations Officer for System Lab Services at MultiCare. "Currently, the lab can't use Kronos' scheduling tool because the way the lab schedules staff is so different from the rest of the hospital.

"For example, I look at a testing location that has 'X' number of staff and maybe wonder why it has so many staff," Zahara explained. "Right now, it's hard for me to dig into that until the location shows me its business reviews every month. But I want that data now."

MultiCare is working with hc1 to explore these options.

"I didn't have access to MultiCare's **Salesforce** account. I probably could have if I wanted it, but the key here is hc1's platform is lab focused," he explained. "I can now drive change. That has been a huge difference to how our outreach client services team operates."

Zahara praised hc1's team for responding quickly to requests from the labs for new dashboards or data needs. "Your mind is the limit on the reports or dashboards you might want to see," he said.

On the other hand, Zahara lamented the amount of time it took to get his lab team to adopt and use the new data

technology. He said pandemic fatigue was likely part of the reason.

"Lab staff felt like this implementation was another thing leaders were asking them to do at a time when they had very limited resources and many of them were working the bench," he observed.

Data Influences Operations

"Lab leadership had to take the time one on one with employees to show them how to use the tool and how it was going to make their lives simpler," he added. "We also had to mandate that they use this tool to communicate with hospital partners and to create monthly business reports to leadership. It took more time to adopt than I would have liked."

Nonetheless, Zahara said that access to data is an improvement for overall laboratory operations. It has also helped better engage laboratory workers, some of whom gravitated to data-based projects, he added.

"Some of the lab's IT-minded folks have taken it upon themselves to dig in and get engaged with this tool," he concluded. "They've started projects without me even having to ask them. All in all, this has been a cool transition."

At a time when clinical labs and pathology groups are under intense pressure to trim costs and improve productivity, the success of the MultiCare lab team in using real-time data to generate $4 million in cost savings is notable.

It affirms that even well-run labs have opportunities to further cut expenses while protecting quality and service levels. MultiCare's experience and success offers two important learnings for other labs:

- The ability to harness internal diagnostic data can have a powerful influence on how a lab operates its day-to-day business.
- Analytics software can more easily allow labs to assign value to their data, such as through cost savings and improved staff productivity. TDR

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UnitedHealthcare Policy Change Requires NPI Numbers on Medicare Advantage Claims

ANOTHER NEW POLICY RECENTLY ANNOUNCED by UnitedHealthcare (UHC) sets a deadline for June 1, 2023, requiring clinical laboratories and other ancillary providers to include the ordering physician's National Provider Identifier (NPI) for UHC's Medicare Advantage plans.

UHC published this change in its May 2023 Medicare Advantage Reimbursement Policy Update Bulletin as follows:

> *Effective with date of service June 1, 2023, UnitedHealthcare Medicare Advantage will align with the Centers for Medicare and Medicaid Services (CMS) requirement that the ordering/referring provider be identified on all claims initiated by orders or referrals.*
>
> *In accordance with CMS Medicare Claims Processing Manual Chapter 1-General Billing Requirements, all claims billed by Clinical Laboratories, Imaging Centers, DME Suppliers, and Home Health Agencies must include the ordering or referring provider name and matching National Provider Identified (NPI).*

Because this policy aligns with Medicare's existing policy for including both the ordering physician's and NPI number, this should not be an issue for those clinical laboratories and anatomic pathology groups currently submitting lab test claims to UHC's Medicare Advantage Plans.

CLIA Lab Accreditors Reveal Most Frequent Deficiencies

Lapses in competency assessments prove to be a common theme among the four accrediting groups

CEO SUMMARY: CAP, The Joint Commission, COLA, and A2LA took the stage at the recent Executive War College to detail their respective lists of the 10 most often-cited standards during their labs inspections in 2022. In presenting these citation rundowns, several common deficiencies repeatedly appeared. These include incomplete assessments of employee competency, inadequate proficiency testing, and unmet laboratory director duties.

ONCE AGAIN, the four major clinical laboratory CLIA accreditation organizations gathered at last month's *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management* in New Orleans to present their lists of top citations in 2022.

The popular panel discussion was chaired by Nora Hess, Senior Consultant, **Accumen**. Participating CLIA accreditors included:

- **American Association for Laboratory Accreditation** (A2LA)
- **COLA**
- **College of American Pathologists** (CAP)
- **The Joint Commission** (TJC)

Citations Show Problems

The most frequently cited standards for each group appear on pages 12-13.

A review of the deficiencies most commonly identified during CLIA lab inspections during 2022 provides lab compliance officers with a highly useful road map to use in preparing their respective clinical labs and pathology groups for their next CLIA inspection.

Representatives from the four accreditors took the podium to explain their lists of citations and to address other relevant aspects of CLIA inspections. The most common citations appearing in the four lists were:

- Failure to assess various aspects of employee competency (No. 1 citations for A2LA, CAP, and COLA).
- Lack of adequate proficiency testing activities (No. 1 citation for TJC).
- Subpar lab procedure manuals.
- Overlooked laboratory director duties.

A lack of proper documentation plays a part in many of the citations as well.

"A lot of us [accreditors] get frustrated that year after year we see competency assessment appear somewhere in the top citations," said Kathy Nucifora, MPH, MT(ASCP), Chief Operating Officer at COLA, during the *Executive War College*.

In future issues, THE DARK REPORT will provide a series of "Inspection Readiness" briefings to provide further insights into the common citations, along with strategies to address these problems.

The goal of this special series is to give senior lab leadership and lab compliance officers both the knowledge and the confidence that their clinical laboratories and anatomic pathology groups are prepared for a successful CLIA inspection. TDR

Four CLIA Accreditors Identify Their Top Ten Lists of Deficiencies

COLLEGE of AMERICAN PATHOLOGISTS

The Joint Commission

A2LA

COLA

College of American Pathologists:
Most Frequent Citations in 2022

1. **GEN.55500 (Laboratory General Checklist)—** The competency of personnel performing nonwaived testing is assessed at the required frequency at the laboratory where testing is performed.
2. **COM.04250 (All Common Checklist)—** Comparability of Instruments and Methods – Nonwaived Testing
3. **COM.01200—**The laboratory's current CAP Activity Menu accurately reflects the testing performed.
4. **COM.10000—**A complete procedure manual is available in a paper-based, electronic, or web-based format at the workbench or in the work area.
5. **COM.01700—**Ongoing evaluation of proficiency testing/external quality assessment and alternative assessment results with appropriate corrective action are taken for each unacceptable result.
6. **COM.30600—**Appropriate maintenance and function checks are performed and records maintained for all instruments and equipment following a defined schedule, at least as frequent as specified by the manufacturer.
7. **COM.04200—**Instrument/equipment maintenance and function check records are reviewed and assessed at least monthly by the laboratory director or designee.
8. **COM.01400—**The proficiency testing/external quality assessment attestation statement is signed by the laboratory director or designee and all individuals involved in the testing process.
9. **COM.30750—**Temperatures are checked and recorded each day of use for all temperature-dependent equipment and environments using a calibrated thermometer.
10. **GEN.20450—**The laboratory follows a written policy for the management and correction of laboratory records, including quality control data, temperature logs, and intermediate test results or worksheets.

The Joint Commission:
Most Frequent Citations in 2022

1. **QSA.01.02.01 (Quality System Assessment for Nonwaived Testing), Element of Performance (EP) 2—**The laboratory investigates causes, provides evidence of review, and performs corrective action for the following: unacceptable proficiency testing (PT) results, late submission of PT results, and nonparticipation in a PT event.
2. **QSA.02.08.01, EP 2—**The laboratory performs and documents correlations at least once every six months.
3. **QSA.02.11.01, EP 7—**The laboratory performs and documents the review of other records (e.g., quality control summaries) at a frequency defined by the laboratory, but at least monthly.
4. **HR.01.06.01 (Human Resources), EP 18—** The staff member's competency assessment includes direct observation of routine patient test performance; monitoring of test results; review of intermediate test results, quality control, and PT; and other criteria.
5. **NPSG.02.03.01 (National Patient Safety Goal), EP 2—**Implement the procedures for managing the critical results of tests and diagnostic procedures.
6. **EC.02.04.03 (Environment of Care), EP 7—**The laboratory performs and documents preventive maintenance, periodic inspection, and performance testing of each piece of equipment.
7. **HR.01.06.01, EP 3—**An individual qualified by education, experience, and knowledge related to the skill being reviewed assesses staff competence.
8. **HR.01.06.01, EP 20—**For new hires, competency must be assessed after one year.
9. **LD.04.05.07 (Leadership), EP 4—**The laboratory director, technical consultant, and/or technical supervisor are responsible for maintaining laboratory performance.
10. **QSA.05.18.01, EP 7—**The organization follows policies and procedures that guide patient monitoring and reporting of suspected transfusion-related adverse events during blood administration.

A2LA:
Most Frequent Citations in 2022

1. **493.1235—**The laboratory must establish and follow written policies and procedures to assess employee and consultant competency.
2. **493.1242 (a)—**The laboratory must establish and follow written policies and procedures for specimen handling.
3. **493.1251 (a)—**A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to and followed by laboratory personnel.
4. **493.1251 (b)(8)—**The procedure manual must include corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
5. **493.1445 (b)—**If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.
6. **493.1252 (b)(2)—**The laboratory must define criteria for temperature that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting.
7. **493.1252 (b)(3)—**The laboratory must define criteria for humidity that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting.
8. **493.1252 (d)—**Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.
9. **493.1254 (a)(2)—**The laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer.
10. **493.1256—**The laboratory must implement outlined control procedures for analytic processes.

Note: Based on regulations under Title 42 Public Health, Part 493 Laboratory Requirements.

COLA:
Most Frequent Citations in 2022

1. **PER 5 (Personnel)—**Complete competency assessment is performed and documented at required intervals for all testing personnel and supervisory staff.
2. **LDR 4 (Laboratory Director Responsibilities)—** Laboratory director fulfills the proficiency testing responsibilities of the position.
3. **PT 16 (Proficiency Testing)—**Laboratory director reviews PT results with supervisory staff and testing personnel.
4. **PER 4C—**Technical consultant / technical supervisor fulfills the responsibilities of the position.
5. **LDR 5—**Laboratory director fulfills the quality control and quality assessment responsibilities of the position.
6. **PER 4E—**Testing personnel fulfill the responsibilities of the position.
7. **PT 9—**All unsatisfactory PT scores and any scores less than 100% are evaluated and corrective action is documented.
8. **PT 15—**PT records include attestations signed by the laboratory director and testing personnel.
9. **PT 10—**Laboratory verifies the accuracy of any analyte, specialty, or subspecialty that is assigned a PT score that does not reflect the accuracy of the laboratory's actual test performance.
10. **WAV 2 (Waived Testing)—**Quality control for all waived testing is performed per manufacturer's requirements, and the results of QC are recorded, reviewed, and found to be acceptable prior to patient result reporting.

Editor's Note: *Each CLIA deeming organization provided its list of the top 10 types of citations its assessors identified across all inspected labs during 2022.*

CMS Ends Remote Reading of Pathology Glass Slides

However, in a nod to digital pathology, remote review of whole slide imaging remains

Karen Lovitch

CEO SUMMARY: On the day the federal government ended the public health emergency for SARS-CoV-2, CMS issued an updated FAQ that ended the allowance for remote reviews of glass slides by pathologists. Remote digital image reviews by pathologists and other lab personnel can continue for now.

Danielle Tangorre

EFFECTIVELY IMMEDIATELY, THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) announced that remote reading of glass slides generally is no longer permitted. This big move may catch clinical laboratory managers and anatomic pathologists off guard.

The news came in a FAQ posted online by the agency on May 11, the same day the federal public health emergency (PHE) for the SARS-CoV-2 pandemic expired. The practice of reading glass slides remotely—such as at a pathologist's home—was a useful concession by the government during social distancing mandates. CMS had earlier implied remote glass slide reviews would no longer be permitted, but the agency had not explicitly stated it until now.

"It surprised me that CMS would make such a substantial shift in policy at the last minute, just as the public health emergency ended and with no grace period for labs," said Karen Lovitch, Chair of the Health Law Practice and Co-Chair of the Healthcare Enforcement Defense Practice at law firm **Mintz** in Washington, D.C.

However, remote digital slide reading by pathologists and other laboratory personnel can continue, at least for now, CMS stated. *(See the text of the relevant FAQs in the sidebar on page 15.)*

Out-of-Compliance Risk

Labs and pathology practices that have staff remotely reading glass slides under the site's primary CLIA certificate should cease doing so or risk being out of compliance, Lovitch warned.

"Technically, right now a lab is in violation of CLIA if a pathologist reads glass slides remotely," she said. "So, if a pathology lab is in that position, it is time to move work around to locations that will be in compliance."

Given current staffing shortages in labs, the CMS announcement may make it even tougher for some labs to cover glass slide review needs. "The CMS news has some huge impacts on workflow, particularly with the challenges of staffing right now," said Danielle Tangorre, JD, partner at **Robinson & Cole LLP** in Albany, New York.

"If labs have been using a remote workforce, including for the review of

CMS Answers Questions about Remote Case Review

BELOW ARE SOME OF THE QUESTIONS AND RESPONSES the Centers for Medicare and Medicaid Services published in a May 11 FAQ:

Q: *Will the enforcement discretion for remote examination of physical slides continue after the PHE is declared over?*

A: No. Physical slides being examined using a microscope which are not digital images cannot be read remotely under a primary location CLIA certificate as described above. Slides must be read at a CLIA-certified laboratory primary location. All applicable CLIA requirements must be met. Test reports must indicate the name and address where the testing is performed. However, in the case of a private residence, the laboratory may use a coding system rather than the home address on the final report. This coding system must be available upon request.

Q: *Will the enforcement discretion for staff reviewing digital clinical laboratory data, digital results, and digital images remotely continue after the PHE is declared over?*

A: Yes. CMS will continue the enforcement discretion allowing staff to review digital clinical laboratory data, digital results, and digital images remotely as long as the criteria in [CMS Memorandum] QSO-23-15-CLIA are met. Primary laboratory test reports must indicate the name and address where the testing is performed. However, in the case of a private residence, the laboratory may use a coding system rather than the home address on the final report. This coding system must be available upon request.

Q: *Does this guidance apply to laboratory personnel who have already obtained CLIA certificates for their home or other sites separate from the primary testing site?*

A: No, this guidance regarding remote sites does not apply to pathologists who have already obtained a CLIA certificate and are not operating under any other CLIA certificate.

physical slides, now suddenly they have to pivot," she noted.

After the PHE was declared in early 2020, CMS issued guidance that said pathologists could work from home and review slides without a separate Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate for that remote location, Lovitch recalled. In such cases, CMS viewed the remote location to be akin to a laboratory as long as the main lab (at the hospital, for example) had a CLIA certificate.

Then in February 2023, CMS issued updated guidance as the PHE end date grew closer. The **American Clinical Laboratory Association** (ACLA) was active in talking to CMS about the updates to the guidance.

"ALCA certainly had conversations with CMS throughout the last six months as the agency was putting together its post-pandemic plans," said Adam Borden, Senior Vice President of Policy and Strategy at ACLA.

Borden noted that many laboratory professionals who are not pathologists are involved with reviewing digital diagnostic information these days, and the CMS guidance reflects that fact.

"ACLA was extremely pleased to see the extension of review of digital data to all lab personnel, not just pathologists," he added.

In theory, a lab that wants to question CMS about its position on glass slides could bring up the issue with the agency. But doing so raises the risk of tipping off CMS that a lab is not in compliance.

"If this restriction is going to a be a significant challenge, labs might want to think about reaching out to CMS or their

state survey agencies," Tangorre said. "There is risk to doing that because a lab could basically disclose its noncompliance to CMS. Interested labs should weigh those risks. This may be where trade associations come in and ask for CMS for more time to adapt to this change."

Remote Digital Reviews

CLIA generally allows slide reading to occur only at the location of a laboratory's primary CLIA certificate.

The claw-back of remote reviews of glass slides is in line with longstanding CLIA provisions. However, the continued allowance of digital slide reads from remote locations highlights a growing trend of the federal government recognizing the benefits of digital pathology technology.

The language within CLIA has not been substantially revised for 30 years, and it makes no mention of digital slides.

But work is underway in the federal Clinical Laboratory Improvement Advisory Committee (CLIAC) to update CLIA to recognize the idea of "data as a specimen"—in other words, data derived from human specimens that provides information for the treatment of disease. *(See TDR, "CLIA On Path to Recognize Lab Data as a Specimen," Jan. 23, 2023.)*

Reforms to CLIA

"CMS is taking into consideration the discussions within CLIAC for the last four or five years," Tangorre observed. "CLIAC's recommendation is that digital reads are effective, and a variety of the trade associations have written that the pandemic proved that. So, I think CMS is slowly adapting to the concept of bioinformatics and related new technology being useful."

As a sidenote, CMS said all cytology slide reviews, even digital ones, must be performed in the primary location of an organization's CLIA certificate and not at a remote site. This is due to limitations in digital pathology technology when it comes to cytology slide needs.

In making a distinction between remote reviews of glass slides and digital whole slide images, CMS stated that handling glass slides away from the primary lab can lead to patient safety errors.

"When slides are reviewed remotely, a microscope and other laboratory equipment are necessary to perform the testing," CMS noted in Memorandum QSO-23-15-CLIA, also published on May 11.

"Such equipment is a hallmark of a separate laboratory and, without heightened oversight, increases the potential for inaccurate laboratory results," CMS continued. "In addition, physically transferring slides from one site to another constitutes a referral to another laboratory and involves increased risk of error."

Adam Borden

➤"ACLA was extremely pleased to see the extension of review of digital data to all lab personnel, not just pathologists."

Meanwhile, CMS officials consider analyzing diagnostic data remotely as far less problematic.

"We consider digital data, results, and images accessed by VPN or other secure method to be an extension of the laboratory that does not require a microscope or other laboratory equipment," CMS stated.

ACLA intends to continue working with CMS to develop permanent regulations centered on reviewing laboratory data remotely. This is a concern, given that the new guidance is based on "enforcement discretion" from the agency, Borden said. TDR

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Legal Update

Elizabeth Holmes Still Wants 'To Contribute' in Healthcare

Theranos founder tells The New York Times she may never be able to fully pay legal bills

Clinical laboratory and anatomic pathology professionals have another reason to shake their heads at the Elizabeth Holmes saga.

On May 6, *The New York Times* ran a strange, somewhat fawning profile piece about Holmes, the convicted founder and former CEO at **Theranos**. In the story, Holmes contended that she still thinks about contributing to the clinical laboratory field.

This notion comes despite the fact that Holmes is scheduled to begin an 11-year, three-month prison sentence for fraud on May 30 at a minimum security facility in Texas. Holmes had attempted to stay free while she pursues an appeal of her January 2022 conviction. However, an appeals court ruled against that request, *The Washington Post* reported on May 17.

Ideas for COVID-19 Testing?

Holmes told *The Times* that she still works on healthcare-related inventions and will continue to do so if she reports to prison.

"Holmes [said] she has ideas for COVID testing, drawing on her work in a Singapore lab as a college student during the SARS outbreak," *The Times* reported in the sprawling, 5,000-word piece.

"I still dream about being able to contribute in that space," Holmes said. "I still feel the same calling to it as I always did, and I still think the need is there."

Observers may note the irony in her words. The faulty performance of Theranos' blood-test analyzer, called Edison, was at the core of Holmes' fraud trial in 2021. She touted Edison's technology to investors while the company privately bypassed its own Edison analyzers and ran many of its finger-prick blood samples on traditional lab instruments.

A jury convicted Holmes on four counts of defrauding investors of $120 million. Her business partner and former boyfriend, Ramesh "Sunny" Balwani, was convicted on 12 counts of fraud.

Balwani—the former President and Chief Operating Officer at Theranos—was sentenced to 12 years, 11 months behind bars and reported to prison on April 20. He has also appealed his conviction.

Legal Bills Mount for Holmes

Holmes told *The Times* she is unable to pay tens of millions of dollars in legal bills.

"I can't," she said. "I have to work for the rest of my life to try to pay for it."

She added that the family of her partner, Billy Evans—whose parents own a luxury hotel chain—is not helping to pay her legal expenses.

Holmes' prior cadre of lawyers quit after she could not compensate them, *The Times* reported. "One pre-sentencing report by the government put her legal fees at more than $30 million," according to the news outlet.

Holmes' current legal team at **Williams & Connolly, LLP**, did not respond to requests for comment about her financial arrangement with the firm, according to *The Times.* TDR

IVD Update

Despite COVID-19 Losses, IVD Execs Remain Upbeat

Companies report on Q1 2023 financials, looking for growth from expanded molecular testing menus

Continuing declines in COVID-19 test revenues was a common theme during the first quarter 2023 earning reports released by the nation's largest *in vitro* diagnostics (IVD) manufacturers.

At the same time, there was optimism as different IVD firms highlighted advancement and business opportunities in the following areas:

- Digital pathology.
- Companion diagnostics.
- New assays to address respiratory viruses, cancer, and women's health.

Looking at each IVD company's quarterly earnings below, it's clear the deep financial bite of decreased COVID-19 testing demand is far from over. But IVD executives appear to be staging their companies for future revenue in traditional and novel diagnostics areas, particularly for infectious diseases.

Here is a summary of financial results and business initiatives from companies serving clinical laboratories.

Roche

ROCHE: Diagnostics Declined 28%, Digital Pathology a Bright Spot

Roche Group in Basel, Switzerland, shared these Q1 data as compared to Q1 2022:

- Group sales fell 7% to 15.3 billion Swiss francs (CHF) (US$16.9 billion) from 16.4 billion CHF (US$18.2 billion).
- Diagnostics Division sales of 3.6 billion CHF (US$3.9 billion) fell 28% from 5.2 billion CHF (US$5.7 billion).
- Core lab services increased 7% to 1.9 billion CHF (US$2 billion) from 1.8 billion CHF (US$2 billion).
- Molecular lab products plummeted 48% to 593 million CHF (US$655 million) from 1.1 billion CHF (US$1.2 billion).
- Point-of-care services plunged 72% to 397 million CHF (US$549 million) from 1.4 billion CHF (US$1.5 billion).
- Pathology was up 7% to 329 million CHF (US$363 million) from 318 million CHF (US$354 million).

Roche Diagnostics CEO Matthew Sause pointed to the nosedive in COVID-19 test sales as the culprit for the diagnostic division's performance.

"The diagnostics division declined by 28% compared to Q1 2022," Sause said during an earnings call on April 26. "And this decline is entirely driven by the expected decrease of COVID-19 testing sales by minus 1.6 billion CHF. When excluding COVID-19 testing sales, our base business growth is plus four percentage points."

Pathology instruments saw a strong quarter. "Our digital pathology systems, the DP200 and DP600 slide scanners, grew at 29%," Sause said. "And our workhorse instruments, the HE600 for primary staining as well as our Benchmark ULTRA and ULTRAPLUS for immunohistochemistry analysis, grew at a healthy plus 12% and plus 10%, respectively."

Sause said the company intends to build services to clinical laboratories in areas such as hepatitis, neuroscience, and ovarian cancer testing.

"It's important to have the broadest menu in the industry, but it's really important that we deliver innovative medical testing solutions that change the standard of care," Sause said.

For example, Roche's Ventana FOLR1 RxDx assay is a **Food and Drug Administration** (FDA)-cleared companion diagnostic test for ovarian cancer, Sause said.

"Our FOLR1 immunohistochemistry test has been co-developed with a new drug for second-line treatment in ovarian cancer … enabling pathologists to identify patients who may be eligible for the new therapy," he added.

Abbott
A Promise for Life

ABBOTT LABORATORIES: Q1 2023 Sales Decline of 18%

Abbott Laboratories in Abbott Park, Illinois, released these Q1 2023 data:

- Total sales decreased 18% to $9.7 billion from $11.9 billion in Q1 2022.
- Diagnostic sales decreased 49% to $2.6 billion from $5.2 billion in Q1 2022.
- Core laboratory sales were flat at $1.1 billion.
- Molecular sales plunged 65% to $147 million from $420 million.
- Rapid diagnostics dropped 65.7% to $1.2 billion from $3.5 billion.

Despite the quarterly loss of revenue on paper, largely attributed to lesser COVID-19 testing sales, Abbott's executives pointed to decent base business performance. During Abbott's earnings call on April 19, CEO Robert Ford shared insight on consumer health trends.

"A behavioral shift that we're seeing in healthcare globally has been the increased priority people are putting on getting healthy and staying healthy," Ford said. "And for our businesses, the impacts have been increased routine diagnostic testing volumes, improved medical device procedure trends, and strong demand for consumer-based health products."

Ford was asked during the call about sales of Alinity, which is Abbott's automated system for core lab, molecular, and transfusion processes. Ford said from 12% to 15% of Alinity customers are up for contract renewal every year, and during the pandemic, those renewals had less priority for hospitals as they focused on providing patient care.

"Definitely into Q4 of last year and going into this quarter, [contract request-for-proposals] are restarting back up again," Ford said.

ThermoFisher
SCIENTIFIC

THERMO FISHER: Lab Products Sales Rose 5.5% in Q1 2023

Thermo Fisher Scientific in Waltham, Massachusetts, shared these Q1 results versus Q1 2022:

- Revenue declined 9% to $10.7 billion from $11.8 billion.
- Life sciences revenue fell 38% to $2.6 billion from $4.2 billion.
- Laboratory products and services revenue increased 5.5% to $5.7 billion from $5.4 billion.
- Analytical instruments revenue went up 13.3% to $1.7 billion from $1.5 billion.
- Specialty diagnostics revenue was down 21% to $1.1 billion from $1.4 billion.

In the quarter, the company introduced the Applied Biosystems QuantStudio Absolute Q AutoRun dPCR to aid molecular research productivity.

"In our clinical diagnostics business, we launched the Thermo Scientific DRI tramadol assay, which broadens our extensive toxicology portfolio with a new drug of abuse assay to help fight the opioid crisis," said CEO Marc Casper during Thermo's April 26 call with investors.

During Q1, Thermo Fisher completed the acquisition of **Binding Site**, a Birmingham, United Kingdom-based specialty diagnostics company offering assays and instruments for blood cancers and immune system disorders.

QuidelOrtho

QUIDELORTHO: Reduces Backlog in Lab Instrument Orders

QuidelOrtho in San Diego reported Q1 data as compared to Q1 2022:

- Revenue of $846 million decreased 44% from $1.5 billion.
- Lab revenue was up 9% to $370.7 million from $339.7 million.
- Point-of-care revenue plunged 67% to $308 million from $943 million.
- Molecular diagnostics revenue plummeted 75% to $11.4 million from $46 million.

The drop in overall revenue was attributed in part to last fall's early onset of respiratory illnesses, which essentially pulled away expected revenue from Q1 2023, said Douglas Bryant, President and CEO at Quidel Corporation, during the firm's earnings call with investors on May 3. The company also pointed to strong Q1 2022 flu and COVID-19 revenue, which made year-over-year comparisons wider.

On a positive note, QuidelOrtho made progress in its backlog of instrument orders during Q1.

"We reduced our instrument backlog in our lab's business by more than 20%, enabling us to ship more instruments than previously anticipated in the quarter," Bryant noted.

Looking ahead this year, QuidelOrtho is also planning a launch in the U.S. of the Savanna molecular platform, which will include panels for respiratory viruses, sexually transmitted diseases (STDs), and gastrointestinal illnesses. The company intends to market the platform to physician office labs, emergency departments, pharmacies, urgent care settings, and hospital and reference labs, Bryant said.

BD

BECTON, DICKINSON AND COMPANY: Seeks FDA Review of New Capillary Blood Test Device

Becton, Dickinson and Company (BD) in Franklin Lakes, New Jersey, shared data for its Q2 ending March 31 as compared to Q2 2022:

- Revenue increased 1.5% to $4.8 billion from $4.7 billion.
- Life sciences revenue dropped 14.2% to $1.2 billion from $1.4 billion.
- Integrated diagnostics solutions revenue was down 22.7% to $888 million from $1.1 billion.

During an earnings call on May 4, CEO Tom Polen noted BD is planning to expand women's health assays and infectious disease tests.

The company is also seeking FDA clearance for MiniDraw, a device making possible less invasive capillary blood draws compared to traditional venipuncture procedure.

SIEMENS Healthineers

SIEMENS HEALTHINEERS: Streamlining Efforts Ongoing in Diagnostics Offerings

Siemens Healthineers in Erlangen, Germany, shared results for its Q2 ending March 31:

- Revenue fell 2.5% to €5.3 billion (US$5.7 billion) from €5.4 billion (US$5.8 billion) in Q2 2022.
- Diagnostics revenue fell 39% to €1 billion (US$1.08 billion) from €1.7 billion (US$1.8 billion).

As THE DARK REPORT previously reported, Siemens Healthineers is in the midst of streamlining the range of diagnostic analyzers and testing solutions as

part of a plan to cut more than $300 million in costs by 2025. *(See TDR, "Siemens Healthineers Plans to Streamline Product Offerings," Jan. 3, 2023.)*

During a May 10 investors call, CEO Bernhard Montag noted that diagnostics profitability for Q2 was impacted by €77 million ($83.3USD million) in streamlining costs, which included sunsetting certain products and closing locations that were producing those lines.

Executives mentioned anticipated severance costs later in the year. This is evidence that there already has been—or will be in the near future—layoffs or buyouts related to the streamlining.

BIOMÉRIEUX: Solid All-Around Financial Performance

bioMérieux, headquartered in Marcy-l'Étoile, France, released Q1 2023 data as compared to Q1 2022:

- Total sales of €905.7 million (US$974 million) were up 7.5% from €837 million (US$901 million).
- Molecular biology sales were up 7.4% to €352.7 million (US$379.6 million) from €320 million (US$344 million).
- Microbiology sales jumped 11.9% to €299.6 million (US$322.4 million) from €269 million (US$289.6 million).
- Immunoassays sales were down 6.9% to €95.6 million (US$102.9 million) from €104.5 million (US$112.5 million).

Sales of the company's BioFire non-respiratory panels showed strong growth of 32% during the quarter. bioMérieux installed 500 new BioFire systems, bringing the total placed to 24,000 worldwide.

The company received FDA clearance for the PCR-based BioFire SpotFire respiratory panel mini, which detects five of the viral causes of upper respiratory tract infections (SARS-CoV-2, flu A, flu B, RSV, and rhinovirus) in 15 minutes, the company said.

"The inclusion of rhinovirus into this syndromic panel increases clinicians' ability to provide their patients with a definitive result compared to the other respiratory tests available in the U.S. which contain only the other one to four viruses," said Mark Miller, Executive VP and Chief Medical Officer at bioMérieux.

DANAHER: Respiratory 4-in-1 Test Exceeds Projections

Danaher in Washington, D.C.—parent company of **Beckman Coulter Diagnostics**, **Cepheid**, and **Leica Biosystems**—reported these Q1 results:

- Revenue decreased 7% to $7.2 billion from $7.6 billion in Q1 2022.
- Diagnostics revenue decreased 10%.
- Life sciences revenue grew 2.5%.
- Base business (non-COVID-19) revenue was up 6%.

During an earnings call on April 25, CEO Rainer Blair said revenue was higher than expected in the quarter for Cepheid respiratory testing (actual $550 million versus projected $450 million).

The increase was driven by strong sales of a four-in-one test for detection of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV).

In women's health, there was also "good momentum," according to Blair, for Cepheid's new Xpert Xpress MPV, a PCR test with FDA clearance.

PERKINELMER: Clinical Diagnostics Business Is Now Called Revvity

PerkinElmer in Waltham, Massachusetts has rebranded its clinical diagnostics and life sciences services as **Revvity**. It also released these Q1 financials:

- Revenue dropped 30% to $675 million as compared to $963 million in the same period last year.

- Diagnostics revenue was down 47% to $347 million as compared to $657 million.
- Life sciences revenue was up 7% to $328 million from $306 million.

The new brand involves changes to product lines. This includes PerkinElmer Informatics, renamed as Revvity Signals Software, and PerkinElmer Genomics, renamed Revvity Omics.

New Mountain Capital announced in August that it had acquired PerkinElmer's applied, food, and enterprise services lines for $2.4 billion. That business will continue to use the PerkinElmer name.

HOLOGIC®
The Science of Sure

HOLOGIC: Molecular Diagnostics Grows, Excluding COVID-19 Sales

Hologic, based in Marlborough, Massachusetts, reported its financial results for its Q2 ending April 1 compared to the same period last year:

- Revenue decreased 28.5% to $1 billion compared to $1.4 billion.
- Diagnostics revenue was down 52.9% to $464.7 million from $987.1 million (when COVID-19 test sales are excluded, diagnostics grew 15% to $355 million from $314.2 million).
- Molecular diagnostics revenue plunged 60.3% to $342.2 million from $862.5 million (excluding COVID-19 sales, molecular diagnostics grew nearly 24%).

What drove growth in molecular diagnostics at Hologic was a vaginitis panel and a core menu for STDs. It appears the objective is to expand the test menu for installed PCR instruments. During the May earnings call, Chief Financial Officer Karleen Oberton said that by the end of the fiscal year, she expected the vaginitis panel would be worth more than $100 million in sales.

BIO-RAD

BIO-RAD LABORATORIES: Core Clinical Diagnostics Revenue Increases

Bio-Rad Laboratories, in Hercules, California, shared these Q1 2023 financial results:

- Sales were down 3.3% to $676.8 million from $700 million in the same period last year.
- Clinical diagnostics sales were flat at $352 million.
- Clinical diagnostics revenue (excluding the impact of decreased COVID-19 related sales) increased 3%.
- Life sciences revenue fell 6.8% to $323.6 million compared to $347.2 million.

Bio-Rad recently launched, for research use, the PTC Temp Thermal Cycler. Bio-Rad also plans to release the Droplet Digital PCR microsatellite instability kit, which is part of the company's "expanding oncology assay menu for Droplet Digital PCR," said Chief Operating Officer Andre Last during his company's May 4 quarterly earnings call with investors and analysts.

sysmex
Lighting the way with diagnostics

SYSMEX CORPORATION: Reports Annual Sales Up More than 12%

Sysmex, with headquarters in Hyōgo, Japan, reported financial results for its full fiscal year ending March 31:

- Sales were up 12.8% to ¥410 billion (US$2.9 billion) from fiscal year 2022.
- Sales in the Americas were up 23% to ¥83 billion (US$607 million).

In its North American market, Sysmex said it saw an uptick in sales of hematology-related instruments, reagents, and maintenance services. "Sales of urinalysis reagents also rose due to a resurgence in tests demand and higher sales of instruments," Sysmex noted. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Hospital laboratory outreach programs continue to be acquisition targets for national laboratory companies. Earlier this month, **Labcorp** in Burlington, North Carolina, announced it will acquire the outreach businesses of **Jefferson Health** in Philadelphia and **Providence Oregon**. Providence Oregon is part of **Providence Health & Services** based in Renton, Washington, which operates in five Western states. In both cases, the health systems will continue to operate their hospital laboratories and offer certain genomics testing services.

MORE ON: *Outreach Deals*

Financial terms of the Jefferson Health and Providence Oregon agreements were not disclosed. Jefferson had $7.9 billion in revenue for its last full fiscal year, which ended on June 30, and experienced operating losses in two of the past three years, the *Philadelphia Inquirer* reported in January. The system also underwent a management reorganization earlier this year. Providence Health took in $26.4 billion in FY 2022 and had an operating loss of $1.7 billion, *Becker's Hospital CFO Report* noted in March. Typically, hospitals posting significant losses will consider selling their laboratory outreach programs as a way to raise much-needed cash.

VA STRIKES NEW DEAL WITH ORACLE CERNER

In response to quality concerns, the **U.S. Department of Veterans Affairs** (VA) has renegotiated its contract with **Oracle Cerner** for a new electronic health records (EHR) system. The VA had previously identified problems with the EHR, including 120,000 improperly routed alerts for clinical lab test orders that had already been cancelled. Under the new agreement, Oracle Cerner in Kansas City, Missouri, will be penalized for not meeting expectations on system reliability, according to U.S. Senator Patty Murray (D-Washington). Instead of another five-year term, the renegotiated contract is for five one-year terms. This gives the VA more opportunities to review progress.

TRANSITIONS

- Advisory services company **HealthTrust Performance Group** in Nashville, Tennessee, has named Dolly Kay, MBA, MLS(ASCP)CM, as Director of Laboratory Services. She previously was the company's Director of Portfolio for Capital Equipment and has worked as a hospital laboratory director.

- Tina Voss has been promoted to Senior Product Marketing Manager at **XiFin** based in San Diego. Previously she was Senior Global Marketing Communications Manager at **Memjet Technology** and Global Product Marketing Manager at **DJO Global**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 19, 2023.

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