Volume XXX, Number 11 Monday, July 31, 2023

»Virchow
New Commentary on Managed Care Contracting
Gain invaluable peeks behind the managed care curtain
(see pages 15-18)

Specialized Information Publishers Foundation
EDITORIAL EXCELLENCE AWARD WINNER

BREAKING NEWS! UHC Delays Z-code Requirement *(see page 6)*

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

INSIDE THIS ISSUE

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

'Virchow' as Your Source of Managed Care Insights

TODAY, WE ARE UNVEILING A VALUABLE INTELLIGENCE RESOURCE FOR YOU! It is a new commentary focused exclusively on managed care contracting for diagnostic services provided by clinical laboratories and anatomic pathology groups. *(See pages 15-18.)* We named it "Virchow" in recognition of Rudolf Virchow (1821-1905), the famed German physician who shaped modern pathology and laboratory medicine.

Lab leaders need help to level the playing field when negotiating with managed care companies. We intend for Virchow to deliver the insights and tangible information that you can use to craft winning negotiating strategies when your lab is contracting with health plans.

The source of this valuable intelligence will be different experts who have worked for years at health insurers. Often, these individuals started in major national lab companies before joining a managed care company to help it administer its provider networks and negotiate contracts with labs.

By contributing to Virchow anonymously, these different experts can bring you their candid and revealing intelligence. The Virchow format allows them to more freely discuss the internal dynamics that are common to health insurers and influence how these payers organize their lab networks and structure contracts with labs. No other source gives you access to this unique information.

You can expect Virchow to give you invaluable peeks behind the managed care curtain. "Those who have the gold make the rules" means managed care companies have the power to dictate terms to lab providers. But "knowledge is power" is the strategy savvy lab managers and pathologists can use to better understand what is unfolding on the payers' side of the table. This knowledge can be used by your lab team to negotiate equitable managed care contracts.

We are confident that Virchow will become a "must read" for you and those on your lab team who interact regularly with health insurers. What makes this new intelligence pipeline even more essential for you is healthcare's continuing transformation away from pure fee-for-service payment in favor of value-based reimbursement. Your lab needs a strategy to deliver more value to managed care companies and Virchow will be an essential guide as your lab team crafts these new clinical service strategies. TDR

OIG: Billing Code 81408 at Risk of 'Improper' Payment

New audit concludes that nearly $1 billion in past claims payments under CPT code could be fraudulent

CEO SUMMARY: Clinical lab executives familiar with molecular test coding and billing will not be surprised to learn that billing code 81408—commonly used on genetic test claims—is at risk of fraudulent Medicare payments. A new report from the Office of Inspector General attaches a remarkable number to this threat: $888 million over four years. Payers now have an even greater reason to inspect 81408 claims from genetic testing labs.

Reaffirming past reporting here and elsewhere, a new audit from the **U.S. Department of Health and Human Services' Office of Inspector General** (OIG) concluded that molecular pathology billing code 81408 is ripe for **Medicare** fraud and abuse.

The news, coming from a federal watchdog agency, may have two important ramifications for clinical labs and pathology practices. First, the announcement could encourage further investigations by the **U.S. Department of Justice** (DOJ) into genetic testing fraud. The DOJ has already taken strong action in the recent past against genetic testing companies in that regard.

Second, the OIG report may give both government and private payers more ammunition to audit and deny claims associated with 81408. Private payers are already heavily interested in verifying the clinical validity and utility of genetic tests given the tsunami of molecular test claims being submitted for reimbursement.

Back in 2020, The Dark Report detailed an independent analysis of Current Procedural Terminology (CPT) code 81408. Los Angeles-based lab payment consultant Bruce Quinn, MD, had determined that certain genetic testing laboratories used 81408 to generate levels of payment that grew by 30 times from 2017 to 2019. At the time, Quinn dubbed 81408 as "fraudomatic." *(See TDR, "One Genetic Test CPT Code Earns 'Fraudomatic' Title," Dec. 7, 2020.)*

The new OIG report backs up Quinn's past research. "Based on the results of our audit, up to $888.2 million in Medicare payments made for CPT code 81408 claims that we identified for our audit period were at risk of improper payment," the OIG stated. The audit covered claims filed from 2018 through 2021.

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

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO The Dark Report Intelligence Service, which includes The Dark Report plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

"CPT code 81408 may be billed when testing for multiple genes associated with rare diseases, such as Duchenne and Becker muscular dystrophy," according to the OIG. "Because these diseases generally manifest in childhood, the genes associated with them would not generally be tested for in the Medicare population, which is predominantly 65 years of age and older. Therefore, there is a risk of Medicare improper payments for this CPT code."

The formal name of the OIG audit report is, "CMS' Oversight of Medicare Payments for the Highest Paid Molecular Pathology Genetic Test Was Not Adequate to Reduce the Risk of Up to $888 Million in Improper Payments." The report number is A-09-22-03010.

Five Troublesome Areas

The OIG chided the **Centers for Medicare and Medicaid Services** (CMS) and its seven Medicare Administrative Contractors (MACs) in five areas:

- Although five of the seven MACs had Local Coverage Article (LCA) guidance that prohibited or limited use of CPT code 81408, two MACs' LCAs did not limit its use.
- CMS and the MACs did not ensure that all enrollees had established relationships with ordering providers.
- CMS and the MACs did not ensure that Medicare payments for 81408 claims were related to diseases associated with the genes.
- CMS and the MACs did not include adequate monitoring of the number of tests billed under 81408 to determine whether that number exceeded the amount of tests billed under Tier 1 molecular pathology procedures (MPP) codes.
- Not all MACs could identify the specific gene tested by laboratories that billed for 81408.

During the audit period, five MACs had LCA guidance that prohibited or limited the use of 81408. But the other two MACs had LCAs that offered no limits for 81408, and the OIG pointed out that those two MACs' payments made up 97% ($865.7 million) of the total Medicare reimbursement for 81408. As opposed to Local Coverage Determinations (LCDs), CMS does not consider LCAs to be Medicare requirements.

Two MACs Didn't Limit 81408

Although the OIG did not specify, the two MACs in question are likely **Novitas** and **First Coast Service Options** (FCSO). In 2021, those two contractors created LCAs regarding 81408. CMS noted in comments attached to the OIG report that it had independently discussed 81408 problems with the MACs.

"Policy changes were implemented by the MACs to address the issue," CMS wrote. "Specifically, while five MACs had LCDs and [LCA] guidance that addressed the use of CPT code 81408, the remaining two MACs did not. CMS notified the two MACs of these findings, and both remaining MACs issued new LCDs and [LCA] guidance that addressed the use of CPT code 81408."

Quinn, who uncovered problems with 81408 years earlier, was critical of CMS' comments. "CMS notes that it informed its contractors of problems with 81408, but the fact it took two MACs (not named, but obviously Novitas and FCSO) several years to stop a billion dollars in blatant erroneous payments is appalling," Quinn wrote on June 23 on his blog, *"Discoveries in Health Policy."*

No Prior Relationship

"During our audit period, of the 239,944 total enrollees associated with the genetic tests billed under CPT code 81408, 193,085 (80%) did not have an established relationship with the ordering provider shown on the claim," the OIG stated.

In fact, two of the top 10 ordering providers of 81408 during the audit period

were part of a fraud scheme involving genetic testing that resulted in $2.1 billion in losses to the Medicare program, the agency added. In that series of cases, lab companies and telemedicine firms allegedly paid doctors to prescribe genetic tests with little interaction, law enforcement officials said. *(See TDR, "DOJ Charges 35 Individuals in Genetic Testing Scam," Oct.14, 2019.)*

OIG noted that CMS and MAC oversight did not ensure that Medicare payments for 81408 were related to diseases associated with genes under that CPT code.

The OIG reviewed diseases associated with the 10 principal diagnosis codes on 81408 claims with the highest payments. The agency found that they did not match up to the genes commonly tested. For example, hypertension made up 24.3% of total Medicare payments for 81408—or $215,850,538 during the audited years.

However, "MAC officials told us that the use of CPT code 81408 is not reasonable and necessary in connection with hypertension," the OIG wrote.

No Oversight for Test Volume

Tier 2 MPPs, such as those billed under 81408, are generally performed in lower volumes than Tier 1 MPPs because diseases for Tier 2 are rarer. Yet that notion conflicts with the actual amount of tests associated with 81408.

"[In] 2021, laboratories billed 137,138 genetic tests under CPT code 81408, which was a greater number of tests billed than for any of the Tier 1 MPP codes," the OIG stated. "The results of our data analysis show that CMS and the MACs' oversight did not adequately address the use of CPT code 81408 in comparison with the use of CPT codes for Tier 1 MPPs."

MACs Couldn't Identify Genes

The seven MACs had various ways to identify genes associated with 81408 claims, yet some of the approaches were ineffective. In one case, a MAC had an LCA about including the specific gene on the claim, but it did not enforce this guidance.

"To reduce the risk of improper payments, it is important for the MAC to be able to identify the gene being tested because CPT code 81408 covers multiple genes," according to the OIG.

THE DARK REPORT's clients and regular readers should note the above areas of contention from the OIG. Whether the DOJ takes further action against genetic test fraud—or is already in the midst of a current investigation—won't be revealed until indictments are announced. Far more urgent may be any actions that other payers take in response to the OIG findings. TDR

OIG Recommendations, CMS Reponses

OIG MADE THE FOLLOWING RECOMMENDATIONS to CMS regarding potentially fraudulent payments for clinical laboratory test claims using CPT code 81408. We have included CMS' responses.

OIG recommendation 1: Review claims billed under 81408 to determine whether they complied with Medicare.

CMS response: The agency will analyze the OIG's data and direct its contractors to review a sample of claims to determine if the coding was accurate.

OIG recommendation 2: Determine amount of improper payments for 81408 claims that did not comply with Medicare and recover payments as appropriate.

CMS response: Any identified overpayments resulting from the reviews "will be recovered consistent with statute and agency policy and procedure."

OIG recommendation 3: Based upon the results of audit, notify appropriate providers so they can identify, report, and return any overpayments.

CMS response: Agency will identify appropriate providers and instruct MACs to notify those providers of OIG's audit and the potential overpayment.

Payer Update

UnitedHealthcare Delays Z-code Enforcement Until Oct. 1

UnitedHealthcare says this extension gives genetic testing labs more time to obtain Z-codes

JUST 12 DAYS BEFORE IT WAS SET TO REQUIRE Z-CODES for a large swath of genetic test claims under private health plans, **UnitedHealthcare** (UHC) pushed back its enforcement date from Aug. 1 to Oct. 1.

The health insurer based in Minnetonka, Minnesota, indicated that the move will provide genetic testing laboratories with more time to prepare for the impending change. "In order to ensure that labs have sufficient time to register the tests they perform, we will allow until Oct. 1 for providers to begin submitting Z-codes on their claims, five months from the date the new policy was announced," Tracey Lempner, a UHC spokesperson, told THE DARK REPORT.

Lempner did not respond to follow-up questions about what prompted the delay. THE DARK REPORT is aware of one major hospital in the Southwest that asked for an extension of the original timeline for the Z-code requirements. It is reasonable to assume other organizations also expressed concerns to UHC.

Deadline Extended to Oct. 1

From UnitedHealthcare's end, the added time may allow the payer to better incorporate any needed changes to its internal systems, one insider said. "UHC is a massive organization. To deploy the Z-code system and associated data, many changes have to be made that affect a lot of departments," the source noted.

To be clear, payers working with Medicare Advantage patients have been required to use Z-codes for genetic testing claims for some time. But UHC's move to require Z-codes for its private plans greatly expands the use of the codes.

For genetic testing labs that need to get Z-codes for UHC claims, the extension to Oct. 1 will be welcome news. Labs that do not already have Z-codes for a specific test must request them through **Palmetto GBA's** Diagnostic Exchange (DEX) registry, which administers the codes.

Palmetto GBA is a Medicare Administrative Contractor based in Columbia, South Carolina.

Once submitted, some tests will require a technical assessment be submitted to Palmetto GBA to review the procedure's analytical validity, clinical validity, and clinical utility. *(See TDR, "Technical Assessment Challenges for Z-code Applications," July 10, 2023.)*

The average turnaround time for a technical assessment is two months. That timeline, combined with UnitedHealthcare's original Aug. 1 deadline, led to genetic testing labs scrambling to request Z-codes or potentially face denied claims.

Other private payers are carefully watching UnitedHealthcare and its Z-code requirement. When and how those payers might follow UnitedHealthcare's lead remains to be seen. Several factors are in play, including some existing displeasure with UHC regarding other health policies. Our new managed care column, "Virchow," explains this aspect in greater detail starting on page 15. TDR

Digital Pathology Rollout Was 'Big Bang' at UofL

Academic pathology department's goal was full implementation, including primary diagnosis

Dibson Dibe Gondim, MD

CEO SUMMARY: It took less than one year to achieve full implementation of whole slide imaging and digitial pathology at the University of Louisville's Department of Pathology. One decision was to scan slides in a central location to promote efficient workflows. Integrating digital pathology with the pathology LIS and artificial intelligence software proved to be complex task.

Once a lab decides it is ready to implement whole slide imaging (WSI) and a digital pathology (DP) system, the next important question is this: Should DP be introduced in a step-wise fashion or all at once?

Pathologists at the **University of Louisville School of Medicine** in Louisville, Kentucky, answered that question by going all-in with their DP implementation. Less than one year later, the lab now scans all of its slides. Yes, kinks still need to be worked out in this "big bang" DP project. But the success of this project can be a roadmap for other pathology groups preparing to "go digital."

Enabling Primary Diagnosis

"When considering DP implementation, people often talk about taking an approach where they implement data, develop use cases, and then hope that by implementing multiple, small use cases, they get to an infrastructure that supports primary diagnosis," said Dibson Dibe Gondim, MD, Assistant Professor of Pathology and Director of Pathology Informatics at the school. "I didn't think that was the right approach for our implementation of WSI and DP because the infrastructure needed for primary diagnosis is different than the infrastructure for small use cases.

"So, from the beginning, the pathology department focused all of its efforts to digitize 100% of the cases," he added. "We also focused our implementation efforts to prepare for artificial intelligence [AI]. We went from minimally scanning to a 100% scanning in only nine months while deploying AI in only six months."

Gondim spoke at the *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management*, conducted last April in New Orleans. His session was titled, "Advancing Digital Pathology Adoption with Effective Workflow and Informatics Changes from Histology and Scanning through Diagnosis, Reporting, and Billing."

The School of Medicine is affiliated with **UofL Health**, an integrated regional academic health system with eight hospitals. The system has annual revenue of $2.2 billion. The central anatomic pathology lab is at 492-bed **Jewish Hospital**, which handles 30,000 annual surgical pathol-

ogy cases, 3,300 cytopathology cases, and 2,500 hematopathology cases.

Gondim began to develop this large-scale plan for digital pathology adoption in November 2020. In doing so, he looked at his early experiences with digital pathology and reflected on the obstacles he encountered.

Past Experiences with DP

"I have been involved in digital pathology and AI research since 2015, when I was a resident at **Indiana University**," Gondim recalled. "My initial exposure to the field involved using the **Aperio** scanner, which had a capacity of 20 slides and was located in a research building. While the scanner was useful for education and research, its distance from the clinical laboratory posed a significant limitation.

"In 2018, the institution acquired the **Phillips** UFS scanner, which had a capacity of 300 slides," he added. "However, it was underutilized at the time due to a lack of IT integration and the difficulty of accessing original digital slide files for research purposes, as they were locked in by the vendor."

Dibson Dibe Gondim, MD

➤"The key is optimal interoperability, which leads to organic adoption of digital pathology. With that, digital pathology is a faster process than reading glass slides."

Gondim instituted the following pillars for the University of Louisville's project, all of which can serve as a foundation for any digital pathology implementation:

- The value of a high-end slide scanner is limited without proper IT integration, which is critical for scalability.
- Access to the original digital files produced by the scanner is essential to avoid being locked in by the vendor.
- The compatibility of scanner images with open-source libraries is necessary to enable the creation of custom solutions and research projects.
- The location of a scanner significantly affects its productivity.

Gondim said his implementation team's guiding principle was that centralization of histology services needed to be combined with decentralization of clinical interpretation using digital pathology.

"Centralization of tissue processing and pathology readings is where the power of digital pathology resides," he said.

Minimal Requirements Are Set

The project team established the following minimal requirements:

- **Achieve 100% slide scanning of all formalin-fixed, paraffin-embedded cases**. "The lab needed to scale from minimal scanning to scanning 125,000 slides a year as quickly as we could," Gondim noted.
- **Centralize digital pathology scanning activities**. "We wanted to have the scanning incorporated into the central histology lab," he said.
- **Create storage for approximately 188 terabytes of information**. "That was the amount of data expected from one year of operation," Gondim explained.
- **Decentralize viewing options**. "The lab wanted to have a web-based viewer that was accessible outside the hospital," he said.
- **Outline expectations for artificial intelligence software**. "The AI had to be FDA approved and clinical grade," Gondim stated. "Also, we have aspirations to develop our own AI model, so we had to select a technology that would allow our lab to do that in the future."
- **Gain smooth technology interaction**. "Interoperability was key between the laboratory information system [LIS], digital pathology system, and AI," he observed. "And it needed to be a technology stack with a low chance of becoming obsolete."

Lessons Learned at University of Louisville from Its Digital Pathology Implementation

UNIVERSITY OF LOUISVILLE SCHOOL OF MEDICINE'S DEPARTMENT OF PATHOLOGY completed a large-scale implementation of digital pathology, but the path forward didn't come without potholes. Here are several important lessons learned, as explained by Dibson Dibe Gondim, MD, Assistant Professor of Pathology and Director of Pathology Informatics.

Mismatched Slide Holders

Slide staining and drying proved to be suboptimal as the clinical laboratory adjusted its workflow to accommodate digital pathology. "The legacy stainer would leave the slides still wet, and the clinical lab scientists would need to wait for them to dry," Gondim said. "Another issue was the slide holder of the legacy machine was incompatible with the slide holder of the Leica Aperio GT 450 digital scanner. Scientists would need to move slides from one slide holder to the other to solve this issue, which was inefficient.

"So, the lab changed out the legacy stainer for a Leica high-throughput stainer that performed staining, cover slipping, and drying," he added. "When the slides are dry, the lab uses the same slide holder for the GT 450. We were able to digitize up to 800 slides a day without adding a single FTE at the lab because we had optimal integration."

The lab also installed two additional GT 450s, bringing the total amount of digital scanners to three.

Scanner Malfunctions

One month after the lab installed the two new GT 450s, the scanners reported dozens of errors. "Leica supported us by providing technicians on short notice," Gondim said. "Eventually Leica decided that one scanner needed to be replaced and the lab implemented maintenance protocols. The project team compiles all scanner issues in a spreadsheet so that we can compare results by month."

In such situations, the lab needed to understand what happened to clinical workflows if one, two, or all three scanners became inoperable. "When one scanner is down, the lab still scans all pathology cases, but it creates delays due to limited scanning," he said. "With two scanners down, the extent of delays escalates significantly, leading to most cases bypassing the scanning process due to pathologists' grievances. If three scanners are down, the histology lab transitions to an alternative process. With no scanning capabilities, they resort to directly sending the traditional glass slides to the pathologists."

The lab plans to buy a fourth GT 450 to further protect workflows in the event one or more scanners goes down.

Project Scope Problems

The digital pathology rollout took place in phases. Phase three, which focused on the interface between the laboratory information system (LIS) and Paige's AI system, was supposed to be completed by June 2022. "The main goal of the interface is to facilitate primary diagnosis," Gondim said. "But we have a delay of 18 months. There are no items deployed to production. Some items will be deployed this summer.

"Unfortunately, some of the requirements that we had are still out of project scope," he continued. "For example, the lab won't be able to order stains from Paige or send report data from Paige to the LIS. Our LIS vendor is working on this issue. Very few vendors have a pathology LIS that provides an out-of-the-box API [application programming interface] to easily create these interfaces."

Veterinary Lab Provides Inspiration

University of Louisville's Department of Pathology chose to take a centralized approach to its digital pathology implementation. One of the deciding factors was a visit to a local veterinary laboratory.

"A vendor connected me with a veterinary pathology lab that's called **Zoetis**," recalled Dibson Dibe Gondim, MD. "Like us, the Zoetis lab is also based in Louisville, Kentucky. And they went fully digital during a five-year implementation that finished in 2020.

"Zoetis has a highly efficient operation where they received animal specimens from all over the U.S. shipped to Louisville," Gondim added. "They do histology processing in Louisville and these cases are read digitally by pathologists all over the country. I was impressed by these efficiencies. This was an attractive model that we wanted to target."

Based on the above requirements, the lab chose **Leica Microsystems'** Aperio GT 450 high-throughput digital scanner. Leica is a subsidiary of **Danaher Corporation** in Washington, DC. "The GT 450 has superb image quality," Gondim said. "It's easy to use for our techs. It's easy to manage for our IT folks. And the SVS image files are accessible, so it's easy to use for our researchers."

Another critical effort was to put the digital pathology equipment near the slide stainers. "We constructed an area for digital pathology that was adjacent to the stainers that would allow us to create an easier workflow," he noted.

A more difficult aspect was finding an approach to integrate the imaging management system (IMS) with AI.

"The expertise to create clinical grade AI in the market is rare, so that was our limiting factor," Gondim noted. "The lab wanted a single vendor to handle the IMS and AI system. This would allow the vendor to handle system updates.

"Other models rely on interfaces between the IMS and AI," Gondim said. "If there are systems from different vendors, the options are to build a custom interface or use a standard interface.

"But imagine if there was one IMS system and four different AI systems. That setup would need four different interfaces. At some point, when updating those systems, the interfaces would break. In those situations, the lab might need to have developers to monitor the interfaces. That is not sustainable."

➤ Acquiring AI Capabilities

The UofL Department of Pathology chose an artificial intelligence system from **Paige** in New York City. "Paige has the clinical expertise and AI expertise," Gondim stressed. "They have one of the largest datasets, which is going to be fundamental for the lab to create a new generation of AI products. And Paige was able to provide a full digital pathology solution."

After the slides are scanned, if there is a use case for AI, the images are uploaded to Paige's system. "The lab can use AI by pressing a single button," Gondim said. "To validate that approach, the lab deployed Paige Prostate, which uses AI. We then conducted a validation study. We found discrepancies in 4% of more than 1,000 slides we've been using for over a year.

"We also are starting to validate other Paige products," he added. *(See TDR, "Paige's Digital AI Tool Aids in Prostate Cancer Diagnosis," Sept. 27, 2021.)*

There were challenges that sidelined some aspects of the project. See the sidebar on page 9 for more details.

For Gondim, widespread technology interoperability should be the number one goal of any digital pathology implementation, regardless of whether it's a big-bang approach or a smaller effort.

He noted that a lack of interoperability prevents scaling up the digital pathology workflow and there can be low adoption of digital scanning as a result. "Moving up that scale, if there is limited interoperability—but not optimal interoperability—it often means that it is easier to continue using glass slides rather than digital pathology," Gondim observed.

"When different technologies don't work well together, the lab cannot sign out cases as fast using digital pathology," he noted. "In such settings, there can be resistance to adoption of DP and leaders will react by pushing a top-down, bulldozer-style adoption. That can backfire on the laboratory.

"So, the key is optimal interoperability that—in turn—leads to organic adoption of digital pathology," he added. "With that approach, digital pathology will prove to be a faster process than reading glass slides. Ideally, pathology labs want the LIS, digital pathology system, and the AI software to all be synchronized. That eliminates the need for a pathologist to manually retrieve cases from multiple applications."

Final Points for Lab Leaders

THE DARK REPORT has long contended that digital pathology represents the future of the clinical laboratory industry. *(See TDR, "Expert Sees Pros, Cons in Digital Pathology and Whole-Slide Imaging Systems," Sept. 23, 2019.)*

As laboratory and pathology leaders become more familiar with the technology—and younger lab professionals anticipate access to such equipment—case studies such as this one from the pathology department at the University of Louisville drive home two important themes.

One, digital pathology systems cannot truly be efficient without connecting to other technology within the pathology department. From that perspective, any rollout will need to consider how the full technology stack will operate cohesively.

Two, setting clear expectations for the endeavor early on benefits project organizers as they encounter challenges. Properly outlining scope helps project leaders and vendors navigate the effort with greater success.

"At this moment, it is recognized that digital pathology is an incredibly useful tool for clinical laboratories," Gondim concluded. "The question becomes how to deal with all the implementation complexities." TDR

Contact Dibson Dibe Gondim, MD, at 502-587-4210 or dibson.gondim@louisville.edu.

8K Monitor Screens Offer Benefits to Pathologists

IT MIGHT BE EASY to overlook the importance of monitors when evaluating sophisticated technology such as digital pathology and AI. However, the University of Louisville's Department of Pathology spent time choosing monitors for its digital pathology rollout.

"The lab decided to go with a commercial grade, 8K monitor," said Dibson Dibe Gondim, MD, Assistant Professor of Pathology and Director of Pathology Informatics. "The importance of an 8K monitor is that a pathologist can see an area that's equivalent to four 4K monitors."

That's because 8K monitors feature 7,680 x 4,320 pixels compared to 4K's 4,840 x 2,160 pixels. "When you consider that 8K includes four times the number of pixels found in 4K, its capacity for additional detail is huge," noted **SmartFrame**, an online image delivery service based in London.

THE DARK REPORT has previously mentioned that monitors are an important aspect of digital pathology workstations. For example, in some cases pathologists may need two screens. *(See TDR, "Digital Pathology Business Plan for Both Clinical and ROI Success," June 19, 2023.)*

2022 Ranking of the World's Top 12 IVD Corporations

WHILE THE TOP FOUR *IN VITRO* DIAGNOSTICS (IVD) MANUFACTURERS kept their collective hold on the market compared to 2021, the big surprise was that **Thermo Fisher Scientific's** Lab Products Division jumped up two positions to become the largest global IVD corporation, based on THE DARK REPORT'S 2022 ranking of the Top 12 IVD Companies.

The top 12 firms took in $99 billion in annual revenue compared to the 2021 ranking, when the biggest 12 IVD companies earned $85 billion.

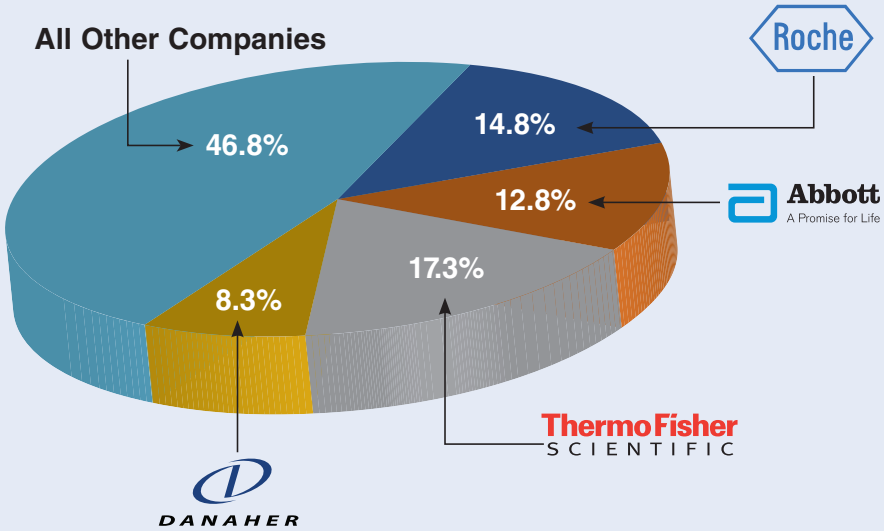
Shifts of note in the 2022 rankings compared to the 2021 rankings: **QuidelOrtho** jumped up four positions in its first year as a combined company following the acquistion **of Ortho Clinical Diagnostics** by **Quidel** in late 2021. Meanwhile, at No. 12 is **Qiagen,** which edged out **PerkinElmer** by just $100 million.

Top 12 IVD Companies by Global Revenue in 2022 (in billions)

IVD Corporation	2022 revenue	Cumulative revenue	Percent of market	Cumulative percent of market	2021 prior rank	
1. Thermo Fisher Scientific–Lab Products Div. *Waltham, Mass., founded 1956*	$22.5	$22.5	17.3%	17.3%	3	▲
2. Roche Holdings–Diagnostics Division *Basel, Switzerland, founded 1896*	$19.2	$41.7	14.8%	32.1%	1	▼
3. Abbott Laboratories–Diagnostics Division *Abbott Park, Ill., founded 1888*	$16.6	$58.3	12.8%	44.9%	2	▼
4. Danaher–Diagnostics Division *Washington, D.C., founded 1969*	$10.8	$69.1	8.3%	53.2%	4	
5. Siemens Healthineers–Diagnostics Division *Erlangen, Germany, founded 1896*	$6.5	$75.6	5.0%	58.2%	6	▲
6. Becton Dickinson–Life Sciences Division *Franklin Lakes, N.J., founded 1897*	$5.6	$81.2	4.3%	62.5%	5	▼
7. bioMérieux *Marcy-l'Étoile, France, founded 1963*	$3.8	$85.0	2.9%	65.4%	7	
8. QuidelOrtho *San Diego, Calif., founded 1979*	$3.3	$88.3	2.5%	67.9%	12	▲
9. Hologic–Diagnostics Division *Marlborough, Mass., founded 1985*	$3.0	$91.3	2.3%	70.2%	8	▼
10. (tie) Bio-Rad Laboratories *Hercules, Calif., founded 1952*	$2.8	$94.1	2.2%	72.4%	9	▼
10. (tie) Sysmex *Hyōgo, Japan, founded 1968*	$2.8	$96.9	2.2%	74.6%	10	
12. Qiagen *Venlo, Netherlands, founded 1984*	$2.1	$99.0	1.6%	76.2%	N/A	▲
Total Market Share Top 12 IVD Firms	$99.0	$99.0	76.2%	76.2%		
Market Share, Other IVD Firms	$31.0	$31.0	23.8%	23.8%		
Total Global IVD Revenue in 2022 (est.)	**$130.0**	**$130.0**	**100.0%**	**100.0%**		

Sources: Company documents, news reports.

Four IVD Companies Make up 53% of Market



GLOBAL SALES OF IVD PRODUCTS AND SERVICES WERE ESTIMATED to be $130 billion in 2022, an increase of 11% from the prior year. The increase was notable given that many IVD companies experienced drops in COVID-19 testing demand during 2022. A refocused effort on selling core laboratory products kept these firms on track.

Thermo Fisher Scientific, **Roche Diagnostics**, **Abbott Laboratories**, and **Danaher**—the top four companies on THE DARK REPORT'S 2022 ranking of IVD manufacturers—collectively hold an impressive 53% of market share in the IVD industry. For the first time since THE DARK REPORT started compiling these rankings in 2020, the top four companies on the list control the majority of the market compared to smaller players (53% to 47%).

Compared to 2021 revenues, in 2022, Thermo Fisher gained the most market share (4.7% more) out of the top 12 contenders, according to our analysis. That reflects Thermo Fisher's increase in the revenue of its lab products division of $7.7 billion from 2021 to 2022. One key to Thermo Fisher's success was its expansion of quantitative polymerase chain reaction (qPCR) technology during the SARS-CoV-2 pandemic. "That led to a huge increase in the installed base of laboratory-based qPCR instruments," CEO Marc Casper said in 2022.

Lab Market Update

Hospital Lab Outreach Selloffs Continue with Labcorp as Buyer

Company announces new agreements with Legacy Health and Providence, both in the Pacific Northwest

OVER THE LAST FEW MONTHS **Labcorp** has shaken up the hospital laboratory market in the Pacific Northwest, particularly as it concerns lab outreach services.

On July 11, the Burlington, North Carolina-based company announced a deal with nonprofit **Legacy Health**, a six-hospital health system in Portland, Oregon. Under the arrangement, Labcorp will acquire select assets of Legacy's laboratory outreach business.

"Labcorp will also manage Legacy's inpatient hospital laboratories through a long-term agreement to provide staffing, leadership, scientific knowledge, analytics, supply chain services, and laboratory support," Labcorp noted in a news release.

Legacy will maintain ownership and licensure of its hospital labs.

The deal is the latest example of how Labcorp and **Quest Diagnostics** are solidly positioned to acquire diagnostic services from struggling hospital systems. These systems face intense operating pressures, including rising labor costs and reduced **Medicare** reimbursements.

"Legacy officials pointed to the health system's severe financial problems as a reason for the sale," *The Oregonian* reported on July 11. "It is losing $10 million a month, which has forced it to raid its own reserves. It suffered one of the worst years in its history, losing $172 million last fiscal year."

Labcorp did not release financial terms for the Legacy deal, although it's possible such details will come out later in **U.S. Securities and Exchange Commission** filings. About 700 Legacy employees associated with its labs will join Labcorp, *The Oregonian* noted.

Providence Health Deal

Labcorp also announced plans in May to acquire **Providence Oregon's** laboratory outreach business. Providence Oregon, which is part of **Providence Health** in Renton, Washington, will maintain operation and ownership of certain anatomic pathology and genomics outreach testing and its hospital laboratories in the region.

Not-for-profit Providence Health posted a $1.7 billion deficit of revenue over expenses from operations for 2022, *Healthcare Finance* reported on March 13.

Labcorp has a 20-year history with Providence in the Northwest. In 2017, Labcorp acquired **Pathology Associates Medical Laboratories** (PAML) from the health system. At that time, PAML was among the largest independent lab companies in the U.S. *(See TDR, "Sale to Labcorp to End Most of PAML's Lab Joint Ventures," March 13, 2017.)*

Enzo Labs Purchase Finalized

Meanwhile, on July 24, Labcorp completed its acquisition of the clinical lab business of **Enzo Biochem** in Farmingdale, New York. The final purchase price was $113.3 million, less than the originally anticipated $146 million. The adjusted price was noted in an amendment filed with the SEC on July 3. Specific reasons for the reduction were not given. TDR

Virchow

Medicine Money Managed Care

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

With Z-codes, Will Other Payers Follow UnitedHealthcare's Lead?

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.

GENETIC TESTING LABORATORIES THROUGHOUT THE UNITED STATES are still reacting to the May 4 announcement by **UnitedHealthcare** (UHC) that, beginning Aug. 1, 2023, its commercial plans would "require **Palmetto GBA's** DEX Z-codes for molecular diagnostic test services on facility and professional claims for the claims to be considered for reimbursement."

According to a recent update from UHC on July 20, enforcement of Z-code requirements will begin on Oct. 1 to allow labs more time to request their codes.

Genetic testing labs were not the only ones caught flat-footed by UHC's announcement of this new policy. My colleagues in the managed care industry tell me that other private health plans now must decide two things:

- One, should they adopt their own Z-code requirement for genetic test claims?
- Two, if yes, how quickly should they roll out their Z-code policy?

My point here is UnitedHealthcare's new mandate impacts not just genetic testing companies, it also raises the competitive bar for health plans. Obviously UHC—one of the nation's largest health insurance companies—believes its Z-code policy is a necessary move to benefit its patients and the employers it serves.

UHC also gets one more tool to prevent payment for medically unnecessary or inappropriate genetic tests while speeding payment for those genetic test claims that meet its coverage guidelines.

Payers Copy Policies

It is typical for a new **Medicare** or private payer coverage policy—including pricing—to be studied by other health plans and copied shortly thereafter. Thus, the odds are good that pathologists and clinical laboratory managers will see other payers implement their own Z-code requirement for genetic test claims.

Because of the complexities of genetic CPT codes, and this somewhat novel use of Z-codes in processing what are rather high numbers of claims, I anticipate that major payers will want to watch and learn from UHC as it processes genetic test claims after Aug. 1. These are reasons why I think other private payers will implement their own Z-code requirements for genetic test claims, but only after they see what happens with UHC's Z-code requirement in the coming months.

It is important to understand the market forces that drive growing payer interest in Z-codes. I can tell you that the volume of genetic tests on the market is time-consuming for payers when it comes to billing and payment policies. Part of the reason for that is the fact that Current Procedural Terminology (CPT) codes simply have not kept up with the genetic testing market.

New molecular assays come out every month. Often these new tests are connected to a particular pharmaceutical drug as part of a long-term treatment plan for a patient. That means if a patient tests positive for a particular genetic test, then physicians will want that patient to take a specific drug because it's going have the best outcome. So, there are substantial business interests with a stake in this genetic testing.

The CPT codes are so old that they can't keep up with ever-growing, modern genetic testing demand. Meanwhile, doctors don't always know what tests they order. And let's face it, sales reps of the genetic testing companies are well-paid to go out and persuade the doctors to order their genetic test panels. These economic push-and-pulls are embedded in lab testing and reimbursement.

➤Awareness of Genetic Tests

Payers are concerned because genetic testing is getting very expensive and that constrains reimbursement funds. Therefore, when a genetic test claim is presented to a health plan for reimbursement, that health plan wants to know:

- Is this genetic test appropriate for the patient's diagnosis (ICD-10 code) and physician's description of symptoms?
- Does this genetic test accurately measure its biomarkers?
- Will the test results guide the doctor to get a better patient outcome?

Answering those three questions upon receipt of a claim is just one challenge for the payer. Historically, if a payer takes the same test from different labs and lays those tests side by side, they're not all the same. That raises questions about what components of a genetic test panel are medically necessary. *(See TDR, "Optum and Avalon Discuss Genetic Test Claims Review," June 19, 2023.)*

There's also an increased public awareness of genetic testing, such as for prenatal screening and rare genetic disorders. But payers don't know what all of these thousands of genetic tests in the marketplace truly do. That is why health plans are working to establish a system to provide them with that information, whether through Z-codes or other systems. **Concert Genetics**' coding engine comes to mind, for example.

The big goal for payers is to reduce their expenses related to genetic testing reimbursement while also making sure that a genetic test is the right one for the patient. Payers have teams working to solve this problem.

➤Spotting Spikes in Claims

Many payers staff a whole genetics department, with an analytics team behind it. They run reports monthly that analyze what the company paid for genetic tests. If something looks odd, the claim may go to payment integrity for investigation. From there, the plan breaks down payments by individual labs—not only the total dollar amount the plan reimbursed the genetic testing lab, but also the specific tests that made up that dollar amount.

Let's suppose the plan noticed an upswing in claims for a molecular assay called the "Jupiter Test" from Genetic Lab A. That lab did not run the Jupiter Test in 2020 or 2021. Next, in 2022, the lab ran a few of those tests, with each one costing $1,000. Now in 2023, suddenly Genetic Lab A is doing 10,000 Jupiter Tests a month.

To a payer, this situation indicates one of two things about the genetic test:

One, the lab is bundling the test incorrectly, or two, the lab is committing fraud. *(See TDR, "Feds Target Genetic Test and Telemedicine Fraud," Sept. 19, 2022.)*

At that point, a payer is going to take a deep dive into Genetic Lab A, all the way down to the CPT code level. The health plan will ask the contracting agent who has a relationship with the lab to make a phone call. Unfortunately, when those types of calls happen, the genetic testing company will often play dumb and say, "Oh, we don't know what you're talking about."

The payer will also look at Genetic Lab A's claims for the Jupiter Test and compare similar claims from Genetic Lab B, which also runs the Jupiter Test but submits a more reasonable number of claims. Based on that comparison, the health plan may ask Genetic Lab B if it will partner with the payer to do some "redirection"—in other words, to move test business away from Genetic Lab A.

To help redirect these tests, the payer sends out nastygram letters to providers asking that they please stop using Genetic Lab A and instead use Genetic Lab B. Sometimes that move will bring Genetic Lab A to the negotiating table.

Will Other Payers Follow?

I've been asked recently by people in the clinical lab industry whether other major payers will follow UnitedHealthcare's lead on requiring Z-codes for genetic tests under private health plans. *(See TDR, "UHC's Z-code Requirement to Commence on Aug. 1," May 30, 2023.)*

Although that might happen, there's no guarantee. As noted earlier, I think other payers will likely take a "wait and see" attitude before instituting Z-codes for their own private plans. Let me explain my thinking further, based on developments outside of clinical laboratory testing.

There are rumblings in reaction to an external brouhaha caused by pushback from providers about UHC's proposed colonoscopy prior-authorization requirements. The pushback came from the gastroenterology societies, who argued that it's hard enough to get patients scheduled for colonoscopies, and now physicians potentially needed to get a prior authorization from UHC for the procedure.

Solid Logic for Z-codes Encourages Adoption

DESPITE THE DRAMA, Z-codes seem to be a sound approach for genetic test claims.

As some of you know, the DEX Diagnostic Exchange registry administers Z-codes in states for **Medicare Advantage** claims under the Molecular Diagnostics (MolDX) Program. Many, if not all, payers are already familiar with Z-codes for genetic tests for Medicare Advantage patients. In that significant regard, Z-codes seem to be the most logical next step for private plans to better manage genetic test reimbursement.

Let's face it: All health plans are worried about their financial situation for 2023 and 2024. Using Z-codes is going to save payers a ton of money. Right now, when a new genetic test claim comes in to UHC, they're not sure what the test does. It may have an ambiguous CPT code on it, but there's no Z-code. So, UHC and other payers must ask for medical records to review, and that costs money and wastes time for the lab, the ordering physician, and the health plan.

On the other hand, Z-codes would spell out for payers a test's components and the diagnostic matches that are needed for reimbursement. And a claim with a Z-code should be able to go through the adjudication process without invoking medical records review. Z-codes can save plans money by quickly letting them see that a test may not be appropriate for a person at this time.

On June 2, *STAT* reported, "After weeks of protest from physician organizations and patients, UnitedHealthcare has put a controversial new prior-authorization policy for gastroenterology procedures on hold. The policy, which requires physicians and patients to get approval from the insurance giant for nearly all gastroenterology procedures, including diagnostic and surveillance colonoscopy, or potentially face paying out of pocket, would have gone into effect on June 1."

Just to be clear, colonoscopies are not genetic tests. But the colonoscopy flareup caused tension in the market. UnitedHealthcare created that tension because of a new policy.

Does that mean UHC will step back from their new Z-codes policy? Maybe. Does that mean UHC is going to scrap Z-codes for commercial claims? I don't think so. There is an undercurrent of concern because of what various laboratory advocacy groups are discussing regarding labs not getting paid by UHC and other payers, as well as because of what the gastro societies are saying about prior authorization for colonoscopies. People are up in arms about what UnitedHealthcare is doing across the board.

In July, **UnitedHealth Group**—UHC's parent company—reported its Q2 earnings. Among the interesting numbers was $5.7 billion in profit for the quarter, up nearly 9% year over year.

Adding to the frustration is UHC's mergers and acquisitions strategy. People in the lab industry are questioning how UHC can talk about reining in costs for genetic test claims while at the same time recently agreeing to acquire **Amedisys**, a home health and hospice company. The deal was worth $3.3 billion, as reported by *Reuters* on June 26.

Reuters wrote, "Interest in the home health sector has been rising since the pandemic as more patients and caregivers prefer accessing medical services from the safety of their homes."

Some naysayers argue that if UnitedHealthcare can spend $3.3 billion to purchase a home health and hospice company, then why can't UHC pay laboratories whose diagnostic results make up a significant part of every member's medical record?

That's the buzz out there with UHC. There is plenty of provider displeasure with UnitedHealthcare right now. So, the other payers are keeping a careful eye on the situation with UHC's Z-Code requirement for genetic test claims.

Employers May Take Notice

For many patients—especially those who need a genetic test quickly if they're suddenly ill or stricken by disease—all of this debate about Z-codes will go over their heads. They are focused on their illness and won't care.

But an external party that will care about Z-codes is at-risk employers. If an employer's health coverage is paying for genetic testing, they may want these Z-codes for more clarity on what they're paying for.

Employers are looking at their bottom line, particularly if genetic test claims from their employees have skyrocketed. This scenario will be repeated at different companies as employers add genetic testing options to their health insurance benefits to attract younger job candidates.

In conclusion, I think it's likely that UHC will follow through on its new Z-code policy, but it does so at the risk of upsetting an already agitated provider side. Other payers are closely watching how UHC handles any resistance it gets to the Z-code mandate. Based on how that response goes, other payers will proceed accordingly.

The bottom line is genetic testing claims have exploded, and both government and private payers are looking for a way to better manage reimbursement for the tests. Z-codes appear to be UnitedHealthcare's answer. TDR

CLIA Assessors Identify Source of Deficiencies

How labs assess laboratory staff competencies is common source of citations during inspections

Denise Driscoll, MS, MT(ASCP)

CEO SUMMARY: *Competency assessment problems rank high among frequently cited deficiencies during CLIA inspections. Representatives from the CAP, COLA, and The Joint Commission explain what areas to watch out for and how to avoid citations. Among the hotspots: ensuring technical consultants and technical supervisors are qualified.*

Kathy Nucifora, MPH, MT(ASCP)

Editor's note: This is the first installment in an occasional series of inspection readiness briefings that focus on how to avoid the most common citations seen during inspections under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

EACH YEAR, ORGANIZATIONS WITH CLIA DEEMING AUTHORITY report that competency assessment citations rank as one of the top 10 sources of deficiencies during CLIA inspections. Even well-run labs often find themselves cited for this type of violation.

This insight was shared at one of the most popular sessions at this year's *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management.* A panel of CLIA accreditors presented their respective lists of the top 10 sources of deficiencies they recorded during CLIA inspections in the prior year. *(See TDR, "CLIA Lab Accreditors Reveal Most Frequent Deficiencies," May 30, 2023.)*

Competency assessment citations ranked high from all the CLIA accrediting groups, which included:

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

This intelligence briefing is designed to help clinical lab managers and pathologists better understand CLIA's competency assessment requirements and the most common sources of citations involving these requirements.

Six Elements of Competency

CLIA falls under Section 493 of the Code of Federal Regulations. Subpart M covers competency assessments for lab personnel involved in nonwaived testing. These evaluations generally cover six areas:

- Direct observations of routine patient test performance, including patient preparation if applicable, specimen handling, processing, and testing.
- Monitoring the recording and reporting of test results.
- Review of intermediate test results or worksheets, quality control records,

proficiency testing results, and preventive maintenance records.

- Direct observation of performance of instrument maintenance and function checks.
- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
- Assessment of problem-solving skills.

These assessments must be completed by technical consultants for moderate-complexity testing and technical supervisors for high-complexity testing. A CLIA laboratory director can fulfill either role in many cases.

"It's a lot of work for labs to do a competency assessment using all six elements for all testing systems," said Denise Driscoll, MS, MT(ASCP)SBB, Senior Director for Laboratory Accreditation and Regulatory Affairs at CAP.

➤CAP: Take Efficient Approach

Driscoll mentioned that clinical labs can often use a single activity to meet multiple competency assessment criteria. "For example, it may be convenient for a laboratory to use proficiency testing to assess test performance and also conduct direct observation, because someone can observe an employee doing the PT [proficiency testing]. Whenever a lab can use a single activity to meet more than one of the requirements, it is a good idea.

"The caveat is that a lab must carefully document this so that activities can be tracked," Driscoll added. "If a staff member handles a patient sample and the technical consultant observes them, can the consultant clearly identify which patient sample was used? Or which maintenance record was used during what month for a competency assessment?"

Careful labs will avoid simplified documentation. "Labs can't just use a lot of checkoff boxes in a big matrix from Excel. That is not going to be adequate," Driscoll explained. "Instead, laboratories need to designate space on the documentation for a date and initials of who was doing that observation. And then a CAP inspector would confirm that the person doing the observation or reviewing reports is qualified—per CLIA requirements—to assess competency."

➤Pay Attention to Travelers

"Another aspect that makes competency assessment difficult today is the shortage of lab staff," she noted. "Staff may have limited time and labs may be using traveling lab scientists who go from site to site," Driscoll said.

"CLIA requires competency assessments per CLIA ID number," Driscoll stated. "CAP often gets asked: If a lab uses temporary travelers who rotate through different sites, can the lab perform competency assessments for those travelers all at once? And the answer is no, because—per the CLIA regs—competency is measured for a location.

"So, if labs have travelers who rotate between three sites, these travelers must have their competency assessed at each site," she added.

Amy Null, MBA, MT (ASCP)

➤"With blood gas testing, The Joint Commission cites HR.01.06.01, EP 3 quite frequently."

CAP-accredited organizations can find useful resources online to help them meet staff competency requirements. "CAP has a lot of templates for competency assessment on its website for its laboratories," Driscoll noted. "The templates are either in Word or Excel. My best advice is to find a template that makes sense for your laboratory, copy it, and then make any necessary modifications. Doing so will save labs a lot of time and prevent them from missing the big pieces.

"It can be difficult to conduct competency assessments to the full extent that's necessary per CLIA requirements," she continued. "Our CAP requirement has a lot of detail in paragraphs and bullets because we try to explain exactly what's required. So, combining that verbiage with a template is a simple way to meet the intent of the CLIA requirement."

COLA: Change Lab's Mindset

It may be unsurprising—and even understandable given today's lab staffing shortages—for clinical laboratories to see competency assessments as a paperwork exercise. But that type of mindset does not live up to the spirit of the CLIA regulations, said Kathy Nucifora, MPH, MT(ASCP), Chief Operating Officer at COLA.

"Properly conducting competency assessments of lab staff has been a difficult challenge, in light of the fact that many laboratories are understaffed and rush to get competency assessments documented as part of inspection preparation," Nucifora explained. "Convincing laboratory leadership that competency assessment is one of the most important responsibilities that they have has been a mission of mine for years now.

"The answer lies in a better understanding of just how important accurate, reliable, and meaningful test results are to patient care," she added. "Without competent staff, we cannot provide data to improve the health and well-being of individuals or communities. After all, that is why we chose our profession, right? To make a difference in the lives of our patients and our communities. So, let's prioritize competency assessment and think of it as essential to the quality of our laboratories, rather than as just a necessary piece of paper to present to the surveyors."

Assessing the competency of technical consultants and supervisors is an area that has caught Nucifora's attention.

"Often, I am asked who should assess the competency of technical consultants, technical supervisors, general supervisors, and clinical consultants," she noted. "While there is not one correct answer to this question, I typically recommend that each person filling one of these positions sits down with the clinical laboratory director and goes through the responsibilities, one by one, explaining to the director what they have done—and what they do on a continuing basis—to meet these responsibilities.

"Have documentation and metrics to demonstrate how technical consultants and technical supervisors have met the responsibilities," Nucifora added. "The involved laboratory director should ask questions and follow up on any outstanding issues with the laboratory operations. This one-on-one meeting not only can serve as an ongoing competency assessment itself, but it will also keep the laboratory director engaged and connected to what is happening in the laboratory."

Routine meetings with the laboratory director throughout the year are essential and can be used as a platform to assess competency of supervisory staff.

Joint Commission Concerns

Echoing COLA's concerns, The Joint Commission notes that the biggest hang-up with staff competency assessments stems from verifying that a technical consultant performing an assessment is qualified to do so. This falls under Human Resources standard HR.01.06.01, Element of Performance (EP) 3, which requires an individual—qualified by education and experience related to the skill being reviewed—to assess staff competence.

"Far and away, the most common reason that this standard and EP are cited by The Joint Commission is because competency assessment for moderate complexity testing is not performed by an individual who meets the qualifications of a technical consultant," said Amy

Null, MBA, MT (ASCP), SBB, Associate Director of the Standards Interpretation Group, Laboratory Accreditation at The Joint Commission.

"With blood gas testing, The Joint Commission cites HR.01.06.01, EP 3 quite frequently," Null added. "Respiratory therapists typically perform blood gas testing, which is moderate-complexity testing. Sometimes the staff member who is assessing competency for therapists does not meet the minimum qualifications required for a technical consultant according to the CLIA regulations."

A helpful resource is The Joint Commission's frequently asked questions (FAQs) page for standards. "We have a FAQ section on *JointCommission.org* under the Standards heading," Null explained. "The questions are broken out according to accreditation program. So, interested parties can filter by 'Laboratory' and click on whatever chapter of the accreditation manual they want to review. We have two FAQs that address competency assessment. That's an ideal place for organizations to gain a little bit more information about requirements for particular CLIA personnel regulations."

Assessment Performance

In closing, it's clear that the frequency of competency assessment citations rise up from a few prickly areas. Observant clinical laboratory managers will want to pay close attention to who fills the roles of technical consultant and technical supervisor, as those jobs directly affect how well competency assessments are performed.

Additionally, careful documentation of competency assessments—including who observed the activities and exact procedures included—will often be a deciding factor in how an accreditor views compliance with an associated standard.

In the next installment, THE DARK REPORT will look into persistent proficiency testing deficiencies that accrediting organizations have noted. TDR

Accreditor Standards for Competency Assessment

HERE ARE STANDARDS typically cited by CLIA accreditation inspectors for poor competency assessments, broken down by accreditor:

A2LA

- 493.1235—The laboratory must establish and follow written policies and procedures to assess employee and consultant competency.

CAP

- 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.

COLA

- PER 4C (Personnel)—Technical consultant/technical supervisor fulfills the responsibilities of the position.
- PER 5—Complete competency assessment is performed and documented at required intervals for all testing personnel and supervisory staff.

The Joint Commission

- HR.01.06.01(Human Resources), Element of Performance (EP) 3—An individual qualified by education, experience, and knowledge related to the skill being reviewed assesses staff competence.
- HR.01.06.01, 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 proficiency testing; and other criteria.

Contact Denise Driscoll, MS, MT(ASCP), SBB at ddrisco@cap.org, Kathy Nucifora, MPH, MT(ASCP) at knucifora@cola.org, and Amy Null, MBA, MT(ASCP), SBB at ANull@jointcommission.org.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Regulatory relief is on the way for clinical laboratories accredited by **The Joint Commission**. An overhaul of the Laboratory Accreditation Program's standards, which goes into effect Aug. 27, will reduce the number of Elements of Performance (EPs) under the lab standards. A review of the changes shows that 79 EPs have either been revised or consolidated, while 19 EPs have been deleted.

MORE ON: *Standards Overhaul at The Joint Commission*

Many of the lab-related changes came under two chapters: environment of care and quality system assessment for nonwaived testing (QSA). The jackpot seems to be standard QSA.15.01.01, which saw 14 of its EPs consolidated into one longer EP. That standard requires written policies and procedures for molecular testing. The Joint Commission noted that its standards overhaul aims to streamline requirements and eliminate mandates that do not add value to surveys.

WERFEN ACQUIRES IMMUCOR FOR $2B

In vitro diagnostics (IVD) market consolidation continues. Barcelona, Spain-based IVD company **Werfen** has completed its acquisition of **Immucor** in Norcross, Georgia. The $2 billion deal will expand Werfen's presence in the specialized diagnostics market. Both companies are privately held.

TRANSITIONS

- John Waugh has retired after 27 years with **Henry Ford Health**, most recently as System Vice President of Pathology and Laboratory Medicine.

- Adam Baldwin has been named the new System Vice President of Pathology and Laboratory Medicine at **Henry Ford Health** in Detroit. He was previously with **University Hospitals** in Cleveland, **Case Western Reserve University School of Medicine** in Cleveland, and **Hackensack Meridian Health** in Edison, New Jersey.

- Gregory Henderson, MD, PhD, is new Executive Vice Chairman of Anatomic and Digital Pathology and Professor at **Mount Sinai Health** Network in New York City. He previously served in executive roles at **Pathline** and **BioReference Health**, both in New Jersey, and is former President of the **American Pathology Foundation**.

- **bioMérieux** in Marcy-l'Étoile, France, has appointed Jennifer Zinn as Executive Vice President of Clinical Operations. She joined the company in 2022 as General Manager. Prior to that, she worked for **Siemens Healthineers** in Germany, **Roche Diagnostics** in Switzerland, and the former **Ortho Clinical Diagnostics** (now part of **QuidelOrtho**).

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 21, 2023.

Executive Publisher: Bob Croce *bcroce@darkreport.com*
Editorial Director: Scott Wallask *swallask@darkreport.com*
Editor-In-Chief: Robert L. Michel *rmichel@darkreport.com*
Managing Editor: Michael McBride *michaelmcbride58@gmail.com*
IVD Reporter: Donna Marie Pocius *donna11019@att.net*