Volume XXXI, Number 16 Monday, November 25, 2024

## *Jane Pine Wood, JD, on...*

### *What to Watch in Lab Lawsuits Challenging FDA's LDT Rule*

***Understanding lab plaintiffs' claims***

(See pages 3-6)

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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

# 129,624 Genetic Tests in the United States

REGULATION OF LABORATORY DEVELOPED TESTS (LDTs) by the federal **Food and Drug Administration** (FDA) certainly has the attention of lab executives and pathologists across the nation. As you will read on pages 3-6, since May two different lab industry lawsuits—now consolidated into one case—were filed in a federal court in Texas and each challenges the FDA's statutory authority to regulate LDTs as medical devices.

Meanwhile, the regulatory landscape seems poised for major changes. A new Congress and a new administration, each with a different attitude toward federal regulations, gives the House of Laboratory Medicine an opportunity to educate legislators and agency directors about the value of LDTs, as well as the need for a regulatory scheme that enables the speedy development and market launch of LDTs that demonstrate clinical value in patient care.

These are worthy goals. At the same time, those who advocate for a more open regulatory scheme involving LDTs should consider that a flood of new tests arrives in the clinical market monthly, and that health insurers and policymakers struggle to understand what biomarkers are involved and how the test results can be used to improve patient care.

Two reports confirm why payers are challenged in keeping up with new LDTs. In 2017, **Concert Genetics** issued a report stating that "60,878 clinical testing products from more than 300 U.S.-based, CLIA-certified labs" were now offered for clinical use. In March 2023, the *Journal of Personalized Medicine* published a study, "Trends in Availability of Genetic Tests in the United States, 2012–2022." This report states that, as of November 2022, there were 129,624 genetic tests offered in the U.S. This is the count in the NIH's Genetic Testing Registry as well *(https://www.ncbi.nlm.nih.gov/gtr/)*.

Such a multiplicity of genetic tests—nearly all of which are LDTs—is itself a problem for physicians treating patients and with payers who receive genetic test claims. It would benefit pathologists, genetic scientists, and lab executives involved in performing LDTs to recommend how doctors and payers can sort the "good" LDTs from the "bad" LDTs. Input of this type from lab professionals would help guide the FDA, legislators, payers, and policymakers when establishing regulations and procedures that recognize a quality LDT without imposing costly, time-consuming burdens on labs. TDR

# Two Different LDT Lawsuits Combined in Federal Court

## Lab industry plaintiffs in both lawsuits agree to combine their legal actions against HHS, FDA

***CEO SUMMARY: Different lawsuits challenging the FDA's LDT rule were filed in recent months by the American Clinical Laboratory Association and the Association for Molecular Pathology. Both lawsuits were filed in the U.S. District Court for the Southern District of Texas, which will continue to oversee the now-unified case as it moves forward. Both plaintiffs make similar challenges to the FDA's authority to regulate LDTs.***

TWO DIFFERENT FEDERAL LAWSUITS that challenge the authority of the federal **Food and Drug Administration** (FDA) to regulate laboratory developed tests (LDTs) will be combined. Plaintiffs and the government in both cases agreed to move forward on this basis.

The first lawsuit was filed on May 29, 2024, by the **American Clinical Laboratory Association** (ACLA) and **HealthTrackRX** in the **United States District Court, Eastern District of Texas, Sherman Division**. The lawsuit names the federal **Department of Health and Human Services** (HHS) and the FDA as defendants.

Plaintiffs ACLA and HealthTrackRX claim that "FDA's final rule is contrary to law; in excess of statutory jurisdiction, authority, or limitations; and arbitrary or capricious, and that FDA is not authorized to regulate laboratory testing services as medical devices under the FDCA [Federal Food, Drug, and Cosmetic Act]." *(See TDR, "ACLA Files Court Challenge to FDA's Final LDT Rule," June 10, 2024.)*

The second lawsuit was filed on Aug. 19, 2024, by The **Association for Molecular Pathology** (AMP), and pathologist Michael Laposta, MD, PhD, Chair of the Department of Pathology at **University of Texas–Galveston**. This lawsuit was filed with the **United States District Court for the Southern District of Texas, Galveston Division**.

Under the current court schedule, the parties were required to file amicus briefs by Oct. 7. Next, the closing briefs by both ACLA and AMP are due by Nov. 25. The FDA will get an additional month to file its closing brief, with a filing deadline of

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

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Dec. 23. It is expected that any final decision may not come until late spring or summer of 2025.

The legal issues put forth in the ACLA and AMP lawsuits are similar. "In reviewing both complaints, including the accompanying exhibits, there is little to differentiate the legal and public policy arguments," explained attorney Jane Pine Wood of Cleveland-based **McDonald Hopkins**. "Both lawsuits make a similar case that the FDA lacks legal authority and its actions are arbitrary and capricious. ACLA's lawsuit uses exhibits to flesh out the public policy and patient jeopardy arguments. The AMP complaint weaves more of the public policy and patient jeopardy arguments into the complaint itself. However, these stylistic differences are not legally significant.

## Arguments to Be Developed

"From a legal perspective, the complaints filed by ACLA and AMP are initial filings and arguments will be developed in depth during the litigation," she continued. "Keep in mind that complaint filings are not an exhaustive list of arguments—they are more like placeholders for litigation arguments, and can always be amended and supplemented, etc.

"As this now-consolidated case goes forward, expect more emphasis on the alignment of the legal arguments, public policy, and patient jeopardy discussions delivered by ACLA and AMP," Wood noted. "To me, a strength in this consolidated case is this: the court will hear from two different associations with different membership, different testing, and serving different types of patient populations. Yet both lab associations come to the same conclusions regarding the FDA's lack of authority and the negative public policy and patient jeopardy consequences."

In its press release about the filing of its lawsuit, AMP said, "The FDA rule threatens the ability of professionals in clinical laboratories—including many academic medical centers, reference laboratories, and community health systems across the country—to create, adapt, and modify LDTs to meet patients' needs, account for supply chain issues, reflect advances in scientific understanding and practice standards, and improve performance characteristics."

## Long-lasting Consequences

"AMP remains very concerned about the wide-sweeping and long-lasting consequences the FDA rule will have for our members and patients across the country," said AMP's president Maria Arcila, MD, in the news release. "We filed this lawsuit to ask the Court to vacate the FDA rule given the agency's lack of authority to regulate LDTs and to avert the significant and harmful disruption to laboratory medicine."

AMP believes updating the current Clinical Laboratory Improvement Amendments (CLIA) regulations is essential to ensure continued progression of accurate and reliable LDTs. The authority to regulate LDTs is now performed by the federal **Centers for Medicare and Medicaid Services** (CMS) as laboratory services under the Public Health Service Act.

## FDA Did Not Act for Decades

ACLA and AMP both assert that Congress has never stated that a laboratory test is a device. They note that it was not until the 1990s—approximately 20 years after Congress enacted the medical device amendments to the Food, Drug, and Cosmetic Act—that the FDA started expressing concerns about LDTs being devices. Nearly 30 more years passed before the agency enacted its final, controversial rule expressing it had the authority to regulate laboratory tests as medical devices.

"The FDA states that CLIA was meant to compliment rather than replace the FDA's authority over LDTs," attorney

Pine Wood explained. "The FDA is saying it has always had the authority to regulate LDTs as they have always been devices. But, the FDA regulations today really don't fit with LDTs. They fit for a physical device or drug. As emphasized in the litigation challenges, aspects of the final rule infringe upon the practice of medicine," she added.

A legislative proposal by AMP to update CLIA builds on the oversight framework for LDTs that currently exists, and it adds enhancements to ensure test quality. In the news release, AMP stated it "believes this approach is a far more streamlined and cost-effective regulatory framework that improves oversight, enhances transparency, preserves innovation, avoids escalating healthcare costs, and ensures widespread patient access to vital medical services."

## Stakeholders Will Collaborate

"AMP will continue working with key stakeholders to develop a more effective and efficient legislative framework that ensures high-quality patient care while continuing to foster rapid innovation and the promise of new diagnostic technologies," said Arcila in the news release.

In discussing the lawsuit filed by AMP, Wood noted that many of its members come from acute care hospitals and academic medical centers, and that AMP has a focused perspective on these same types of highly complex LDTs where the FDA believes there are significant patient safety issues.

"AMP can take a focused and informed view on the impact the FDA LDT rule will have on the availability of these highly complex LDTs," she added. "AMP will have credibility, particularly on how the final rule will significantly and negatively affect patients who are undergoing diagnostic testing for cancer and testing relevant to their cancer treatments.

"Laboratory developed tests are critical in order to meet patient care needs in this sector of laboratory medicine," Wood observed. "These clinical laboratories cannot wait for years to modify or develop new tests because they are the leading edge of medicine and advances in the treatment of cancer and other serious health conditions.

"The FDA focuses upon its statutory interpretation arguing that it has the authority to regulate devices," she noted.

## Lab Groups File Amicus Curiae Brief

**OTHER ORGANIZATIONS HAVE JOINED** with ACLA and AMP in challenging the FDAs final ruling on LDTs.

In October, the **Association for Diagnostics and Laboratory Medicine** (ADLM), the **American Association of Bioanalysts**, the **American Society for Clinical Pathology**, the **American Society for Microbiology**, and the **Infectious Disease Society of America** all filed an *amicus curiae* brief backing ACLA in its challenge against the FDA. This type of brief is filed by unsolicited factions who are not a party to the case, but who offer additional information pertinent to a case.

The brief emphasizes the FDA's ruling is already having a negative effect on patient care and that it will drastically diminish the ability of labs to innovate. It supports ACLA's belief that the FDA's final LDT rule exceeds the agency's authority and urges the court to overturn the rule before it causes irreparable patient harm.

"We at ADLM commend ACLA for acting to safeguard patient access to laboratory developed tests," said Anthony Killeen, MD, PhD, ADLM president in a news release. "Along with our partners, we are pleased to support ACLA in helping explain to the court, not only how the FDA has exceeded its authority, but also why the agency's unilateral action is so detrimental to patient care."

"Both ACLA and AMP take the position that an LDT is not a device under the FDA for a variety of reasons. "Lots are really services," she continued. "The FDA's position that LDTs are devices is a bit counterintuitive. Moreover, its definition of the term 'device' is so broad that it would seem as though it could cover anything."

An equally major concern is the true cost of compliance as labs work to comply with the new LDT rule. That concern is compounded by the recognized, acute shortages of laboratory professionals in the United States. Most labs are cash-strapped and struggle to maintain a fully staffed laboratory.

"Even the FDA has said the cost of compliance for LDTs can run many millions of dollars per test, so the FDA has acknowledged that many laboratories are not going to be able to afford to go through the process with all their LDTs," Wood said.

## Fewer LDTs Will Be Created

"It means there are clinical laboratories that will cease performing their LDTs or developing new LDTs," she continued. "For lab professionals and other clinicians who are on the cutting edge of science and medicine, where is the incentive to devote resources to discovering and developing useful new diagnostic tests?

"Another concern that centers on the FDA's position is that these LDTs should have always been subject to its regulation and that, but for its enforcement discretion, the services provided by these laboratory professionals would be in violation of the law," Wood noted.

"Going forward, for those labs determined to be out of compliance, the FDA states that it intends to take harsh action against them. That is very discouraging," she said.

"Most laboratory professionals are very dedicated people. They're working very hard. The quality of U.S. laboratory testing is incredibly high," Wood added. "There is a reason why private hospital and private clinics throughout the world contract with U.S. laboratories to have high-end laboratory testing done because of the quality."

## Contacting Elected Officials

Wood encourages lab professionals to reach out to their elected officials and explain why the FDA's ruling on LDTs need to be modified.

"Turn-around time is going to increase because you're going to have fewer players performing these services and they're going to have a higher test load," she said.

"One of the things that has been so exciting over the past decades with respect to the diagnosis and treatment of cancer has been all the rapid development in terms of testing to help focus what chemotherapy treatments are appropriate for patients," she added.

"It reduces access to care because there are going to be fewer labs performing the testing," she said.

## Less Innovation

"We're not going to have the same innovation as before. Right now for someone to develop a new test as an LDT, there's still significant failure, validation, and other quality standards under CLIA to go through," Wood noted.

"Today, as a knowledgeable patient, I'm very confident and comfortable that my laboratory testing is safe, it's effective, it's validated," she continued. "I'm very comfortable with the laboratory testing in this country, but what's going to happen in the future?"

The FDA has not yet responded to the original ACLA lawsuit. THE DARK REPORT will keep clients informed of any updates regarding this situation. TDR

*Contact Jane Pine Wood at jwood@-mcdonaldhopkins.com.*

Obituary

# Pathologist Frederick Kiechle, MD, Molecular Pioneer, Dies at 78

*He was one of the first to bring molecular tests into hospital laboratories and build outreach volumes*

CLINICAL PATHOLOGY LOST ONE OF ITS GREATEST PRACTITIONERS when pathologist Frederick L. Kiechle, MD, PhD, FCAP, of Cooper City, Fla., died on July 30, 2024, at the age of 78.

Kiechle—known as Fritz to his colleagues and friends—was continually at the forefront of laboratory medicine. In the late 1980s he was among the first pathologists to introduce molecular testing in patient care while Chair of Clinical Pathology at **William Beaumont University Hospital** in Royal Oak, Michigan.

Frederick Kiechle, MD
1946-2024

In the early 1990s, Kiechle quickly followed the introduction of molecular testing in his lab by offering a series of seminars to train other pathologists and laboratory scientists in the rapidly developing field of molecular diagnostics.

## Remarkable Career

Throughout his career Kiechle was prolific in how he shared his knowledge and experience, whether it be published studies, public presentations, or as editor of a long-running column in *CAP Today*. His family listed the following accomplishments on his obituary page:

> *Fritz remained an active member of the* ***College of American Pathologists*** *throughout his career. He served on multiple committees including the Publications Committee. He was involved in writing the CAP phlebotomy instruction manual "So You Want to Collect a Blood Specimen" for three decades, serving as editor for more than 10 editions. Throughout his career, Fritz published 181 peer-reviewed articles, 24 book chapters, two books, 231 abstracts, and gave 238 presentations. He published his first solo authored book "Disruptive Technologies in Clinical Medicine" in 2023.*

In addition to Kiechle's notable contributions to the practice of clinical pathology, he was successful at growing the laboratories he supervised. Those who worked with him observed that his motivation was less about building a revenue-generating laboratory business and more about how to build the specimen volume in ways that would allow him to offer more types of molecular and reference tests. This served his passion as a pathologist because his lab was providing services to physicians throughout Michigan with an expanding test menu that helped them deliver better care to their patients.

Leo Serrano, now retired, recalls how Kiechle was always ready with advice and insight. "I go back to the 1980s with Fritz," he said. "At the same time that Fritz was establishing **Beaumont Reference Labs** as an outreach laboratory program, I was

in Florida creating **Wuesthoff Reference Labs** for **Wuesthoff Health Systems**. In the 1980s, there was no business model for a hospital-based reference laboratory.

"Fritz and I talked regularly," Serrano continued. "Fritz was always full of ideas and ready to share them. This was the time when he was growing Beaumont Reference Labs until it covered the entire state of Michigan.

## Always Ready to Share Advice

"He advised me to expand the Wuesthoff lab throughout the state of Florida," Serrano said. "He gave me the idea to provide lab testing services to medical examiners. This advice helped us build specimen volume in ways that allowed us to perform more types of tests in-house. In turn, our clinicians benefited from the expanded menu of locally performed reference and esotric tests.

"It's noteworthy that Fritz was doing molecular testing in an academic center before PCR was discovered and patented," Serrano added. "This is a clinical pathologist who was always at the front edge of advances in diagnostic technology."

Another retired clinical laboratory CEO who worked closely with Kiechle is Joe Skrisson, director of business development and operations at Beaumont Reference Labs for almost a decade. "Of all the clinical pathologists I worked with during my career, Fritz was definitely one of the best," he declared.

## A Rebel to Acquire Tests

"In many ways, he was a rebel to get the types of innovative lab tests he believed would improve patient care," Skrisson recalled. "In my business development role, I had one of the best lab services to offer physicians in the state of Michigan.

"Fritz developed a full-service reference lab that was comparable to other major national reference labs of the 1980s and 1990s, such as **Mayo Medical Laboratories**," he continued. "One sign of his leadership in molecular testing was the respect the laboratory profession had for the molecular training workshops and programs he organized at Beaumont. Because of their quality, they became must-attend events for any lab scientist ready to dive into the rapidly evolving field of molecular diagnostics."

After almost 23 years at Beaumont Health Services, Kiechle left the cold climate of Michigan and moved south to Florida. He served as medical director of clinical pathology at **Pathology Consultants of South Broward**. This pathology group was contracted with the five hospitals of **Memorial Healthcare System** in Hollywood, Fla.

## Interesting Coincidence

Coincidentally, Serrano and Kiechle ended their respective lab careers in the same county in Florida. During several of those years, Serrano also worked in Broward County as corporate director of laboratory services at **Broward Health**, in Ft. Lauderdale, Fla. The two continued their professional and personal friendship during those years.

One example of Kiechle's willingness to help came during the **Theranos** years. Then-CEO Elizabeth Holmes claimed that Theranos could perform up to 100 or more assays on a capillary specimen. THE DARK REPORT was the only news source to go to the expert of experts on lab specimens. We published Kiechle's statements about the limitations of using capillary blood for lab tests.

One closing thought that Skrisson wanted to add about Kiechle is that "he had a giving nature. If anyone ever needed help, Fritz was the first to step up!"

Leo Serrano had the definitive last word when describing Kiechle's talents and remarkable career. "My career in laboratory medicine spanned 60 years," Serrano declared. "Throughout those full six decades, Fritz Kiechle's expertise in clinical pathology was unmatched!" TDR

Market Update

# Latest Kaufman Hall Report: 40% of Hospitals Losing Money

*Analysis compared finances of 1,300 hospitals for April, compared to this March and last year*

MANY HOSPITALS REPORT HEALTHIER FINANCIAL PERFORMANCE IN THE PAST 18 MONTHS. At the same time, a large proportion of U.S. hospitals have negative operating margins.

This means the gap is widening between the group of hospitals with positive operating margins, compared to hospitals with negative operating margins. This has implications for clinical laboratory administrators in the nation's hospitals and integrated delivery networks (IDNs).

The recent data on the financial performance of the nation's hospitals came from monthly reports issued by Chicago-based **Kaufman Hall** (KH). Its "National Hospital Flash Report" was released on June 3. The report compared the financial performance of hospitals in April to that in March and the same month in 2023.

## 40% of Hospitals Lost Money

One key finding was mentioned by Erik Swanson, KH's senior vice president of data and analytics and reported by *Becker's Hospital Review*. He stated that "40% of hospitals are losing money."

Kaufman Hall worked with the data from 1,300 hospitals, as provided by **Syntellis Performance Solutions**, a business unit of **Roper Technologies**, which also owns **Clinisys** (formerly **Sunquest Information Systems**). KH reported that hospital operating margins were improving overall. At the same time, there is a widening gap separating top-performing hospitals from those at the bottom. KH's analysis showed that best performing hospitals had a margin of 28.9%. By contrast, the group of worst-performing hospitals had an operating margin of -16.1%.

## High- and Low-Performers

"While financial performance looks solid on the surface, a closer examination of the [Syntellis] data shows a greater divide between high-performing hospitals and low-performing hospitals," Swanson commented. "Organizations that weathered the challenges of the last few years have adopted a wide range of proactive and growth-related strategies, including improving discharge transitions and building a larger outpatient footprint."

April did show improvement for not-for-profit hospitals, with Kaufman Hall stating their margins were 4.3% in April, a gain of 33% from April 2023. Inpatient revenue climbed 12% year over year in April while outpatient revenue increased 10% during that same period.

Because 40% of the 1,300 hospitals studied by Kaufman Hall are losing money, industry analysts expect stronger health systems will continue to acquire financially struggling health systems. This will further consolidate the hospital industry.

Similarly, more sales of lab outreach programs will happen as money-losing hospitals and IDNs take steps to raise cash and bolster their balance sheets. TDR

## How Innovative Pathology Groups Gen

# Proven Ways to Pathologist Proc and Compensati

**➤➤ *CEO SUMMARY: There is now extensive data ogists serving in 230 pathology groups that sh and business strategies can lift a group's colle increase the total annual compensation of the gr This is the first of a series of intelligence briefing findings from a study conducted by the National Leaders and shared at last spring's Executive W***

### PART ONE OF A SERIES

THERE IS STRONG EVIDENCE THAT MOST ANATOMIC PATHOLOGY PRACTICES fail to maximize the reimbursement they receive. This is true for the pathology services they provide, their Part A Pathology Service Agreements with hospitals, and how they negotiate managed care contracts with payers.

Two respected experts with a combined 52 years of experience in the financial and operational management of anatomic pathology practices assert that many pathologists are leaving substantial amounts of money on the table and they only need to take simple steps to capture this additional income.

The recommendations of these two experts will be of particular interest to pathology practice administrators and the pathologist-business leaders of their groups. Lab administrators in multi-hospital health systems can also use this information to boost the net collected revenue of the anatomic pathology service lines delivered by their organization.

The experts are Robert Tessier, MPH, co-founder of **Panel of National Pathology Leaders** (PNPL) in Woodbridge, CT, and Al Sirmon,

# erate More Income

# Improve ductivity ion

***from 1,400 pathol- ow certain clinical ected revenue and oup's pathologists. s that presents the Panel of Pathology ar College.***

founder, **Pathology Practice Advisors, LLC**, Pawleys Island, SC.

In part one of this series, Tessier and Sirmon discuss two areas of practice management. One deals with the most effective approaches to identify and organize pathologist productivity. The other addresses the specific compensation arrangements that can lift the revenue of pathology groups and boost the compensation of individual pathologists.

In coming issues, the series will share information from Tessier and Sirmon on Hospital Part A compensation agreements and negotiations with managed care companies and other third parties.

Tessier presented the information which follows at the 29th annual *Executive War College* on April 30-May 1, 2024, in New Orleans, in a session titled, "What's New in Pathologist Productivity and Compensation; Plus Boosting Profitability through Effective Negotiations with Hospitals and Payers." Future installments of this series will cover Sirmon's part of the presentation.

## PATHOLOGIST PRODUCTIVITY

### Best Measurement Methods

The productivity of individual pathologists within a group setting is the foundation for all the income-generating activities that sustain the group's ability to deliver state-of-the-art diagnostic services in a financially sustainable manner.

"Use of work relative value units (wRVUs) by group is one way to identify anatomic pathology labs that are top performers," Tessier noted. "These groups are the 'best practice' sites that teach us the necessary steps to optimize pathologist productivity in ways that enhance a group's revenue and the compensation it pays its pathologists."

Tessier presented a study of 2019 pathologist productivity that PNPL performed in 2021. The survey evaluated data provided by 230 pathology groups, involving approximately 1,400 pathologists and their clinical activities in private practice. The study segmented the wRVU by group size, ranging from practices of 1-3 to 25+ pathologists.

"Keep in mind, for every patient exam or procedure performed, a certain number of work RVUs are applied," Tessier explained. "Every CPT code has a coordinating wRVU based on the complexity of the procedure or patient visit."

The median annual number of wRVUs per pathologist was 6,582, while the mean was 7,452. *(See sidebar on page 13.)*

"Please note that only six large pathology groups of 25+ pathologists were

represented, while by far the largest percentage (43%) were smaller groups," Tessier observed.

PNPL then took the analysis one step further, Tessier said. "We talk about the 75th percentile versus the 90th percentile of productivity. *(See sidebar page 13.)* For the 75th percentile, we're talking about each pathologist performing 9,300 workload units a year. At the 90th percentile, each pathologist averages as many as 12,000 workload units a year. Obviously, compensation directly ties into that."

**Pathologist Compensation**

## ➤'Innovative' vs. 'The Norm'

Following the analysis of pathologist productivity, Tessier then presented what the PNPL 2019 study revealed about how different compensation arrangements can significantly increase the income earned by a group's pathologists.

To illustrate the sizable compensation difference between a high-performing pathology group practice versus an average-performing pathology practice, Tessier provided what he called a "Tale of Two Cities/Tale of Two Practices." This is an analysis of an "innovative practice" versus "the norm practice." As explained earlier, the data for this comparison came from the 2021 survey completed by 1,400 pathologists practicing in 230 pathology groups.

"The common element in this analysis is that every pathologist in each practice performs about 10,000 wRVUs annually," he noted. "'The norm' practice pathologists were paid about $400,000 per year plus about $75,000 for fringe benefits and other costs. However, the 'innovative practice' pathologist, was paid about $578,000 plus $75,000 for fringe benefits and other costs. Base salaries and benefits were the same, about $325,000, but the additional income came from bonuses—$150,000 per year for 'the norm' and about $328,000 for 'innovative practice.'"

The "innovative practice" was dubbed a "Small Community Hospital" while "the norm" practice was a "Big City Institution." The most successful practice, he noted, was in the Community Hospital.

"Pathologists working in this setting work with referring physicians much more effectively. These pathologists strive to do things they consider appropriate and in a much more detailed fashion. This is reason why they were more successful at lifting their average annual compensation," Tessier said.

## ➤Components of Path Revenue

Tessier and Sirmon then showed an analysis of the revenue components of the "innovative pathology practice" that allowed it to generate more revenue than the "normal pathology practice." The factors include:

- **Part A Support:** Tessier noted, "In our study, we saw that the innovative pathology practice generated more in the way of Part A support. It was paid roughly $125,000 of Part A support per pathologist. By contrast, the normal pathology group generated about $50,000 per year in Part A support."
- In addition, the "innovative practice" incorporated a performance-based incentive plan. Because of this incentive, each pathologist in the "innovative practice" was paid an additional $10,000 a year above and beyond the $125,000 from Part A.
- **Part B Support:** This includes: 1) Part Third-Party Reimbursement; 2) Global Billing for Referred Services; 3) Professional component of clinical pathology billing (PCCP), net of operating costs, and gastroenterology (GI) physicians office laboratory (POL), which was broken into Professional Component (PC) and Technical Component (TC).

On the Part B side, "the 'innovative practice' had approached different

# Using Pathology Work RVUs to Identify Groups That Outperform Their Peers

**BELOW ARE THE DATA PRESENTED** by Bob Tessier and Al Sirmon at the *Executive War College* last spring. Based on 2019 information provided by 230 groups representing 1,400 pathologists, the first table shows the median and mean work Relative Value Units (wRVUs) for different size pathology groups. The second table shows the wRVU percentiles for groups of different sizes.

## 2019 Pathology Work RVUs: Statistics by Group Size

*(Shows the yearly average wRVUs produced by each pathologists in each bracket)*

| Practice Size | # of Groups | % of Total | #of Pathologists | Median wRVU | Mean wRVU |
|---|---|---|---|---|---|
| 1-3 | 98 | 43% | 192 | 6,309 | 8,192 |
| 4-6 | 57 | 25% | 267 | 6,282 | 7,663 |
| 7-9 | 32 | 14% | 257 | 7,107 | 7,606 |
| 10-14 | 25 | 11% | 295 | 6,565 | 7,124 |
| 15-24 | 12 | 5% | 218 | 6,156 | 7,049 |
| 25+ | 6 | 3% | 209 | 6,988 | 7,196 |
| **All Groups** | **230** | **100%** | **1,438** | **6,582** | **7,452** |

## 2019 Pathology Work RVUs: Percentiles

*(Based on the yearly average wRVUs produced by each pathologists in each bracket)*

| Practice Size | 25th | 50th | 75th | 90th |
|---|---|---|---|---|
| 1-3 | 4,269 | 6,309 | 9,390 | 16,205 |
| 4-6 | 4,740 | 6,282 | 9,454 | 12,762 |
| 7-9 | 4,710 | 7,107 | 9,557 | 12,190 |
| 10-14 | 4,365 | 6,565 | 9,075 | 11,763 |
| 15-24 | 4,520 | 6,156 | 9,115 | 11,312 |
| 25+ | 5,105 | 6,988 | 9,180 | 10,557 |
| **All Groups** | **4,619** | **6,582** | **9,309** | **11,842** |

## Comparing 'Innovative' vs. 'Normal' Path Groups

| Income | Innovative Practice | The Norm | Incremental |
|---|---|---|---|
| **Part A** | | | |
| 1. Hospital Support | $125,000 | $50,000 | $75,000 |
| 2. Performance Based Incentive | 10,000 | 0 | 10,000 |
| **Part B** | | | |
| 3. Third Party Reimbursement | 50,000 Above Norm | Norm | 50,000 |
| 4. Global Billing Referred Services | 25,000 Technical Overage | 0 | 25,000 |
| 5. PCCP (net of operating costs) | 100,000 Non-PAR | 60,000 PAR | 40,000 |
| 6. GI POL | | | |
| Professional Component | 150,000=Medicare ($40=88305) | 75,000=Flat Fee ($20=88305) | 75,000 |
| Technical Component | 25,000=Overage (Non Care/Non Caid) | 0 | 25,000 |
| | | | **$ 300,000** |

*Data provided by Panel of National Pathology Leaders (PNPL), Woodbridge, CT*

## 230 Path Groups Show Proven Path to Profits

**FINDINGS FROM A STUDY** involving productivity and compensation data from 230 pathology groups representing 1,400 pathologists provide valuable insights on the clinical and business strategies that generate the most income.

Conducted by the Panel of National Pathology Leaders (PNPL) in 2021, using data collected from 2019, the findings were presented at this spring's *Executive War College*.

"This data produced several invaluable insights," declared Robert Tessier, MPH, co-founder of PNPL. "The data demonstrates how pathology groups pursuing several strategies involving pathologist productivity and revenue-generating approaches are able to pay their pathologists significantly more compensation, compared to a 'typical' pathology group.

"Given the evidence from this study of 230 pathology group practices, every group should have strategies for:

- Professional component (PC).
- Global billing for referred services.
- Professional component clinical pathology (PCCP) billing.

"There is compelling data that confirm the value of these strategies in boosting pathologist income," he added.

payers and the third parties and talked about raising the bar in ways that would improve patient care and control costs," Tessier explained.

"The practice that was 'the norm' was complacent and wasn't spending the time and effort to do that," he added. "As a result, using the same volume of activity and roughly the same third-party payer activity, the 'innovative pathology practice' was creating about $50,000 more per pathologist in Part B reimbursement. The group also had Global Billing for Referred Services. We also analyzed the PCCP and PAR factors in these pathology groups.

### PCCP and PAR

"PCCP stands for Professional Component of Clinical Pathology, which refers to the pathologist billing for his or her services for oversight of a hospital pathology laboratory," he continued. "PAR refers to physicians who comply with various laws and regulations related to certain aspects of the practice's participation with the Commercial insurance programs. Non-PAR, of course, refers to non-participating pathologists. Data showed that the 'innovative practice' participating in PAR generated $25,000 more/pathologist due to billing for the technical work. And with the PCCP, it brought in about $100,000 per pathologist versus a non-PAR group doing about $60,000. This illustrates the financial consequences of a group with PAR status versus non-PAR status."

### Serving GI Practices

The final component of the Part B compensation was Relationships with GI practices (Physician Office Laboratories, POL). "Rates can vary," Tessier said. "One example was a pathologist group getting paid at the Medicare rates of about $40 for the 88305, contrasted with another pathology practice working on a percentage contract with GI practices and bringing in around $20 for the 88305.

"The first pathology group in the example above also had a technical component differential on the GI practices that brought in about $25,000 more a year," he added. "There are many different ways that pathology practices can break down activities that can be tied to more reimbursement."

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***This series will continue in coming issues of THE DARK REPORT.***

IVD Update

# Global IVD Companies Issue Third Quarter 2024 Earnings

*Nearly all in vitro diagnostics firms report modest growth, discuss plans for 2025*

HERE IS A SUMMARY OF THE SECOND QUARTER FINANCIAL PERFORMANCE of the largest IVD manufacturers serving clinical laboratories.

Lab managers and pathologists can use this information to track the market successes or setbacks by the different IVD vendors. These insights can be particularly helpful when considering different companies when it is time to replace or upgrade lab automation and analyzers.

Abbott
A Promise for Life

## *ABBOTT LABORATORIES:* Q3 Total Sales Up Nearly 5%

**Abbott Laboratories**, Abbott Park, Ill., shared these Q3 2024 financial results as compared to Q3 2023:

- Q3 sales grew 4.9% to $10.63 billion from $10.14 billion.
- Nine-month revenue was up 3.7% to $30.97 billion from $29.86 billion.
- Q3 Diagnostics sales were down 1.5% to $2.41 billion from $2.44 billion.
- Q3 Core laboratory sales were flat at $1.31 billion.
- Q3 Molecular sales decreased 3.6% to $128 million from $133 million.
- Q3 Rapid diagnostics fell 4.4% to $824 million from $862 million.

During an earnings call, CEO Robert Ford said that when the COVID-19 sales effect was excluded, both Diagnostics and Core laboratory diagnostics increased 4.5%.

"Growth in core lab was driven by global demand for routine testing and continued adoption of our market-leading diagnostic systems and testing platforms. This includes recent large account wins that will help sustain our growth into 2025," he said.

"In our rapid and point-of-care diagnostics businesses, we continue to expand our test menus and capitalize on the growing demand for respiratory tests that can be performed at home or in more traditional healthcare settings," continued Ford, who hinted at a new product, saying, "Soon, we'll probably be talking about a new system that we will launch for a whole new segment of the diagnostic industry."

Roche

## *ROCHE:* Increases in Pathology Lab Sales and Core Lab Sales

**Roche Group**, Basel, Switzerland, released these financials for nine months of 2024 as compared to nine months of 2023:

- Group sales were up 2% to 44.98 billion Swiss francs (CHF) (US$51.06 billion) compared to 44.05 billion CHF (US$50 billion) last year.
- Diagnostics Division sales were up slightly to 10.72 billion CHF (US$12.17 billion) versus 10.68 billion CHF (US$12.12 billion).
- Core lab sales grew 4% to 6.05 billion CHF (US$6.86 billion) from 5.83 billion CHF (US$6.61 billion).

- Molecular lab revenue was flat at 1.90 billion CHF (US$2.15 billion) versus 1.89 billion CHF (US$2.14 billion).
- Pathology lab sales were up 11% to 1.15 billion CHF (US$1.30 billion) from 1.04 billion CHF (US$1.18 billion).

Roche said its immunodiagnostic products (including cardiac, oncology, and thyroid tests) drove growth in diagnostics, along with pathology and molecular solutions.

Roche recently closed its acquisition of **LumiraDx's** point-of-care technology, which it described as multi-modal tech to perform clinical chemistry, immunoassay, and "potentially molecular diagnostics."

ThermoFisher SCIENTIFIC

## *THERMO FISHER:* Q3 Specialty Diagnostics Revenue Up

**Thermo Fisher Scientific**, Waltham, Mass., reported Q3 2024 financial results as compared to Q3 2023:

- Q3 revenue was up slightly to $10.60 billion from $10.57 billion.
- Nine-month revenue was $31.48 billion compared to $31.97 billion.
- Q3 Laboratory Products and BioPharma Services segment revenue was $5.74 billion up slightly from $5.72 billion.
- Q3 Life Sciences Solutions segment revenue was down 2.05% to $2.38 billion from $2.43 billion.
- Q3 Analytical Instruments segment revenue was up 2.8% to $1.80 billion from $1.75 billion.
- Q3 Specialty Diagnostics segment revenue was up 3.7% to $1.12 billion from $1.08 billion.

On the earnings call, CEO Marc Casper addressed growth in diagnostics. "During the quarter, the team delivered good revenue growth in our transplant diagnostics and immunodiagnostics business, as well as the healthcare market channel."

SIEMENS Healthineers

## *SIEMENS HEALTHINEERS:* Boosts FY 2024 Revenue 3%

**Siemens Healthineers**, Erlangen, Germany, released Q4 and full 2024 fiscal year financials as compared to 2023:

- Q4 revenue was up 4.5% to €6.32 billion (US$6.71 billion) from €6.05 billion (US$6.42 billion).
- Full-year revenue was up 3.1% to €22.36 billion (US$23.75 billion) from €21.68 billion (US$23.03 billion).
- Q4 Diagnostics revenue was down 5.1% to €1.14 billion (US$1.21 billion) from €1.20 billion (US$1.27 billion).

In a presentation to investors, Siemens said a diagnostics "transformation" has resulted in €300 million (US$318 million) savings during the fiscal years 2023 and 2024. The company expects low single digit revenue growth in diagnostics during 2025.

BIO-RAD

## *BIO-RAD LABORATORIES:* Clinical Diagnostics Drives Sales Increase

**Bio-Rad Laboratories**, in Hercules, Calif., shared Q3 2024 financial results as compared to Q3 2023:

- Q3 Sales were up 2.8% to $649.7 million from $632.1 million.
- Nine-month revenue was $1.89 billion, down 5% from $1.99 billion.
- Q3 Clinical Diagnostics segment sales jumped 5.6% to $388.8 million from $368.1 million.
- Q3 Life Science segment sales were down 1.0% to $260.9 million as compared to last year's $263.5 million.

Bio-Rad's net sales increase was reportedly driven by its Clinical Diagnostics segment. "Overall, we continue to see strong interest in our recently launched ddPCR

(droplet digital PCR) assays targeted at the oncology, cell, and gene therapy markets. We also continue to maintain a strong win-loss and loss ratio for our digital PCR platform in our current market segments," said CEO Norman Schwartz during an earnings call.

QuidelOrtho

### *QUIDELORTHO:* Q3 Revenue Down 2.3%, Molecular Diagnostics Eyed for Future Growth

**QuidelOrtho**, San Diego, shared Q2 2024 financials as compared to Q2 2023:

- Q3 revenue decreased 2.3% to $727.1 million compared to $744.0 million.
- Nine-month revenue was down 18.8% to $2.07 billion from $2.55 billion.
- Q3 Labs revenue fell 4.2% to $355.9 million from $341.4 million.
- Q3 Point-of-care revenue was down 11.8% to $205.6 million from $233.1 million.
- Q3 Molecular Diagnostics revenue was flat at $5.6 million.

The financial results reflect initiatives including a plan to realize $100 million in cost savings through the first half of 2025, according to CEO Brian Blaser, who spoke during an earnings call. He called QuidelOrtho's Savanna and molecular diagnostics drivers of "future profitable revenue growth."

BD

### *BECTON, DICKINSON AND COMPANY:* Announces Full-Year Revenue Up 4%

**Becton, Dickinson and Company** (BD), Franklin Lakes, N.J., shared data for its Q4 and full fiscal year 2024 as compared to the prior year periods:

- Q4 revenue increased 6.9% to $5.43 billion from $5.08 billion.
- Full-year revenue was up 4.2% to $20.17 billion from $19.37 billion.
- Q4 Life Sciences revenue (including the Integrated Diagnostics and Biosciences business units) ticked up 0.7% to $1.34 billion from $1.33 billion.

BD said the growth in Life Sciences was driven by Integrated Diagnostics Solutions' specimen management including "broad volume strength and double-digit growth in BD MAX IVD and BD COR."

sysmex
Lighting the way with diagnostics

### *SYSMEX CORPORATION:* Shares Six Months Sales Up 14%

**Sysmex,** headquartered in Hyogo, Japan, released financial results for six months of its fiscal year ending in March:

- Six-month sales were up 14% to ¥242,479 million (US$1.56 billion) from ¥212,698 million (US$1.37 billion).

HOLOGIC®
The Science of Sure

### *HOLOGIC:* Ends its FY 2024 with 9% Jump in Molecular Diagnostics Sales

**Hologic,** Marlborough, Mass., reported Q3 financials as compared to the third quarter of 2023:

- Q4 revenue was up 4.5% to $987.9 million as compared to $945.3 million.
- Full-year revenue stayed constant at $4.03 billion.
- Q4 Diagnostics revenue increased 6.5% to $443.3 million from $416.4 million.
- Q4 Molecular Diagnostics revenue jumped 9.4% to $319.3 from $291.9.

Hologic said the boost in Molecular Diagnostics was due to more sales of the Aptima BV CV/TV and non-COVID-19 respiratory assays, as well as

**Biotheranostics, Inc.** genomic lab testing which Hologic acquired in 2021. During an earnings call, CEO Stephen MacMillan said the results "should put to rest any concerns regarding Panther utilization in a post-COVID-19 environment."

## *DANAHER:* Diagnostics Q3 Revenue Up 5% and Analyzer for Low Volume Labs Released

**Danaher** Corporation, Washington, D.C., included in its Q3 reports financial results for subsidiaries **Beckman Coulter Diagnostics**, **Cepheid**, and **Leica Biosystems**:

- Q3 sales were up 3% to $5.79 billion from $5.62 billion in Q3 2023.
- Nine-month revenue decreased 0.8% to $17.33 billion versus $17.48 billion in 2023.
- Q3 Diagnostic sales jumped 5%.
- Q3 Life Sciences revenue was up 4.5%.

In molecular diagnostics, Cepheid had core revenue of $425 million, which Blair attributed to advance purchases for the respiratory season "and a favorable mix of our four-in-one test for COVID-19, Flu A, Flu B, and RSV (respiratory syncytial virus)."

## *QIAGEN:* Sees 10% Jump in Diagnostics Solutions Q3 Sales

**Qiagen**, headquartered in Venlo, Netherlands, shared Q3 2024 financials as compared to Q3 2023:

- Q3 sales were up 5% to $502 million from $476 million.
- Nine-month sales were flat at $1.45 billion.
- Q3 Diagnostics solutions sales jumped 10% to $197 million from $179 million.
- Q3 Sample technologies increased 1% to $162 million from $160 million.

During the quarter, Qiagen launched the QIAcuityDx digital PCR system, which is aimed at "providing highly precise, absolute quantitation of target DNA and RNA, and can support liquid biopsy applications," a Qiagen statement noted. The company struck partnerships with three pharmaceutical companies to develop companion diagnostics with the QIAcuityDx.

## *BIOMÉRIEUX:* Increases Q3 Revenue in Nearly All Segments

At **bioMérieux**, in Marcy-l'Étoile, France, Q3 sales grew as follows, compared to Q3 2023:

- Q3 sales were up 7.8% to €968.7 million (US$1.0 billion), as compared to €898.4 million (US$954.1 million).
- Nine-month sales jumped 7.6% to €2.87 billion (US$3.0 billion) versus €2.66 billion (US$2.82 billion).
- Q3 Molecular biology sales soared 15.7% to €379.4 million (US$409.9 million) from €327.9 million (US$348.2 million).
- Q3 Microbiology sales increased by 6.5% to €342.4 million (US$363.7 million) from €321.6 million (US$341.6 million).
- Q3 Immunoassays sales fell 8.4% to €86.3 million (US$91.6 million) from €94.2 million (US$100 million).

In an earnings call, bioMérieux explained that the growth in its molecular biology segment was due to an 18% increase in the sales of non-respiratory **BIOFIRE** panels "with all panels contributing strongly." The BIOFIRE installed base grew with the sales of 150 more units, now totaling 26,250 units at the end of the September. TDR

# INTELLIGENCE

## LATE & LATENT

*Items too late to print, too early to report*

Disruption is happening in the consumer genetic testing marketplace. In recent weeks, news outlets in the United Kingdom reported that **Atlas Biomed**, a consumer genetic testing company founded in 2016, had simply "disappeared." *Malwarebytes* said Atlas Biomed's "London offices are closed, nobody answers the phone, and clients are no longer capable of accessing their online records. All the company's social media accounts haven't been updated since 2023 at the latest." Customers were quick to publicly complain that they could no longer access their genetic results and expressed fears that their personal data may have become accessible to unauthorized individuals.

### ADD TO: *Atlas Biomed*

In its reporting on Atlas Biomed, the *BBC* said "the firm's **Instagram** account, with over 11,000 followers, was last updated in March 2022. Its final post on **X** was in August the same year. It shared a post on **Facebook** in June 2023, but did not respond to any of the comments—which were full of people complaining about being unable to contact it or access their profiles." News coverage warned of the dangers of giving personal information to consumer genetic testing firms and often mentioned **Ancestry.com** as another such company experiencing financial woes.

### TRANSITIONS

• Michelle Tarver, MD, PhD, was selected as the new permanent director of the federal **Food and Drug Administration** (FDA) Center for Devices and Radiological Health (CDRH). She will replace the retiring Jeff Shuren, who held that position since 2009. Tarver, an ophthalmologist and epidemiologist, has been with the FDA since 2009.

• Robert Guigley is the new Chief Commercial Officer for **Delfi Diagnostics** of Palo Alto, Calif. Guigley previously served at **Invitae**, **Ambry Genetics**, **Omada Health**, **Counsyl**, **Quest Diagnostics**, and **AstraZeneca**.

• **Sophia Genetics** of Lausanne, Switzerland and Boston, selected George Cardoza to become its new CFO. Cardoza previously worked at **Biocartis**, **AccuraGen**, **NeoGenomics**, **Protocol Marketing**, and **Quest Diagnostics**.

• Jannalee Johnson was named Sales and Market Development Leader for **Precision Epigenomics** of Tucson, Ariz. Her previous positions were with **XiFin**, **Inform Diagnostics**, **Leica Biosystems**, **Abbott Molecular**, **TriCore Reference Laboratories**, **Avero Diagnostics**, **Gynecor/Bostwick Laboratories**.

• Julia Wang was named the new Chief Financial Officer of **Labcorp**, following the retirement of long-serving CFO Glen Eisenberg. Wang's previous positions were with **BeiGene**, **Alexion Pharmaceuticals**, **Quest Diagnostics**, **Johnson & Johnson**, and **Pepsico**.

***That's all the insider intelligence for this report.***
***Look for the next briefing on Monday, December 16, 2024.***

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- ***'2024's Top Ten Lab Industry Stories' features THE DARK REPORT'S picks of the most influential events.***
- ***Part 2 on anatomic pathology income opportunities: Hospital Part A compensation agreements.***
- ***Identifying new sources of stress on the operations and clinical services of labs in today's marketplace.***

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