



TOP 10 LAB STORIES OF 2022!

See Pages 3-9.

From the Desk of R. Lewis Dark...

THE R. LEWIS DARK REPORT

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

INSIDE THIS ISSUE

R. Lewis Dark:

Two Positive Messages to Focus on at Year's End.....Page 2

2022's Top 10 Lab Industry Stories Confirm Challenging Times.....Page 3

- 1. Hospitals Lose Billions of Dollars, Shrinking Labs' Bottom Lines...Page 5
- 2. Acute Lab Staff Shortage Across All Positions Strains Services..Page 5
- 3. Unprecedented Demand for Pathologists.....Page 6
- 4. Consumer Expectations Take Healthcare in a New DirectionPage 6
- 5. Surprise! Multiple Lab-Related Bills Brewing within Congress..Page 7
- 6. Hospital/Systems Consolidation Spells Changes for Labs.....Page 7
- 7. Anatomic Path Mergers Reflect Cash/Technology ObstaclesPage 8
- 8. Lab Informatics, IVD Acquisitions Reshaped Those SectorsPage 8
- 9. Inflation Increases Prices of Lab Supplies and StaffingPage 9
- 10. It's Prison Time for Ex-Theranos Execs Holmes, Balwani.....Page 9

Legal Update: Holmes, Balwani Both Get Lengthy Prison Terms for Theranos Fraud.....Page 10

Analytics Helps Laboratories Offset Staffing WoesPage 11

IVD Update: Top Public IVD Companies Report Q3/Q4 2022 Earnings.....Page 14

Intelligence: Late-Breaking Lab News.....Page 19

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher



Two Positive Messages to Focus on at Year's End

CLINICAL LABORATORY MANAGERS AND ANATOMIC PATHOLOGISTS are winding down another tumultuous year for the healthcare industry. It was a year marked by unexpected twists and turns.

It was also a year marked by two positive developments for labs. First, the SARS-CoV-2 pandemic seems to have peaked, even as new variants appear. Second, labs continue to prove to be extraordinarily resourceful.

At this time, COVID-19 appears to be heading towards endemic territory. Judging by how many people have stayed home from work, school, or holiday parties this year because they had possible symptoms of COVID-19, a reasonable conclusion is that consumers are hearing the messages from clinicians about the need to monitor this disease through testing and isolation when needed.

Certainly the public currently is bombarded weekly from the media about threats of a “tripledeemic” involving COVID-19, influenza, and respiratory syncytial virus (RSV). RSV is a common illness among young children that suddenly got tremendous amounts of publicity because of rising cases this fall. Flu hospitalizations are increasing, particularly for pediatric RSV cases.

In response to these developments, one big lab lesson of the past three years continues to be true: clinical laboratories have the expertise, creativity, and technology to support the country through difficult periods with infectious diseases.

As for being resourceful, we are preaching to those many pathologists, clinical chemists, medical technologists, microbiologists, and other lab scientists who have demonstrated this talent as they react to the continual changes in test volumes and needs of the U.S. healthcare system. This continues to happen, despite the ongoing cuts to lab test reimbursement made by Medicare and private health insurers that erode the ability of labs to consistently deliver top service and high quality test results for the physicians and patients they serve.

As we here at THE DARK REPORT wrap up 2022 and prepare to greet the New Year, we send all of you our thanks and appreciation for your ongoing support. We do our best to help you and your lab teams stay resourceful and effective. Cheers to the New Year!

2022's Top 10 Lab Stories Confirm Challenging Times

➤ **Financial difficulties faced by clinical laboratories usurp COVID-19 as the dominant theme of 2022**

➤➤ **CEO SUMMARY: There are valuable insights to be gleaned from The Dark Report's "Top 10 Lab Industry Stories for 2022." Several of this year's story picks involve external forces reshaping healthcare in the United States in profound ways. Other story picks for 2022 illustrate the most difficult challenges confronting clinical laboratories and anatomic pathology groups. That includes medical technologist staffing shortages and the demand for pathologists that outstrips supply. Of note, 2022 may be the last year that former Theranos CEO Elizabeth Holmes makes our list of top stories!**

FOR THE FIRST TIME SINCE 2019, the SARS-CoV-2 pandemic did not take the top spot among THE DARK REPORT's "Top 10 Lab Industry Stories for 2022." That is a positive development, both for the clinical laboratory industry and the American healthcare system.

Instead, one primary theme of 2022 was the overall financial difficulties confronting hospitals, health systems, governments, and consumers. Economic woes, supply chain problems, labor costs, and inflation were among the top issues during the previous 12 months.

COVID-19 continued as a factor during 2022. Circumstances indicate that the worst of the pandemic is over, even as healthcare providers and labs find themselves dealing with other respiratory viruses. For example, at this moment, a

dramatic increase in the number of cases and hospitalizations of pediatric RSV is stressing the healthcare system.

In hindsight, 2022 may be recognized as the year that the long-predicted shortage of medical technologists (MTs), pathologists, and other types of laboratory scientists exploded across the entire spectrum of laboratories that operate in the United States in a way that finally attracted the attention—and news coverage—of major media organizations.

This is why THE DARK REPORT's "Top 10 Lab Industry Stories for 2022" ranks the shortage of MTs and other types of lab staff as the number two biggest story of the year. (See story 2, page 5.) Ranked three is the skyrocketing demand for pathologists—called by some experts as the biggest gap between open positions

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and the available supply of pathologists in the past 20 years. (See story 3, page 6.)

What will also be notable as pathologists and lab administrators look back on 2022 is how multiple factors were at work eroding the financial stability of hospitals, health systems, and many clinical laboratory organizations, as noted below:

- During 2022, a substantial number of hospitals and health systems reported losses in the hundreds of millions, even billions of dollars, further depleting their cash on hand and eroding financial solvency. (See story 1, page 5.)
- By mid-year, inflation dominated national news headlines. The consequence is much higher costs of supplies, labor, and services, even as clinical laboratories were already under substantial pressure to cut their budgets. (See story 9, page 9.)
- In several different mergers, multi-hospital integrated delivery networks combined into bigger systems. This is market evidence that consolidation continues in the hospital industry. (See story 6, page 7.)

► Good News/Bad News Bills

During 2022, in the legislative arena, there is what some would judge to be a good news/bad news story. Many lab professionals believe that the Verifying Accurate Leading-edge IVCT Development (VALID) Act—intended to give the **Food and Drug Administration** oversight over laboratory-developed tests (LDTs)—would be an unwelcome burden for labs working to bring new diagnostics assays to market.

By contrast, the proposed Saving Access to Laboratory Services Act (SALSA) would reform parts of the previously enacted Protecting Access to Medicare Act, or PAMA. In particular, it would forestall implementation of the 15% price cuts to the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) that are scheduled to happen on Jan. 1, 2023. (See story 5, page 7.)

Another important story for the clinical laboratory industry in 2022 was the continuing climb in influence of consumers. Leading this charge are the Millennials, who will make up 75% of the workforce by 2025! Millennials, also known as Generation Y, want speedy access to medical care. They are comfortable seeing their doctors via FaceTime, Zoom, and other virtual meeting platforms.

► New Healthcare Consumer

This is also increasingly true of Generation X and the Baby Boomers. During the pandemic, they accepted telehealth services as a way to access their doctors.

More importantly for clinical labs, the pandemic taught many consumers how easy it was to order their own diagnostic tests. Consumers also were taught to collect their own COVID-19 test samples at home or work. Labs will be dealing with the implications of this trend for years to come. (See story 4, page 6.)

Some may be surprised at THE DARK REPORT's pick for the number 7 biggest lab industry story for 2022, titled, "Mergers in Anatomic Pathology Reflect Cash Flow and Technology Obstacles." Independent pathology groups—both small and large regional pathology super practices—are choosing to merge themselves into larger pathology organizations.

Two forces are contributing to this ongoing consolidation of pathology groups. In no order of priority they are:

- Retirement of pathologists and inability to recruit young new pathologists into the group.
- The need for investment capital to acquire the histology automation, digital scanners, and digital pathology systems needed to remain competitive. (See story 7, page 8.)

Clinical laboratory leaders many want to incorporate these 10 top lab stories for 2022 into their strategic planning. Doing so could help sustain clinical quality and financial stability.

TOP 10 LAB STORIES OF 2022

1

Hospitals Losing Hundreds of Billions of Dollars, Crunching Labs' Bottom Lines

THERE WAS NO GREATER THREAT IN 2022 to the financial stability of clinical laboratories and pathology practices serving hospitals in the U.S. than the poor financial performance of these acute care institutions.

Several reasons are to blame, including lower inpatient volumes compared to before the pandemic, increased labor costs, and sky-high expenses. Consulting firm **Kaufman Hall** predicted more than half of the country's hospitals would report a financial loss in 2022. (See TDR, "U.S. Hospitals Will Lose Billions of Dollars in 2022," Oct. 31, 2022.)

As a result, lab administrators and pathologists faced constant pressure to cut lab costs. Proven methods such as Lean Six Sigma provided one way to

reduce costs in laboratories while sustaining quality. (See TDR, "Lean is Smart Approach to Major Lab Cost Savings," Sept. 19, 2022.)

Meanwhile, some health systems—wanting to raise cash to offset losses—put their hospital laboratory outreach businesses up for sale. The billion-dollar lab corporations bought sizeable lab outreach programs from at least four hospital chains in 2022, which no doubt caught the attention of other struggling systems. (See TDR, "Public Laboratory Companies Eye More Lab Outreach Acquisitions," Aug. 29, 2022.)

Predictions are that many hospitals will continue to lose money during 2023. If that proves true, there may be more sales of hospital lab outreach programs.

TOP 10 LAB STORIES OF 2022

2

Acute Shortage of Laboratory Staff Across All Positions Strains Services

WORKFORCE SHORTAGES in the clinical laboratory industry have been a reality for years, but 2022 triggered a new peak with the staffing crisis. A pathology director told THE DARK REPORT earlier this year that he worries each night about whether he'll have enough bench staff available to fill the shifts the next day, a scenario that other lab leaders often ponder.

The Great Resignation, less interest in lab careers, and a declining number of training schools are reasons behind the ongoing shortage of medical technologists (MTs) and other lab scientists. Even though the SARS-CoV-2 pandemic raised the profile of laboratory professionals and what they do, it also created a pressure cooker in which large volumes of diagnostic tests had to be turned

around quickly, leading to long hours, much overtime, and staff burnout.

Lab salaries have risen in many places with mixed success at filling open positions. It is also suggested that labs establish early relationships with math and science students in local high schools; audit work processes to allow lab professionals to work to their highest potential; and create non-traditional educational paths for future lab scientists, such as apprenticeships. (See TDR, "Insights and Advice about the Lab Staffing Crisis," Oct. 10, 2022.)

Because the volume of lab testing will continue to grow, achieving full staffing in most laboratories may become the number one management issue for 2023.

TOP 10 LAB STORIES OF 2022

3

Unprecedented Demand for Lab Pathologists Sparks New Approaches

WANT TO HIRE A NEW ANATOMIC PATHOLOGIST? Best of luck. Experts say the pathologist job market is the hottest it has been in 20 years and there are many more job openings than qualified pathologists to fill them.

A recent search on the job board at *PathologyOutlines.com* revealed that as of early December, there were 731 open positions for pathologists in the U.S. That number has remained fairly constant throughout 2022 and it is more than double the figure from July 2020.

As current pathologists retire or otherwise leave the industry, the supply of up-and-comers cannot meet the demand. As well, most new pathologists have specialized training, so it takes them longer once they graduate to gain experience in other diagnostic areas. (See *TDR*, “*Lab*

Workforce Crisis Takes Top Spot,” Says *CAP Today*,” April 25, 2022.)

Clinical laboratories and practice groups may need to reset their approaches to recruiting, hiring, and retaining pathologists given the current huge gap in the demand versus the supply.

For example, laboratory hiring managers should anticipate emphasizing different points to Millennial candidates as opposed to Generation X job seekers. (See *TDR*, “*How to Better Recruit Millennial Pathologists,*” June 27, 2022.)

No future developments are projected to close the current supply/demand gap for pathologists. That will cause forward-looking pathology leaders to consider adopting digital pathology systems and whole slide images as a way to automate workflow and increase their pathologists’ productivity.

TOP 10 LAB STORIES OF 2022

4

Evolving Consumer Expectations Take Healthcare in a New Direction

MORE CONSUMERS ARE CHANGING how they access and use healthcare services. This is particularly true of consumers’ use of telehealth services and that has major implications for clinical laboratories.

COVID-19 forever altered how people receive diagnostic tests. It opened up different ways to choose appointment locations, and evolved the public’s understanding of infectious diseases. These factors all present new opportunities for entrepreneurial lab leaders to explore as potential revenue sources.

One important development is the changing nature of phlebotomy draws. Both **Getlabs** and **Teladoc Health** grew their services to collect blood samples

at home or at the workplace, providing more convenience for busy customers wanting to avoid the time and hassle of traveling to a blood draw center. (See *TDR*, “*Telemedicine Firms Offer At-Home Phlebotomy Service,*” Sept. 19, 2022.)

Another forces for change is how retail pharmacies continue to place themselves at the forefront of diagnostic testing. In 2022, **Walmart** and **Quest Diagnostics** announced an expanded partnership to serve customers interested in ordering their own lab tests. Why? Quest estimates the consumer-initiated testing market could be worth \$2 billion. (See *TDR*, “*Quest and Walmart to Expand Consumer-Initiated Test Options,*” Feb. 22, 2022.)

TOP 10 LAB STORIES OF 2022

5

Surprise! Multiple Lab-Related Bills Brewing within Congress

NOT IN RECENT MEMORY HAVE SO MANY LEGISLATIVE BILLS with implications for clinical laboratories and pathology groups been circulating around Congress.

This situation may be an extension of how the SARS-CoV-2 pandemic made people—including lawmakers—more aware of clinical diagnostic services.

Of top importance to laboratory professionals is the proposed Saving Access to Laboratory Services Act (SALSA). SALSA seeks to reform parts of the previously enacted Protecting Access to Medicare Act, or PAMA.

If passed soon, SALSA will prevent PAMA decreases to laboratory test payments scheduled to go into effect on Jan. 1. Up to 800 tests could face reimbursement cuts of 15% otherwise. (See TDR, “VALID and SALSA

Acts Still Pending in Congress,” Dec. 21, 2022.)

A separate bill, the Verifying Accurate Leading-edge IVCT Development (VALID) Act, seeks to move oversight of laboratory-developed tests to the **Food and Drug Administration**. It is still in play, despite some ups and downs with lawmakers’ support during 2022.

Another, newer proposed bill is the Supporting Medicare Providers Act (SMPA), which would temporarily reduce cuts to the Physician Fee Schedule, including to pathology services, that will go into effect in 2023.

Debate on these bills may still happen before year’s end. Any of these proposals could be attached to an expected “must pass” spending bill needed to keep other aspects of the government funded and that must be passed in coming weeks.

TOP 10 LAB STORIES OF 2022

6

Consolidation in Hospitals and Health Systems Spells Changes for Labs

INTEGRATED DELIVERY NETWORKS (IDNs) continued to consolidate in the U.S. in 2022, which presented opportunities for clinical laboratories to run with new efficiencies across larger systems.

In May, a mega-merger between **Atrium Health** and **Advocate Aurora Health** resulted in a new system of 67 hospitals and more than 1,000 ambulatory clinics across several states in the Upper Midwest and Southeast. (See TDR, “Atrium, Advocate Aurora Merge into \$27b System,” June 6, 2022.)

Earlier this year, **Beaumont Health** and **Spectrum Health** merged in Michigan, creating a larger IDN with 22 hospitals and more than 300 outpatient

clinics. Also, two small West Virginia systems merged to create a new IDN called **Vandalia Health**.

The Atrium/Advocate-Aurora deal signals that health systems in different regions are likely to find mergers attractive because of economies of scale, managed care contract clout, and shared staff.

After such deals are announced, an early priority for the clinical labs is to standardize instruments, tests, and processes across the combined integrated delivering network. This brings economies of scale, supports performing more assays in-house to cut turnaround times for inpatients, and makes it easier to move staff to different labs as needed.

TOP 10 LAB STORIES OF 2022

7

Mergers in Anatomic Pathology Reflect Cash Flow and Technology Obstacles

THIS YEAR PROVED TO BE AN ACTIVE ONE for anatomic pathology consolidation as smaller private practices struggled to compete in the areas of technology and recruitment while also needing funds.

In January, **PathGroup** in Nashville announced it had acquired **Pathology Consultants** of South Carolina, bringing its total pathologists on staff to 255.

An equally large merger occurred at the very end of 2021. That's when Australia-based **Sonic Healthcare** bought Dallas-based **ProPath**, adding to its previous series of U.S. acquisitions that included **Aurora Diagnostics** and **CBL Path**. (See *TDR*, "Sonic Healthcare Acquires ProPath, PathGroup Buys Path Consultants," Jan. 31, 2022.)

In both acquisitions, a successful regional practice decided to sell to a larger one, indicating that the smaller groups were finding it increasingly challenging to stay financially stable.

THE DARK REPORT noted that three factors are guiding this wave of pathology practice consolidations in recent years. Included is the need for cash to buy out the equity retiring partners; required capital to purchase advanced technology, including digital pathology tools; and the need to put more resources behind recruitment of younger pathologists.

As acquisition-minded pathology practices continue to grow, they will gain market clout and wield more purchasing power and contract influence.

TOP 10 LAB STORIES OF 2022

8

Lab Informatics and IVD Acquisitions Reshaped Those Market Sectors

CONTINUING ON A DECADES-LONG ROLL, *in vitro* diagnostics (IVD) mergers occurred at a brisk pace in 2022, while simultaneously, laboratory informatics deals included one of the heaviest hitters in the high tech world.

Technology giant **Oracle** stepped into the lab informatics industry at the tail end of 2021 with its purchase of **Cerner**, long known for its electronic health record and laboratory information system (LIS) software. Just weeks later, U.K.-based **CliniSys** (owner of recently renamed **Sunquest Information Systems**) acquired **Horizon Lab Systems** in North Carolina. (See *TDR*, "LIS Market Will Change after Oracle, CliniSys Deals," Jan 31, 2022.) CliniSys next acquired Nashville-base **ApolloLIMS** in May.

Motivations behind the deals were different. In CliniSys' case, it intends to expand its product suite beyond clinical labs, such as in environmental testing. For Oracle, its deal gave it a stronger foothold in healthcare, particularly in patient data.

In the IVD arena, **Quidel** closed on its \$6 billion acquisition of **Ortho Clinical Diagnostics** at the end of May, becoming **QuidelOrtho**. By the end of 2022, the deal will rearrange the list of top global IVD companies by sales.

AS THE DARK REPORT noted, Ortho and Quidel were Nos. 12 and 13 in revenue. (See *TDR*, "2021 Rankings of the World's Top 12 IVD Companies," Aug. 29, 2022.) The combined company is likely to crack the top seven IVD firms in future rankings.

TOP 10 LAB STORIES OF 2022

9

Inflation Fuels Big Price Increases in Lab Supplies, Staffing, Operations

INFLATION IS A CONTRIBUTING ELEMENT in several of this year's list of Top Ten Biggest Lab Industry Stories.

Start with the fact that inflation hit a 40-year high in 2022. Faced with rising costs, consumers are cutting back their spending and that includes visits to doctors. Similarly, hospitals, clinical labs, and pathology groups are dealing with major increases in the cost of doing business.

Maybe 2022 was a "perfect storm" for rising prices. Excessive federal spending was the direct cause of current inflation. But supply chain disruptions caused by the pandemic, and the disruption to the international flow of goods, including manufactured products, exacerbated continuing price increases.

Further, inflation drives up labor costs at a time when there is already too few lab scientists and pathologists to fully staff the nation's laboratories. (*See TDR, "Tough Times Ahead for Hospitals and Their Labs," Aug. 8, 2022.*)

With clinical lab budgets already shrinking, inflation had an insidious effect of forcing labs to spend more money for instruments, reagents, and workers. As 2022 ends and the New Year approaches, there are few signs that inflation will ease in the short term.

What made inflation a surprise story for the clinical laboratory profession during 2022 is that, early in the year, there was little advance notice that rising prices would become a headline by mid-year.

TOP 10 LAB STORIES OF 2022

10

Ex-Theranos Execs Elizabeth Holmes and Ramesh Balwani Sentenced to Prison

ELIZABETH HOLMES' DOWNFALL IS NOW COMPLETE, SEVERAL years after her company, **Theranos**, collapsed amid scandal. In January, the former CEO was convicted on four counts of conspiracy and wire fraud after a months-long trial in 2021.

Then in June, former Theranos Chief Operating Officer Ramesh "Sunny" Balwani also was convicted, this time on 12 counts of conspiracy and wire fraud.

Holmes and Balwani spent the next few months trying to avoid what may have been inevitable: prison time. They both requested new trials, which were denied. When government witness and former Theranos Laboratory Director Adam Rosendorff attempted to speak with Holmes at her residence, the lab industry's attention was again captured.

However, in the end, a judge decided these fraudsters had behaved so badly towards Theranos investors that both will report to authorities in 2023 to begin lengthy sentences. Holmes will serve 11 years, three months behind bars, while Balwani will be in prison for 12 years, 11 months. (*See the story on page 10 of this issue for more details.*)

Will lawyers file appeals of their convictions? Of course. But in all likelihood, it is the end of the road for Balwani and Holmes. Beyond their professional disgrace, each will soon pay a high personal price because of the fraud for which they were convicted. Balwani will be nearly 70 when he is freed, if he serves his full sentence. And Holmes—currently pregnant with her second child—will miss out on a decade of her two young kids' lives. **TDR**


Legal Update

Holmes, Balwani Get Lengthy Prison Terms for Theranos Fraud

SENTENCING OF ELIZABETH HOLMES AND RAMESH “SUNNY” BALWANI in federal court caps the strange, yet captivating, saga of **Theranos** and its flawed blood testing technology.

For laboratory professionals, the four years of legal wranglings that surrounded the Theranos fraud case may be remembered for shining a spotlight on the responsibilities of laboratory directors under the Clinical Laboratory Improvement Amendments of 1988. (See *TDR*, “*CLIA Lab Director Testimony Shows Risks to Pathologists*,” Nov. 8, 2021.)

Holmes—the founder and former CEO at Theranos—was sentenced on Nov. 18 in federal court in San Jose, Calif. Judge Edward Davila gave her 11 years, three months in prison. Holmes will report to authorities on April 27 to begin her sentence. A jury convicted Holmes in January 2022 on three counts of wire fraud and one count of conspiracy related to defrauding Theranos investors of millions of dollars.

“I am devastated by my failings,” Holmes told the judge, according to *NBC Bay Area* reporter Scott Budman, who was in the courtroom. “I have felt deep pain for what people went through because I have failed them ... To investors, patients, I am sorry.”

► Balwani Gets Nearly 13 Years

Less than three weeks later, on Dec. 7, Davila sentenced Balwani—the former Chief Operating Officer and President at Theranos—to 12 years, 11 months behind bars.

In July, a jury found him guilty of 10 counts of wire fraud and two counts of conspiracy. Balwani must report to prison on March 15.

Budman noted that Balwani did not address the judge at all during sentencing.

Holmes and Balwani were unsuccessful in seeking new trials in October based on an odd conversation between Holmes’ partner, William Evans, and government star witness and pathologist Adam Rosendorff, MD.

Rosendorff, a former lab director at Theranos, showed up at Evans’ and Holmes’ residence in August and allegedly said the trial results were weighing on him, according to court filings by Holmes’ lawyers. (See *TDR*, “*Ex-Theranos CEO Elizabeth Holmes Awaits Ruling on New Trial Request*,” Oct. 31, 2022.)

► Legal Chain Reaction

That set off a legal chain reaction as Holmes and Balwani sought new trials based on the belief that Rosendorff’s testimony was tainted. However, in a later affidavit filed with the court, Rosendorff maintained his testimony was accurate, but that he felt bad about the trial’s effects on the families of the defendants.

Holmes and Evans have a one-year-old child, and she is currently pregnant with another child.

From the start, Theranos left a bad taste in the mouths of many clinical laboratory managers and pathologists.

During the peak period of news coverage about Holmes’ plans to disrupt the clinical lab industry, hospital and health system CEOs believed they would be able to downsize their in-house medical laboratories and obtain lab tests from Theranos at savings of 50% or more. Consequently, from 2013 through 2015, numerous hospital lab leaders saw administrators deny or delay requests for capital investment in their labs. **TDR**

Analytics Lets Labs Offset Staffing Woes

➤ Data reports generated by clinical labs can stem staff burnout and help better allocate resources



**Tim
Bickley**

➤➤ **CEO SUMMARY:** *For hospital laboratories confronting worker shortages, data analytics can be useful for improving workflows and determining effective staffing levels. This information can also induce changes that may improve employee morale. Two experts discuss three analytics reports that should be available for clinical lab managers juggling staffing concerns.*



**Kathleen
Ohrt**

AS HOSPITAL LABORATORIES STRUGGLE WITH WORKFORCE SHORTAGES brought on by the Great Resignation and diminished interest in diagnostic careers, effective use of clinical lab analytics in real time can help boost staff efficiency and reduce burnout.

“Data can often provide evidence that problems exist somewhere in a laboratory’s workflow—or even disprove perceived issues,” said Tim Bickley, MBA, MT(ASCP), CPHIMS, Vice President of Sales at **Visiun**. The company is a **Labcorp** subsidiary based in Ann Arbor, Mich., that offers lab analytics software. (See *TDR*, “*HCL, Visiun, and Viewics: Analytics Market Evolves*,” Feb. 28, 2021.)

“There are excellent analytics reports that our laboratory customers use to monitor staff hour by hour,” Bickley noted. “In real time, laboratory managers can take appropriate action when they assess staff performance.”

“Staffing issues are just the latest reason for labs to have a clear view of their diagnostic and workflow data,” said Kathleen Ohrt, MBA, MT(ASCP), SM, Program Manager at Visiun.

“Labs are data-rich environments and labs must always report test results and related data, regardless of what staffing concerns look like,” Ohrt noted. “As well, there is regularly the need for a lab director who needs some type of statistic 30 minutes before a meeting with his executives.

“Lab supervisors get phone calls from doctors who don’t believe their potassium results and they want to see more,” she added. “Labs must also regularly provide data to the **College of American Pathologists** and **The Joint Commission**.”

Ohrt and Bickley—who both worked as medical laboratory technologists early in their careers—spoke during a session at this year’s *Executive War College Conference for Laboratory and Pathology Management*. Their presentation was titled, “How Hospital Laboratory Analytics Helps Your Lab Optimize Staff Productivity and Minimize Burnout During the Great Resignation.”

Generating reports might sound like an activity that will take up a lot of a lab administrator’s time. The key, Ohrt suggested, is to use automation to reduce the time needed to create the reports and to

empower staff so they don't have to rely on the hospital's IT department.

"We had a lab client who needed to see the last six months of positive HCG results," she recalled. "It took their hospital's IT department five days to get those results back to them. That's not productive for timely management action."

Ohrt outlined three broad categories of reporting that clinical laboratories should consider:

- Key performance indicators (KPIs).
- Specialized productivity reports.
- High-level specialized reports.

► KPI-based Reports

KPI refers to a metric that indicates progress towards a goal. KPI reports can be automated and delivered daily to lead technicians and bench-level supervisors, allowing them to take rapid action if the lab falls short in a certain area, Ohrt explained. One common example is a report that shows the lab's average turnaround time and volume for specific tests by the hour.

Ohrt described a hypothetical scenario in which a KPI report indicates that the turnaround time (TAT) for a troponin test was dramatically longer between midnight and 1 a.m. "The lead or supervisor will look at the factors that affect TATs. Did an analyzer go down? Did someone go off to a break when they shouldn't have?"

A report like this puts the supervisor in a stronger position to respond if a physician calls to complain about slow turnaround, she noted. "It may only be one turnaround time to the emergency room, but the physicians may mistakenly say all of their turnaround times are off. Now the supervisor has a report to visually show them that it's an outlier," Ort explained.

Reports also can use the same underlying data to show how often the lab met established goals for these metrics. Another common KPI report ranks the tests performed in the lab by order vol-

ume, which saves the time needed to count the tests manually.

In the examples noted above, the KPI reports do not relate directly to staffing shortages. However, being able to report accurately about turnaround times could improve staff morale if steps are subsequently taken to improve turnaround.

► Specialized Productivity

Other data analytics, however, point directly to staffing issues. For example, specialized productivity reports can help lab managers and supervisors get a quick handle on metrics involving staffing, scheduling, test activity, and other areas without having to rely on gut instinct.

"When we talk about burnout, often there's this extra time that the lab management staff has to spend compiling the statistics, while at the same time they must work the chemistry bench or draw blood in the outpatient lab for the rest of the afternoon," Ohrt explained.

One example is a line chart for each month that shows the average number of activities by the hour, including patient collection, container shipment, accession, and testing. It might indicate that in the previous month, a big spike in the early morning was followed by a mid-morning drop.

"Everybody has that big morning rush," she observed. "But what is happening during that period? Is a courier not arriving in a timely manner? Is another department sending tests about which the lab is unaware?"

► Productivity Assessment

Another example is a monthly workflow and productivity assessment that relates the average activity by hour to the number of technicians working during those hours. Ohrt noted that this could help managers improve staff deployment at different times of the day or make changes to courier schedules.

"Can the lab bring in some of the outpatient courier specimens later in the day

to take advantage of having more staff on duty at those times?" she asked.

Ohrt also pointed to a report she found helpful as a phlebotomy manager that shows how many patients each phlebotomist saw per hour.

"It is common for phlebotomists to tell managers that they're so busy and there's nothing more they can do," Ohrt said. "With this report, managers can pull up the numbers. This opened the opportunity for me to have a tough conversation with the phlebotomy team to say, 'Tell me your definition of busy so we can come to an understanding of what is expected and what you're capable of doing.'

"This is important, especially when the morning phlebotomy team is going room to room; something they can do much faster than the evening shift, which has to cover the whole hospital and the emergency room," she continued. "Managers can tailor their needs for different departments or different times."

➤ High-Level Reports

High-level specialized reports take more time and are akin to conducting mini data projects. But they can also provide major benefits, such as justifying additional staff or suggesting process improvements.

One example is a staffing analysis that details how many employees—and how much time—it takes to perform specified diagnostic tasks for each hour of the day.

"A manager can look at this report and say, 'My activity falls off at this time of day, but my staffing level does not drop. Can we shift things to offset the activity gap? Can the lab bring in couriers later in the day instead? Can we shift staff hours to earlier in the day?'" Ohrt said.

For hospitals with multiple labs, or labs with multiple locations, other reports allow managers to compare the performance of one lab against another, such as turnaround times for a specified test. "This comparison allows managers to determine if they have best practices at one lab that they can bring to the other locations," she explained.

Data Analytics Meets Lab Challenges

THREE THEMES HAVE REOCCURRED in THE DARK REPORT'S coverage of the challenges facing the clinical laboratory industry: staffing shortages, pressure to cut costs, and new revenue generation.

It is clear that data analytics can play a role in overcoming those obstacles. Our accompanying story about using analytics reports to fend off worker shortages is one example.

Earlier this year, THE DARK REPORT explored how **Jefferson Health** used data analytics to determine that its anemia management program could be tweaked to bring in additional earnings. (*See TDR, "Lab's Anemia Program Brings in New Revenue," June 27, 2022.*)

We also previously reported how data analytics on test utilization at the **Cleveland Clinic** led to 160,000 less tests ordered over a seven-year period, resulting in cost savings of \$5 million. (*See TDR, "Cleveland Clinic Lab Has Multi-Year Test Utilization Success," May 7, 2018.*)

Analyzing clinical laboratory data on its own will not solve lab staffing shortages or employee burnout. But the information presented in analytics reports can lead to changes that ease stress in useful ways. In turn, that improves staff retention while giving the lab additional tools to do more with the staff at hand. "This is one way that analytics can help deter staffing shortages," Bickley said.

Hospital laboratory managers with seasoned analytics teams should be able to roll out similar reports quickly. Lab leaders with limited analytics resources will need to prioritize which data reports will be most useful at the start, working with either the IT department or in-lab data champions to create the automated reports. **TDR**

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**IVD Update**

Top Public IVD Companies Report Q3/Q4 2022 Earnings

Many firms looking beyond SARS-CoV-2, with testing demand generally dropping year over year

IT WAS A MIXED BAG OF THIRD QUARTER FINANCIAL RESULTS for the nation's largest *in vitro* diagnostics (IVD) manufacturers, with COVID-19 testing volume a contributing factor.

Fluctuating demand for SARS-CoV-2 testing proved perplexing, as some IVD companies saw an increase in sales of these tests, while some IVD firms reported a nosedive in related test earnings. Meanwhile, global supply chain challenges caused some businesses to delay instrument rollouts.

Generally, IVD companies expect demand for COVID-19 diagnostics to level off, even as they experience growth in their sales pipelines for analyzers, tests, and associated products.

Here is a summary of reported diagnostics sales, IVD industry challenges, company product launches, and projected growth plans for a post-COVID-19 pandemic market.



ROCHE: Diagnostics Division Grows 6% Thanks to Core Business

Roche, in Basel, Switzerland, said its diagnostics division sales remained strong even as demand for COVID-19 testing fell sharply in Q3. Roche shared this data:

- Group sales grew 2% to 47 billion Swiss francs (CHF) (US \$47 billion).
- Diagnostics division year-to-date sales increased 6% to 13.8 billion CHF (US \$14 billion).

- COVID-19 tests sales were significantly lower at 600 million CHF (US \$608 million) in Q3 as compared to one billion CHF (US \$1.06 billion) in Q3 2021.

“Group sales are up by 2% ... in spite of the sharp decline we have seen with our COVID-related sales,” said Roche CEO Severin Schwan during an earnings call. “All of that was only possible because of the strong growth of the underlying business of our newer medicines and the strong performance of the base business in diagnostics.”

During an earnings call, Thomas Schinecker, PhD, CEO at Roche Diagnostics, reported these year-to-date details on Q3 diagnostics sales:

- Core lab product sales increased 5% to 5.8 billion CHF (US \$5.8 billion).
- Point-of-care sales went up 30% to three billion CHF (US \$3.04 billion).
- Molecular lab sales decreased 8% to 2.7 billion CHF (US \$2.7 billion).
- Pathology lab sales grew 10% to 975 million CHF (US \$989 million).
- Diabetes care sales fell 3% to 1.2 billion CHF (US \$1.2 billion).

Since the onset of the pandemic, Roche has delivered 1.8 billion SARS-CoV-2 tests and sold approximately 2,000 cobas 6800/8000 systems, which run automated PCR-based nucleic acid testing.

“In the meantime, with the launch of [cobas] 5800 at the end of last year outside of the U.S.—we’re still waiting for the U.S. approval—we’ve had more than 250 placements there as well,” Schinecker

said. The compact cobas 5800 runs real-time PCR molecular testing for low-volume labs.

Schinecker also expressed confidence about the Elecsys amyloid plasma panel, which received breakthrough device designation from the **U.S. Food and Drug Administration (FDA)** in July to address early detection of Alzheimer's disease.



BECTON, DICKINSON AND COMPANY: Revenue Down Slightly

Becton, Dickinson and Company (BD) in Franklin Lakes, N.J., shared data for its Q4 ending Sept. 30:

- Revenue decreased 1.8% to \$4.8 billion.
- Life sciences revenue, which includes diagnostics, was down 5.8% to \$1.2 billion.

“COVID-only testing revenues were \$37 million [in Q4], which is an expected decline from \$316 million last year,” Executive Vice President and CFO Christopher DeLorefice said during an earnings call.

Commenting on the long-term view for labs and hospitals, Thomas Polen, President and CEO, noted external forces that will shape the future of the healthcare industry. “There’s an increasing need for digitalization and automation of healthcare processes as providers look for ways to increase efficiency and address labor and inflationary challenges,” Polen said.

ThermoFisher SCIENTIFIC

THERMO FISHER: Overall Revenue Up, but Diagnostics Down 30%

Thermo Fisher Scientific in Waltham, Mass., reported these Q3 financial results:

- Revenue grew 14% to \$10.6 billion.
- Life sciences segment revenue was down 12.2% to \$2.9 billion.
- Laboratory products and services segment revenue increased 14.9% to \$5.8 billion.

- Analytical instruments segment revenue was flat at \$1.6 billion.
- Specialty diagnostics segment revenue fell 4.6% to \$1 billion.

“In diagnostics and healthcare, as expected, our revenue was approximately 30% lower than the prior year quarter,” said CEO Marc Casper in an earnings call. He tempered that news by adding, “We delivered good core business growth, led by our microbiology and transplant diagnostics businesses.”

The company expects to take in \$2.8 billion in total COVID-19 testing revenue by year’s end, but that number will drop significantly in the future based on current testing demand. COVID-19 testing revenue was \$440 million in Q3.

“We’re assuming in the fourth quarter that we’re at an endemic level of COVID-19 testing,” Casper said. “So, that’s \$100 million of revenue in the quarter. And if that plays out in that way, then I think that’s a reasonable assumption per quarter for next year.”

During the earnings call, an analyst asked about raised prices for products and services because of inflation. “We’re passing through an appropriate level of pricing to reflect real cost increase, and we’re helping our customers through this period of time,” Casper responded.



DANAHER Corp.: Sales Leveling Off after ‘Red-Hot Pandemic’

Danaher in Washington, D.C., reported its Q3 results:

- Sales grew 6% to \$7.7 billion.
- Diagnostics segment revenue was up 9.5% (specific dollar amounts were not given).
- Molecular diagnostics revenue grew 10%.

Beckman Coulter is part of Danaher. “Beckman Coulter Diagnostics delivered solid results, with mid-single-digit core growth despite ongoing COVID-19 head-

winds in China,” said Danaher CEO and President Rainer Blair during an earnings call. Rainer credited a May platform launch from **Leica Biosystems**, another Danaher company, for healthy initial interest from customers.

“As customers seek to improve productivity with their labs, we’re seeing strong early momentum for Leica’s recent [release of] Bond-Prime—a fully automated advanced staining platform,” Blair added. Danaher’s genomics business also enjoyed another quarter of double-digit core revenue growth.

In response to an analyst’s question about growth potential, Blair described orders coming within the context of a major market readjustment.

“What we’re seeing now is the normalization of the marketplace coming from a red-hot pandemic, where orders ramped up significantly,” Blair explained. “Now, orders are normalizing, and customers are adjusting their order cadence. And the COVID-19 volumes are down. But we also see the strength of the non-COVID-19 market. That is much larger market, and currently it is growing at well over 20% as there is a backlog.”



ABBOTT LABORATORIES: Diagnostic Sales Down 6%, Demand for COVID-19 Rapid Tests Continues

Abbott in Abbott Park, Ill., released these Q3 numbers:

- Total sales decreased 4.7% to \$10.4 billion.
- COVID-19 testing sales were \$1.7 billion, down from \$1.9 billion a year earlier.
- Diagnostic sales fell 6.2% to \$3.6 billion.
- Core laboratory sales were down 5.6% to \$1.2 billion.
- Molecular sales plunged 47% to \$183 million.

- Point-of-care sales decreased 5.6% to \$127 million.
- Rapid diagnostics sales were up 0.1% to \$2.1 billion.

“Inflation continues to be a stubborn force globally, but we’ve started to see some moderating impacts in certain areas of our businesses compared to earlier in the year,” CEO Robert Ford said during an earnings call. “COVID-19 remains an unpredictable as ever with intermittent surges continuing throughout the world. And, lastly, global supply chain dynamics and staffing shortages continued to impact our healthcare markets.”

He noted less demand of laboratory-based COVID-19 tests, while sales of rapid tests were strong and consistent with Q3 2021. However, Ford anticipated COVID-19 to continue its path to endemic status in Q4 and 2023.

“Excluding COVID-19 testing revenues, sales of routine diagnostic tests grew 6% in the quarter overall and even faster internationally, fueled by the continued global rollout of our Alinity instrument for immunoassay, clinical chemistry, and molecular testing,” he noted.

Some of the company’s declined earnings stemmed from the temporary closure of an Abbott infant formula factory earlier this year. The FDA investigated the facility over concerns of contamination, which led in part to a shortage in the U.S.



PERKINELMER: Diagnostics Revenue Down 39%, Company Split Coming

PerkinElmer in Waltham, Mass., reported results for its Q3:

- Company revenue dropped 17% to \$712 million.
- Diagnostics revenue fell 39% to \$399 million.

During a presentation to investors, company leaders said the drop off in diagnostics revenue was due to COVID-19 testing decline as well as lockdowns in China.

Meanwhile, the company is in the midst of selling its applied markets, food, and enterprise services businesses to private equity firm **New Mountain Capital**, for \$2.45 billion. The move will allow PerkinElmer to focus on its diagnostics and life sciences divisions, which will operate under a new, to-be-announced company name.

“The energy and excitement among our employees in all our businesses remains exceptional as we continue to prepare for the upcoming split into two separate companies,” said company President and CEO Prahlad Singh.

BIO-RAD

BIO-RAD LABORATORIES: Faces Supply Chain Hurdles, Alludes to Possible Merger

Bio-Rad Laboratories, in Hercules, Calif., reported Q3 financial results:

- Sales were down 8.9% to \$680.8 million.
- COVID-19 related revenue was \$17 million compared to \$57 million in the same period last year.
- Clinical diagnostics segment sales fell 2.8% to \$361.9 million (when excluding impact of decreased COVID-19-related sales, sales increased 3.7%).
- Life sciences segment revenue was down 14.9% to \$317.9 million (excluding COVID-19-related sales and legal settlements, revenue increased 9.4%).

During an earnings call, Chief Operating Officer Andrew Last described the effect of supply chain disruptions on instrument placements.

“Improvement in product supply in the quarter was slower to materialize than we expected, which negatively impacted

sales across several product lines, and we continue to carry a significant order backlog,” he said.

CEO Norman Schwartz addressed the *Wall Street Journal's* previous reporting that Bio-Rad was in potential merger discussions with molecular testing firm Qiagen. (See TDR, “*Reports Say Qiagen and Bio-Rad Discussing Potential IVD Merger*,” Oct. 31, 2022.)

Schwartz noted that over the last few years Bio-Rad Laboratories has made “smaller acquisitions which have contributed to about one-third of our growth ... and we now feel we could acquire and absorb a larger and more transformational opportunity if it met our strategic and financial metrics.”

SIEMENS Healthineers

SIEMENS HEALTHINEERS: Diagnostics Faces Significant Cost Cutting by 2025

Siemens Healthineers in Erlangen, Germany, shared results for its Q4 ending Sept. 30:

- Overall revenue increased 6.8% to €6 billion (US \$6.02 billion).
- Diagnostics revenue increased 5.8% to €1.44 billion (US \$1.49 billion).

During a presentation, CEO Bernd Montag, PhD, said the company “had a strong finish in a more than challenging year.”

He explained diagnostic growth was driven by rapid COVID-19 antigen sales, which were €232 million (US \$235 million) in Q4, compared to €160 million (US \$162 million) in Q4 2021.

However, the COVID-19 test revenues overcompensated for higher logistics and supply chain costs. Those factors, among others, have resulted in Siemens taking next steps to cut €300 million (US \$309 million) in costs through 2025.



BIOMÉRIEUX: Sales Down 5%, Microbiology Shows Life

bioMérieux, in Marcy-l'Étoile, France, released these Q3 numbers:

- Total sales of €902 million (US \$915 million) fell 5.3%.
- Clinical applications (about 84% of sales) decreased 7.4% to €763 million (US \$774 million).
- Molecular biology sales decreased 11.8% to €333.5 million (US \$338.4 million).
- Microbiology sales increased 8.8% to €311.8 million (US \$316.5 million).
- Immunoassays sales were down 20.2% to €101.4 million (US \$102.9 million).

There was less demand for COVID-19 tests, but also a rebound of core services.



HOLOGIC: Diagnostics Revenue Down 35% Due to Less COVID-19 Testing

Hologic in Marlborough, Mass., reported on results for its Q4 ending Sept. 24:

- Revenue decreased 25.6% to \$953.3 million due to lower COVID-19 assay sales and supply chain challenges.
- Diagnostics revenue was down 35.6% to \$520.9 million (without comparison to Q4 2021 COVID-19 assay revenue, diagnostics revenue was up 11% in Q4.)
- Molecular diagnostics revenue, within diagnostics, declined 41.3% (excluding COVID-19 revenue, it grew 17.2%).

The company emphasized that comparing Q4 2022 against Q4 2021 is misleading because the prior year saw the Delta variant heavily increasing demand for SARS-CoV-2 testing.

CEO Stephen MacMillan noted that consumers want to know more about diseases that infect them, which will benefit IVD companies in the long run.

MacMillan cited respiratory syncytial virus (RSV) as an example.

“I’d argue that 99.9% of the public had never heard of RSV [before this fall],” he said. “We’re getting into these levels of granularity that people want to know more about what [infections] they have, and we think that will be a positive.”

The company is also pinning hopes on continued expanded use of its Panther automated assay system. The company has 3,250 Panthers operating globally, up from about 1,700 at the end of fiscal 2019.



SYSMEX CORPORATION: American Testing Demand Has Resurgence

Sysmex in Hyōgo, Japan, reported financial results for six months ending Sept. 30 of its 2023 fiscal year:

- Sales were up 15% to ¥194 billion yen (US \$1.3 billion).
- Sales in the Americas increased 37.6%.

Sysmex saw a resurgence in testing demand in the Americas and increased sales of instruments, reagents, and maintenance in hematology and urinalysis.

QuidelOrtho

QUIDELORTHO: Focus on Integration of Two Companies

QuidelOrtho in San Diego, named for the consolidation earlier this year of Ortho Clinical Diagnostics and Quidel, reported:

- Combined Q3 revenue went up 54% to \$783.8 million due to the merger.
- Point-of-care and donor screening product lines drove revenue growth.

The company said instrument revenue was negatively affected by global supply chain challenges and that “labs softness was due to continued challenges in China and instrument supply chains.”

TDR

INTELLIGENCE

LATE & LATENT
 Items too late to print,
 too early to report



Is it time to allow consumers to do at-home testing for influenza?

Given the already-raging influenza season—flu-related hospitalizations doubled the week of Nov. 20 compared to a week earlier, according to the **Centers for Disease Control and Prevention**—the *STAT* medical news site raised an interesting question about why at-home flu tests were not available. That may be a surprising fact given how many consumers continue to self-check possible COVID-19 symptoms with rapid tests. Yet historically, physicians and the **U.S. Food and Drug Administration** (FDA) have shied away from supporting at-home flu testing.



MORE ON: Flu Tests

“It is really rare, and it is really new, that people are allowed to know about what’s happening inside their body without a physician in the middle,” Michael Mina, MD, Chief Science Officer at **eMed**, told *STAT*. The Miami company sells virtual-

ly-proctored at-home COVID-19 tests. One concern is that some prototype rapid flu tests proved to be reliable only 11% of the time in accurately detecting the illness, *STAT* reported. Because prominent influenza strains change year to year, the FDA also has worries about people using a prior year’s at-home test. However, there are rapid flu tests used at emergency rooms and retail pharmacies that are waived under the Clinical Laboratory Improvement Amendments, according to a July 2019 report in the *Journal of Clinical Virology*. Bringing telemedicine into the picture so that a physician or nurse can virtually observe a patient swab for the flu, might assuage regulator concerns, Mina suggested.



SANFORD OFFERS FREE GENETIC TESTS TO MILITARY

Sanford Health in Sioux Falls, S.D., now offers free genetic testing to current U.S. military personnel and veterans who receive their primary care from

the health system, according to *Valley News Live*. THE DARK REPORT previously noted that Sanford began offering a genetic test panel to patients in July 2018. It remains uncommon for healthcare systems to offer a pharmacogenetics test in primary care settings, so Sanford continues to pioneer this area of genetic diagnostics and clinical laboratory medicine.

TRANSITIONS

- Brad Moore has been named President and CEO of **Roche Diagnostics** North America effective Jan. 1. He is currently Senior Vice President of Core Lab and Point of Care at Roche Diagnostics North America. He previously worked at **Johnson and Johnson** and **LifeScan Canada**.

- Precision cancer diagnostics firm **Epredia** in Kalamazoo, Mich., has promoted Dave Sanford to Senior Director of Global Product Marketing. He has been at Epredia since 2019. Previously, he worked in marketing roles at **Thermo Fisher Scientific**.

*That’s all the insider intelligence for this report.
 Look for the next briefing on Tuesday, January 3, 2023.*

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