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Robert Michel on...

Identifying Clinical Laboratory Trends from Experiences of Labcorp, Quest Diagnostics

Goldmine of insights from earnings reports

(See pages 10-17)

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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

INSIDE THIS ISSUE

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Watch Out Pathologists! They're Coming for Histology!

FOR ANY LAB THAT DEPENDS ON REVENUE FROM ITS HISTOLOGY LABORATORY, this issue of THE DARK REPORT has important intelligence about a serious threat to this existing business model. One of your biggest, best-financed competitors is preparing to make a foray into this market segment of lab testing.

I direct you to the sidebar on page 15 with the headline, "Digital Pathology Gains Momentum at Quest, Plans to Offer Histology Services to Hospitals." During **Quest Diagnostics'** recent quarterly earnings call, its executive team told investors and financial analysts that its acquisition of certain assets of **PathAI** in recent months was specifically to expand its capabilities in digital pathology and use of whole slide images.

Pay close attention to the last paragraph on page 15, where you will read the comment made by Jim Davis, CEO of Quest Diagnostics, that his company sees histology as a lucrative line of business. He stated quite bluntly, "With digital pathology, it opens up a realm of new just histology-only types of operations. Meaning, we will take on the histology work for a health system. They'll still keep the pathologists, but they'll shut down their histology operations.

"We'll do the slide preparation, digitize it, and send that back to the hospital pathologist for them ... to do the reading," he continued. "We call this a technical-only solution. It's a solution starting to take off and the margins on the technical component of histology are quite good. So, we're bullish on the overall market opportunity here."

Once again, THE DARK REPORT is first to alert you to an important new development. Across the nation, most pathology laboratories rely on reimbursement generated by the technical component of pathology cases. Now, one of the billion-dollar lab corporations has articulated a strategy to aggressively capture that business, particularly targeting hospitals that operate their own histology laboratories. But why would a public lab company stop at histology and the technical component? Precedence indicates it would act quickly to convince the source of the pathology biopsies that its own pathologists could read those cases, thus cutting out the local pathologists at that hospital.

The appetite of any publicly-traded lab company for new sources of revenue is insatiable. Pathologists are now forewarned. A credible competitor is coming after the histology business of hospitals and other biopsy sources. TDR

How Is COVID-19 Evolving? It's Not Like Flu or Colds

Yes, it is a coronavirus, as are influenza and colds, but its infections show a pattern of summer surges

CEO SUMMARY: It's been 53 months since the SARS-CoV-2 virus triggered the worst global pandemic since 1918's influenza pandemic. The coronavirus continues to surprise public health officials as new variants are detected, along with a multi-year pattern of summer surges in new cases. The pandemic made wastewater testing an essential tool for public health officials and a newly-published study found COVID-19 in six species of wildlife in Virginia.

EVIDENCE CONTINUES TO SUPPORT THE BELIEF that the SARS-CoV-2 coronavirus will probably be infecting humans for years to come. This has long-term consequences for the nation's clinical laboratories.

COVID-19 hit the world like a sledgehammer in the winter of 2020. Not until 2022 did the number of hospitalizations and deaths decline as the pandemic burned itself out. But the end of the pandemic was not the end of COVID-19.

Instead of disappearing, since mid-2022, new hospitalizations and deaths from COVID-19 have continued at a lesser—but concerning—rate. It is why clinical laboratories have continued to offer SARS-CoV-2 testing, with the added challenge of staying up with the stream of new variants that constantly emerge.

Data published by the **Centers for Disease Control and Prevention** (CDC) provide evidence that COVID-19 has taken hold as an endemic disease in the United States. *(See sidebar and chart on page 5.)*

Despite these statistics involving ongoing new infections, it is interesting that, to our knowledge, no public health official or medical expert has made an "official" announcement that COVID-19 should now be classified as an endemic disease. One federal agency—the **U.S. Department of Health and Human Services** (HHS)—did officially announce the end of the COVID-19 Public Health Emergency on May 11, 2023.

According to *MedLinePlus*: "Endemic means a disease that is always present in a population within a geographic area, typically year-round." Since its arrival in the United States in early 2020, the COVID-19 coronavirus has certainly met that criteria.

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Today's reality is that new SARS-CoV-2 infections are ongoing. Clinical labs continue to receive test requisitions and newly-infected patients are visiting their physicians or showing up in hospital emergency departments.

Wastewater Testing

Meanwhile, the COVID-19 pandemic introduced a new tool for public health officials—wastewater testing. During the pandemic, some pioneering labs learned that by testing wastewater for the DNA of SARS-CoV-2, they could identify towns and even neighborhoods where the number of infections were increasing, before doctors or hospitals experienced the related surge in patient visits. *(See TDR, "SARS-CoV-2 Variant Sequencing Offers Clinical Opportunities," March 1, 2021.)*

On July 31, *Newsweek* reported on the incidence of COVID-19 in wastewater. It noted that the CDC issued data showing that 20 states "detected 'very high' levels of COVID-19 in their wastewater." This was an increase from only seven states reporting "very high levels" as of July 15. *Newsweek* explained how, "when wastewater is tested, the virus could be detected earlier than clinical testing and before people who are sick go to their doctor or hospital."

Early Warning of Infections

Newsweek continued, stating that "wastewater data can also provide important information about whether the virus is increasing, decreasing, or staying the same in a community.

"If the levels of COVID-19 in wastewater start to go up, it can signal that more people are getting infected. This helps communities take action faster to control the spread of the virus."

What is significant for clinical laboratory managers is that CDC data generated this summer show that current SARS-CoV-2 virus levels "in the U.S. overall are on track to exceed last summer's wave."

The increased number of infections show up in more physician referrals of SARS-CoV-2 tests to clinical laboratories during the summer months. For example, last month, *Health* interviewed Vontrelle Roundtree, MD, a board-certified family physician and Associate Chief Medical Officer at **MDLive,** a telehealth Clinic. She said her clinic was seeing "a steep surge in COVID-19 cases since the beginning of the summer," with diagnoses up 108% and Paxlovid prescriptions running 130% higher in June, compared to the monthly average for April and May.

Two Factors Trigger Cases

Experts tell the public that these summers of increased infections are probably due to two factors. One factor is the ongoing emergence of new variants of the SARS-CoV-2 virus. "I honestly think that this [surge in the number of new infections] is about viral evolution and the fact that new subvariants of Omicron are always emerging under the pressure of community immunity," Shira Doron, MD, Chief Infection Control Officer at **Tufts Medicine**, told *WBZ News* in Boston.

The other factor mentioned frequently is the social gatherings of people and extensive travel that happen during the summer months. Akiko Iwasaki, PhD, is Professor of Immunobiology and Molecular, Cellular, and Developmental Biology at **Yale University**. She told reporters at the *BBC* that "the summer COVID-19 wave is likely to be partially exacerbated by factors such as people gathering in close proximity at festivals and concerts, and the heavy use of air conditioning which dries the air and encourages viral spread."

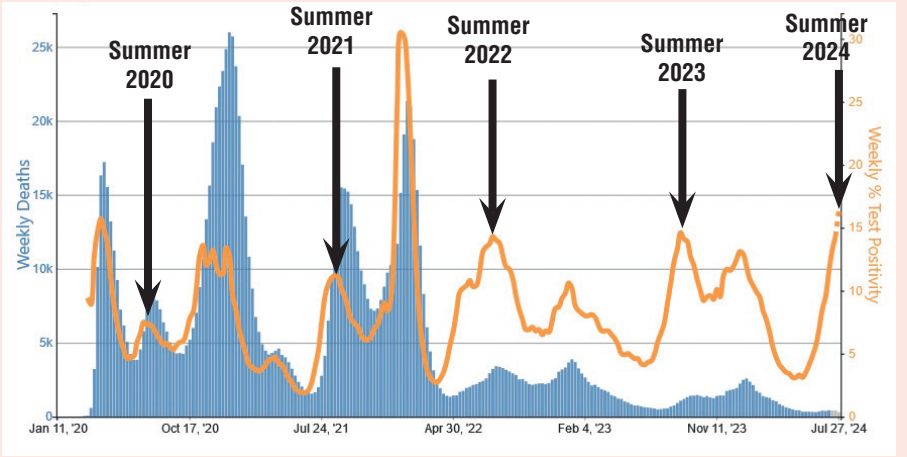
The newest development associated with the emergence of SARS-CoV-2 is that scientists are finding the virus in wildlife. On July 29, 2024, *Nature Communications* published the study "Widespread Exposure to SARS-CoV-2 in Wildlife Communities."

COVID-19 Infections Show Peaks Twice Yearly, One in Winter, the Other in Summer

DATA COLLECTED BY THE FEDERAL CENTERS FOR DISEASE PREVENTION AND CONTROL (CDC) show that, since the original outbreak of COVID-19 in early 2020, each subsequent year showed two peaks in the number of new infections. One peak is during the winter, tracking the typical influenza season. The second peak of new COVID-19 infections arrives in the summer, a time when few new cases of influenza are reported.

The graph below, taken from the CDC's website, shows the summer peaks in the number of new COVID-19 infections. "Provisional COVID-19 deaths" are the blue bars, while"COVID-19 Nucleaic Acid Amplication Test Percent Positivity, by Week" is shown as a yellow line.

Each summer, there is a surge in the percent of positive COVID-19 tests, as marked by the arrows. At the same time, there is an increase in the number of visits to physicians' offices and hospital emergency departments. These summer surges show why clinical laboratory testing for SARS-CoV-2 continues to be important, even if the daily volume of COVID-19 tests is substantially less than during the pandemic.



Source: Centers for Disease Control and Prevention: COVID Data Tracker: 2024 August 04; https//covid.cdc.gov/covid-data-tracker

Researchers in Virginia found the COVID-19 virus in six wild species: deer mice, Virginia opossum, raccoons, groundhogs, Eastern cottontails, and Eastern red bats. Because the viruses were associated with the Omicron variant, researchers attributed these infections to human-to-animal transmission events.

The summer surges of COVID-19 show clinical lab managers that this virus is probably now endemic. The current daily volume of new cases requiring lab tests are well below the peak of testing during the pandemic's most intense period. CDC data show that the most SARS-CoV-2 tests run on a single day by the nation's clinical labs was approximately 1.15 million on Nov. 26, 2020.

Four years after the outbreak, what seems to be true is that clinical labs will continue to do this testing and be confronted regularly with new variants of SARS-CoV-2. Moreover, unlike the coronaviruses of influenza and the common cold, COVID-19 infections surge in the summer as well as in the winter. TDR

Lab Market Update

Clarapath Raises $36 Million for Automated Histology Solution

Numerous major health system laboratories say they are eager to purchase and deploy this new solution

As the histology workforce struggles to keep up with rising case demand, **Clarapath**—a Hawthorne, N.Y. company intent on changing the way laboratories process human tissue—recently raised $36 million in funding for its SectionStar tissue sectioning and transfer robot.

Leading the recent funding round was **Northwell Ventures**, the for-profit arm of **Northwell Health**, New York, N.Y. Additional participants included **Ochsner Ventures**, New Orleans; **Mayo Clinic**, Rochester, Minn.; and others, bringing Clarapath's total funding to $75 million. The technology has been registered with the **U.S. Food and Drug Administration** and a U.S. launch is pending. *(See TDR, "Clarapath Automates Slide Prep, Microtomy Workflow," July 1, 2024.)*

"Clarapath is really on the cusp now of being in the market. There is a long line of very reputable institutions that want their SectionStars," said James Crawford, MD, PhD, Chair Emeritus, Pathology and Laboratory Medicine, Northwell Health. Crawford, a non-voting member of the Clarapath board of directors, spoke in an exclusive interview with THE DARK REPORT.

With the additional capital, Clarapath said it plans to step up SectionStar's manufacturing (done in New York) as well as sales and research. The SectionStar robot, which can fit atop a laboratory bench, is an automated microtomy system "that takes paraffin tissue blocks as inputs and creates glass slides as outputs," the company website explains.

As Crawford put it, "SectionStar is a highly reliable robotics device for the production of the highest quality histology."

Northwell is currently sending paraffin blocks to the Clarapath facility in Hawthorne, N.Y. Once SectionStar formally goes to market, Northwell Health anticipates placing machines at its own facilities, according to Crawford.

Clarapath and AI

But why are leading healthcare organizations and anatomic pathology laboratories (including histology labs) in line for the technology? Histology, which involves the microscopic anatomy of biological tissues, is in need of a jumpstart, or what Crawford termed, "a vault into the realm of reproducibility and quality." This advance is needed, in part, due to artificial intelligence (AI).

"Histology is a 150-year-old professional activity. While there has been outstanding histology through the years, it is not consistently outstanding. There are defects in the process of manual histology," he said, referring to such artifacts as tissue folds and tears and inconsistent section thickness and tinctural staining.

Since AI algorithms are being developed based on digitized histologic images, the interpretations computers make should be based on images of the highest quality—a requirement for consistency above what the human eye can adapt to with less-than-perfect manual histology, Crawford noted.

"We as pathologists look at the tissue folds, the tears, and the variable colorations of tissue sections, see through those imperfections, and do a very good job in our interpretations," Crawford said.

"But if you are going to run computer algorithms on digital images, you need consistently high input of the histology sections," Crawford continued, positing that SectionStar could even be the "platform for the development of AI algorithms across the industry."

Histopathologist Shortage

Also prompting need for new technology is the rising demand for histology professionals amid a limited supply of job candidates and medical students. According to **U.S. Bureau of Labor** statistics, 18,000 histologists work in the nation's labs, and there is a 9% vacancy rate, the **National Society for Histotechnology** reported.

"The need for the histology workforce is at an inflection point. There is a shortage of histopathologists, which is not going to change in the foreseeable future," said Crawford, who noted that with a population of 17 million, New York state only has 400 licensed histotechnologists in the state.

Further, the work histotechnologists do to prepare, process, and analyze patient tissue specimens is likely to increase in light of escalation of cancer cases. **WHO** data predicts 35 million new cancer cases in 2050, a 77% increase from 22 million new cases in 2022. "SectionStar is arriving at exactly the right time," he said.

Help for Histology Labs

Crawford notes that the new system is not intended to replace histologists. "It is going to enable the current histology workforce to meet the needs they are struggling to meet now," Crawford said.

"What SectionStar can do is increase what I call 'production capacity,' enabling the existing histotechnologists to monitor production, which is robotic. The histotechnologist becomes a traffic controller, and can have a higher rate of productivity, enabling anatomic pathology to operate at a level that can meet future needs as well," he said. "Histotechnologists can then focus on the off-production detail work that takes maximal advantage of their extraordinary skills."

Clarapath, on its website, summarized the advantages of SectionStar for histology labs: "Reduction of overhead by up to 30%; faster turnaround time, processing multiple blocks an hour, having a standardized process, consistent three to five micron sections, and elimination of operator bias."

In making the equity posture decision in Clarapath's recent Series B-1 funding round, Northwell applied two criteria: Is the company's mission aligned with Northwell? Is the organization known to Northwell?

"We identified Clarapath seven years ago as a company with a bold vision to radically change laboratory medicine, and we are committed to continued support of their progressive journey, which will transform medical diagnostics," said Rich Mulry, president and CEO of Northwell Holdings.

Meanwhile, Ochsner Ventures, a partnership and investment group within **Ochsner Health**, sought technology and healthcare expertise.

"Clarapath demonstrates the right mix of technical robotic expertise coupled with healthcare workflow experience," said Gregg Sossaman, MD, Chair of Pathology and Laboratory Medicine and incoming president of the **American Society for Clinical Pathology**.

"For too long, pathology laboratories have not seen the level of technology innovation that other areas of medicine have seen," he said. **TDR**

Contact James Crawford, MD, PhD, at jcrawford1@northwell.edu.

Lab Market Update

New Huron Survey Illuminates Consumer Healthcare Trends

Consumers' interest in online and mobile apps to manage their healthcare is lab opportunity

Regularly, The Dark Report points out that consumers are an important force in healthcare's transformation. Those clinical laboratories wanting to stay in the forefront of diagnostic testing services would be wise to heed emerging trends in consumer preferences.

The latest sign of those trends comes from **Huron Consulting Group**, which issued a report based on a survey of 3,000 U.S. healthcare consumers. Some findings have direct implications for clinical laboratories and pathology groups.

"What consumers want from their healthcare experience is in transition," the report stated. "Emerging technologies and tools like artificial intelligence (AI), automation, and advanced analytics are redefining what's possible, leaving some consumers eager for innovation and others favoring traditional care approaches."

Top Preferences

The biggest factors driving consumer preference, Huron reported, are:

- 50% desire high-quality care as most important;
- 30% identify affordability—including transparent billing—as their top consideration; and,
- 32% said they'd pay extra for "exceptional quality of care and outcomes."

Respondents also listed convenience and personalized interactions with providers as key factors. Close to 66% rated "convenient location" and "short wait time," such as availability of same- or next-day appointments, as being important to them.

But of key interest to clinical laboratories, 55% rated "on-site diagnostic services," including lab tests and imaging, as being important.

This suggests that clinical laboratories should position themselves to provide speedy access to test results. If patients need to see their doctors on short notice, it is likely that they are worried about their health, and obviously labs have an important role to play in that interaction.

Digital Technologies

Huron also queried respondents about their use of digital health apps and devices. Notably, nearly half reported using these tools at least once/week, as follows:

- 44% use online portals or mobile apps to schedule appointments or check their medical records;
- 41% use fitness or exercise apps; and,
- 35% use wearable devices to track exercise or fitness.

A solid majority of respondents (70%) said they prefer to get healthcare in person, but an even higher number (84%) said it was important to have virtual care options.

Another finding of interest to labs: consumers are willing to share personal health data—including test results, medical history, and biometrics—to help providers assess their risk factors for a variety of conditions.

Survey respondents were most willing to share data to predict risk of cardiovascular disease and cancer, but far less are willing to share information related to behavioral health, such as risk of anxiety or depression.

Three Action Items

The report concluded with three suggestions for how providers—including clinical laboratories—can boost loyalty among existing patients and attract new ones:

- **Facilitate Access to Care**: Close to half of the respondents said their choice of providers is based on referrals from primary care physicians or other healthcare professionals. In response, "healthcare organizations can provide a more seamless experience by strengthening relationships with in-network providers, prioritizing self-service digital tools to guide consumers' care decisions, and using data to strengthen physician referral management programs, which drive patient retention and volume," Huron stated.
- **Provide Timely Communications**: This includes information about pricing of services as well as financial planning resources to address concerns about healthcare costs, Huron said. Providers should learn consumers' communication preferences, including their preferred channels, and consider adopting tools such as artificial intelligence software and customer relationship management systems to personalize outreach in an efficient manner.
- **Invest Wisely in Digital Technology**: "Virtual care and digital tools are becoming increasingly influential in consumers' healthcare choices," Huron stated, noting that close to 60% of the survey respondents used these tools at least moderately. "Investments should be analyzed to ensure they match the demands of an organization's consumer base, while keeping emerging preferences in mind," Huron said. TDR

Consumer Differences in Attitudes, Aptitudes

BASED ON THE SURVEY RESULTS, Huron grouped healthcare consumers into six categories determined by "differences in attitudes, preferences, and digital aptitude." Huron also noted that consumers want easier access to care and "relevant, timely communications with providers."

Huron grouped consumers' approach to healthcare on a continuum from "slightly" digital to "hyper" digital:

- **Traditional and Affordable:** This group uses health services an average of once per year. They want an experience that is "quick and easy with minimal use of technology."
- **Life-long Relationships:** These consumers use health services an average of two or three times per year. They want "a consistent healthcare experience" with providers they "know and trust."
- **Self-advocacy:** These are "moderately digital" consumers who use health services an average of once per month. They want to be "actively involved in care decisions," engaging in "open communication with my provider."
- **Affordable Access:** These consumers use health services two or three times per month on average. They want "an affordable and convenient healthcare experience with access to a diverse mix of providers and specialists."
- **Personalized Options:** These consumers use health services two or three times per month. They want personalized healthcare and choice about their options.
- **High-tech and Holistic:** This is the "hyper-digital" group. They use health services an average of once per week but engage with digital health apps on a daily basis.

➤➤ ***CEO SUMMARY: Many different factors influence the operations of clinical laboratories in the United States today. One good source of competitive business intelligence is for lab administrators to follow the quarterly earnings calls of the nation's two biggest public lab corporations. With coast-to-coast operations, they are often first to experience and respond to new trends—whether its more consumers ordering their own lab tests, hospitals selling lab outreach, or use of AI in lab operations. Here's a look at what was discussed in recent earnings calls by each of the Two Blood Brothers.***

Two lab corporations are first to experience changes in lab test marketplace

Identifying Current Lab Trends from Labcorp & Quest Experience

by Robert L. Michel

In the United States, the market for clinical laboratory services continues to evolve in powerful ways. However, unlike the past two decades, it is more challenging to spot and understand the forces now reshaping how labs are organized, the technologies they deploy, and new models of lab operations.

This complicates strategic planning by lab administrators and pathologists, particularly because many lab organizations operate at less-than-authorized staffing. It means management at all levels is pressed to deal with day-to-day issues, leaving little time for market research and regular updates to their labs' strategic plans.

However, there is one good shortcut to aid labs in their own strategic planning. That is to study the quarterly earnings reports of the Two Blood Brothers. In this intelligence briefing, we help you in two ways. First, we will explain why these quarterly earnings reports are a gold mine of insights for clinical lab administrators and pathologists responsible for updating their labs' strategic plans and market tactics.

Second, using the recent quarterly earnings calls of **Labcorp** and **Quest Diagnostics**, we will highlight their executives' comments about the most significant market forces and business successes the two public lab corporations discussed with their investors and financial analysts. For the reasons explained below, during these investor calls, Quest and Labcorp executives regularly describe:

- How market forces are changing the way physicians use lab tests;
- Trends with consumers ordering their own tests;
- Specific issues with labor turnover and salaries;
- Which new diagnostic technologies and lab tests are generating growth in the number of test referrals and revenue;
- Innovations in their laboratories internal workflow;
- Managed care contracting developments; and,
- Current thinking concerning the laboratory developed test (LDT) rule published by the **U.S. Food and Drug Administration** (FDA).

➤ Source for Strategic Plans

There are solid reasons why these quarterly earnings reports are a gold mine of insights for other lab organizations. It is because of the following eight factors:

One: When their market shares are combined, **Labcorp** and **Quest Diagnostics** easily have 80% or more of the national market share of routine and reference testing provided to physicians in the outpatient/outreach sector. They are first to experience new developments involving the use of clinical lab tests.

Two: These two billion-dollar lab companies provide routine and reference testing to office-based physicians in nearly every metro, city, and town of size throughout the U.S. This extensive geographical coverage enables Quest and Labcorp—and possibly **Sonic Healthcare, Ltd.,** the other billion-dollar lab player primarily serving office-based physicians—to understand the regional differences in the delivery of healthcare before any other lab. For example, are growing numbers of consumers on the West Coast ordering their own lab tests? Or, in the heartland states with high rates of obesity, diabetes, chronic kidney disease, and heart conditions, are physicians ordering more tests to find the undiagnosed patients with chronic conditions, close care gaps, and more closely monitor patients with these chronic diseases? Labcorp and Quest are the first clinical lab providers to see these trends emerge in different regions and understand how they may be changing the way physicians and consumers order and use lab tests locally.

Three: Distinct from observing regional developments, these two lab companies are equally positioned to identify/understand national trends in how physicians and consumers use lab tests.

Four: The two billion-dollar lab corporations hold managed care contracts with almost every health plan of size and influence. This gives them inside knowledge on how Medicare, state Medicaid programs, and private payers are setting priorities for physicians and striving to deliver value-based care. Related to this are the scorecards of HEDIS and STAR ratings for health plans and how health insurers set new or different targets for physicians.

Five: Because of the sizeable regional labs operated by Labcorp and Quest, these lab sites have the huge volumes of specimens necessary to justify automating every aspect of their operations, whether in the flow of specimens within the lab or the experience of consumers in their patient service centers.

Six: The Two Blood Brothers are first to see new diagnostic technologies and tests under development and poised to come to market. This is because test developers know that Quest and Labcorp have large sales forces to educate physicians about the benefits of using new lab tests with their patients.

AI in Lab Operations

Seven: Both lab companies now use artificial intelligence (AI) and machine learning across the span of their operations and interactions with physicians, patients, and payers. They can be considered "early adopters" in this field and their AI vendors now have credible data and experience to sell these AI-powered solutions to other clinical laboratories.

Eight: Labcorp and Quest employ more clinical laboratory scientists (CLSs), pathologists, and other skilled lab scientists than any lab organization in the U.S. The two companies deal with the full range of issues associated with lab labor, including shortages of CLSs, accessioners, phlebotomists and others, and their turnover as they change jobs. This can also involve salaries, benefits, and bonuses. Or it can be the different approach to work and lifestyle unique to Baby Boomers, Gen Xer's, Millennials, and Zoomers—all now working together in the laboratory.

Each of the eight factors listed above explains why these two huge lab corporations—who together control more than 80% of the national market for routine and reference testing provided to office-based physicians—can be the source of useful insights into changes in the market for clinical laboratory testing services.

Most of these elements were discussed in the two lab companies' second quarter earnings calls. Quest Diagnostics conducted its Q2-2024 call on July 23. Labcorp's call took place on Aug. 1. The financial performance of each lab corporation during Q2-2024 and the first six months of 2024 is shown in the sidebar on page 13.

➤➤ CLINICAL LAB MARKET DYNAMICS

Positive Financial Reports for Second Quarter 2024

In the opening minutes of each lab company's quarterly earnings call, executives were upbeat when summarizing their second quarter performance. At Labcorp, CEO Adam Schecter stated he was looking forward to "sharing our strong results for the quarter."

He explained that "... second quarter, revenue totaled $3.2 billion ... Enterprise revenue increased 6% compared to the second quarter of 2023. Diagnostics revenue was up 8%, driven by strong organic growth and acquisitions."

In the Quest Diagnostics conference call, Chief Financial Officer Sam Samad summarized key financial measures. He said, "In the second quarter, consolidated revenues were $2.4 billion, up 2.5% versus the prior year while base business revenues grew 3.8%. Organic base business revenues grew by 3.1%. Revenues for Diagnostic Information Services were up 2.8% compared to the prior year reflecting strong growth in our base testing revenues partially offset by lower revenues from COVID-19 testing services."

Q2-2024 and Six-month 2024 Earnings Reports Show Gains at Labcorp, Quest Diagnostics

GIVEN THE MASSIVE MARKET SHARE OF OFFICE-BASED PHYSICIAN TESTING held by the two biggest public laboratory companies in the United States, there is always interest in the quarterly earnings reports they issue. These earnings reports are snapshots revealing how the market for clinical laboratory testing is evolving. For example, both Labcorp and Quest Diagnostics issued earning reports for the second quarter 2024 which show that COVID-19 testing is no longer a dominant factor the way it was only 18 months ago.

labcorp

Labcorp announced these Q2 2024 and six-month 2024 financial results as compared to same periods in 2023:

- Q2 revenue was up 6.3% to $3.22 billion from $3.03 billion.
- Q2 diagnostic laboratories revenue was up 7.9% to $2.52 billion, an increase from $2.34 billion.
- Q2 test requisition volume grew 5.7%.
- Q2 biopharma laboratory services revenue was up 1.1% to $707.0 million, an increase from $699.0 million.
- Six-month 2024 revenue was up 2.5% to $12.16 billion from $11.86 billion.
- Six-month 2024 diagnostics laboratories revenue increased 6.4% to $5.0 billion from $4.7 billion.

Source: Labcorp Q2 and Six Month 2024 Earnings Report.

Quest Diagnostics™

Quest Diagnostics reported these Q2 2024 and six-month 2024 financial results as compared to Q2 2023 and first six months of 2023:

- Q2 revenue was up 4.3% to $2.4 billion from $2.3 billion.
- Q2 test requisition volume grew 1.1%.
- Q2 revenue-per-requisition grew 1.6%.
- Clinical base business revenues increased 5.1% and volume rose by 3.2%.
- Six-month 2024 revenue was up 2.1% to $4.8 billion from $4.7 billion.

Source: Quest Diagnostics Q2 and Six Month 2024 Earnings Report.

Quest CEO Jim Davis added to that, saying "we delivered another strong quarter, with base business revenue growth of nearly 4% and total revenue growth of 2.5% as well as continued improvement in productivity and profitability in the base business."

>> CLINICAL LAB MARKET DYNAMICS

Lab Acquisitions, Outreach Deals Fuel Growth

Both lab corporations touted major lab acquisitions. At Labcorp, it was the purchase of selected **Invitae** assets for $239 million from the bankruptcy court. *(See TDR, "Invitae's Troubled Journey: Rise, Fall, and Bankruptcy," July 22, 2024.)*

At Quest Diagnostics, it was the pending acquisition of **LifeLabs**, one of the two large commercial lab companies in Canada. *(See TDR, "Quest Diagnostics Moves to Acquire Life Labs of Canada," July 22, 2024.)*

But that's only part of the lab acquisition story at both companies. During the past year, each of the Two Blood Brothers has closed multiple transactions involving

the purchase of outreach laboratory businesses of hospitals and health systems.

On its purchases involving lab assets from **OhioHealth** and **Allina Health**, Quest CEO Davis said, "Both transactions will broaden our presence in geographic areas of the United States where we've had limited access to providers due to the predominance of health systems. These acquisitions show our ability to attract and partner with top, growing health systems that share our commitment to expanding patient access to innovative and more affordable testing. We expect to complete both transactions in the third quarter."

Davis explained the reasons why hospital administrators are more willing to consider selling their lab assets, compared to past years. "Hospitals face several challenges, including high supply costs, high wages and decisions about how and where to deploy their capital," he said.

"Patients want better value from lab services as well as easier access," he continued. "Plus, diagnostic innovation is evolving at a fast pace. These dynamics are contributing to an accelerating trend of [hospital lab] outreach acquisitions and professional lab service arrangements with the national labs."

Labcorp purchased lab assets from **Bay State Health** in Massachusetts and **Providence Health** in California. CEO Schecter was positive about similar transactions. "Today, our pipeline remains very, very strong for those hospital deals. The local regional laboratories, I think, are struggling a bit after COVID."

>>> CLINICAL LAB MARKET DYNAMICS

Plans for Compliance with FDA Final LDT Rule

Probably the single most disruptive development for clinical laboratories at this time is the Food and Drug Administration's final rule on LDTs. Each lab company's CEO addressed this issue during their respective conference calls.

Quest Diagnostics CEO Jim Davis said "The LDT rule is in place. We are running the company and operating the company with the rule in place. There are certain requirements that we need to have in place by May of next year. That includes a complaint handling unit up and running, as well as the ability to report adverse events. These capabilities—some of which we had in the company, some of which we have to add—are ongoing as we speak.

"We've launched training for the organization, in particular our R&D teams, our product marketing teams around design controls," he continued. "We're living with the rule and implementing things for the directive of the FDA. We've said this year, it's not going to add a material cost into the business, but we continue to evaluate what we need to be fully compliant, especially if the lawsuit [filed by the **American Clinical Laboratory Association**–ACLA] is not successful."

Labcorp's CEO, Adam Schecter, stated "ACLA did file a lawsuit and they're challenging the FDA's final rule and we are supportive of ACLA doing that. In the meantime, of course, we are prepared to adhere to the LDT rule."

On the issue of LDTs approved by New York State's Clinical Laboratory Evaluation Program, Schecter stated, "When you look at the science ... we submit ... most if not all of our LDTs to New York state already. At the same time, there are some things that we have to be prepared for in terms of monitoring and reporting requirements and so forth.

"We have a team in place that ensure that we're ready for that to occur as soon as the LDT rule is final," he added. "At the same time, [the LDT rule] is not going to have a significant impact to our revenue or to our expenses. I think the bigger impact is going to be to patients."

Schecter explained, "These LDTs are typically for people with rare diseases or smaller patient populations. The question is, will the FDA even have the ability

Digital Pathology Gains Momentum at Quest, Plans to Offer Histology Services to Hospitals

IN MAY, QUEST DIAGNOSTICS STRUCK A MULTI-FACETED DEAL WITH PATHAI. Quest wants to boost its use of digital pathology solutions and artificial intelligence (AI).

During the second quarter earnings call, Quest executives described its strategy for digital pathology and the role this acquisition would play in implementation of that strategy. Quest purchased the pathology testing assets of PathAI that were located in Memphis. This is the former **Poplar Healthcare** pathology lab that PathAI acquired in 2021. *(See TDR, "PathAI Buys Poplar Health, Creates Unique Company," Sept. 7, 2021.)*

In its announcement of the acquisition Quest stated, "At closing, PathAI Diagnostics' state-of-the-art digitized laboratory in Memphis, Tenn., will become Quest's AI and digital R&D and solutions center, supporting Quest's specialty pathology businesses, **AmeriPath** and **Dermpath Diagnostics**."

Quest Diagnostics' CEO, Jim Davis, addressed this move during the Q2-2024 earnings call. "Our acquisition of PathAI Diagnostics ... provides a readymade platform on which to scale digital pathology and AI to help health systems and other providers improve quality, speed, and efficiency in cancer diagnosis," he said. "Just on our revenue from anatomical pathology ... and this was pre-PathAI diagnostics ... [we] said it was roughly a $500 million book of business. But we're excited about the digital pathology opportunity on numerous fronts.

"Digital pathology does not naturally lower your cost, because you ... still need to create the slide ... then digitize the slide ... so there is an extra step in the process," he said, adding that the whole slide image is where the opportunity exists to improve productivity and quality.

"We do anatomical pathology in over 20 locations across the country, because you want the pathologist to sit right near where you prepare the slide, so that you don't have to move [glass] slides [to pathologists at other locations]. We believe that ... digital pathology will allow us to collapse the network of sites that actually do ... the histology work to prepare the slides ... [and that] there will be cost savings when we collapse that network," he stated.

"It allows us to route the image to expert pathologists wherever they sit in the country," Davis said. "If our guru for breast pathology sits on the West Coast, you move those slides [digital images] out there. If the prostate guru sits on the East Coast, you move those slides [digital images] there."

Higher Reimbursments

Davis explained the opportunity to use algorithms with whole slide images. "There [are algorithms] that have been FDA approved that allow you to [analyze] the digital image to improve the quality of the read," he stated. "We believe there's a strong case to be made for a higher reimbursement using these algorithms.

"[Digital pathology] opens up a realm of new histology-only operations," Davis noted. "We will take on the histology work for a health system. They'll still keep the pathologists, but they'll shut down their histology operations.

"We'll do the slide preparation, digitize it, and send that back to the hospital pathologist for them ... to read. We call this a technical-only solution. It's a solution starting to take off and the margins on the technical component of histology are quite good. So, we're bullish on the overall market opportunity here."

to approve these quick enough so that all patients have access to these important tests as quickly as possible? To me, it's more of a 'patient access' and 'important for patients' issue than it is any type of impact to Labcorp."

>> CLINICAL LAB MARKET DYNAMICS

Direct-to-Consumer Testing Is Fast-Growing Opportunity

Direct-to-Consumer (DTC) testing services are expanding swiftly at Quest. Davis explained that "in consumer-initiated testing, our consumer-facing platform, *questhealth.com,* grew total revenues nearly 40% while base business revenues grew more than 50% versus the prior year. Today, about 25% of our revenues are from existing customers and 20% of our revenues are from tests we introduced in the past year."

DTC testing activities were not described in detail during Labcorp's earnings call. But CEO Schecter did mention that "we continue to expand Labcorp On-Demand, our consumer-initiated testing offering, with the launch of several new tests in May and June, including standard drug, complete drug comprehensive testosterone, HIV, and complete heart health."

>> CLINICAL LAB MARKET DYNAMICS

Physicians Order New Lab Tests That Improve Care

The types of lab tests where specimen referrals are growing the fastest is useful insight for strategic planning. Both CEOs discussed what areas of lab testing services were expanding at above average rates.

During his earnings call, Labcorp's Schecter stated, "We've talked about the importance of tests in four areas, specifically women's health, oncology, neurology, and autoimmune disease. We've focused on launching new tests in those areas to ensure we are having discussions with opinion leaders ... the reason we are focused on [these tests] is they grow faster than the other parts of diagnostic testing."

For Quest CEO Davis, strong growth is coming from certain lines of tests. On this point, as explained below, lab administrators and pathologists will want to note that Quest is recording a significant increase in the average number of tests per requisition. This is probably due to the fact that physicians are constantly using new lab tests that have improved diagnostic capabilities for an increasing range of health conditions.

As Davis explained during the earnings call, Quest "saw a meaningful improvement in revenue-per-requisition in the quarter ... [this] improvement is really coming in three areas. One, test-per-requisition continued to be very strong, north of four [tests per requisition]. Pre-COVID, that was a number that was south of four, it was in the threes. That's a nice uptick, and that's coming from some of our advanced testing around allergy, tick testing, cardiometabolic testing, the neurology testing."

>> CLINICAL LAB MARKET DYNAMICS

More Hospitals Increasing Their Send-Out Testing

Another source of growth in lab test volume came from hospital test referrals. "In hospital lab services, we grew base business revenues by nearly 4%," Quest's Davis observed. "Growth of reference testing remains higher than historical levels as hospitals struggle to fill open positions—especially in technical fields, such as histotechnology, microbiology, and cytotechnology. Our advanced diagnostics portfolio provides a compelling alternative for hospitals to send us more reference work."

Davis' comments confirm that—as many hospital labs are unable to stay fully staffed at authorized levels of FTEs—they are opting to stop doing certain tests in-house. Instead, they are referring more tests to the primary reference labs, including the Two Blood Brothers.

CLINICAL LAB MARKET DYNAMICS

Both Lab Firms Continue to Support SALSA Bill

One topic that will be of keen interest to clinical labs throughout the United States is the prospect of **Congress** passing the Saving Access to Laboratory Services Act (SALSA) during this year.

On this subject, Labcorp's Schecter was emphatic about his company's support. "Yes. We continue to strongly support the SALSA legislation. I said this for four years now. And it has strong bipartisan support. It's kind of remarkable to me that it has not passed yet. It's also hard to know if it will be passed again this year even though we're going to try to push for it to be passed.

"What I would say is that—if it is not passed this year—I do believe that there's a likelihood that it will be delayed again. If it's delayed again, that would be $80 million that we would not see as a downside next year, and a lot of that would fall to the bottom line. So let's wait to see how the year plays out ... in the meantime, we're going to continue to push to [pass] SALSA as best we can."

There were similar sentiments at Quest Diagnostics. "In terms of PAMA and SALSA, while we ... and our trade association and other independent labs continue to push the case for SALSA, we acknowledge it's going to be difficult to get that [bill] through in ... an election year," Davis stated. "Especially now given many of the changes that occurred in the last week," he added, referencing the presidential race.

"Having said that, we will continue to push very hard for another one-year delay in PAMA," he continued. "The recent CBO scoring on this was actually bigger than it was last year. They projected it would save the government over $3 billion. And in addition, the committee in the House that oversees this is looking for a pay-for-program to pay for continued telehealth benefits. So this becomes a nice pay-for-program that can satisfy the requirements to fund telehealth.

"So we are confident that—at a minimum—that would be a one-year delay in PAMA," Davis said. "Hopefully we can get this done and figure it out in the October-November timeframe as opposed to waiting for the December timeframe like we've seen [Congress do] in the past."

Tracking Lab Market Changes

Over the years, the quarterly earnings reports and conference calls conducted by Labcorp and Quest Diagnostics typically had some useful insights, usually limited to a few key topics.

As you have read in this intelligence briefing, that was not true of these second quarter earnings reports and conference calls with investors and financial analysts. Each company spoke to numerous important subjects, often commenting in response to a question by one of the investors or analysts.

For strategic planning purposes, the numerous market developments identified by the lab company executives—in tandem with descriptions of how their companies are responding—is itself a useful insight. It shows that the lab market is being pulled and tugged by many different and unrelated factors simultaneously.

This complicates strategic planning, regardless of the size or type of clinical laboratory. For example, advances in AI and machine learning are important and every lab needs a go-forward plan for acquiring and deploying these solutions on a timely, effective basis.

The goal of this intelligence briefing was to call attention to the major developments to which the nation's biggest clinical laboratories are watching. If they are making efforts to respond and leverage the opportunities presented by these new developments, then it would be smart for other clinical labs to know these facts and adjust their strategic plans accordingly. Remember the saying, "Fortune favors the bold!" TDR

Regulatory Update

HHS Issues Final Rule to Deal with Information Blocking

Hospital and physician associations criticized rule, worried their members won't know how to comply

ANY HEALTHCARE PROVIDER DETERMINED TO HAVE COMMITTED "INFORMATION BLOCKING" can now be assessed penalties by federal agencies. On June 24, the federal **Department of Health and Human Services** (HHS) issued a final rule dealing with information blocking under the authority of the 21st Century Cures Act (Cures Act).

The rule describes the disincentives that can be assessed against hospitals, physician groups, and accountable care organizations (ACOs) when it is determined that they committed information blocking.

There is teeth in this new federal rule. In its report on the rule, the **American Hospital Association** (AHA) noted that:

> *In the final rule, hospitals under the Medicare Promoting Interoperability Program found to have committed information blocking would experience a reduction of the market basket update by 75%. Critical access hospitals would see a reduction from 101% to 100% of reasonable costs, while clinicians in Medicare's Merit-based Incentive Payment System would receive a score of zero in the MIPS Promoting Interoperability performance category. Providers in accountable care organizations that commit information blocking would be ineligible to participate in the Medicare Shared Savings program for at least one year and may not receive revenue they may have earned through the program.*

The federal government has taken several steps to foster data transferability among healthcare organizations. This information blocking rule is part of the effort.

Clinical labs and pathology groups have an interest in data transferability. They must connect their lab's information systems with the electronic health record (EHR) systems of their client physicians. Often, EHR companies charge substantial fees and take months to enable such interfaces. For labs, this raises the cost of these necessary interfaces and delays their ability to achieve a working interface with referring physicians. Thus, the new federal rule may prove beneficial to labs.

Providers Unhappy with Rule

Reaction to the information blocking rule by hospital groups and physician associations was immediate and generally negative. The AHA issued this statement: "AHA is disappointed that HHS chose to disregard most of the comments they received and is highly concerned that the disincentive structure retained in the final rule is excessive, confusing, and imbalanced."

Similarly, the **Medical Group Management Association** (MGMA) expressed its disappointment that HHS issued the final rule with "significant administrative and financial penalties."

Clinical labs and pathology groups will want to review the final rule with their legal experts to ensure that their organizations are in compliance. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In recent years, many of the national retail pharmacy chain operators announced big plans to open primary care clinics. Now, after substantial investments of billions of dollars, those same retail pharmacy chains are unwinding these business lines. This spring, **Walmart** announced it was shutting down its **Walmart Health** initiative. That includes closing all 51 of its doctor-staffed health clinics. At one point, Walmart's board declared a goal of building 4,000 wellness centers by 2029. The company issued a statement about the closure stating, "through our experience managing Walmart Health centers and Walmart Health Virtual Care, we determined there is not a sustainable business model for us to continue."

MORE ON: *Primary Care*

Also this spring, **Walgreens Boots** reported a $6 billion quarterly loss, much of it attributed to problems with its **VillageMD** chain of primary care clinics. Since paying $5 billion to acquire a controlling stake in VillageMD in 2021, Walgreens built 200 primary clinics. Now it will close 160 of the existing clinics. Walgreens says it will keep clinics in more densely-populated areas, with the expectation that this will permit a single physician to treat more patients.

OPTUM TO CLOSE MEDICAL CLINICS

Optum, which has grown to employ 90,000 physicians—10% of the doctors practicing in the United States—disclosed that it is closing more clinics in multiple states. In California alone, it will lay off 524 employees, according to *Beckers Hospital Review*. Over the past year, Optum has done multiple reductions in force in Washington, Colorado, Florida, Texas, and Ohio. Optum currently employs 310,000 people worldwide.

TRANSITIONS

• Timothy Stenzel, MD, PhD, joined **Illumina** as an Advisor. He previously served with the **Food and Drug Administration**, **Invivoscribe**, **Quidel**, and **Duke University School of Medicine**.

• **Exai Bio** of Palo Alto, Calif., appointed Dave Daly as CEO. His prior positions were with **Singular Genomics**, **ArcherDx**, **Thermo Fisher**, **Abbott Laboratories**, and **Illumina**.

• **Leica Biosystems** announced that Gabrielle Huff is its new national Sales Director, Health System Executives. Huff previous worked at **Mammotome**, **Beckman Coulter**, **Eastman**, **AmeriPath**, **Labcorp, and Quest Diagnostics**.

• Jenifer Giraud is the new Director of Sales and Marketing at **Pacific Diagnostic Laboratories** of Santa Barbara, Calif. Her prior positions were with **Dignity Health**, **Central Coast Pathology**, **NeoGenomics**, and **Pfizer**.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, September 3, 2024.

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★SPECIAL WEBINAR!★

FDA's LDT RULE: Understanding What's Compulsory, What's Not

Protect Your Lab's Essential LDTs! Assess the Financial Impact!

Webinar: SEPTEMBER 12 @ 1:00 PM EDT

Every lab with laboratory developed tests (LDTs) now faces a complex path to comply with the final FDA LDT rule. Complicating your lab's compliance is the uncertainty in the rule's interpretation.

To help you and your team stay ahead of the LDT rule deadlines, we've assembled a top-flight panel of the lab industry's recognized experts for this special webinar. Our experts will provide you understanding and context for the requirements of the LDT rule. You'll get invaluable insight, recommendations, and admonitions about compliance.

Best of all, our interactive webinar format allows you and your team to interact with these experts during the webinar. You'll gain the essential knowledge you need to assess existing LDTs, prioritize your compliance steps, and protect the income stream produced today by your existing LDTs.

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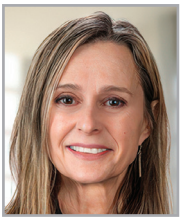

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- ***Latest Kaufman Hall report finds 40% of 1,300 hospitals are losing money.***
- ***What's next for digital pathology, whole-slide imaging? Competition heats up for DP systems and scanners.***
- ***FDA's final LDT rule: Are any LDTs "grandfathered?" New insights as experts dig deeper into rule's language.***

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