Volume XXXI, Number 13 Monday, September 23, 2024

Hospital Lab Outreach Analysis

Recent lab outreach sales confirm substantial operating margins, capital value to hospitals

(See pages 9-11)

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

It is THE DARK REPORT's 30th Anniversary!

IT WAS 30 YEARS AGO, IN SEPTEMBER 1995, when the first issue of THE DARK REPORT was published and distributed to the clinical laboratory profession. For nearly one-third of a century, our editorial team has worked to bring you the most relevant news, market assessments, and case studies of lab innovations.

Many of you have been long-time clients and regular readers for a decade or more. We are honored by your support and loyalty. We also understand how you and your lab's management team frequently use the intelligence presented on these pages as the basis for major strategic and tactical decisions that affect the clinical viability and financial integrity of your clinical laboratory and anatomic pathology organizations.

Your trust motivates the entire team here at THE DARK REPORT to dig deeper to ferret out the real story behind the headlines. Early in my career a management mentor taught me a valuable adage: "You need good information to make good decisions." That credo guides our editorial team.

As you read the intelligence briefings that follow in this issue, you will see that philosophy at work. For example, our Editor-In-Chief traveled to Utrecht, The Netherlands, in recent weeks to investigate the new "autonomous blood drawing system" developed by **Vitestro**. He spent a full day at their headquarters learning about all aspects of this novel invention with the potential to disrupt the classic delivery of phlebotomy services that has gone unchanged for more than 100 years.

Similarly, our Editor-In-Chief spend several days with **Milestone Medical** in Bergamo, Italy, learning about what he considers to be "the world's first fully-automated pre-analytical histology solution." The engineering genius behind the different automated systems could allow a histology laboratory to eliminate most of the recurring sources of non-conforming events that negatively impact analytical quality and patient safety.

You are gaining insights into the technologies and business models laboratories will use in coming years to continue delivering state-of-the-art diagnostic services in a financially sustainable manner. That's good for patients, for physicians, and for your lab organization! TDR

Lab Innovators in Europe Have Solutions for USA

Many of the diagnostic products sold here were first developed and used in other countries

CEO SUMMARY: Rapid advances in a wide range of technologies over the past 15 years are enabling entrepreneurs to create transformative products for use by clinical laboratories and anatomic pathology groups. THE DARK REPORT recently toured Europe to visit several such innovative companies. One clever invention is an "autonomous blood drawing system" that automatically performs venipunctures and has an EU mark for use in clinical care.

by Robert L. Michel

IN RECENT WEEKS, **THE DARK REPORT** COMPLETED A FACT-FINDING TRIP to medical laboratories and lab vendors in several European nations. Conversations with clinical laboratory leaders and anatomic pathologists confirmed that healthcare systems in their countries are dealing with what can be characterized as "universal challenges."

Stated differently, the same fundamental market dynamics shaping the delivery of medical services here in the United States are equally at play in The Netherlands, Germany, and Italy—the three countries your Editor-In-Chief visited on this trip.

This is relevant for an important reason. Except for the fact that the same fundamental problems of providing medical care exist in most developed nations, new technologies and new clinical innovations surfacing in these same countries have the ability to address identical problems in all of those nations.

This will be true of clinical laboratory testing and anatomic pathology services. For instance, when a new diagnostic technology emerges within the European Union, demonstrates that it improves patient care, and earns an EU Mark, it can be expected that the inventors will want to introduce that same diagnostic technology here in the United States.

The motivation is pure economics. The United States is the world's largest healthcare market by a huge margin. Recent data show the annual healthcare spend in the U.S. as $4.3 trillion. In Europe, the spend is $500 billion in Germany, $280

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

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

billion in the United Kingdom, and $200 billion in Italy. *(See sidebar on page 7.)*

If a company has developed an innovation that advances patient care in a single European country, the company quickly recognizes that the U.S. healthcare market is 10 to 20 times larger, in terms of spending. This is why European diagnostics companies with a product that delivers better care and which has an EU mark, typically want the U.S. **Food and Drug Administration** (FDA) to review their products and clear them for sale and use in patient care in the United States.

On this trip, I was privileged to visit two lab vendors and two anatomic pathology laboratories. Here are a few key insights gained from each of these four site visits.

VITESTRO

VITESTRO

Utrecht, The Netherlands

One stop during my visit to Europe was to the city of Utrecht in The Netherlands to visit **Vitestro**. This is a young company that is on a mission to improve the experience and process of phlebotomy. Their solution should catch your full attention. Vitestro wants to fully automate the venipuncture process for collecting whole blood!

Long serving clinical laboratory mangers and pathologists understand the complexities of drawing blood. The venipuncture process has its own complications. Those are compounded by the unique circumstances of patients whose blood needs to be collected.

One might say that there is infinite variability in these two dimensions of a blood draw, further complicated by the different skill levels of individual phlebotomists. These are reasons why experienced clinical laboratory professionals are skeptical that any organization can successfully automate the venipuncture process.

Of course, prior to my visit to Vitestro, I also understood all the complexities inherent with a venipuncture. It was difficult to imagine how a machine could be engineered to handle all the variabilities that confront the human phlebotomist from day to day.

Roundtable Discussion

Upon arrival at the Vitestro offices, the day started with a roundtable discussion involving the company's two founders and key executive team members:

- Toon Overbeeke, co-founder and CEO.
- Brian Joseph, co-founder and Commercial Director.
- Luuk Giesen, MD, Chief Medical Officer.
- Zakaria Tazi Hnyine, Strategic Projects Manager.

Vitestro's co-founders recognized that the typical phlebotomy experience often falls far short of delivering a consistent, high-quality blood collection experience for many patients. Thus, using automation to reduce or eliminate the variability in the quality of an individual venipuncture procedure was an opportunity to improve patient care.

Phlebotomist Shortage

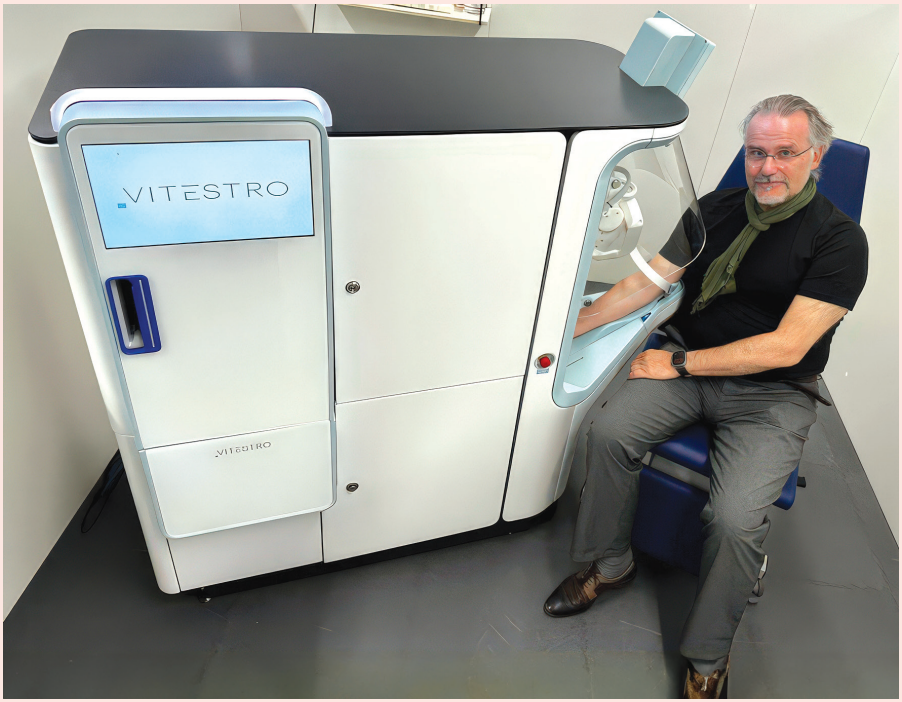
Automating the blood draw also has the benefit of addressing the shortage of phlebotomists. The variability in the attendance, productivity, and skill levels across a lab's team of phlebotomists are additional opportunities for improvement.

Daily, every laboratory's phlebotomy service copes with all these factors. If Vitestro can develop a solution that delivers a standardized, high quality venipuncture experience that is patient friendly, the market demand for this solution would be substantial.

Founded in 2017, the engineering team at Vitestro has created a novel system that automates the phlebotomy process. The resulting "autonomous blood drawing system" functions in ways that improve all the issues described above.

Improving the Patient's Phlebotomy Experience with a Novel Autonomous Blood Draw System

While in Europe last Month, The Dark Report visited Vitestro, a company based in Utrecht, The Netherlands to see and learn about the company's automated system for blood draws. The executive team shared the vision for improving the patient's phlebotomy experience while at the same time delivering a consistent venipuncture procedure and improving the productivity of phlebotomists.



Pictured above is Vitestro's "autonomous blood drawing system." It is designed to be patient friendly. The screen at left instructs the patient how to insert the rack of blood tubes to be filled in the slot below the screen. The patient then sits in the chair and follows the directions shown on the screen above the patient. A phlebotomist stands nearby to provide guidance. The system's automation will then apply alcohol to the skin, tighten the tourniquet, select a vein, perform the venipuncture, fill all the blood tubes, and apply a bandage to the site of the venipuncture. *(Photo copyright: Vitestro.)*

Following the morning discussion about the development of Vitestro and its organizational goals, it was time to demonstrate the automated phlebotomy system.

The first important point is that this novel system uses proven technologies that are combined in a unique way to automate the venipuncture process. Second, the patient interaction with this novel system is designed to ease anxiety and deliver what I will call "the perfect needle stick."

Third, the automated processes within the venipuncture system harvest the blood specimens and process them in a stan-

dardized manner that protects the integrity of the specimens. Fourth, the return on investment for this autonomous blood drawing system should make it a valuable tool for clinical laboratories and hospitals where recruiting and retaining adequate numbers of human phlebotomists is a challenge.

It is important to note that the Vitestro system is EU-marked for patients aged 16 years and older. This means that pediatric blood draws will still need to be performed by a phlebotomist.

Upcoming issues of THE DARK REPORT will provide a full interview with the co-founders of Vitestro.

LABPON
Laboratorium Pathologie Oost-Nederland

LabPON
Hengelo, The Netherlands

While in The Netherlands, the next stop was to Hengelo, home to **LabPON**, an anatomic pathology laboratory. LabPON may be familiar to pathologists and lab managers closely involved in digital pathology. Back in 2015, LabPON issued a press release claiming to be "the first laboratory in the world to reach 100% digital pathology (DP) diagnosis."

Alexi Baidoshvili, MD, PhD, Prof. clinical pathologist, hosted the site visit, which included a meeting with Rycolt Hamoen, LabPON's Director (CEO). An important part of the LabPON back story is that it was the anatomic pathology lab engaged by **Phillips** to develop the digital pathology product that was the first such DP system cleared by the FDA in 2017. *(See TDR, "FDA Clears Digital Path for Primary Diagnosis," April 24, 2017.)*

Because of this relationship, by 2015, LabPON—a not-for-profit healthcare organization—was able to achieve "100% digital pathology diagnosis." In the following years, developments in the pathology market in The Netherlands caused an increase in the proportion of cases utilizing traditional glass slides.

LabPON's laboratory facility is spacious and immaculately clean. The histology laboratory has a full array of instrumentation to support molecular and genetic analysis. A noteworthy feature is that there is no aroma of formalin or related chemicals in the histology workspaces because the air handling systems are so efficient. This design feature was intended to reduce the exposure of the histotechnologists and pathologists to these potent substances.

Not Enough Pathologists

The issues in anatomic pathology in The Netherlands mirror those in the United States. There are not enough anatomic pathologists to handle the demand for testing. At the same time, new diagnostic technologies require pathologists to spend more time per case to develop the diagnosis and advise the referring physician on appropriate therapies.

Reimbursement for pathology services lags behind increased costs. This limits LabPON's ability to acquire and deploy some of the artificial intelligence-powered image analysis algorithms. It was explained that, for some AI diagnostic solutions, the cost equals or exceeds the total per-case reimbursement paid to LabPON.

On the plus side, LabPON's digital pathology capabilities means it is often referred cases from other regions for consultations and second opinions. This includes pathology cases originating from the nation of Georgia because of Baidoshvili's relationships with pathologists in that country.

SYNLAB

SYNLAB
Milan, Italy

The next lab site visit took place with **Synlab**, located in Milan, Italy. This is the Italian lab facility for a company with medical labs in 30 countries across four continents. Hosting this site visit was

Prof. Dr. Marcello Gambacorta, Director of Anatomic Pathology, Histology, and Cytogenetics. The Synlab Milan facility serves a large region that includes Italy and areas in the surrounding countries. It has a sizeable clinical laboratory performing thousands of tests per day.

The anatomic pathology laboratory is equally busy. It receives between 500 and 1,000 patient cases per day. The histology lab has the latest automated systems to speed throughput and optimize efficiency. Molecular and genetic testing areas support a full menu of advanced anatomic pathology services.

Digital pathology represents a growing proportion of the total caseload, according to Gambacorta. One barrier to the adoption of image analysis solutions powered by artificial intelligence is the tight reimbursement paid for an anatomic pathology case. Gambacorta noted that the healthcare system in Italy pays about 10 Euros (US$11.17) per pathology case. He then explained that use of an AI-powered image analysis algorithm, such as for prostate cancer, can cost an additional 10 Euros per case. The economics of this situation discourage the use of AI-powered image analysis.

MILESTONE
HELPING PATIENTS

Milestone Medical
Bergamo, Italy

Bergamo, Italy, is the home of **Milestone Medical**, a company that manufactures a full line of histology solutions. Founded in 1988, its products are sold in 75 countries. Its U.S. headquarters is in Kalamazoo, Mich. We last visited Milestone Medical in Bergamo about 12 years ago.

Greeting your DARK REPORT team was Franco Visinoni, Founder/CEO, and Dr. Vanessa Visinoni, VP and soon to be CEO. Milestone Medical is recognized for delivering innovative products covering the full spectrum of pre-analytic steps done by histology laboratories.

U.S. Has Largest Healthcare Market

SPENDING ON HEALTHCARE IN THE UNITED STATES DWARFS—BY A HUGE MARGIN—WHAT IS SPENT BY INDIVIDUAL COUNTRIES. This important fact is why any individual or company overseas that has invented a new and better solution for medical services and patient care wants to market these products in the United States.

This important fact is demonstrated by the ranking below of the 10 countries globally that spend the most on healthcare (shown in U.S. dollars):

Based on data from 2024, here are the top 10 countries by total healthcare spending in U.S. dollars:

- United States: $4.3 trillion
- China: $1.1 trillion
- Germany: $500 billion
- Japan: $450 billion
- France: $300 billion
- United Kingdom: $280 billion
- Italy: $200 billion
- Canada: $180 billion
- Brazil: $160 billion
- Australia: $150 billion

That innovation was on display in the company's product showroom. For example, in cases where a biopsy will be analyzed by molecular and genetic methods, Milestone has a solution for use in or near the operating room.

Vacuum-packing Specimens

This system vacuum-packs the tissue in a plastic bag, thus preserving it for genetic analysis. It also avoids the need to include a fixative.

That is a significant factor in the European Union, where regulatory oversight of formaldehyde and related pathology fixatives is tighter than in other nations. This benefits operating room staff and the histology team because it reduces use of—and exposure to—formalin and other fixatives.

Accompanying the plastic specimen bag (in a pocket) is an RFID chip with a USB plug. This chip monitors ambient temperature and time from when the speciman was packed. This allows histology to track ischemic time of the specimen from operating room to the histology laboratory, along with the location of the specimen as it is transported to the laboratory.

Chip Travels with Specimen

Upon arrival at accessioning, the RFID chip is inserted into a USB port at the Milestone grossing station. The chip continues to collect data, including images of the gross specimen and the sections selected for analysis.

The tour of products continued. As the design, form, and features of each histology solution was explained, it became clear that Milestone has something unique. It has a complete, integrated point-to-point solution for every step in the process of receiving a specimen to the production of a glass slide ready for digital scanning or analysis by a pathologist.

What will be of particular interest to any histology labs using Lean/Six Sigma methods is that every Milestone solution is producing data on action and time for each individual specimen. This supports value stream mapping, the identification of non-conforming events, and the ability to monitor turnaround times and the quality of each process on every specimen.

Critical Perspectives

The Dark Report's multi-country tour provided up-to-the-minute perspectives on major developments shaping anatomic pathology services within the European Union. The following four points are most relevant:

One, as in the U.S., the number of cancer cases is increasing, even as advances in molecular and genetic analysis mean pathologists must spend, on average, more time to properly diagnose each case.

Two, across the EU member countries, the number of pathologists falls far short of the demand for their services. Pathologists at the labs visited by The Dark Report all recognized this situation and commented that there are not enough academic training positions to ease this shortage in the near future.

Three, the pathology laboratories visited in both The Netherlands and Italy confirmed that reimbursement for anatomic pathology services lags behind rising costs. Consequently, labs are under pressure to control costs even as they recognize the need to invest in digital pathology capabilities.

Four, the economics of anatomic pathology reimbursement in these two countries means that further adoption of digital pathology will happen slowly. For this reason, companies selling diagnostic solutions that use artificial intelligence (AI) and similar technologies to analyze whole slide images (WSIs) have an uphill battle to place their products.

Hurdles for AI in Pathology

The artificial intelligence image-analysis algorithm companies have two hurdles to overcome in Europe. First, they need more anatomic pathology laboratories to adopt digital scanning and whole slide imaging. Second, once this happens, these same pathology labs need to have an adequate budget that will pay for the cost of the AI image-analysis algorithms.

The information provided in this intelligence briefing by The Dark Report demonstrates how, in developed countries, the main forces transforming healthcare and clinical laboratory medicine are much the same as here in the United States.

Medical laboratories in the European Union must deal with identical issues of reimbursement that lags behind increased costs and a demand for pathologists and anatomic pathology services that exceeds available supply. TDR

Hospital Lab Outreach: Still a Valuable Asset!

Recent sales of lab outreach programs confirm the capital value created by this clinical service line

CEO SUMMARY: Hospital lab administrators everywhere are watching press releases announcing the latest agreement of a major health system selling its laboratory outreach business to one of the billion-dollar lab corporations. The pace of these sales is accelerating. These deals confirm the underlying truth that lab outreach programs do deliver significant operating margins—and capital value—for their parent hospitals.

Over the past four decades, publicly-traded clinical laboratory companies regularly sent sales reps into hospital C-suites with a message for their CEOs: "We'd like to pay you for your lab outreach business ... and, by the way ... we think we can run your inpatient labs better and cheaper than your current team. Can we talk?"

This message seldom resulted in a successful deal. Going back into the 1980s, public lab companies typically only completed three to six purchases of a hospital laboratory outreach business in any one year. New contracts to manage the inpatient laboratories of hospitals were even fewer in number.

Substantial Cash Value

During these same 40 years, the motivation for most hospitals and health systems to sell their lab outreach programs was to harvest the substantial cash value of those businesses. The selling institution generally had lost money in recent years and the influx of tens of millions of dollars from the lab outreach sale was a welcome cash infusion to bolster uncertain finances.

Given this multi-decade history of hospital laboratory outreach program sales, a different pattern has emerged in the past two or three years. In each of these years, an increased number of hospital laboratory outreach businesses were announced.

More Lab Outreach Sales

That is a significant development. Recently, a larger number of hospitals and health systems have proved willing to sell their lab outreach programs. In the majority of cases, the motive for the sale can be traced to poor financial performance by the selling institution and the need for a substantial infusion of the cash generated by the lab outreach sale.

This is consistent with ongoing headlines about the troubled finances of the hospital industry. However, there is a bigger story to be told about the surge in the number of hospitals and health systems deciding now is the time to sell their hospital laboratory outreach businesses.

This bigger story hinges on the simple and obvious fact that regularly eludes the thinking of senior health system adminis-

trators. Properly-run hospital laboratory outreach programs generate substantial operating margins.

It is these operating margins that give a hospital lab outreach program a capital value in tens to even hundreds of millions of dollars. To illustrate, in early 2022, when **Ascension Health** sold the lab outreach businesses (and certain inpatient lab management contracts) of some 75 hospitals in 10 states to **Labcorp**, the press release about the deal mentioned a payment by Labcorp of approximately $400 million. *(See TDR, "Labcorp to Buy Outreach, Manage Ascension Labs," Feb. 22, 2022.)*

Each time a public lab company succeeds in purchasing a hospital laboratory outreach program, it issues a press release that is tracked by Wall Street investors and the public. One theme of these press releases and the presentations made by the two Blood Brothers at conferences hosted by financial analysts is that they can run hospital labs at lower cost and better than the existing management at these health systems. That regularly repeated refrain shapes the thinking of professional investors and financial analysts tracking the two Blood Brothers.

Another Reality

But there is another reality associated with hospital laboratory outreach programs. They generate significant operating margins, even when not well-managed. And if managed aggressively, they can produce operating margins for the parent health system in the hundreds of millions of dollars annually.

This is because savvy hospital lab managers understand that their inpatient laboratories go unused after 6:00 PM each day. This unused capacity can be put to work performing outreach lab tests.

The truth of this observation about the operating margins of lab outreach programs is the fact that money-losing hospitals and health systems are selling their lab outreach programs for substantial amounts of money. The eager buyers are **Quest Diagnostics** and Labcorp.

Why are they eager buyers? It is because of the economics of fee-for-service reimbursement. The public lab companies have the lowest average cost-per-test of any lab organization in the world. This means they make a larger margin on each fee-for-service payment than did the hospital lab outreach business. They can pay a hefty price for the hospital lab outreach business, shift those tests to their regional labs, and eliminate the outreach lab's costs by laying off lab staff, accessioners, and couriers all to enjoy a higher margin on that same volume of lab test referrals.

Robust Outreach Programs

More evidence of the robust nature of hospital laboratory outreach programs for the majority of the nation's hospitals and health systems was on display last week at the **Mayo Clinic** in Rochester, Minn. It was the 35th annual laboratory outreach conference hosted by **Mayo Clinic Laboratories**.

There was a record attendance. As many as 15% of the nation's approximately 480 health systems made the substantial investment to send one, two, or three of their lab leaders to learn best practices in lab outreach.

Viability of Lab Outreach

The fact that upwards of 15% of the nation's health system laboratories made the investment to send several of their lab leaders to this lab outreach conference demonstrates that the concept of hospital laboratory outreach remains viable and profitable. It is a worthwhile clinical service line extension for multi-hospital health systems.

The benefits of laboratory outreach programs were documented by two case studies presented during the Mayo lab

outreach program. The first presentation involved **Kootenai Health** of Coeur d'Alene, Idaho. The presenters described how the acquisition of the major lab in nearby Spokane, Wash., by one of the national lab companies created the opportunity for the lab team at Kootenai Health's 397-bed hospital to deliver local testing services and faster test turnaround times to the office-based physicians in that community. Outreach test volume and the associated revenue climbed steadily and Kootenai still reports growth today.

Lab Outreach Case Study

The second case study involved **Boone Health** in Columbia, Missouri. When the local clinical lab company was acquired by a national lab in early 2019, much of that lab's testing was moved away from Columbia to the acquiring lab's big regional testing centers. Most of the employees of the acquired lab found themselves looking for new jobs.

Administration and the lab team at 392-bed Boone Health saw the opportunity. They made the commitment to put the infrastructure and staff in place to support a commercially competitive outreach lab service. Now, five years later, lab leaders report continuing year-over-year increases in test referrals and revenue. During this presentation, they also described the benefits to the community's physicians and patients because there is now a complete, longitudinal test record—with the same test methodology and reference ranges—for a patient's inpatient, outpatient, and outreach lab test results.

Raising Needed Cash

So long as health systems and hospitals are under severe financial pressure, it can be expected that some will decide to sell their hospital laboratory outreach businesses to raise millions of dollars to bolster their operations. This will be auspicious for Labcorp and Quest Diagnostics.

Two-Year History of Lab Outreach Sales

DURING THE PAST TWO YEARS, A NUMBER OF WELL-KNOWN HEALTH SYSTEMS INKED DEALS to sell their respective hospital laboratory outreach businesses to either Quest Diagnostics or Labcorp, as shown below:

Quest Diagnostics:

- August 2024: **University Hospitals** to sell its lab outreach services to Quest.
- June 2024: **Allina Health** sells select laboratory assets to Quest.
- August 2023: **Summa Health's** LabCare Plus lab outreach program sells to Quest.
- July 2023: **OhioHealth** sells laboratory outreach to Quest.
- February 2023: **New York-Presbyterian** sells some of its lab services assets, including outreach, to Quest.

Labcorp:

- September 2024: **Ballad Health** to sell its lab outreach services to Labcorp.
- August 2023: **Tufts Medicine** sells laboratory outreach to Labcorp.
- July 2023: **Legacy Health** sells laboratory outreach to Labcorp.
- May 2023: **Providence Health and Services–Oregon** sells laboratory outreach to Labcorp.

At the same time, financially strapped health systems selling their lab outreach businesses is confirmation that this clinical service line generates worthwhile operating margins and represents capital value that can be monetized. This is market experience that all hospital lab administrators should emphasize to their health system leaders. TDR

Virchow
Medicine ➤ Money ➤ Managed Care

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

Hurdles Continue When Labs Request Genetic Test Coverage

EDITOR'S NOTE: Our column, Virchow, is written by anonymous insiders working within the managed care world. The column aims to help clients of The Dark Report better understand the decisions, policies, and actions of payers as they manage their laboratory networks, establish coverage guidelines, process lab test claims, and audit labs.

Clinical laboratories bringing new genetic tests to market must now jump through two sets of hoops. The first is the **U.S. Food and Drug Administration's** (FDA) controversial final rule regarding regulation of laboratory developed tests (LDTs). The second predates the LDT rule and involves the ongoing challenge of convincing payers to issue favorable coverage guidelines and reimbursement for these new genetic tests.

It remains an open question as to how the FDA's LDT rule might change how health insurers assess a new genetic test when considering it for coverage. Meanwhile, I can assure you that colleagues of mine at the major payers continue to closely scrutinize every new genetic test submitted for a coverage and reimbursement decision.

What is not helping clinical laboratories on this point are ongoing staffing cutbacks at the nation's largest health insurance companies. This has two consequences when your lab or genetic testing company wants your new genetic assay to be reviewed for coverage. On one hand, there are fewer people tasked with making coverage decisions—and don't forget that these same people are reviewing coverage requests across the entire range of healthcare services.

On the other hand, these staffing cutbacks often include the longest-serving and most knowledgeable staff members who understand clinical diagnostics and the technologies involved in molecular and genetic tests. The staff who remain are much less knowledgeable about the complex technologies and the medicine involved in a specific genetic test. *(See TDR, Virchow on "Layoffs at Major Health Plans Slow Processing of Lab Claims," Jan. 16, 2024.)*

Tough Questions

The two factors described above mean that the nation's largest payers have fewer employees with adequate capabilities to perform knowledgeable and timely reviews of new genetic tests. There simply is not enough skilled staff members to handle the incoming volume of requests for genetic test coverage.

Now consider another factor. We all know that economics is a powerful driver. It is a well-known fact that the amount of reimbursement for genetic test claims is increasing faster than almost any other clinical service. It is reasonable to assume

that controlling the year-over-year cost of genetic test claims is a major objective at health plans.

What paints payers in a corner is the fact that consumers want genetic tests. Consumers are savvy these days. They want personalized medicine and genetic testing ties into that demand. Let's face it, for clinical labs, there isn't much money anymore in what I call "bread and butter" testing, such as CBC and lipids.

One recent study projected that the global genetic testing market will grow to $52.1 billion by 2032, compared with $19.4 billion in 2023. *(See sidebar on this page.)*

But consumer demand for genetic tests doesn't do a lab much good if health insurers won't pay those test claims. The issue is especially vexing for smaller labs that have limited experience bringing LDTs to market.

Medical Needs

Having worked at several important payers, I've seen what savvy labs do to obtain favorable coverage decisions from their health plans. I've also seen what causes most payers to reject or continually defer a coverage decision for new genetic tests.

Suppose a lab spent the past five years developing a new genetic test. Now it wants to offer the test to providers and their patients. Before requesting a review for coverage, the lab needs to answer some tough questions: Is any other lab offering a test like this, or is it me-too? Truly proprietary genetic tests—such as the Cologuard Test from **Exact Sciences**—are rare. That test has its own CPT code. If a lab has a unique proprietary test, the managed care companies will probably want to talk. On the other hand, if it's a new noninvasive prenatal test (NIPT) … well, everybody has one and a lab shouldn't expect much payer interest.

Does the test meet a medical need? Maybe a lab has proprietary technology to detect a mutation in a certain gene that is supported by solid research that links the mutation to a treatable medical condition. This is true of the BRCA mutation for breast cancer. It is why this genetic test was covered by almost all payers. But if the test lacks these factors, it will almost certainly be flagged as lacking clinical validity and the lab can pretty much forget about reimbursement.

Importance of Test Dossier

Does the lab have a dossier on the test? A dossier includes the information that a payer's medical review committee needs to determine whether the test merits coverage. Does it address an unmet need? What research data supports the use of the test? What's the specificity and sensitivity? How does it improve health outcomes? How does it affect health costs?

Once the lab has answered these basic questions, it should review each plan's reimbursement and medical policies to ensure that the test is covered and under what circumstances.

Explosive Growth in Genetic Testing

GLOBAL MARKET INSIGHTS (GMI) REPORTS THAT THE GLOBAL MARKET FOR GENETIC TESTING is set to explode over the next decade. That's according to a recent study which pegged the total global value of the genetic testing market at $19.4 billion in 2023, with slightly more than half coming from North America. That's projected to grow at an annual rate of 11.7%, reaching a whopping $52.1 billion by 2032.

Diagnostic testing accounts for about half of the current total, GMI reported, followed by DNA sequencing at 30.1%. However, GMI also identified challenges that could limit growth, including the high cost of genetic testing, shortages of skilled professionals, and a lack of needed infrastructure.

For example, each plan has criteria to determine the situations where NIPT is considered medically necessary—or not. Plans will also have varying policies regarding which tests require prior authorization and what documentation is required to support claims.

For many labs, the first hurdle—before they even approach the commercial plans—will be getting approval from the **Centers for Medicare and Medicaid Services** (CMS) for Medicare reimbursement. In many states, the first step here will be to obtain a Z-code through MolDX. This is a program managed by Medicare contractor **GPT Palmetto** on behalf of CMS.

The Z-code is a unique identifier for certain kinds of molecular diagnostic tests. Labs in 28 states are required to include them in Medicare claim submissions. Some Medicare Advantage Plans also require use of Z-codes, and in June, **UnitedHealthcare** began requiring Z-codes in certain genetic test claims submitted to its commercial plans.

To obtain a Z-code, the lab submits data about the test, after which the test undergoes a technical assessment by GPT Palmetto. The degree of scrutiny depends on the complexity of the test.

Lack of Trust

If the test is new and novel, labs should brace themselves for distrust and skepticism from payers, especially in the early stages. Payers are wary of bad actors, and the lab may have to take pains to demonstrate that it's not another **Theranos**. *(See TDR, "How Genomic Testing Labs Can Improve Their Relationships with Payers," Oct. 10, 2022.)* But once they've landed a few contracts, they will likely find it easier to get new ones.

All this was true before the FDA issued its final rule on LDTs. Unless the courts intervene, most genetic tests brought to market after May 6, 2024, will be subject to the full regulatory framework, including registration and, in many cases, premarket review. *(See TDR, "Assessing the Clinical Service and Revenue Issues of the LDT Rule," Sept. 3, 2024).*

Given the costs of compliance with the new LDT rule, some experts advise clinical laboratories to take a hard look at their test menus to determine which tests are worth keeping and which should be outsourced—and that's for LDTs that are already covered by payers. If a lab is confident a new test meets a need, it should ask hard questions and take steps to demonstrate the test's value to patients, providers, and payers. TDR

Most Major Payers Reducing Staff

REDUCTIONS IN FORCE (RIF) AT MOST OF THE MAJOR PAYERS HAVE BEEN ALMOST CONTINOUS SINCE 2019. For clinical laboratories seeking a coverage decision for a new genetic test, these layoffs mean fewer staff available to respond to such requests.

Some of these RIFs involve thousands of employees. For example, in February 2024, as **Elevance Health** (formerly **Anthem**) was cutting staff, *Healthcare Dive* wrote, "It's not yet clear how many workers Elevance is laying off overall, but thousands of employees in multiple states have been let go to date, according to several sources familiar with the matter who spoke to *Healthcare Dive*. The sources, who requested anonymity to discuss sensitive matters, said the layoffs could be affecting as many as 10,000 employees or more."

In November 2023, *Becker's Payer Issues* reported on 15 different health insurers that were laying off staff. The list included **Cigna**, Elevance, **Centene Corporation**, **Humana**, **Blue Cross Blue Shield of California**, and **UnitedHealth's Optum**. Since that date, some of these payers have implemented additional reductions in force.

IVD Update

Global IVD Companies Report Second Quarter 2024 Earnings

In Vitro diagnostics companies report solid revenue gains in Q2, new tests and plans

In the second quarter of 2024, *in vitro* diagnostics (IVD) companies reported solid revenues as well as new tests, analyzers, and automation.

Most of the IVD companies boosted diagnostic sales in low single digit amounts.

During the earnings calls, financial analysts asked company leaders about growth they may see in 2025. Overall, with the decline in COVID-19 test revenue now off the balance sheets, executives appear positive about how the companies will end 2024.

Here is a summary of recently released financials and accomplishments from some of the world's top IVD manufacturers serving clinical laboratories and anatomic pathology groups.

Abbott
A Promise for Life

ABBOTT LABORATORIES: Increases Total Sales 4%, Sees Market Gain Potential

Abbott Laboratories, Abbott Park, Ill., shared these Q2 2024 financial results as compared to Q2 2023:

- Total sales were up 4% to $10.4 billion from $10 billion.
- Total diagnostics sales were down 5% to $2.19 billion from $2.31 billion.
- Core laboratory sales were up 2.3% to $1.32 billion from $1.29 billion.
- Molecular sales were down 9.9% to $127 million from $141 million.

Abbott reported FDA clearance of continuous glucose monitoring systems, Lingo and Libre Rio.

During their earnings call, CEO Robert Ford pointed out that diagnostics sales, excluding COVID-19 test sales, grew 6%. "In Core laboratory diagnostics, we continue to drive growth through increased adoption and utilization of our market-leading systems and global demand for our extensive testing menus across the areas of immunoassay, clinical chemistry, hematology, and blood screening," Ford said.

Roche

ROCHE: Reports Strong Results in Six-Months, Adds Tests and Automation

Roche Group, Basel, Switzerland, released data for the six months of 2024 as compared to the first half of 2023:

- Group sales were up slightly by 0.2% to 29.84 billion Swiss francs (CHF) (US$34.1 billion) as compared to 29.77 billion CHF (US$34.1 billion).
- Diagnostics Division sales were down 1% to 7.21 billion CHF (US$8.2 billion) from 7.26 CHF (US$8.3 billion).
- Core lab sales grew 3% to 4.06 billion CHF (US$4.6 billion) from 3.93 billion CHF (US$4.5 billion).
- Molecular lab revenue fell 1% to $1.27 billion CHF (US$1.4 billion) from 1.28 billion CHF (US$1.4 billion).

- Pathology lab sales were up 12% to 770 million CHF (US$882 million) from 687 million CHF (US$787 million).

"In the second quarter, we saw an acceleration of our growth momentum as group sales were no longer impacted by the decline in COVID-19 sales, resulting in very strong sales growth for the group," said Roche CEO Thomas Schinecker, PhD.

Roche reported:

- **U.S. Food and Drug Administration** (FDA) Emergency Use Authorization (EUA) for the cobas liat four-in-one molecular test for detection at point of care of SARS-CoV-2, respiratory syncytial virus (RSV), and Influenza A and B.
- FDA clearance for a human papillomavirus (HPV) self-collection solution.
- cobas c 703 and cobas ISE neo for "higher testing capacity."

ThermoFisher SCIENTIFIC

THERMO FISHER: Revenue $10.5B in Q2, Expects Momentum Going into 2025

Thermo Fisher Scientific, Waltham, Mass., reported Q2 financial results as compared to Q2 2023:

- Revenue was down slightly by 1.3% to $10.54 billion from $10.68 billion.
- Laboratory products and biopharma services segment revenue saw a slight decline of 1.3% to $5.75 billion from $5.83 billion.
- Life sciences solutions segment revenue fell 4.4% to $2.35 billion from $2.46 billion.
- Analytical instruments segment revenue was up 2.2% to $1.78 billion from $1.74 billion.
- Specialty diagnostics segment revenue was flat at $1.1 billion.

Thermo Fisher launched the Stellar mass spectrometer, which the company says enables "more putative biomarkers in less time and effort." And in Laboratory Products it introduced Energy-Star-certified TSX Universal Series Ultra-Low Temperature Freezers to help labs meet cold storage needs with energy efficiency.

Thermo Fisher said it anticipates advancement of protein research offerings in light of completion during Q2 of its acquisition of **Olink**, a Sweden-based proteomics solutions provider.

During an earnings call, Marc Casper, CEO, responded to a request about the outlook for 2025: "We expect that the market will continue to improve modestly in the back half of the year, this quarter being a little better than the quarter before. Our performance will also continue to step-up and that will give us momentum going into 2025."

SIEMENS Healthineers

SIEMENS HEALTHINEERS: Diagnostics Revenue Up 2.1%, Adds New CI Analyzer

Siemens Healthineers, Erlangen, Germany, released financial results for its fiscal year Q3 as compared to Q3 2023:

- Revenue was up 4.3% to €5.42 billion (US$5.99 billion) from €5.20 billion (US$5.75 billion).
- Diagnostics revenue was up 2.1% to €1.10 billion (US$1.21 billion) from €1.09 billion (US$1.20 billion).

During a presentation to investors, CEO Bernd Montag, PhD, gave an example of a Siemens offering to labs of all sizes. "With the completion of the Atellica family with the CI Analyzer (integrated chemistry and immunoassay analyzer which works in a small space), we can cater for all settings and all customers—large, medium, small, hub, and spoke," Montag said.

Assays being added by Siemens, he said, include "the Neurofilament Light Chain or Nf blood test for accurate diag-

nosis and personalized management of multiple sclerosis."

BIO-RAD LABORATORIES: Diagnostics Sales Up 2.1% in Q2

Bio-Rad Laboratories, in Hercules, Calif., shared Q2 2024 financial results as compared to Q2 2023:

- Sales were down 6.3% to $638.5 million as compared to $681.1 million.
- Clinical diagnostics segment sales were up 2.1% to $387.9 million from $380.1 million.
- Life science segment revenue fell 16.5% to $250.5 million from $300.2 million.

During an earnings call, Andrew Last, PhD, COO, said clinical diagnostics showed "solid performance in our immunohematology business when compared against the supply chain constraints we experienced in prior year. As we look toward the second half of this year, we are anticipating a continuation of normalized growth within our clinical diagnostics business."

QUIDELORTHO: Revenue Down 2% in Q2, Aims to Save $50M by Year-End

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

- Revenue decreased 4.2% to $637.0 million from $665.1 million.
- Labs revenue was down 2.0% to $354.2 million from $361.4 million.
- Point-of-care revenue fell 12.7% to $117.1 million from $134.2 million.
- Molecular diagnostics revenue decreased 29% to $4.4 million from $6.2 million.

Segments performed "in line with expectations," and QuidelOrtho conducted a review of assets, operations, and opportunities for savings, according to Brian Blaser, CEO.

During an earnings call, he explained that $50 million of savings are expected to be realized in the second half of 2024 and $50 million more in the first half of 2025.

"Our challenges are not structural to our business. Rather, they are mainly internal cost execution and process issues, which are largely under our control," he said.

QuidelOrtho plans to conduct clinical trials on a respiratory panel later this year and launch it in 2025, Blaser added.

BECTON, DICKINSON AND COMPANY: Revenue Up 4.5%, MiniDraw and More Coming in 2025

Becton, Dickinson and Company (BD), Franklin Lakes, N.J., shared data for its Q3, as compared to Q3 2023:

- Revenue increased 2.3% to $4.99 billion from $4.87 billion.
- Life sciences (including the Integrated Diagnostic Solutions and Biosciences business units) was up 2.7% to $1.26 billion from $1.22 billion.
- Integrated diagnostics solutions revenue was up 4.5% to $896 million compared to $858 million.
- Biosciences revenue saw a slight decline of 1.4% to $363 million from $368 million.

In integrated diagnostics, BD received FDA clearance for a test enabling self-collection for cervical cancer care screening in a healthcare setting.

In biosciences, BD launched Rhapsody ATAC-Seq Assays aimed at single cell capabilities for epigenomics research. During Q3, BD announced an intent to acquire for $4.2 billion the Critical Care Product Group of **Edwards Lifesciences**, Irvine, Calif.

HOLOGIC: Sees Revenue Increase in its Q3

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

- Revenue was up 2.7% to $1.01 billion from $984.4 million.
- Diagnostics revenue was up 0.3% to $440.8 million from $439.7 million.
- Molecular diagnostics revenue was up 2.8% to $310.7 million from $302.2 million.

DANAHER: Beckman Coulter Sales Up Slightly, Adds New Heart Failure Test

Danaher Corporation, Washington, D.C., included in its Q2 report these updates on its subsidiaries **Beckman Coulter Diagnostics**, **Cepheid**, and **Leica Biosystems**:

- Total sales decreased 3% to $5.74 billion from $5.91 billion.
- Diagnostics sales were up 1.5%.
- Life sciences sciences revenue was down 1.5%.

"In molecular diagnostics, Cepheid's respiratory revenue of approximately $300 million in the quarter exceeded our expectation of $200 million driven by both higher volumes and a favorable mix of our four-in-one tests for COVID-19, Flu A and B, and RSV," said Rainer Blair, CEO during an earnings call.

REVVITY: Sees Slight Increase in Q2 Diagnostics Revenue

Revvity, Waltham, Mass. (formerly **PerkinElmer**) reported for Q2 as compared to Q2 2023:

- Revenue was down 2.3% to $692 million as compared to $709 million.
- Diagnostics revenue was up 1.3% to $378 million from $373 million.
- Life sciences revenue decreased 6.5% to $314 million from $336 million.

SYSMEX CORPORATION: Has Healthy Start to Its Fiscal 2025 Year

Sysmex, with headquarters in Hyōgo, Japan, shared financial results for its fiscal year ending March 31, 2024, as compared to fiscal year 2023:

- Sales were up 17.4% to ¥111,946 million (US$$763.2 million) from ¥95,351 million (US$650.1 million).

"Changes in the market environment pushed up demand, which boosted sales of instruments in the medical robotics business. Also, sales of hematology instruments increased," Sysmex reported.

QIAGEN: Sales Up, Adds Gastrointestinal, Respiratory Assays

Qiagen, headquartered in Venlo, Netherlands, released Q2 financials as compared to Q2 2023:

- Sales were up slightly by 0.2% to $496 million from $495 million.
- Molecular diagnostics sales were up 3% to $266 million from $260 million.
- Life sciences sales decreased 2% to $230 million from $235 million.
- Instruments sales fell 11% to $54 million from $60 million.

Qiagen plans to "phase out" its NeuMoDx clinical PCR system. It received FDA clearances for a new gastrointestinal panel and an updated respiratory panel. Both assays are performed on the QIAstat-Dx. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

One sign of the financial turmoil associated with the market for genetic tests is the news that all seven independent directors of **23andMe's** board resigned at the same time on Sept. 18. The reason given was that these directors opposed the plan of CEO and co-founder Anne Wojcicki to take the company private. The once high-flying genetic testing company has hit hard times. When 23andMe went public in 2021, it was valued at as much as $3.5 billion and its stock traded as high as $16.04 per share. Today, the market cap is under $200 million and its share price is less than $0.35. The **NASDAQ** exchange sent a notice requiring the company to get its share price above $1.00 or it will be delisted.

MORE ON: *23andMe*

Reporting on these developments, *The Washington Post* said, "the company [23andMe] ended the quarter with about $170 million in cash, which it said will be enough to fund its operations for at least 12 months. Last week, it endorsed a proposed settlement to a class-action lawsuit over a data breach last year for $30 million, acknowledging its "extremely uncertain financial condition." It was only five months after the breach of protected health information that 23andMe became aware of the hack. In October 2023, the company confirmed the breach, but the full details were not disclosed until months later in December 2023.

HUMANA REQUIRES Z-CODES FOR TEST CLAIMS

Effective September 18, 2024, **Humana** Medicare Advantage plans began requiring Z-codes for certain molecular and genetic tests.

TRANSITIONS

• Sean Tucker, MLS(ASCP), was appointed Executive Director of Laboratories at **BJC STL Children's Washington University Academic Campus**. His prior positions were with **North Kansas City Hospital**, **Children's Mercy Kansas City**, and **Shawnee Mission Medical Center**.

• **Eppendorf** appointed Christine Munz as the new CEO of the **Eppendorf Group**, effective Oct. 1, 2024. Munz previously worked at **Leica Biosystems** and **Roche**.

• Jon DiVincenzo is the new President and COO at **Bio-Rad Laboratories**. Previously, he served at **Labcorp**, **PerkinElmer**, and **Enzymatics**.

• **HCA Healthcare** announced that Natasha Villanueva, MHA, MLS(ASCP) will become the Division Director of Laboratory Services. Villaneuav's prior positions were with **MAWD Pathology Group** and **North Kansas City Hospital**.

• Kristen Keenan is the new Director, Laboratory Services of Laboratory Outreach at **Sentara Health**. Keenan previously was with **Labcorp** and the **Coca-Cola Company**.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, October 14, 2024.

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