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Ortho Clinical Diagnostics to be Acquired by Quidel for $6 billion!
(See pages 7-9)

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

2022 Closes with Two Major Lab Industry Events

Normally, the time around Christmas and New Year passes quietly, typically without any significant developments. Such was not the case for the clinical laboratory industry in the last month of 2022 because of two announcements, each of which confirms ongoing market trends in healthcare and the lab testing industry.

The first announcement was on Dec. 14 when **XIFIN, Inc.**, of San Diego, revealed its agreement to acquire **OmniSYS, Inc.**, of Dallas, a company that provides information services and products to 30,000 retail pharmacies across the United States. A purchase price was not disclosed. *(See pages 3-6.)*

The second announcement was made by San Diego-based **Quidel Corporation** on Dec. 23. It broke the news that it had an agreement to acquire **Ortho Clinical Diagnostics** of Raritan, N.J., for a purchase price of $6 billion. Once this deal closes, Quidel will become one of the 10 largest *in vitro* diagnostics (IVD) companies in the world, with combined annual revenue of about $5.2 billion. *(See pages 7-9.)*

Quidel's acquisition of Ortho Clinical continues a multi-decade trend of bigger IVD corporations purchasing smaller diagnostics companies. In this case, however, both companies were of a similar size. Since it was spun off by parent company **Johnson & Johnson** in 2014, Ortho Clinical has struggled to show sustained growth in revenue and profitability. Quidel offered a 25% premium over Ortho Clinical's share price and that proved to be attractive to Ortho Clinical's shareholders, who voted to accept the deal.

By contrast, XIFIN's purchase of OmniSYS represents a major foray into the retail pharmacy marketplace. As you will read in our briefing about this development, XIFIN recognizes that retail pharmacies are expanding their point-of-care testing services to their customers—and COVID-19 testing provided by pharmacies is accelerating this process. The ongoing construction of primary care clinics within retail pharmacies is another factor that XIFIN recognized. Because OmniSYS already provides information and patient-oriented services to 30,000 pharmacies, XIFIN is confident that it has a pathway to encourage these pharmacies to use its competencies in handling lab data and revenue cycle management. It could prove that XIFIN's acquisition of OmniSYS was the perfect entry point into serving retail pharmacies. TDR

XIFIN Buys OmniSYS, Bridges Lab to Pharmacy

Acquisition is response to growing trend of retail pharmacies offering clinical services to consumers

CEO SUMMARY: XIFIN's acquisition of pharmacy technology company OmniSYS is the latest evidence that retail pharmacies are preparing to become a new front door to healthcare for consumers. The deal allows XIFIN to bring clinical lab information about patients directly to pharmacists while also helping retail pharmacies with clinical service billing and reimbursement needs as they develop primary care clinics in their stores.

One of the clinical laboratory industry's biggest players in lab revenue cycle management (RCM) just made a bold move to become a valuable resource to retail pharmacies. On Dec. 14, **XIFIN, Inc.**, of San Diego announced its acquisition of Dallas-based **OmniSYS**, a provider of information services to retail pharmacies.

With this acquisition, XIFIN immediately positions itself to have access to the 30,000 retail pharmacies that use the information technology products provided by OmniSYS. To give that number perspective, in 2019, the **Pharmaceutical Care Management Association** published a study showing 39,084 chain pharmacies and 23,601 independent pharmacies. XIFIN thus gains access to more than 50% of the nation's retail pharmacies.

This may turn out to be a shrewd move, as most of the national pharmacy chains are expanding the types of diagnostic tests they offer to their customers. Additionally, most of the national pharmacy companies are well along the path of building full-service primary care clinics in their retail stores and those clinics will need the full menu of clinical laboratory testing services. *(See TDR, "New Players May Alter Who Buys & Who Orders Lab Tests," June 14, 2021.)*

"Clinical labs have an opportunity to be in many of the pharmacies," said Lâle White, founder and CEO at **XIFIN**, a healthcare information technology company based in San Diego. "With all the point-of-care testing being done now, we can see that there is room in retail pharmacies for laboratories to be there as an extra referral for confirmations and to provide other, more complex testing."

Interwoven into this evolving situation are new billing and clinical data needs

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at retail pharmacies, which encouraged XIFIN to step into this market by acquiring OmniSYS. The deal was announced on December 14, 2021, and establishes a clear data pathway between pharmacies, XIFIN, and clinical labs. Financial terms were not disclosed.

XIFIN provides cloud-based revenue cycle management, healthcare informatics, and laboratory information systems, while OmniSYS offers a software suite to support pharmacists in the administration and reimbursement of clinical services.

"Combining our capabilities will allow XIFIN to do more than simply help process the testing and clinical service claims," White explained. "It opens the door to more extensive, patient-directed data exchange. With the appropriate authorizations, XIFIN will be able to deliver clinical lab information about patients to the pharmacists who see those people face-to-face."

XIFIN is betting that pharmacies will need this type of behind-the-scenes help not only to stay competitive, but to also prove to private insurers and Medicare that these pharmacy-based clinical services are helping patients stay healthier more economically as the industry moves toward value-based care.

Path from Lab to Pharmacy

"If pharmacists have access to laboratory data—and they can interpret and visualize that data and the expected outcomes for those patients during the provision of care at the retail pharmacy in a precise, results-driven way—pharmacists can prove to payers that they positively contribute to improved health outcomes," said John King, former CEO at OmniSYS and the new president of the OmniSYS division at XIFIN.

"To help pharmacies expand payer relationships and grow their clinical services business to achieve better patient outcomes would be the home run we expect from combining XIFIN and OmniSYS," King added.

Two large shifts forced retail pharmacies to re-imagine their roles in healthcare delivery: intense competition and the SARS-CoV-2 pandemic. Pharmacies have seen their margins erode due to the growth of generic prescription drugs, mail-order prescription services, and new online competitors like **Amazon**. As with many other types of brick-and-mortar businesses, online prescriptions have drawn away customers from pharmacies.

Why Now for Pharmacies?

"Once pharmacies started losing their share of prescription drug orders to mail order systems and disrupters like Amazon, they didn't just sit idly by and accept their declining business," White observed. "They knew their marketplace and understood the consumer's demand for convenience and rapidly pivoted into offering clinical services."

On a different tangent, when the pandemic hit full swing in the U.S. in March 2020, it opened the door for COVID-19 testing. Pharmacies' interest in offering more point-of-care (POC) testing and related diagnostic services got a huge boost. Pharmacy operators were quick to recognize that—just as flu shots have rapidly shifted to the retail pharmacy setting as a more convenient way for consumers to obtain their immunizations—they could provide SARS-CoV-2 vaccines and tests to consumers.

Thus, most pharmacy operators quickly offered COVID-19 vaccines and POC testing to their shoppers. This proved to be a major source of new revenue, particularly for the largest pharmacy chains, like **Walgreens**, **CVS**, and **Walmart**. But COVID-19 tests and other clinical services exacerbated the need for the pharmacies to be able to code, bill, and submit claims to the proper health insurer, government entity, or other organization.

That need to improve coding, billing, and collections for clinical services in a pharmacy setting plays to the strength

of XIFIN and OmniSYS, which together are electronically interfaced to almost every health insurance plan in the United States. OmniSYS can help pave the way for XIFIN to bridge the business needs of labs and pharmacies because OmniSYS already manages medical claims and provides clinical systems for more than 30,000 pharmacies nationally.

Moreover, expect national pharmacy chains to build on their experience with COVID-19 vaccines and testing and apply it to other common primary care services, confident that consumers will prefer to access these services at their local pharmacy, often at cheaper prices.

"When you look at clinical lab tests for blood glucose, cholesterol, or checking for kidney and liver functions, there's a huge opportunity for pharmacies, but only if they have access to laboratory data and the necessary partnerships to begin moving into value-based-care arrangements," King explained.

XIFIN's Goals

As part of its acquisition of OmniSYS, XIFIN has short-term and long-term objectives to integrate the tech offerings of both companies. "A quick win for us will be to see how our systems can integrate with each other and how we can carry data and information for lab and pharmacy to the consumer, as well as back to providers, and provide them with the insight they need," White stated.

Through the longer-term lens, XIFIN expects to capitalize on the trend of retail pharmacies offering primary care services directly to consumers. The pharmacy industry has already laid groundwork for this, with national regulations that allow pharmacists to perform a variety of clinical services, including immunizations, diabetic counseling, and medication management. Many individual states are going even further with laws that allow pharmacists to provide services such as hormonal contraceptive prescriptions.

At-a-Glance: XIFIN, OmniSYS

THIS OVERVIEW DETAILS the pre-merger characteristics of XIFIN and OmniSYS:

XIFIN

- CEO: Lâle White
- Founded: 1997
- Industry: Clinical laboratories, anatomic pathology, radiology
- Revenue: Not reported, private company
- Core products: Cloud-based revenue cycle management software for labs; laboratory information system
- Market reach: Processes more than 70 million lab test claims per year.

OmniSYS

- CEO: John King, who will become the new president of XIFIN's OmniSYS division
- Founded: 1988
- Industry: Retail pharmacies
- Revenue: Not reported, private company
- Core products: Cloud-based electronic health record system for pharmacies; cloud-based medical claims billing software for pharmacies
- Market reach: Serves more than 30,000 pharmacies in the U.S.

The list of clinical services that pharmacies are allowed to perform is rapidly growing, White noted. Combine that convenience with consumers' growing desire to manage their own care through technology and there is an open market into which clinical laboratories can step.

However, clinical laboratory executives and pathologists have been slow to seize this opportunity. "What we haven't seen are synergies between regional labs and pharmacies," White said. "We've seen synergies at the large-lab scale, where

Opportunities for Clinical Laboratories as Retail Pharmacies Offer More Diagnostic Tests

CLINICAL LABORATORIES AND PATHOLOGY LEADERS would be wise to monitor the progress of retail pharmacies that are in the process of creating a new front door to healthcare for millions of consumers.

Mail order pharmacies, the growth of generics, and online delivery services have caused local and national pharmacies to lose market share and margins in the traditional drug prescription business. That is why pharmacies want to protect and expand their market share by launching clinical services in retail pharmacies that are in the same neighborhoods where patients live and work.

For clinical lab administrators, this new arrangement is an opportunity. As more pharmacies provide point-of-care (POC) tests and the full menu of medical lab testing, local clinical labs can step in and provide those diagnostic testing services. But if local labs ignore this opportunity, they may lose that business to more nimble labs. Lab managers and pathologists may want to consider these next steps as part of their lab's evolving clinical and business strategies:

- Evaluate the local retail pharmacy scene to determine if a lab-testing, specimen-collection partnership with a pharmacy is viable. Consider supporting a point-of-care testing program within the pharmacy.
- If such an arrangement could be fruitful, investigate whether the lab and the pharmacy have the technology in place to allow clinical and billing data to flow between both sides.
- Estimate what diagnostic testing services may shift away from physician offices to retail pharmacies and the primary care clinics they operate. Then develop strategies to partner with local pharmacies to provide specimen collection services and lab tests.

the big public laboratory companies have done some exclusive contracts with CVS, Walgreens, and Walmart, but not necessarily at the middle and lower tier pharmacy chains.

"We see the opportunity to democratize this synergy between laboratories and pharmacies with the appropriate use of technology," she added. "With the consumer-driven economy, we see that consumers truly are becoming hands-on with decisions about their clinical care and—like pharmacies—consumers need technology tools to bring their healthcare data together. At the same time, both public and private payers have acknowledged the cost savings associated with providing healthcare in more accessible settings."

XIFIN sees an opportunity to help pharmacists more effectively use lab test data. "We'd like to enable clinical decision support tools for pharmacies so that pharmacists know, for example, what other services patients might need based on their current vaccination status or diagnostic test results," White said.

Over the past year, THE DARK REPORT has provided intelligence briefings about why retail pharmacies want to become primary care providers. These in-store clinics will need clinical lab testing services. The decision by XIFIN to acquire a company that has a significant presence providing billing and electronic health record systems to retail pharmacies—while also helping those in-pharmacy clinics bill payers for COVID-19 vaccines and tests as well as the full menu of lab tests and other clinical services—is market evidence that this trend is real and will continue to develop. **TDR**

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Ortho Clinical Diagnostics to Be Acquired by Quidel

Latest major consolidation within IVD industry means large companies continue to get bigger

CEO SUMMARY: In an announcement released before the end of 2021, Quidel said it had signed an agreement to acquire Ortho Clinical Diagnostics (OCD) for $6 billion. Laboratories that are customers of either company should expect changes after the deal closes as Quidel moves to integrate OCD. One IVD expert says Quidel will become more prominent in chemistry, immunoassay, and immunohematology product lines.

ONCE AGAIN, A BIG *IN VITRO* DIAGNOSTICS (IVD) COMPANY WILL GET BIGGER because of an acquisition. This time, it is **Quidel Corporation**, which announced on Dec. 23 that it had a definitive agreement to acquire **Ortho Clinical Diagnostics**.

Quidel, a San Diego-based company and developer of point-of-care (POC) diagnostics and rapid testing, plans to buy Ortho Clinical Diagnostics in Raritan, N.J., for $6 billion. Quidel said "the transaction is expected to close during the first half of fiscal year 2022, subject to customary closing conditions."

Clinical laboratories that use Ortho Clinical products should anticipate possible changes in customer support, sales, and marketing later in 2022, once the merger is final and Quidel can begin to consolidate the two companies and integrate their product lines and support teams.

Another significant fact about this acquisition is that it continues the trend of consolidation in the IVD industry. Since the 1990s, larger IVD corporations have regularly bought up small and mid-sized IVD companies as a way to grow. Often these acquisitions conveniently removed a competitor from the marketplace or allowed the acquiring company to gain access to patients and proprietary technology that they believed they could use to good advantage with their own product mix of instrument systems and test kits.

"The transaction is not unexpected. Quidel—with its windfall revenue from COVID-19 testing—has the resources to fill out its product offerings," said Lawrence Worden, Principal at **IVD Logix** in Dallas, in an exclusive interview with THE DARK REPORT. "The benefit to Ortho Clinical is that its merger with Quidel gets them into other markets, including immunohematology, in a big way."

Two Growing Companies

The deal highlights a case of two similarly-sized companies combining their arsenal. Ortho Clinical provides hospitals, clinical labs, and blood banks worldwide with technology and tests. THE DARK REPORT (TDR) ranked Ortho Clinical 11th on its list of the world's top 11 IVD companies in 2020. *(See TDR, "2020 Rankings of the World's Largest IVD Corporations," Sept. 7, 2021.)*

In recent reporting about IVD companies' record sales in 2021, we noted Ortho Clinical's revenue was $508.9 million in

At-a-Glance: Quidel, Ortho Clinical

HERE'S A BRIEF LOOK at the companies involved in Quidel's purchase of Ortho Clinical Diagnostics:

Quidel

- CEO: Douglas Bryant
- Founded: 1979
- Industry: *In vitro* diagnostics
- Revenue: $1.7 billion for 2020
- Core products: Cardiac immunoassay; rapid immunoassay; specialized diagnostics, such as direct fluorescent antibodies; molecular diagnostics
- Market reach: Installation of 70,000 Sofia analyzers for immunoassay testing as of March 2021

Ortho Clinical Diagnostics

- CEO: Chris Smith
- Founded: 1939
- Industry: *In vitro* diagnostics
- Revenue: $1.8 billion in 2020
- Core products: Digital chemistry systems; immunodiagnostics systems; transfusion medicine instruments
- Market reach: Installation of 20,000 instruments

the third quarter, up 13.2% from Q3 2020. *(See TDR, Dec. 20, 2021.)* By comparison, Quidel's Q3 2021 revenue was $509.7 million, up 7% from the prior year, according to an earnings report.

The combined company will have work to do if it wants to challenge other top IVD firms, Worden said. "While Quidel will have access to chemistry, immunoassay, immunohematology, and other markets Ortho Clinical serves, it is not in a fully-competitive position with some of the top IVD companies."

Worden added that Ortho Clinical Diagnostics, with its patented dry-slide technology, has served "low- to moderate-size accounts" in the chemistry and immunoassay markets. In a presentation to its investors, Quidel noted the deal presents a $50 billion market opportunity after the acquisition—including $23 billion in POC services, $25 billion from automation in clinical labs, and $2 billion in transfusion medicine.

In that presentation, Quidel listed reasons why the acquisition was desirable:

- Improved global reach.
- A broad portfolio to meet testing needs at all points of the care continuum, such as reference labs, hospitals, physicians' offices, and retail locations.
- Enhanced research and development opportunities.

Seventh Largest IVD Vendor

The combined company envisions becoming the seventh largest IVD vendor. In the investors presentation, Quidel noted $3.9 billion in Q3-2021 revenue for the trailing 12 months (TTM), which reflected a combination of $1.9 billion in Quidel Q3-2021 TTM revenue and $2 billion in Ortho Clinical Q3-2021 TTM revenue.

"We expect the combined company will emerge as a global player with top-tier research and development capabilities, a more diverse product pipeline, and a broader geographic footprint," said Douglas Bryant, Quidel's President and CEO, in the news release. Bryant will serve as CEO at the combined company.

Plans for Ortho Clinical

The deal is aimed at uniting technologies and platforms related to clinical chemistry, immunoassays, molecular diagnostics, immunohematology, donor screening, and POC services, according to the company.

"Quidel will have the ability to bundle more products together to penetrate laboratories that they may not have been able to compete in previously," Worden said. "Having a fuller product line is always going to be a benefit in a competitive process. For example, there may be an oppor-

Several Blockbuster IVD Acquisitions Brought Significant Changes to Clinical Lab Marketplace

WHEN QUIDEL COMPLETES ITS ACQUISITION OF ORTHO CLINICAL DIAGNOSTICS later this year, the $6 billion deal will be one of the largest purchases involving an *in vitro* diagnostics (IVD) company in recent years.

It was in the 1990s when large IVD corporations began to use acquisitions as a way to grow, to add missing products to its offerings, and to acquire diagnostic technology and patents. An added benefit was that these consolidations often removed a pesky competitor.

The first of the two biggest IVD consolidation deals of the 1990s happened in May 1997 when **Roche Holdings** acquired **Corange Ltd.**, parent company of **Boehringer Mannheim**. Roche paid $11 billion and, once the deal closed, eclipsed **Abbott Laboratories** as the world's largest diagnostics company, a position it still holds today. *(See TDR, "Roche Holdings, Ltd. Acquires Behringer Mannheim in Merger," June 2, 1997.)*

Another blockbuster IVD consolidation deal happened just months later. On Sept. 3, 1997, **Beckman Corporation** announced its acquisition of **Coulter Corporation**. Beckman paid $1.5 billion and, post-aquisition, the company was renamed **Beckman Coulter Corporation**. *(See TDR, "Lab Market Trends Drive Beckman-Coulter Deal," Oct. 6, 1992.)*

Similiarly, **Siemens**, a huge global player in radiology and imaging, used acquisitions to enter the IVD market in a big way. On April 27, 2006, it spent $1.86 billion to buy **Diagnostics Products Corporation** (DPC), closing the sale on June 28. *(See TDR, May 22, 2006.)*

Then, a day later, Siemens disclosed a deal to pay $5.21 billion to buy **Bayer Diagnostics** from **Bayer Healthcare AG**. *(See TDR, July 3, 2006.)*

The following year, on July 25, 2007, Siemens acquired **Dade Behring** in a deal priced at $7 billion. *(See TDR, Aug. 6, 2007.)* These three acquisitions cost Siemens $14 billion and immediately positioned it with Roche and **Abbott Laboratories** as one the world's three largest IVD corporations.

tunity for Quidel to bundle its technology on a bench in the lab with chemistry or other Ortho Clinical offerings."

A report by *Reuters* said the acquisition is an indicator of ongoing growth in the diagnostics market, particularly because demand for COVID-19 testing continues. *Reuters* further noted that, on a call with analysts, Quidel shared expectations that its Savanna PCR test (for diagnosis of two types of influenza and COVID-19) had strong prospects for growth as a result of Ortho-Clinical's international market.

As with all large corporate acquisitions, the companies involved will take time to figure out combined services and overlaps. Customers of Quidel and Ortho Clinical should expect changes in how products are sold, and potential new reps to deal with within sales and marketing at the combined entity.

As Worden notes, most of the larger IVD corporations are flush with cash, generated by the still-surging demand for automation, analyzers, primers, and test kits used for SARS-CoV-2 testing. Because of that, there may be more acquisitions within the diagnostics sector that further consolidate the IVD industry.

That may also prove true in the developing market for artificial intelligence-powered tools for analyzing digital pathology images. One or more of the bigger IVD companies may do such an acquisition to acquire that technology. **TDR**

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Legal Update

Jury Finds Elizabeth Holmes Guilty in Four of 11 Criminal Counts

THERANOS' FOUNDER ELIZABETH HOLMES received four convictions out of 11 charges in her blockbuster trial, which likely means a federal prison sentence for the former CEO.

The guilty verdicts arrived Jan. 3 after months of testimony and jury deliberations that lasted more than 50 hours.

Holmes was convicted on the following charges, as outlined by technology news site *Ars Technica*:

- Defrauding **Lakeshore Capital Management** of $100 million. The firm is owned by the family of Betsy DeVos, the former U.S. Secretary of Education.
- Defrauding **PFM Health Sciences** of $38 million. The healthcare investment firm is led by Brian Grossman.
- Defrauding a company associated with Daniel Mosley of $6 million. Mosley is the former estate attorney for former U.S. Secretary of State Henry Kissinger.
- Conspiracy to commit wire fraud against various investors.

Holmes was found not guilty of four charges that involved defrauding patients who took Theranos blood tests. Finally, the jury deadlocked on three other charges of wire fraud against investors.

No Evidence of Patient Fraud

It's interesting to note that the trial results favored the losses to investors who poured millions of dollars into Theranos and its flawed technology, as opposed to patient complaints. Bobby Allyn, a reporter for *NPR* who covered the trial, commented that the jury was not convinced there was enough evidence about patients who claimed fraud in the trial.

"The jury … acquitted Holmes of separate charges connected to the allegation that she intentionally deceived patients who went into **Walgreens** in Palo Alto, California, or in Arizona, got a Theranos blood test, and got a bad result," Allyn said on the Jan. 4 edition of *NPR's* podcast, Up First. "The jury didn't think there was enough evidence to convict Holmes of defrauding those patients."

Theranos had initially struck a deal with **Walgreens Boots Alliance** in 2012 to offer specimen collections services in some stores in those states.

Lab Director Testimony

For clinical laboratory and pathology leaders, the trial's conclusion ends a voyeuristic journey into a high-tech lab's collapse amid accusations of false test data and defrauded investors. But it also uncovered the need for regular, everyday laboratories to carefully consider their responsibilities under the Clinical Laboratory Improvement Amendments of 1988 *(See TDR, Nov. 8, 2021, and Nov. 29, 2021.)*

Key to the convictions was testimony from numerous witnesses, including four former Theranos laboratory directors who knew the company's Edison finger-prick blood analyzer did not work as touted. *(See TDR, Oct. 18, 2021, and Nov. 8, 2021.)*

Holmes' sentencing date has not been set. She faces up to 20 years on each conviction, although the judge could reduce those sentences and make them run concurrently. Some court watchers believe factors that could lighten the sentence might be the not guilty verdicts in the case as well as the fact that Holmes has a baby at home. TDR

Rural Hospital Lab Hits Automation Home Run

Goal was to position existing lab to handle expanding test menu, growing outreach volume

CEO SUMMARY: With the hospital adding specialist physicians and at the same time enjoying sustained growth in outreach test volume, the lab was hit with the dual need to expand the in-house test menu and reconfigure workflow to handle predictions of ongoing growth in outreach testing. Sarah Bush Lincoln Health System's laboratory examined bottlenecks in its work process, created a multi-year strategy to address those problems, and used automation to improve testing services.

CLINICAL LABORATORY DIRECTORS CONTINUE TO FACE TOUGH CIRCUMSTANCES as 2022 gets underway, including staffing shortages, greater demand for COVID-19 testing amid the ongoing pandemic, and stress.

If clinical laboratories have not increased their automation capabilities in recent memory, now is a good time to expand use of the technology.

Multi-Faceted Success

Newfound inspiration may come from the clinical laboratory at **Sarah Bush Lincoln Health System** in Mattoon, Ill., which achieved multi-faceted success by ramping up its automated processes. In doing so, the lab increased operational efficiency—including an impressive 75% reduction in process steps—and improved turnaround times (TAT). Lean and Six Sigma methods informed and enabled the lab team to leverage the new automation to its fullest potential.

"We aimed to focus on processes and production," said Jodie Warner, Director of Laboratory Services at Sarah Bush Lincoln. "And the best way to do that was through new automation in our core laboratory."

Sarah Bush Lincoln's hospital laboratory has been on a five-year journey to automate workflow and improve efficiency and quality of diagnostic services. Leadership at the lab knew transformation was needed to handle growth and changes in test volume, menus, and orders originating from more physician specialists served by the laboratory outreach program.

Located in east central Illinois, 103-bed Sarah Bush Lincoln Health System serves a nine-county area. Included in the market are a hospital, regional cancer center, 17 primary care sites, and 14 community clinics. Additionally, lab services extend outreach to a 20-county area. A satellite lab operates in Effingham, Ill.

Increased Test Volumes

"The laboratory was experiencing growth with more physician offices and outpatient business," Warner said. "Because of new tests, new methodologies and new diseases, we saw regular increases in specimen volumes and expansion of our test

menu. At the same time, our hospital was adding specialists, which meant a higher acuity of patients.

"All of those things were coming into play," explained Warner during her session at the 2021 *Executive War College*, titled, "Our Lab's Multi-Year Journey to Automate Work Processes and Use Analytics to Reduce Errors, Boost Efficiencies, and Improve Care."

"So, growth was great, but also a pain point," she continued. "We asked ourselves how our lab could handle that growth, especially with strong growth in specimen volume projected for several years into the future?"

Growth in Tight Labor Market

Warner acknowledged that the shortage of laboratory professionals in a tight labor market made it difficult to address growth with more staff. Since early 2020, the pandemic has also increased the difficulty of hiring experienced lab staff.

"To handle projected year-over-year growth, our big imperative was to improve efficiencies and quality," Warner stated. "Consistent with Lean methods, we strive for continuous improvement while looking for opportunities to eliminate or reduce errors and to establish consistent processes.

"There were differences in how our lab handled stat orders versus routine work, and the variability was impacting staff, quality, and results output," she noted. "The consistency just wasn't there. And we needed to have the appropriate staff performing the right types of work."

To meet these challenges, decision-makers chose to implement **Beckman Coulter's** DxA 5000 Total Laboratory Automation System, with the following configuration:

- Two centrifuges
- Two clinical chemistry analyzers
- Immunoassay systems
- Hematology workstations
- Refrigerated units for samples

The DxA 5000 offers a streamlined hospital lab workflow through pre-analytic connection to chemistry and hematology analyzers to post-analytic volume detection, according to Beckman Coulter.

Setting Lab Goals

A preliminary challenge was appropriately scaling the automation equipment and software.

"One goal was to plan far enough ahead to have the capacity to handle future growth," Warner said. "No matter what you build, you often feel you have outgrown it a few months later. Our lab team wanted to manage capacity and grow our outreach business, as well."

The team set a goal of 3% annual growth by 2024, which represented 1,900 specimens total per day. Then, lab managers began the tedious work of mapping out lab processes to create value stream maps. This helped identify when wait times happened and where probable sources of errors originated.

"Much effort went into this," Warner said of the attention to workflow. "Concentrating on the detailed steps between specimen and result, as well as the pre- and post-analytical phases of testing, was critical to determining the right fit for our lab."

Applying Six Sigma

To further help promote efficiency, the lab team incorporated elements of Six Sigma methodology. Six Sigma aims to make processes, such as those used in clinical labs and pathology groups, more uniform and precise through application of statistical methods.

The term "Six Sigma" comes from the goal of producing services that meet a quality specification that is within six standard deviations (SD) from the mean value. The lower the SD, the closer the value is to the mean.

The team at Sarah Bush Lincoln worked with Beckman Coulter on its

Quality Improvement Methods Implemented with New Lab Automation to Deliver Solid Results

PROCESS IMPROVEMENT CAN WORK HAND-IN-HAND with core laboratory automation to deliver substantial gains in productivity, faster test turnaround times, and lower costs. During her presentation at last November's *Executive War College*, Jodie Warner, Director of Laboratory Services at Sarah Bush Lincoln Health, described how the lab team used Lean, Six Sigma, and other quality improvement initiatives in tandem with the installation of new lab automation, as follows:

- Interfaces with electronic health records (EHRs) in outreach client offices resulted in cleaner claims and needed data for improved reimbursement.
- Positive patient identification enabled phlebotomists to print labels for specimens at bedside, transfer collection information (e.g., collector, date, and time) back to the laboratory information system and document delays and "no draw" reasons.
- Automated examination of peripheral blood smears (especially for oncology patients) allowed the lab to more efficiently complete differentials on low white blood cell counts and confer with specialists and pathologists.
- Auto-verification expedited the reporting of results meeting established criteria and acceptable quality control and enabled clinical laboratory technicians to focus on tasks and results needing their attention.
- Laboratory expansion and redesign of standardized equipment reduced the risk of repetitive-use injuries and enhanced teamwork.
- Customer service systems, point-of-delivery devices, and GPS improved client relations with better documentation of interactions and marketing, courier dispatch, recording of specimens and pick-up times, and route optimization.
- Point-of-care connectivity helped capture results in the hospital's EHR system and allowed the lab to monitor users' competency and quality control.

map of current processes to identify steps without value (e.g., waiting, movement, over-production, and over-processing) and how automation could eliminate waste and biohazards.

The team also focused on closing the gap in TAT for routine testing and stat testing. "We wanted to implement a consistent solution to handle both stat and routine processes so we could eliminate outliers," said Warner, who noted wide dispersion of data from the mean for key tests' TAT.

Promising Results

With the assistance of technology, Sarah Bush Lincoln's lab saw impressive results through a more consistent testing process and improved TAT.

"We have one process now and know that it is working well for tests—stat and routine," Warner said.

In fact, the implementation of Beckman's DxA 5000 automation line decreased steps in the lab process from 122 to 31 for a 75% reduction, she added.

Also, according to Warner, standard deviations (SD) and TAT for these high-volume tests improved as follows:

- Potassium: SD improved from 10 minutes (stats) and 22 minutes (routines) to a consistent SD of nine minutes; mean TATs were reduced from 35 minutes (stats) and 50 minutes (routines) to 25 minutes for all potassium tests.
- Complete blood count (CBC): SD improved from 15 minutes (stats) and

20 minutes (routines) to a consistent SD of four minutes; mean TATs were reduced from 14 minutes (stats) and 20 minutes (routines) to nine minutes for all CBCs.

- Troponin: SD improved from 14 minutes (stats and routines) to six minutes; mean TATs were reduced from 37 minutes to 34 minutes.

As for capacity with the automated system, the lab quickly surpassed its target set for 2024, as it processed 2,200 tubes in one day during the COVID-19 pandemic.

"The volume of testing on that day far exceeded what we projected would be future volume," she noted. "The surge in specimen volume was initially due to the pandemic but has continued. However, our new automation and core lab workflow give us the horsepower and throughput to handle that growth."

Access to real time data is another important factor in helping the lab team handle the increased daily volume of testing. Beckman Coulter's data management integration tools made it possible for lab leaders to use granular dashboards to determine use of automation. "We looked at staff's adoption—comparing auto load to total load—and utilization is at 90%, confirming that lab staff are using the new automation effectively."

The automated system also allows the laboratory to review workload balancing. That guides the distribution of tubes while allowing the medical technologists to investigate any variances that might indicate supply or maintenance issues with a particular analyzer or reagent.

Leveraging Lab Automation

As the experience of the laboratory at Sarah Bush Lincoln Health System demonstrates, today's generation of laboratory automation can deliver increased productivity, improved accuracy, and lower costs even to smaller and mid-sized hospitals. Two other elements in this successful lab operations case study are integral to the lab's ability to grow while maintaining service levels to the inpatient, outpatient, and outreach clients it serves. One is the diligent application of Lean and Six Sigma methods with the automation.

The second is the use of informatics and management dashboards to provide data in real time that allow laboratory staff to spot problems and identify underperforming instruments and congestion in work processes.

Clinical lab administrators and pathologists should not overlook several other interesting and relevant aspects of this laboratory case study. First, this is a 103-bed hospital in a town with a population of 17,394 in 2021. Yet, the hospital has a strategy of adding specialist physicians to provide a wider range of clinical services to the communities it covers in the 20 counties that it serves.

This strategy requires the lab to expand the menu of in-house tests commonly used by the new specialists. But this also comes with the benefit of shortening turnaround times for inpatient test results. The ability to get a fast test result may mean that the inpatient can be discharged a day early. That is a major cost saving to the hospital.

Second, continuing improvements in lab automation and testing instruments mean that they are smaller and more efficient. This allows smaller hospitals to utilize more automation in their labs. That's true at Sarah Bush Lincoln Health, but its lab's journey to automate its lab work process will go on, according to Warner.

"We want to continue what we started. And the way to do that is with continuous quality improvement utilizing technologies like automation and analytics as our profession continues to innovate and evolve," she said. "We've been fortunate to plan and implement solutions that augment the talents and ability of our staff to grow and be successful. We plan to continue that strategy." TDR

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Expert Lists Strategies to Cope with Cyber Attacks

Details of ransomware attack on Quest subsidiary serve as latest warning for clinical laboratories

CEO SUMMARY: Class action lawsuits filed by patients whose protected health information (PHI) was breached during a cyber attack may be one additional unwelcome consequence for clinical laboratories and anatomic pathology groups hit by a ransomware or cyber attack. This is what happened to ReproSource Fertility Diagnostics, a subsidiary of Quest Diagnostics. An expert offers steps that clinical laboratory and pathology leaders can take to better prepare for such attacks.

Ransomeware attacks continue to be a significant threat to clinical laboratories, pathology practices, hospitals, and physician groups. But one case shows how a new wrinkle has developed in this trend: a class action lawsuit from patients whose data was exposed during an attack last summer.

In August, a subsidiary of **Quest Diagnostics** was the victim of a ransomware attack on its information systems. As a result, one of the patients whose data may have been compromised filed a legal complaint against the subsidiary, **ReproSource Fertility Diagnostics**, a lab in Providence, R.I., that specializes in testing for reproductive health and fertility.

Class Action Lawsuit

In November, Rhode Island resident Jasmyn Bickham filed the lawsuit in **U.S. District Court in Massachusetts**. In the court filing, Bickham's attorneys said they filed the lawsuit on behalf of Bickham and 350,000 other patients as "a class action for damages."

For this lawsuit to move forward, the plaintiffs' attorneys will need to persuade the court to certify the complaint as a class action. That decision will depend on how many patients claim to be harmed and decide to join the case. *(See comments about this case and the cyber attack incident from Quest Diagnostics on page 18.)*

The ReproSource situation is a reminder to lab administrators and pathologists that an encryption attack, followed by a ransom demand, is not the only financial risk to the lab organization. There could be substantial legal costs if a lab needs to defend itself from litigious patients whose protected health information (PHI) was breached during the attack.

Labs Should Prepare

To protect themselves from ransomware attacks, all labs need to prepare in three ways. First, they should regularly upgrade their information systems to ensure that they have the latest in state-of-the-art security features and that all associated software is up to date. Second, they need to train staff in how to respond the instant anyone in the lab detects an attack. Third, all labs, pathology groups, and other healthcare providers need to follow the

steps that federal and state laws require after a security breach involving PHI.

To help clinical laboratories and anatomic pathology groups prepare for cyber attacks, Emily Johnson, a lawyer in Chicago with the national law firm of **McDonald Hopkins**, recommended these four steps:

- Train all laboratory staff on the proper cybersecurity protection measures, and how to identify and respond to any cyber attack.
- Add language into business associate agreements whenever possible to protect the lab if a business associate (or a subcontractor of a business associate) causes a data breach.
- Obtain insurance coverage that includes cyber liability and information security provisions.
- Establish an incident-response team that will take the lead in the event of an attack.

Cybersecurity Training

The first recommendation is that breach-prevention measures must include more than technological assistance, Johnson said.

"In addition to implementing appropriate measures—such as firewalls, data encryption, and a requirement for multifactor authentication—all healthcare providers also need to educate and train staff on how to identify and respond to cyber attacks," she said. "That's the single most important step a lab can take to protect itself because every lab is only as strong as its weakest link.

"A clinical lab can have all of the recommended IT and security safeguards in place, but it still takes just one person to create an access point, whether that's through a phishing email or some other opportunity in which the threat actors take advantage and trick somebody into giving up their credentials," added Johnson.

The second recommendation involves how labs contract with third parties. One of the most infamous data breaches involved the retailer **Target**, which received a considerable amount of bad publicity following news of an incident in 2013. While the publicity damaged Target's reputation, the breach occurred due to the missteps of a heating and air conditioning contractor that exposed Target's information system to the attack, Johnson noted.

Review Business Contracts

"Keep this situation in mind when your lab negotiates contracts with external companies," she stated. "When negotiating an agreement with other business partners, labs and pathology groups should try to get some sort of indemnity language into their contracts that addresses what happens if the business associate or one of its subcontractors causes a breach. In those circumstances, the lab should contractually obligate, where possible, those parties to be financially liable for any damages that result."

Such language, however, isn't necessarily infallible if a case goes to court. "Unfortunately, when it comes to damages, a court can decide who's responsible for what level of damages in each case," Johnson commented. "Another problem with such language is that insurance policies sometimes prohibit indemnity language in contracts, and the inclusion of such language could nullify the insurance policy.

Adjust Insurance Coverage

"On the subject of insurance, my third recommendation is that the legal teams at clinical labs and pathology groups should have insurance policies that address liability for cyber attacks and information security beaches," Johnson suggested. "Keep in mind, however, that such coverage can be costly.

"Years ago, those policies were relatively inexpensive," she continued.

"However, because of the growing number of healthcare entities suffering breaches, premiums for this coverage have been rising. Despite growing costs of such policies, it is absolutely critical that labs and pathology groups have some sort of cyber liability coverage."

Recommendation number four is that labs also should have an incident response team in case of a cyber attack.

"With that team in place, the clinical laboratory has a trained team ready to respond to any attack immediately," Johnson said. "The team would work together to respond to the attack, and should include the lab's IT experts, human resources staff, legal team, and a cyber liability insurance broker.

Incident Response Team

"When any lab gets hit with a ransomware attack, it's also important to have cybersecurity forensic investigators ready to review what happened," she added. "Every lab needs someone with that expertise to investigate which files—if any—were viewed and whether any of the lab's files were exfiltrated, meaning they were taken off of a server either by copying or removing and deleting the originals.

"The forensic team will review the available evidence in an attempt to identify any files that were compromised," Johnson stated. "Having that information will be critical in determining whether the incident resulted in a breach that requires notification to impacted individuals."

Mac McMillan, CEO and President of **CynergisTek**, a company in Austin, Texas, that specializes in healthcare cybersecurity, privacy, and compliance, agreed that a response team is needed after a ransomware attack or data breach.

"The investigation will involve looking at all the data in your system, including the system logs, to identify when the organization was first aware that something was wrong," McMillan advised. "The date and time that the clinical laboratory staff knew about any breach or malware attack is always important to lawyers and government regulators.

Hackers Got Patients' Financial Data

ON AUG. 8, 2021, HACKERS ACCESSED THE NETWORK AT REPROSOURCE FERTILITY DIAGNOSTICS, a lab company in Providence, R.I., and exposed the protected health information (PHI) of at least 350,000 individuals, according to a court filing.

The PHI included Social Security numbers, addresses, dates of birth, and health insurance billing information, which healthcare data experts have said are among the most valuable to hackers who sell that information on the dark web. *(See TDR, "Ransomware Attackers Target Healthcare Providers," May 24, 2021.)*

In a lawsuit that a patient filed in November, lawyers for the plaintiff alleged that ReproSource discovered the ransomware attack on Aug. 10 and began notifying customers on Sept. 24.

The plaintiff is Jasmyn Bickham, who received care at a ReproSource clinic in Providence in 2015. ReproSource notified Bickham on Oct. 21, 2021, that her PHI had been compromised in the breach, the 53-page lawsuit said.

In the complaint, the plaintiff charges that ReproSource's actions in the case include negligence, breach of contract, breach of implied contract, and breach of fiduciary duty. Under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, a patient's PHI is protected.

The complaint charges that ReproSource failed to take appropriate steps to protect patients' data while healthcare providers' systems have come under repeated attacks and after officials have issued warnings about the need for all companies to protect their data from hackers, the lawsuit charged.

"In the ReproSource case, the date of the incident is important because the plaintiff's lawyers have argued that ReproSource failed to report the incident to its patients within the 60 days as required by law," he added.

Patients Notified of Attack

In response to a request for comment by The Dark Report, Quest explained that it is not clear whether any PHI was stolen.

"ReproSource provided notice that it experienced a data security incident in which an unauthorized party may have accessed or acquired protected health information and personally identifiable information of ReproSource patients. Quest Diagnostics' systems were not affected by this incident," Quest said.

"While an investigation did not confirm that the unauthorized party acquired data in the incident, out of an abundance of caution, ReproSource notified individuals whose personal information may have been accessed," Quest added.

On Oct. 8, ReproSource issued a notice about the data breach. In the five-page notice, the subsidiary explained the steps it took to address the issue and offered assistance to individuals whose PHI may have been compromised, including complimentary credit and identity monitoring services.

Unauthorized Access

"On Aug. 8, 2021, an unauthorized party accessed the ReproSource network," the notice says. "We discovered ransomware on the morning of Aug. 10, and in less than an hour we severed all network connection activity and contained the incident. We immediately launched a comprehensive investigation to determine the cause and scope of the incident. We retained leading cybersecurity experts to assist with our investigation, confirmed containment of the ransomware, and quickly and securely recovered operations. Additionally, we promptly notified law enforcement."

Beyond looking at the ReproSource case, clinical lab executives will also want to keep an eye on more recent threats.

For example, on Dec. 16, *Wired* magazine reported that in the first week of December, hackers committed what the publication called "a seismic event." The report noted that an open-source library called Log4J, which web servers use worldwide, was exposed to relatively simple attacks from hackers.

The Federal Trade Commission recognized this threat and posted the following statement on its website:

> *Log4J is a ubiquitous piece of software used to record activities in a wide range of systems found in consumer-facing products and services. Recently, a serious vulnerability in the popular Java logging package, Log4J (CVE-2021-44228) was disclosed, posing a severe risk to millions of consumer products to enterprise software and web applications. This vulnerability is being widely exploited by a growing set of attackers.*

Log4J Cyber Threat

"The first wave of hacking is well underway," *Wired* noted in its coverage of the Log4J hack. "But it's what comes next that should worry you."

McMillan warned that what's disturbing about the Log4J attack is that in the coming weeks or months, it could lead to more ransomware and other attacks on cybersecurity infrastructure in healthcare and other industries.

It is recommended that lab administrators and pathologists elevate cybersecurity threat protection in their labs' strategic planning and daily operations. Prevention is the best strategy, given the fact that an encryption attack can totally shut down all information system access and functions in the targeted lab. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Imagine a medical lab temporarily closing because of the demand for too many tests! That's just what happened at one of Australia's largest medical lab companies. **Australian Clinical Labs** had to temporarily discontinue offering COVID-19 testing because test volumes had gotten too large. Australian Clinical Labs operates dozens of drive-through and walk-in testing sites in Sydney, but the company announced on Jan. 3 that many of those locations would temporarily close because of overwhelming demand, reported the *Australian Broadcasting Company* (ABC). The Health Services Union, which represents hospital workers, told ABC that healthcare providers are feeling the strain from "under investment" in COVID-19-related resources.

MORE ON: *COVID-19 Testing Volumes*

Meanwhile in U.S., **Quest Diagnostics** in Secaucus, N.J., reported two-to-three-day turnaround times for PCR COVID-19 tests, which the company categorized as abnormally long. To combat the delays, Quest planned to use its ground couriers and aircraft to balance test volume across its two dozen COVID-19 testing labs while also reactivating a partner program to send excess SARS-CoV-2 test volumes to other commercial and academic laboratories.

RAPID GROWTH IN GENETIC TESTING

Recently the **US Department of Health and Human Services** (HHS) **Office of the Inspector General** (OIG) released a report on Medicare Part B clinical laboratory testing. For the years 2016-2019, the OIG reported that genetic test claims paid by Medicare jumped from from 627,000 to 2.1 million (up 235%). During that same time, payments for laboratory genetic tests quadrupled from $351 million to $1.41 billion. Investors are responding to this opportunity, because the OIG noted that the number of lab organizations that were paid more than $1 million per year by Medicare grew from 26 in 2016 to 72 in 2019.

TRANSITIONS

- **Your Health Lab** of Victoria, Texas, named Gary Huff as the new CEO. Huff previously was CEO at **Labcorp Diagnostics**, and worked at **Baylor Genetics**, **Solstas Lab Partners**, and **Affinity Solutions International**.

- Charles Root, PhD, Founder and Senior Consultant of **CodeMap**, based in Chicago, died on Sept. 15, 2022. He was 79. Root's PhD was in nuclear physics. He was a serial entrepreneur and co-founded CodeMap with his son, Gregory Root, in 1998. CodeMap was respected for its expertise in coding and reimbursement issues concerning clinical laboratory services, particularly molecular and genetic tests.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 31, 2022.

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UPCOMING...

- ***What CLIA inspectors found when inspecting State of California's Valencia COVID-19 testing lab.***
- ***Australian-based Harrison.ai raises AU$129 million to develop AI for use in pathology and radiology.***
- ***How clinical laboratories are responding to the Omicron-fueled wave of COVID-19 testing.***

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