



# Med Tech Training Breakthrough!

**ARUP Labs, Univ. of Utah Obtain Federal Funds to Start New Medical Technologist Training Center**

See pages 9-12.



From the Desk of R. Lewis Dark...

# THE R. LEWIS 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



### Acquisitions Bloom, at the Expense of Hospital Labs?

READERS WILL UNCOVER A THEME OF MERGERS AND CONSOLIDATIONS running throughout this issue of THE DARK REPORT. Whether it be health systems acquiring or merging with each other or national laboratory companies seeking to run hospital lab businesses, it is an unstable time for just about any type of healthcare organization.

This is consistent with a 2023 trend we identified in our Jan. 3 issue involving the acquisitions and mergers of hospitals and health systems. Multiple forces fuel this trend, ranging from supply chain disruptions and mandated cost cutting to increased labor expenses and high rates of inflation. These factors contribute to an environment in which mergers and acquisitions can blossom.

Case in point is our story on pages 3-8 about the pending merger between **Sanford Health** and **Fairview Health Services**. If the deal goes through, the new system will have 58 hospitals across five states.

Fairview reported a loss of \$562.9 million for the nine months that ended on Sept. 30, according to *Becker's Hospital CFO Report*. Sanford, meanwhile, has its own payer arm, and it may believe that increasing its market reach is worth shouldering half a billion dollars in losses from this merger. Expect to see serious cost-cutting post-merger as duplicate and redundant services are axed. Talk of increased efficiencies might also lead health system administrators to examine clinical laboratory and pathology services, possibly as a service line to sell or outsource to a third party.

Such an action would please the two Blood Brothers. They see taking over hospital laboratories as a major opportunity. For example, in 2022, **Labcorp** began running as many as 100 hospital laboratories for **Ascension Health**. The company also acquired certain assets of Ascension's lab outreach business in different regions. Meanwhile, Ascension says it received \$400 million for the lab outreach assets, which it may view as a win in the current financial climate.

Clinical laboratory administrators and pathologists also should not overlook the significance of two big, multi-hospital health systems merging, such as the Sanford and Fairview deal. Each time two such health systems merge, odds are great that the merged organization will want to standardize, rationalize, and consolidate all clinical lab testing within the combined system. **TDJR**

# Sanford Health to Merge with Fairview Health

➤ Deal would create 58 hospital mega-system; merger date moved back from March to May 31

➤➤ **CEO SUMMARY:** *It's the latest example of a merger involving two big integrated delivery networks (IDNs). Sanford Health in South Dakota inked an agreement to merge with Fairview Health Services in Minneapolis. This deal confirms the growing trend of consolidation among multi-hospital health systems. The question of greater interest for clinical lab managers and pathologists is this: Does consolidation among health systems mean more consolidation of those hospital labs involved in these IDN mergers?*

**W**HEN COMPLETED LATER THIS YEAR, THE MERGER of **Sanford Health** of Sioux Falls, South Dakota, and **Fairview Health Services** of Minneapolis will alter the competitive landscape in both metropolitan areas. The merger will result in a system with 58 hospitals and nearly 79,000 employees across Minnesota, North Dakota, South Dakota, Iowa, and Wisconsin.

Clinical laboratory administrators and pathologists should recognize this deal as an important example of the growing trend of sizeable multi-hospital health systems merging to create what can be described as mega-IDNs (Integrated Delivery Networks).

These blockbuster deals are concentrating the ownership and control of the country's healthcare and diagnostic services. Also, post-merger, what lies in the

future for the clinical laboratories of these two organization is unknown.

Sanford is one of the largest rural health systems in the country. In an announcement of the merger, Sanford said the move would bring together its experience serving rural populations with the experience in serving urban areas that Fairview brings to the deal.

The merger's stated goals include providing more people better access to equitable healthcare services and accelerating value-based care. News of the pending merger was met with opposition by the **University of Minnesota** and Minnesota state officials.

Sanford has its own partnership for medical student training with the **University of South Dakota Sanford School of Medicine** and the **University of North Dakota School of Medicine and**

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

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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).

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**Health Sciences.** Sanford also has a payer arm called **Sanford Health Plan** with 200,000 members.

Should the merger be finalized, Sanford and Fairview will remain non-profit companies, each with their own regional presence, leadership, and board of directors. The name of the parent company will be Sanford Health. Sanford CEO Bill Gassen will serve as president and CEO of the combined system, while Fairview CEO James Hereford will serve as co-CEO for a period of one year following the completion of the deal.

### ► **Billions at Stake**

System finances likely played a part in merger talks between Sanford and Fairview. Hospitals across the country are struggling with the triple whammy of exploding costs, rising labor expenses, and a surge in the rate of inflation. Clinical laboratories within those facilities face the same pressures.

Sanford earned \$5.2 billion in revenue in 2021, according to IRS documents provided by the company to *KELO-TV* in Sioux Falls. That amount was similar to its 2020 earnings.

Fairview's earnings in 2021 were \$6.5 billion, according to *ProPublica*. That was up from \$6.1 billion in 2020. However, Fairview posted an operating loss of \$164 million for the first half of 2022, more than double that year over year.

### ► **Financial Challenges**

Healthcare management consulting firm **Kaufman Hall** in Chicago reported in February that hospitals entered 2023 with continuing financial challenges.

"Volumes, emergency department visits, discharges, and total revenues were down in January 2023 compared to December 2022," according to a **Kaufman Hall** update. "Expenses—particularly related to labor—increased over the same time period, though not as fast as in previous months."

"Sanford in this deal is the more powerful system with the stronger finances," said Tyler Trask, Director of New Product Development at **Darwin Research**, a healthcare consulting and research firm in Scottsdale, Arizona. "Fairview has had financial difficulties for the last several years. If you look at Fairview's patient revenue growth and its margins, it is not nearly as strong as Sanford."

### ► **Minnesota Attorney General**

Cross-regional mergers of IDNs and health systems often include a level of outside scrutiny. That quickly became the case when Sanford announced its intent to merge with Fairview.

Almost immediately following the November announcement, Minnesota Attorney General Keith Ellison announced a series of public hearings to gauge the community's feelings about the merger. Sanford and Fairview planned to complete the merger on March 31, but Ellison asked the systems to delay that closing to provide more time for community input, *Healthcare Dive* reported on Jan. 30.

The systems agreed to extend the target completion date until May 31, according to a Feb. 10 report by *Minnesota Public Radio*.

Back in 2013, Sanford also attempted to merge with Fairview. That deal fell apart after the Attorney's General Office raised concerns and Sanford backed out. Sanford had also announced plans in 2020 to merge with **Intermountain Healthcare** (as of 2023 known as **Intermountain Health**), but a CEO shuffle prompted Sanford to back away from the deal.

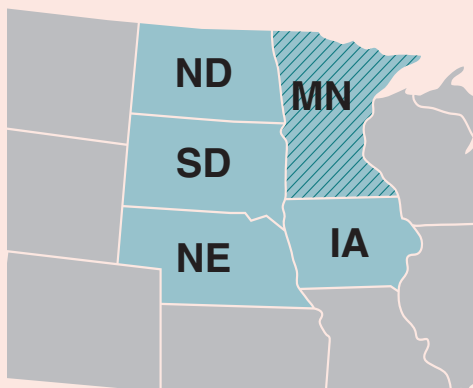
Adding to the mix, on Feb. 24, the University of Minnesota—which maintains a business relationship with Fairview—asked the state to purchase three hospitals and other clinics from Fairview and operate them.

The request would cost the state \$950 million and was made in opposition to a merged Sanford/Fairview controlling Minnesota's academic medical centers.

# Sanford Health and Fairview Health Services Is the Latest Mega-Merger of Two Huge IDNs

**T**HERE ARE INTERESTING ASPECTS TO THE PENDING MERGER of Sioux Falls, S.D.-based Sanford Health and Minneapolis-based Fairview Health Services. For starters, the geographies covered by the two integrated delivery networks (IDNs) abut and some-

what overlap each other. There is also the potential for Sanford, proficient at serving rural communities, and Fairview, experienced at serving urban areas, to exchange best practices that benefit patients and physicians in their respective service areas.



## Map of States to be Served Post-Merger by Sanford, Fairview

At left is a map that shows where each health system operates hospitals, free-standing emergency rooms, physician clinics, and other clinical services.

-  Blue: States served by Sanford Health
-  Cross Hatch: State served by Fairview Health Services

## At-a-Glance Two IDNs Poised to Merge

**SANFORD**  
HEALTH

### Sanford Health

- **CEO:** Bill Gassen
- **Founded:** 1894 (renamed in 2007)
- **Number of hospitals:** 47
- **Number of employees:** 47,757
- **Revenue:** \$5.2 billion in 2021
- **Market reach:** One million patients across four states

 **FAIRVIEW**

### Fairview Health Services

- **CEO:** James Hereford
- **Founded:** 1906
- **Number of hospitals:** 11
- **Number of employees:** 31,000
- **Revenue:** \$6.5 billion in 2021
- **Market reach:** 2.1 million patients in two states

Sanford and Fairview indicated they were willing to work with the university regarding plans for the hospitals.

► **Hospital Ownership Change**

Anytime a hospital is involved in a change of ownership, stakeholders in the community regularly rise up to oppose or criticize such transactions. This is par for the course and one of the risks of healthcare mergers and acquisitions that involve multiple hospitals across multiple communities, Trask said.

He noted that multi-state system mergers often run into regional cultural issues when an outside entity proposes to run local healthcare services, so it was not a surprise to see Sanford and Fairview attempt to get ahead of the concern.

“Sanford is trying to move into a new state and they’re saying, ‘We’re just like you. We’ve got the same small-town, hardworking, Midwestern values,’” Trask observed.

► **Pushback to Mergers**

“Anytime these large IDNs merge, there’s going to be some pushback from legislatures, from clinicians, and from community members,” he noted. “If the health systems involved in the merger can get through all of that and maintain their brand images, then deals finalize and go forward. The economics—at least from the health systems’ perspective—generally support those mergers.”

One of the more interesting aspects of the merger is whether the Dakotas have the same culture as Minnesota, and in particular the metropolitan Twin Cities area. In announcing the merger, the two IDNs noted that the combined system would share their Midwest values.

Yet, University of Minnesota officials balked at a company in a different state controlling Minnesota academic medical centers.

“Control of Minnesota’s academic healthcare assets by a South Dakota-based entity is a non-starter,” said Jakub Tolar,

**T. Denny Sanford Is Major Benefactor**

**A**LTHOUGH ITS ROOTS STRETCH BACK TO 1894 and the establishment of **Sioux Falls Hospital** in South Dakota, the modern-day Sanford Health got its moniker from a philanthropist in 2007. That year, T. Denny Sanford bestowed a gift of \$400 million to the former **Sioux Valley Health System**.

Sanford grew up in a working-class neighborhood in St. Paul, Minnesota. He founded multiple companies, including **Contech, Threshold Ventures, and First Premier Bank**.

In total, Sanford has given \$1.3 billion to the integrated delivery network, including \$650 million in 2021 alone during the SARS-CoV-2 pandemic, according to Sanford Health Foundation.

Sanford’s money has been earmarked for endeavors such as increasing healthcare access to rural residents, expanding opportunities for graduate medical education, and launching an initiative to include genomic medicine in primary care for adults.

“[Our effort] aims to bridge the separation between laboratory research and clinical practice,” Sanford told *Philanthropy Roundtable* in a 2016 interview.

“Denny Sanford is part of a group of a select few individuals who are trying to make an impact on American healthcare through philanthropy,” said Tyler Trask, Director of New Product Development at consulting firm Darwin Research.

MD, PhD, Dean of the University of Minnesota Medical School, in a news release.

“The charitable assets of the university’s academic health facilities and operations have been supported by Minnesotans and must be governed by the University of Minnesota,” Tolar added. **TDR**

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# Laboratory Implications of Sanford, Fairview Merger

➤ Post-merger, IDN administration often rethinks value of the combined system's clinical laboratories



Tyler Trask

➤➤ **CEO SUMMARY:** *Not too many years ago, many hospitals and health systems were bullish on their laboratory outreach businesses. But financial pressures on hospitals and health systems may be causing the pendulum to swing in the direction of hospitals selling their lab outreach programs, suggest two healthcare researchers.*



Genna Hill

**C**OMMENTING ON THE SIGNIFICANCE OF THE PENDING MERGER of Sanford Health and Fairview Health Services, two keen observers of healthcare and the hospital sectors think these health system mega-mergers may cause administrators to look differently at the financial opportunities associated with their hospital laboratories.

“Generally, when we see these huge [health system] mergers, it may take a while, but eventually within a few years the parent system begins reviewing the clinical lab capabilities,” said Tyler Trask, Director of New Product Development at Darwin Research, a healthcare consulting and research firm in Scottsdale, Arizona.

## ➤ Increased Lab Investment?

“Eventually in this merger between Sanford Health and Fairview Health Services, you could see some improved lab capabilities and increased investment in rural sites,” Trask added. “But almost inevitably you’ll see a shift in which some of the testing is done by centralized laboratories. Also, we don’t fully know what arrangements either Sanford or Fairview

has with third-party laboratories that they’ll need to reconcile.”

There is evidence to support the assertion that mergers between multi-hospital health systems can contribute to the erosion of hospitals controlling their own clinical laboratory services and outreach programs. In some cases, to raise cash, the health system may sell its laboratory outreach business to one of the billion-dollar lab corporations. There are examples of health systems outsourcing inpatient lab management to national lab companies.

“Something to watch with deals involving two or more health systems that cover a large geographic area is the ownership of these hospital laboratory outreach programs,” observed Genna Hill, National Account Director at Darwin Research. “Years ago, it seemed to be everybody in a hospital system was rushing to put together laboratory outreach programs.

“Now we see the pendulum swing a bit the other way, with some hospitals leaning more towards having the **Labcorps** and **Quest Diagnostics** of the world buy the lab outreach business and maybe also take over a hospital’s inpatient core lab

and run it,” she continued. “Especially with more complicated diagnostic tests and screenings coming on board, hospital systems seem to be more open to having a commercial laboratory as a partner.”

### ► Recent Hospital Lab Deal

For example, in August 2022, Labcorp acquired the laboratory outreach business of 11-hospital **RWJBarnabas Health** in New Jersey. RWJBarnabas was formed by the merger of the **Robert Wood Johnson Health System** and **Saint Barnabas Health Care System** in 2015.

“A twist in the Sanford Health/Fairview Health Services deal is that both health systems have access to academic medical centers that have specialized laboratory analyzers capable of conducting complex diagnostic tests,” Trask observed. He said that it remains to be seen how the academic relationship might affect a prospective offer from a national laboratory company to run diagnostic operations at the post-merger Sanford-Fairview IDN.

### ► Pendulum Swing Metaphor

Trask and Hill make an interesting observation, using the metaphor of the pendulum swing. They note how it was widespread some years ago for hospitals and health systems to invest in laboratory outreach programs. In assessing the post-merger actions by a number of large health systems, they speculate that the pendulum is now swinging in the opposite direction, with some health system administrators more willing to sell their laboratory outreach programs, as well as invite a commercial lab company to operate their inpatient laboratories.

Of course, there are many lab administrators and pathologists who make persuasive arguments that selling the outreach lab business and/or having a third party manage the inpatient labs is not in the best interest of the parent hospitals. **TDR**

Contact Tyler Trask at [ttrask@darwin-research.com](mailto:ttrask@darwin-research.com) and Genna Hill at [ghill@darwinresearch.com](mailto:ghill@darwinresearch.com).

## Recent Mergers Involving Large IDNs

**INTEGRATED DELIVERY NETWORK MERGERS** have marked significant shakeups of hospital ownership in the U.S. Here are a few:

- In 2023, a proposed merger is expected to close between Sanford Health in Sioux Falls, South Dakota, and Fairview Health Services in Minneapolis. The new company, which will be called Sanford Health, will have 58 hospitals, and take in an estimated \$12 billion in revenue.
- In 2022, **Atrium Health** in Charlotte, North Carolina, announced a merger with **Advocate Aurora Health**, co-headquartered in Downers Grove, Illinois, and Milwaukee. The combined company is called **Advocate Health**. This merger resulted in a health system with 67 hospitals and more than 1,000 ambulatory clinics across six states, with \$27.1 billion in revenue.
- In 2022, **Intermountain Healthcare** in Salt Lake City and **SCL Health** in Broomfield, Colorado, combined into Intermountain Healthcare. With 33 hospitals, the new IDN has estimated earnings of \$14.2 billion.
- In 2013, **Baylor Health Care System** in Dallas and **Scott & White Healthcare** in Temple, Texas, merged to become the largest not-for-profit health system in Texas. Subsequently known as **Baylor Scott & White Health**, the system currently has 51 hospitals and 800 patient care sites. It boasted annual revenue of about \$10.5 billion in 2021.
- In recent weeks, Des Moines, Iowa-based **UnityPoint Health** and Albuquerque, New Mexico-based **Presbyterian Healthcare Services** announced merger plans that would form a system with more than 40 hospitals across four states.



# ARUP, University of Utah Create MT Training Center

➤ **ARUP Laboratories and University of Utah used employment data to secure \$3M in federal funding**



**Tracy George,  
MD**

➤➤ **CEO SUMMARY:** *To help resolve the ongoing shortage of MTs and MLSs, ARUP Laboratories and the University of Utah's Medical Laboratory Sciences Division took a novel approach to secure funding for a new laboratory scientist training center. They worked with their congressional representative to obtain federal funds for the project.*



**Diana  
Wilkins, PhD**

## PART ONE OF TWO PARTS

**F**ACED WITH THE SAME SHORTAGE OF MEDICAL TECHNOLOGISTS (MTs) AND MEDICAL LABORATORY SCIENTIST (MLSs) as other clinical laboratories across the United States, two Utah lab organizations took a uniquely creative approach to fund and launch a training center for laboratory scientists.

**ARUP Laboratories** recently secured federal funding of \$3 million specifically to build a new clinical lab training center in partnership with the Medical Laboratory Sciences Division at the **University of Utah School of Medicine**. Both organizations are based in Salt Lake City and worked closely together.

The project offers a novel solution to the MT and MLS staffing shortage that medical labs in other parts of the country will want to study and emulate.

"We want this training center for laboratory scientists to be a model for the nation," said Tracy George, MD, President and Chief Scientific Officer at ARUP. "We're fully invested in making this work."

George—along with Jonathan Genzen, MD, PhD, Chief Medical Officer at ARUP,

and Diana Wilkins, MS, PhD, Chief of the Division of Medical Laboratory Sciences in the university's Department of Pathology—spoke to THE DARK REPORT about the project.

These innovators explained the steps they took to get the endeavor rolling, beneficial political nuances they recognized, and considerations for other labs facing long-term training needs for future workers.

Part one of our intelligence briefing on this important accomplishment is presented in the following pages. It explains the data that organizers uncovered in support of a request for federal funding, where they found this evidence, and how they presented it to lawmakers.

Part two, to be published in a subsequent issue, outlines the path forward for ARUP and the University of Utah as they bring this training center up to speed, along with advice for how other labs can replicate their success in funding and building their own MT and MLS training centers.

ARUP received \$3,055,000 for the project in the year-end omnibus bill that

Congress passed to keep the federal government operating. That bill received plenty of attention from clinical laboratories because several high-stakes lab initiatives were dropped from the 4,000-page legislation. (See *TDR*, “Congress Averts PAMA Cuts to Lab Test Rates for 2023,” Jan. 3, 2023.)

### ► Details on Training Center

Formally called the Advanced Practice Clinical Laboratory Training Center, the new facility will be completed in 2024.

Medical laboratory science students at the University of Utah will gain advanced clinical diagnostic testing experience at the new clinical lab training center before finishing their clinical education in more specialized testing environments at ARUP Laboratories or other locations.

The federal funds will pay for the center’s construction as well as state-of-the-art instrumentation that students will use there.

The university’s Medical Laboratory Sciences Division will develop and fund new educational curriculum and provide the necessary faculty and staff for the training center.



In addition, the division received internal university grant funding to purchase a laboratory information system (LIS) that can be used by students at the new training center.

Wilkins said the new facility—which will be located on the ARUP Laboratories campus at the **University of Utah Research Park**—will enable the division to reach a goal of doubling to 80 the number of annual medical laboratory science undergraduates.

“Many programs across this country are exploring ways to offset their need for clinical site training by establishing simulation training facilities,” Wilkins observed. “But those can be difficult to scale up. They also are expensive to fund and maintain over the long term for most academic institutions. However, the ARUP training center is designed to scale up so as to rapidly accommodate growth of the program while also providing the mechanism required to maintain this center over the long term.”

### ► Evidence to Support Funding

Strong evidence of the need for more MTs and MLs helped the training center proposal make it past stiff competition from hundreds of other funding requests submitted during the last Congress.

“We looked at two major sources of information,” Wilkins said. “The first was data that’s available through the **Bureau of Labor Statistics**. The bureau gives a projected outlook at what occupations will be in demand in coming years. Data for both 2021 and 2022 suggested there is a continuing, nationwide shortage of medical lab scientists. We used that data to support the rationale for federal funding of the new training center.”

ARUP and the university’s Medical Laboratory Sciences Division also turned to data from the **American Society for Clinical Pathology’s** (ASCP) 2020 Vacancy Survey. Analysis of the survey indicated a need for more qualified laboratory personnel and additional solutions to staffing challenges, according to ASCP.

“We used the data to show a growing need for qualified, well-trained people in the clinical laboratory field,” Wilkins noted. “Having this information available while also being in the middle of a pandemic—when labs were being increasingly called upon to handle the testing needs for the community at large very quickly—confirmed that labs need more graduates in the medical lab science field.”

## Where to Find Useful Laboratory Employment Statistics

**C**LINICAL LABORATORY LEADERS WILL FIND IT HELPFUL TO UNDERSTAND where ARUP Laboratories and the University of Utah found the lab employment data they used to build their case for federal funding of the new lab scientist training center.

Two primary sources of information became pivotal: the U.S. Bureau of Labor Statistics and the American Society for Clinical Pathology's (ASCP) 2020 Vacancy Survey results.

### ➤ Bureau of Labor Statistics

The Bureau of Labor Statistics publishes a substantial volume of data about job demand and employment. But there are ways for clinical labs to significantly narrow information gathered from the bureau.

ARUP Laboratories and the University of Utah turned to the federal agency's online Occupational Outlook Handbook. The handbook outlines professional information about thousands of job categories, including clinical laboratory scientists and medical technologists.

In its entry on that lab occupation, the handbook explains what the job entails, typical salary, and expected demand for the position, among other items.

"Employment of clinical laboratory technologists and technicians is projected

to grow 7% from 2021 to 2031," the handbook notes. "About 25,600 openings for clinical laboratory technologists and technicians are projected each year, on average, over the decade. Many of those openings are expected to result from the need to replace workers who transfer to different occupations or exit the labor force, such as to retire." Go to [www.bls.gov/oooh/](http://www.bls.gov/oooh/) to view the handbook's homepage.

### ➤ ASCP Vacancy Survey

Meanwhile, the ASCP conducts its Vacancy Survey every two years to chronicle workforce shortages in medical labs. Results of the 2020 survey were released in the June 2022 issue of the *American Journal of Clinical Pathology* (AJCP).

The AJCP's article provided in-depth detail about employment trends across various clinical lab specialties, retirement patterns, and job vacancy rates by region of the United States.

"According to some participants, it is becoming more difficult to find qualified staff and retain them, especially for certain shifts and in rural areas," the article's authors noted. Go to [academic.oup.com/ajcp/](http://academic.oup.com/ajcp/) to read the full results in the journal's archives.

So, the data supported the rationale that we were in the right place at the right time for this federal funding."

Wilkins and George knew each other from lab executive leadership meetings both attended in the Salt Lake City area.

"I remember Diana bringing up the idea of a mock laboratory—a training facility intended to meet the need of getting more students into clinical lab rotations," George recalled. "And we thought, 'How can we make this work?'"

George knew of community partnership funding available through the office of U.S. Rep. Chris Stewart (R-Utah).

"ARUP has been giving lab tours to various Utah legislators to let them know they had a great laboratory right in their backyard," George said. "We showed the legislators some of the cool work we're doing and told them we have a big outreach in STEM with high schools and academic medical centers. So, we were making the right political connections when this idea for the training center came about."

In early 2022, organizers of the training center filed an application for this funding with Stewart's office. The organizers provided the data gathered from the

## University Funds New LIS

**A**DVANCED PRACTICE CLINICAL LABORATORY TRAINING CENTER'S new laboratory information system (LIS) was not part of the federal funding request made for the project. Instead, the University of Utah provided internal grant money to its Medical Laboratory Sciences Division for the LIS.

"The university has an annual grant mechanism in which faculty can put together an application for technology funding through the university for unique projects," said Diana Wilkins, PhD. "One thing we did not have in our student lab was an LIS. It would be ideal to expose students to an LIS before they enter the workplace.

"So, we put together a proposal," she added. "We obtained funding through the university's educational computing fund to help support the LIS software and licensing purchase. We also received internal funds through the Department of Pathology for requisite hardware."

IT and software teams are currently in the process of implementing the LIS so that it will be operational once the training center opens.

Bureau of Labor Statistics and American Society for Clinical Pathology, as well as community support letters.

### ► Use of Taxpayer Dollars

"There is a formal application process that we worked through," Genzen explained. "I can't speak to how legislators prioritize projects, but it was a thorough and fair submission process where we described what we thought the training facility should be. I imagine that was a big factor in how Congress prioritizes which projects ultimately receive funding."

The clinical laboratory training center was among 15 projects Representative Stewart submitted for federal commu-

nity funding and subsequently certified to the U.S. House of Representatives' Appropriations Committee.

"This project is a good use of taxpayer dollars due to the impact to the workforce and development of medical science students," Representative Stewart wrote in his certification letter.

### ► Economic Value Predicted

George predicted that, once the laboratory scientist training center is complete, the return on investment will be achieved in only a few years.

"If we're talk conservatively about doubling the medical school's laboratory scientists program from 40 to 80 students, this training center will be a critical piece of it," she explained. "If the school graduates an extra 40 students per year, in five years that's 200 more students. There's an economic impact in producing 200 additional clinical laboratory scientists."

More MTs and MLSs will also bring benefits to healthcare services in a community even if those people move out of the Salt Lake City area.

"The value of more graduates is their ability to deliver healthcare to patients all across the country," Genzen noted. "And that could impact millions of people just based on the number of students that we're able to train."

Progressive clinical laboratories and pathology practices will be quick to note that the efforts of ARUP and the University of Utah could be replicated elsewhere, perhaps with different circumstances but ultimately the same results.

In part two of our report, training center organizers will explain the tactics they recommend other labs use when submitting requests for funding of laboratory scientist training programs to government agencies or other sources. **TDR**

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**Legal Update**

# Elizabeth Holmes' Appeal Questions Competence of CLIA Lab Director

*Former Theranos CEO is labeled a 'flight risk' by prosecutors, drawing the ire of defense team*

**T**ANTALIZING DETAILS ABOUT FORMER **THERANOS** CEO ELIZABETH HOLMES' purchase of a one-way-plane ticket to Mexico prior to her conviction grabbed headlines following the filing of a motion to appeal her conviction.

However, for clinical laboratory directors, the relevant information in the latest motion filed by Holmes' lawyers centers on Adam Rosendorff, MD, a pathologist who was a star government witness in Holmes' trial. Rosendorff was lab director for Theranos under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). He worked for 21 months at the troubled blood testing lab.

## ➤ Appeal Mentions Pathologist

Following his departure as laboratory director at Theranos in 2014, Rosendorff worked in similar roles at **Invitae**, **uBiome**, and **PerkinElmer**. All three companies experienced alleged testing or CLIA improprieties during Rosendorff's tenures there, according to the defense. **THE DARK REPORT** chronicled those situations.

During Holmes' trial, the judge limited defense questioning of Rosendorff about problems at the three companies where he served as the CLIA laboratory director after working at Theranos.

"The fact that three laboratories Dr. Rosendorff oversaw after leaving Theranos had problems was probative of Dr. Rosendorff's competence as a laboratory director, his credibility as a witness, and the frequency of potential issues at high complexity laboratories," the defense stated.

Prosecutors retorted that there is no evidence Rosendorff's work at subsequent companies provided any "motive for Dr. Rosendorff to lie or slant his testimony," the government wrote in its response.

## ➤ Holmes a Flight Risk?

In the same court filings, prosecutors said Holmes and her partner, William Evans, bought one-way tickets to Mexico in December 2021, a fact confirmed by her lawyers. Prosecutors argued this information paints Holmes as a "flight risk" and that she should not be allowed to remain free pending her appeal, as her lawyers have requested.

Holmes is scheduled to report to federal prison on April 27 to serve 11 years and three months for defrauding Theranos investors. (*See TDR, "Holmes, Balwani Get Lengthy Prison Terms for Theranos Fraud," Dec. 12, 2022.*)

The defense team countered that Holmes bought the ticket to attend a friend's wedding prior to her conviction in January 2022. She did not take the flight and surrendered her passport as part of the terms of her release pending sentencing. Evans did make the trip and returned to the U.S. later.

Defense lawyers said the government was aware of what had transpired with the ticket in 2022 and had made "factual misrepresentations" in its recent filing. A hearing on Elizabeth Holmes' motion to delay the start of her prison term pending her appeal will be held on March 17, *PBS News Hour* reported.


**Lab Market Update**

# Labcorp: Ascension Deal Will Earn \$550 Million in 2023

*Public lab companies report on Q4 and full year 2022, aim to grow business in post-COVID-19 world*

**P**UBLICLY TRADED LABORATORY COMPANIES OFFERED INSIGHTS INTO how acquisitions of hospital lab operations and outreach businesses add to their bottom lines, according to recent reports on full-year 2022 and fourth quarter earnings.

Last year was a busy one for the billion-dollar lab corporations in terms of acquisitions. These huge laboratory companies are on the prowl to win contracts to operate inpatient hospital labs. They often transition local lab employees to the national company as part of those deals.

## ► Running Hospital Labs

For example, **Labcorp** in Burlington, North Carolina, signed a deal in February 2022 to manage nearly 100 hospital labs for **Ascension Health** based in St. Louis and to acquire the laboratory outreach business at a number of Ascension locations. (See TDR, “*Labcorp to Buy Outreach, Manage Ascension Labs*,” Feb. 22, 2022.)

Labcorp reported recently that the Ascension deal alone resulted in a 7% increase in non-COVID-19 base business in Q4 2022.

“We are seeing an increased number of people [hospital administrators] that are interested in looking at us running and acquiring parts of the hospital business,” said Labcorp CEO Adam Schechter during a Feb. 16 earnings call. “If you look at 2023, Ascension revenue is going to be about 5% of the base business growth. So, if you do the math, it’s approximately \$550 million to \$600 million in 2023.”

In August, Labcorp also acquired the lab outreach business of **RWJBarnabas Health** in West Orange, New Jersey.

Also last year, health system **Summa Health** in Akron, Ohio, sold select assets of its laboratory outreach business to **Quest Diagnostics** in Secaucus, New Jersey. Quest also announced in late 2022 plans to acquire outreach services and run operations for nine hospital labs at **Northern Light Health** in Brewer, Maine.

“Our [merger and acquisitions] pipeline is strong, including potential deals with health systems, small regional labs, and other capability-building assets,” commented Jim Davis, CEO at Quest, during a Feb. 2 earnings call. “In particular, the funnel of opportunities with health systems that are facing major margin pressures due to labor challenges and mix shift from inpatient to outpatient care is very active.”



## **LABCORP: Revenue Down 7.7% for Full Year 2022**

Labcorp’s revenue was down in 2022 compared to 2021, although it appears a large part of the drop was related to decreases in the number of COVID-19 tests it performed. The company announced the following results:

- 2022 revenue decreased 7.7% to \$14.9 billion compared to 2021.
- Q4 revenue dropped 9.4% to \$3.7 billion compared to Q4 2021.

- Q4 diagnostics revenue fell 12.8% to \$2.3 billion.
- Q4 COVID-19 testing revenue fell 20.7%.
- Q4 base business (i.e., non-COVID-19) growth of 10.6%.

Schechter updated analysts and investors on Labcorp's plans:

- The spinoff of the company's clinical development business, now named **Fortrea**, will be effective in mid-2023.
- Oncology expansion continues to be a priority, as in Q4 Labcorp launched a liquid biopsy test called Plasma Focus intended "to match cancer patients with FDA-approved therapies using the patient's circulating tumor DNA taken from a blood draw," Schechter explained.
- Labcorp sees opportunities to grow with tests related to neurodegenerative, autoimmune, and liver diseases, as well as cell and gene therapy, he said.

Labcorp's diagnostic test volume for Q4 2022, based on number of requisitions, decreased by 11.8% compared to Q4 2021. Less demand for COVID-19 testing played a role in the drop.

The price per test dropped 1% in Q4 2022 compared to the prior year. However, taking COVID-19 tests out of the equation, the base business price per test increased by 7.6%. That included the addition of Ascension's labs.

The company did not release full-year figures for volume and price.



### QUEST DIAGNOSTICS: COVID-19 Revenue Plummets

Similarly, Quest Diagnostics reported lower earnings compared to 2021, but it said non-COVID-19 business was a bright spot during the past year. Results included the following:

- 2022 revenue was \$9.9 billion, down 8.5% from 2021.
- 2022 base business revenue (non-COVID-19) climbed 5.1% to \$8.4 billion.

- 2022 COVID-19 testing revenue dropped 47.5% to \$1.4 billion.
- Q4 revenue was down 15% to \$2.3 billion compared to Q4 2021.
- Q4 base business revenue grew 6.3% to \$2.1 billion.
- Q4 COVID-19 testing revenue plunged 74.6% to \$184 million.

Davis shared these business observations and growth plans:

- Quest Diagnostics' fastest growing opportunities are genomic sequencing services, prenatal and hereditary genetic testing, and pharmaceutical services.
- To grow prenatal genetics, Quest added reps to its women's health sales team.

In response to an analyst's question on growth in 2023, Davis said at-home testing is an area on which to focus.

"Consumer-initiated testing will continue to grow on the base side of our testing in 2023," he noted.

Tied into that objective, Quest will invest in genomic sequencing. "[Another] big area of investments has been in oncology and what we call genomic sequencing services and building out what we call our integrated genomics platform," Davis noted.

He added that Quest will increase participation in the development of companion diagnostics. A companion diagnostic is a lab test used in tandem with a drug therapy developed by a pharmaceutical company.

The companion diagnostic test verifies beforehand that a patient is a good candidate for the drug, based on expected benefits and side effects. This type of genetic testing is the foundation for precision medicine models of patient care.

Companion diagnostics associated with pharmaceutical work grew 15% year over year in 2022, Davis said.

Requisition volume for Quest was down 4.5% for the year and 11.2% for Q4. Revenue per requisition was down 4.5% in 2022 and 5.1% for the quarter compared to 2021.

## BioReference

LABORATORIES

### BIOREFERENCE LABORATORIES: Focus on Cutting Costs in 2023

OPKO Health, the parent company of BioReference Laboratories in Elmwood Park, New Jersey, is in cost-cutting mode after a disappointing Q4 and full year. OPKO reported the following:

- OPKO's Q4 diagnostics revenue through BioReference was \$139.4 million, a drop of 61.6% from the same quarter in 2021.
- OPKO's overall Q4 revenue, which includes other business lines, was \$185.4 million, down 53.8% from \$401.3 million.
- OPKO's total revenue was \$1 billion for 2022, down 43% from 2021. Full-year diagnostics revenue comparisons were not reported.

During an earnings call, OPKO President Elias Zerhouni, MD, shared ways the company is cutting costs and seeking to be profitable:

- BioReference eliminated \$140 million of expenses over the past year.
- Still, a \$30 million cost reduction is planned for 2023 (or 5% of the company's annual spend).
- In Q4, the company added eight new oncology sales territories and five new molecular oncology sales positions to focus on offering BioReference's cancer genomics to cancer centers, health systems, and oncology practices.
- In addition to oncology, the company plans to grow testing segments focused on women's health, urology, as well as large health system partnerships, Zerhouni said.

"Our continued priority is to return this business back to profitability post-COVID-19," Zerhouni told analysts.

Part of BioReference's cost cutting has been in employee ranks. Zerhouni said at the end of 2021, BioReference had 8,000 employees. As of February 2023, it has

## How National Lab Companies Use AI

**D**URING RECENT EARNINGS CALLS, Quest Diagnostics and Labcorp provided updates on how they use artificial intelligence (AI) in their operations.

For example:

- Progress continues on Labcorp's use of digital technology and AI in various ways, including result reports that provide deeper clinical insights to guide patient care.
- Quest stepped up use of automation and AI with an automation conversion project at its lab in Lenexa, Kansas, which should lead to quicker turnaround times and the ability to add capacity rapidly if needed. Quest is also working on an AI-powered microbiology platform to aid in sample analysis.

Labcorp has used artificial intelligence for years, applying the technology to drug development and diagnostics, including clinical laboratory workflow and operations. (*See TDR, "Labcorp Now Using AI for Operations, Patient Care," July 6, 2021.*)

THE DARK REPORT noted previously that successful AI projects at clinical laboratories analyze large amounts of data to automate processes, improve test result accuracy, and reduce human labor needed for routine tasks. (*See TDR "Artificial Intelligence Is Ready to Deliver for Labs," July 26, 2021.*)

3,330—the same as it had in 2019 before the COVID-19 pandemic.

OPKO's pharmaceutical business has one commercial stage pharm product and several pharmaceutical compounds and technologies in various stages of research and development. For lab testing services, it operates laboratory divisions, such as BioReference, GenPath (Oncology), and GenPath (Women's Health). **TDR**




**IVD Update**

# QuidelOrtho Earns \$3.3B in First Year as Combined Firm

*Company is now on the list of 12 largest IVD firms after acquiring Ortho Clinical Diagnostics in 2022*

IN OUR FEBRUARY 13, 2023, ISSUE OF THE DARK REPORT, we analyzed the 2022 full-year and Q4 earnings of major IVD companies. At the time our prior issue went to press, **QuidelOrtho** had not yet reported its year-end results.

This is the first time that San Diego-based QuidelOrtho released full-year financial results as an integrated organization. It reported revenue (excluding COVID-19 testing) of \$3.3 billion.

Formerly known as **Quidel**, the diagnostics manufacturer used its windfall revenue from sales of COVID-19 test products to acquire the similarly sized **Ortho Clinical Diagnostics** for \$6 billion in 2022. Both were *in vitro* diagnostics (IVD) companies. (See TDR, “*Ortho Clinical Diagnostics to Be Acquired by Quidel*,” Jan. 10, 2022.)

## ➤ Among 12 Biggest IVD Firms

The combined 2022 revenue total for QuidelOrtho lifts its ranking in THE DARK REPORT’S “Top 12 IVD Companies by Global Revenue” compared to the two former companies’ individual placements. Most recently, Ortho Clinical Diagnostics—with \$2 billion in 2021 revenue—was ranked 12th, the last spot on our list, and Quidel did not rank.

When the new rankings are calculated later this year, QuidelOrtho may reach the seventh or eighth position. That significant jump represents an increased share of the global IVD market and illustrates what motivates IVD manufacturers to either acquire or merge with similar companies.

Also, such consolidations are intended to bolster the competitive market position of the companies involved in such mergers.

Pre-merger, Quidel was a developer of point-of-care diagnostics and rapid tests, while Ortho Clinical manufactured chemistry, immunoassay, immunohematology technology and tests. The acquisition brought together complementary services on which the new company hopes to capitalize.

## ➤ ‘Tremendous Opportunities’

“With our combined portfolio, we see tremendous opportunities to cross-sell our products in new markets,” said CEO Douglas Bryant in a statement.

Comparing year-over-year results for QuidelOrtho compared to Quidel and Ortho Clinical as separate entities is tricky.

In its 2022 report, the merged company in some cases used “supplemental combined revenue” to compare prior financial performance, but it is not clear how this estimate was generated based on financial statements.

For this reason, though THE DARK REPORT used past earnings in our comparisons, we acknowledge this is an imperfect comparison. (For example, certain costs in separate companies, such as human resources, could be less in a merged organization.) Here are full year and Q4 details for QuidelOrtho:

- 2022 total revenue was \$3.7 billion. Ortho Clinical reported \$2 billion in revenue in 2021, while Quidel reported

\$1.7 billion, so in a simple year-over-year comparison, growth appeared flat.

- 2022 labs business unit revenue was \$1.3 billion.
- 2022 point-of-care revenue was \$2 billion.
- 2022 molecular diagnostics revenue was \$96.7 million.
- Q4 total revenue was \$866.5 million. Quidel reported \$636.9 million in Q4 2021, while Ortho Clinical reported \$518.9 million, which is a noticeable difference compared to 2022. The company attributed the Q4 drop to foreign currency being weaker compared to the U.S. dollar.
- Q4 labs business unit revenue was \$314.7 million.
- Q4 point-of-care revenue was \$374.7 million.
- Q4 molecular diagnostics revenue was \$14.6 million.

### ► Analyzer Growth Predicted

During an earnings call, Bryant told investors that QuidelOrtho sees growth potential in 2023 for Sofia, a benchtop fluorescent immunoassay analyzer; Savanna, a multiplex, real-time PCR testing platform; and VITROS, an integrated chemistry and immunoassay system.

There are currently more than 85,000 Sofia instruments installed worldwide, Bryant noted. He further broke down the percentage of Sofia instruments in different settings: physician office laboratories (POLs) (50%); hospitals (23%); urgent care centers (17%); and corporate accounts (10%).

“The Sofia franchise, with its huge installed base, is clearly a valuable asset—one that can and should be leveraged by us to the greatest extent possible,” Bryant told investors. “This is why the R&D team is so focused on developing additional tests to be added to the menu for our Sofia customers.

## Bio-Rad, PerkinElmer Sales Down in 2022

**T**WO OTHER PROMINENT *IN VITRO* DIAGNOSTICS COMPANIES reported end-of-year and Q4 financial results recently.

**Bio-Rad Laboratories** in Hercules, California, shared these numbers:

- 2022 sales decreased 4.1% to \$2.8 billion year over year.
- 2022 COVID-19 test-related revenue dropped 59% to \$109 million.
- 2022 clinical diagnostics sales were flat at \$1.4 billion.
- 2022 life sciences revenue increased 2.7% to \$1.3 billion.
- Q4 2022 sales were flat at \$730.3 million compared to Q4 2021.
- Q4 2022 COVID-19 revenue plummeted 71.7% to \$13 million.
- Q4 clinical diagnostics sales were down 8.7% to \$369.6 million.
- Q4 life science sales increased 10.1% to \$359.7 million.

During an earnings call, Andrew Last, PhD, Chief Operating Officer at Bio-Rad, said reducing clinical diagnostics order backlogs is a priority in 2023.

Meanwhile, **PerkinElmer** in Waltham, Massachusetts, reported these financial results for 2022 and Q4:

- 2022 revenue was down 13.5% to \$3.3 billion.
- 2022 diagnostics revenue fell 31% to \$2 billion.
- Q4 revenue dropped 28% to \$741 million.
- Q4 diagnostics revenue plunged 44% to \$394 million.

“The number of Sofia customers in the United States is up 6% year-over-year to around 21,400,” he added. “The number of POL customers is up 8%; hospital customers are up 2%; and urgent care customers are up 9%.”

**TDR**

# INTELLIGENCE

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



Since Congress did not include new regulations for laboratory-developed tests (LDTs) in a year-end spending budget, it appears the **Food and Drug Administration (FDA)** will take steps of its own to increase the agency's oversight of LDTs. "We are moving forward with rulemaking," said Elizabeth Hillebrenner, Associate Director for Scientific and Regulatory Programs at the FDA's **Center for Devices and Radiological Health**, at the **American Clinical Laboratory Association's** annual meeting on March 1 in Washington, D.C. The news was reported by *BioWorld*. There is no timeline yet for the rulemaking, Hillebrenner said, according to *BioWorld*.

## ➤➤➤ MORE ON: FDA LDT Oversight

The FDA had previously hinted that it would propose new LDT rules if congressional action—such as through the Verifying Accurate Lead-

ing-edge IVCT Development (VALID) Act—didn't receive support. As of mid-2022, the VALID Act appeared to be on its way to passing in Congress before pathologists, particularly, at academic medical centers, publicly voiced opposition to the bill. The VALID Act was in play in Congress' year-end spending bill in December but was cut from the final language of the legislation.

## ➤➤➤ LAB PAYS \$16,500 TO SETTLE ALLEGED HIPAA MISSTEPS

A recent settlement cost a clinical laboratory \$16,500 in fines for allegedly not providing a timely response to a routine records request. On July 1, 2021, an individual asked **Life Hope Labs** in Sandy Springs, Georgia, to provide diagnostic records for her deceased father. However, she allegedly did not receive them until February 16, 2022. In addition to the monetary settlement with the **Department of Health**

and **Human Services Office of Civil Rights**, Life Hope Labs also had to file a corrective action plan. Generally, HIPAA's Privacy Rule requires labs to provide medical records within 30 days of a request by either the patient or a personal representative of the patient.

## ➤➤➤ TRANSITIONS

- Karen Saldaña is the new Chief Operating Officer at lab IT consulting firm **U.S. HealthTek** in Haymarket, Virginia. Saldaña comes off a two-year stint at **BioReference Laboratories** and prior to that spent 20 years at Quest Diagnostics.

- Liron Pantanowitz, MBBCh, will return to the **University of Pittsburgh School of Medicine** as Chair of the Department of Pathology, effective May 1. He had a 10-year run at Pittsburgh before going to the **University of Michigan**. Pantanowitz is also President of the **Digital Pathology Association**.

*That's all the insider intelligence for this report.  
 Look for the next briefing on Monday, March 27, 2023.*

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## UPCOMING...

- **ARUP Laboratories and University of Utah offer tips on how to approach external funding requests.**
- **Atrium Health's lab leaders showcase new processes to report "closely critical" test results.**
- **New revenue! How labs can earn extra money through anonymized remnant sample data.**

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