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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

You Asked for It. We Organized It.

DESPITE THE EASING OF THE COVID-19 PANDEMIC IN RECENT MONTHS, a pre-pandemic normal does not yet exist—if it ever will. Currently, most clinical laboratories, particularly those serving hospitals and health systems, are under the most intense pressure seen in decades.

At this moment, the big three sources of major headaches for lab managers are the urgent need to control lab costs, the struggle to maintain adequate staffing across all positions, and the challenge of increasing revenue (that would help pay for increased labor costs while shrinking the budget gap). During last April's *Executive War College*, a number of lab leaders asked if it was possible to organize a gathering where lab managers could learn what's working to address the cost, staffing, and revenue issues listed above. Importantly, they wanted these gatherings to include networking with peers and an open exchange of ideas.

You asked for it. We organized it. As you will read on pages 3-6, we've developed a strategic roundtable series that will travel from city to city this fall and winter, starting with Chicago and Miami. Each roundtable is one and one-half days. Morning of day one will address cost-cutting and workflow redesign. Afternoon of day one will focus on the spectrum of staff recruiting, best hiring tactics, and effective approaches to improve staff retention. Following a networking event that evening, the morning of day two takes up the best ways to increase revenue, build operating margins, and win new clients. At noon, the strategic roundtable concludes and your lab managers will be back in your lab, armed with proven ideas and energized to get results.

Each learning module has two leaders from labs delivering value on that topic. After short presentations, attendees will engage in candid brainstorming and networking sessions so that ideas and best practices can be shared. This is the hands-on, peer engagement process that many of you requested from us.

The beauty of this strategic roundtable concept is that it happens near your lab, tuition is affordable, travel expenses are minimal, and the lab managers you send will be out of the lab only two days. Upon their return, they will have proven approaches to cutting costs that can swiftly deliver monthly savings of $10K, $20K, or more! This is the most powerful value proposition we can offer you at a time when it can make a huge difference for your lab, your parent organization, and the physicians and patients you serve. TDR

Solutions to Lab Staffing, Supply, Revenue Problems

It's a first-ever opportunity for the lab industry: a hands-on workshop to share proven best practices

CEO SUMMARY: Responding to requests from numerous lab managers, THE DARK REPORT is organizing a 1½-day program that will come to your city. Workshop leaders are from labs successful at cutting costs, at staff hiring/retention, and at increasing their lab's revenue. The learning will take place in facilitated sessions to encourage networking and sharing of best practices and clever ideas. Participating lab managers with come away with everything needed to implement solutions in their own labs.

THIS FALL, INNOVATIVE CLINICAL LABORATORY LEADERS will assemble in Chicago and Miami specifically to share what's working in cutting lab costs, recruiting more lab staff, and producing more revenue at their labs. All three problems are creating high stress for lab managers across the nation today.

These three elements of lab operations—cost-cutting, staffing, and producing more revenue—are interlinked. For example, when a lab cuts costs the wrong way, the resulting stress in the lab can cause valuable medical technologists to quit and take the same job at another lab across town. This is one reason why there is a close relationship in how a lab operates and its success in retaining its best employees.

This program series is titled "Lab Management Essentials to Effectively Cut Costs, Improve Staff Hiring and Retention, and Generate More New Revenue." The first event happens on Oct. 20-21 in Chicago. The second happens Nov. 10-11 in Miami.

"Last April, more than 900 lab professionals attended our *Executive War College* in New Orleans," stated Robert L. Michel, Founder and Director of the conference. "Three topics dominated the interest of attendees during the sessions.

"First is the sustained pressure on labs to cut costs," he said. "Many hospital labs are being asked by administration to reduce spending, even as inflation increases the price of analyzers, tests, and other lab products.

"Second is the near-impossible task of hiring and retaining lab staff across all types of positions and skills," continued

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

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

Michel. "In every region of the country, labs report that they operate with unfilled positions representing as much as 20% of authorized staff levels.

"The third issue is the pressing need to increase revenue," Michel added. "More revenue can ease the pressure to cut expenses—particularly if drastic cost cuts erode customer service levels in ways that cause referring physicians to switch to a new lab provider. More revenue also makes it possible to fund the salary increases necessary in both staff recruitment and staff retention."

Never Offered Before Now!

Building on the suggestions and requests from attendees at this spring's *Executive War College*, THE DARK REPORT team has organized something never before available to clinical laboratory managers: a one-and-a-half day workshop with case studies, facilitated networking, and sharing of best practices by invited speakers and practitioners.

Smart Cost Cutting: The morning of the first day is devoted to proven ways to cut costs. Innovative labs will provide case studies of effective cost cutting and workflow redesign, followed by facilitated discussions and a sharing of best practices.

Effective Staffing: The afternoon of the first day deals with the recruiting, hiring, and retention of lab staff. Case studies will provide approaches that are working in today's competitive lab recruiting market, again followed by facilitated discussions of what's working among the participants.

Generating More Revenue

Increasing Revenue: The morning of the second day tackles the important goal of generating more revenue. These are proven ways that increase your lab's net profits and provide additional cash to help close budget shortfalls.

Lab case studies and the facilitated discussions ensure that all participants acquire the knowledge, insights, and confidence they need to return to their labs and produce new streams of profitable revenue.

"It is important to understand that we are bringing to Chicago and Miami the same proven learning approach that has made our annual *Executive War College* the nation's largest conference on the business and management of labs and pathology groups," Michel explained. "By design, labs within driving distance of these first two strategic roundtables can send teams of their most effective lab leaders to use these local workshops as the opportunity to learn what's working and what's not in cost reduction, lab staffing, and building lab revenue.

"This unique learning opportunity will deliver high value to the labs who send their most talented managers," he noted. "The benefit to your lab is obvious when they return from this information-packed program with proven methods to cut costs that quickly produce ongoing savings of $20K, $40K, or more per month.

Benefits of More Revenue

"Similarly, how valuable will it be to you and your lab team when those same managers apply the lessons on staff recruiting, hiring, and retention and are able to swiftly close your FTE staffing gap by five, 10, 20 individuals or more?" Michel asked. "It's the same with new revenue. How differently would things be in your lab if—within months—your sales team added $10K to $50K in monthly revenue from new physician clients? These are three reasons why this workshop is a low-cost, high-return opportunity."

The strategic roundtables will be limited to 50 participants. Each of the three learning modules will start with two short, concise lab cases studies, presented by the lab executives responsible for implementation in their respective labs. Their experience, advice, and techniques will be applicable in labs large and small, whether independent labs or hospital labs.

Following the two case studies, participants will break up into groups of 10-12

Experts with Proven Ways to Swiftly Achieve Lab Cost-Cutting, Staffing, and New Revenue

LAB MANAGERS IN CHICAGO AND MIAMI WILL HAVE THE EXCEPTIONAL OPPORTUNITY TO PARTICIPATE in a lab industry first. It is a 1½-day strategic roundtable that teaches what is working best in three important operational areas: lab cost-cutting, lab staff hiring/retention, and increasing lab revenue and the number of new clients.

Titled "Lab Management Essentials to Effectively Cut Costs, Improve Staff Hiring and Retention, and Generate More New Revenue," the strategic roundtables will take place at the **Aloft Chicago O'Hare** on Oct. 20-21 and at the **Sheraton Miami Airport Hotel** on Nov. 10-11. Attendance is limited to increase networking and allow all attendees to work one-on-one with the presenters and experts. There are three learning modules during the 1½-days. For full details, visit https://tinyurl.com/dyr3ab2c.

Morning, Day One:

Smart Cost-Cutting and More Efficient Lab Workflow

Master techniques to cut costs while maintaining quality. Identify how to leverage Lean/Six Sigma methods to lower expenses while boosting labor productivity. Effectively review the performance of lab analyzers in preparation for vendor price negotiations. Develop methods of continuous improvement that reduce stress on lab staff while delivering a predictable, efficient workflow at reduced cost.

Facilitators:

Carlton Burgess
Vice President, Laboratory Services, Prime Healthcare, Ontario, Calif.

Tafney Gunderson
Quality Systems Supervisor, Avera McKennan Laboratory, Sioux Falls, S.D.

Afternoon, Day One:

Effective Approaches to Lab Staff Recruiting, Hiring, Retention

Understand effective ways to attract candidates for the range of skills and experience needed in the laboratory. Learn how to attract candidates for on-site clinical training programs. Uncover fresh approaches to building a pipeline of MT and leader candidates. Master ways to reduce unnecessary work and create more bandwidth for staff in ways that help staff retention.

Facilitators:

Dorothy Martin
Regional Laboratory Manager, Dartmouth Hitchcock, Lebanon, N.H.

Kim Zunker, MBA, MLS(ASCP), CAPM
Consulting Manager, Accumen, Scottsdale, Ariz.

Morning, Day Two:

Winning Strategies to Rapidly Generate More New Lab Revenue

Several key approaches can be used to boost revenues. Master innovative approaches that will gain higher reimbursement from payers. Another strategy is to expand the test menu in ways that attract new customers to the lab. Combining lab test data with other healthcare data sets enables a lab to add extra value that helps improve patient outcomes and for which health insurers will pay.

Facilitators:

Jane Hermansen, MBA, MT(ASCP)
Manager, Outreach & Network Development, Mayo Clinic, Rochester, Minn.

Rick VanNess
Director of Product Management, Rhodes Group, Albuquerque, N.M.

individuals. Skilled strategic facilitators will lead the discussion that follows. All attendees will have the opportunity to share what's working in their labs and what's not. The case study presenters will be proctors during these discussions.

Idea Exchange

This is where the collective savvy of the participants guarantees a rich exchange of valuable ideas. The essential resources needed to enable the lab to reach its goals will be discussed. These discussions will generate a prioritized list of the actions that are most achievable and which will produce the biggest results in the shortest time.

Each module will end with the individual discussion groups reassembling together. As a single group, they will share, compare, and identify the best strategies, and tactics. All of this information will be captured by the strategic facilitators. Every participant will get a digital file with the key discussion points and recommended action items.

The sidebar on page five, "Experts with Proven Ways to Swiftly Achieve Lab Cost-Cutting, Staffing, and New Revenue," provides information about the case study presenters and the range of topics that will be discussed in each of the three modules presented during the 1½-day strategic roundtables.

Achieving Fast Results

It is recommended that labs plan to send four or more of their most productive managers. Having their key contributors learn together will allow them to return to the lab and speedily launch programs designed to reduce costs, and to fill more open positions at the lab.

This is a unique opportunity for lab managers with initiative to interact with peers while learning powerful approaches to cutting costs and boosting revenue for their labs. Information and more details are available at this link: *https://tinyurl.com/dyr3ab2c.* TDR

Strategic Roundtables Fill Lab Industry Vacuum

THERE WERE MANY CONVERSATIONS at the *Executive War College* in New Orleans last April that directly spurred the creation of the first two strategic roundtables for lab managers to be held in Chicago and Miami this fall.

"During that week, lab leaders told us that a huge void in their lab's management development efforts was the lack of appropriate management development training that was specific to clinical labs and pathology," stated Robert L. Michel, Editor-In-Chief of THE DARK REPORT. "Several said that if we developed such a program, their health system would support it and allow the lab to send their most promising young managers.

"This was the genesis of the 1½-day strategic roundtable series we will launch this fall," he added. "The senior lab leaders said that, if it was a regional training, they could send several managers at once to learn as a team. Not only could they drive to the program and back, they would only be out of the lab for two days."

This set the parameters for a strategic roundtable series that will be a valuable double play for clinical labs. "First, all the participants in the Chicago and Miami roundtables will learn proven ways to cut costs, recruit/retain staff, and generate more lab revenue," Michel noted. "Second, at the same time they will be learning effective management methods tailored to the needs of clinical labs and pathology groups.

"Shrewd lab administrators will also recognize that sending their lab's most productive managers to this 1½-day strategic roundtable can pay big dividends if they return and then smartly cut costs that almost immediately generate major monthly savings," Michel concluded.

On Appeal, ACLA Gains PAMA Victory in Court

Ruling Criticizes HHS Over How the Agency Determined Whether PAMA Applied to Hospital Labs

Karen Lovitch

CEO SUMMARY: Last month, a U.S. Court of Appeals issued a ruling that criticized how the Department of Health and Human Services originally implemented the Protecting Access to Medicare Act of 2014 (PAMA). This ruling was a win for the American Clinical Laboratory Association in its lawsuit against the Department of Health and Human Services.

Even as Congress considers legislation to reform how Medicare officials reduce clinical laboratory test reimbursement under the Protecting Access to Medicare Act of 2014 (PAMA), the **American Clinical Laboratory Association** (ACLA) notched a victory in a long-standing lawsuit against the government over PAMA.

On July 15, the **U.S. Court of Appeals for the District of Columbia Circuit** issued a ruling that criticized the **U.S. Department of Health and Human Services** (HHS) in how the agency originally implemented PAMA, which the ACLA argued has subsequently skewed data reporting and corresponding test reimbursement payment cuts. The Court of Appeals also remanded the case back to U.S. District Court.

"[HHS], without adequate explanation, exempted a sizable portion of the laboratories covered by the statute from 13 data reporting requirements," the Appeals Court wrote.

There are subtleties at work here. For example, after Congress passed PAMA, HHS implemented a rule to carry out the law in 2016 that exempted most hospital labs offering outreach services from PAMA's reporting requirements. A subsequent 2018 rule from HHS changed the scope of laboratories that must report payment data under PAMA, which resulted in many hospital outreach labs being subject to the reporting requirements. The ACLA's suit, filed in 2017, concerned the 2016 rule.

Firm Stand by Appeals Court

The Court of Appeals took a firm stand that the 2016 rule was flawed and that it negatively affected many labs' reimbursement rates from Medicare.

"The ruling hopefully will bolster the ACLA's fight to make sure that PAMA is implemented fairly, but congressional action likely will be needed," said attorney Karen Lovitch, Chair of Health Law and Healthcare Enforcement Defense Practices at law firm **Mintz** in Washington.

A separate effort is underway to cap PAMA's lab test reimbursement cuts through a proposed new bill, the Saving Access to Laboratory Services Act (SALSA). If passed by Congress, SALSA will permanently reduce the amount of payment cuts for tests under PAMA. The proposed bill also would overhaul how the

government collects data about private payer rates for clinical laboratory tests. *(See TDR, "PAMA Cuts Might Be Reduced to Zero for 2023," Aug. 8, 2022.)*

Clinical laboratory administrators and pathologists should note that the appeals court did not force changes upon HHS or the **Centers for Medicare and Medicaid Services** (CMS) regarding PAMA.

"The court technically didn't order CMS to do anything differently, such as review payment rates established under PAMA," Lovitch explained.

Under its language, PAMA prohibits judicial review of payment rates set by the law, so reimbursement cuts were not up for debate by the judges.

Lawsuit Filed in 2017

The ACLA initially filed suit against HHS in 2017, shortly after PAMA went into effect. PAMA requires clinical labs to report the lab test prices they are paid by private insurers. CMS then uses that data to set the prices for what Medicare will reimburse for the same tests. In practical terms, this process caused labs to collectively lose hundreds of millions of dollars in Medicare payments in recent years.

Congress delayed some of the planned rate cuts due to the pandemic, but an upcoming cut of up to 15% for 800 lab tests is scheduled to occur on Jan. 1 unless other legislative action is taken. *(See TDR, "PAMA Test Price Cuts Deferred: It's a 'Huge Win' for Labs," Dec. 20, 2021.)*

An important aspect of the ACLA lawsuit concerned how PAMA determined if the law applied to an individual clinical laboratory. "The core argument that the ACLA made was that the 2016 rule crafted by CMS to define an 'applicable lab' that was required to report conflicted with PAMA's statutory definition," Lovitch explained. "An applicable lab is basically a lab that must report private payer payment rates under PAMA."

PAMA generally defined an applicable lab as one that received most of its Medicare funding from the Physician Fee Schedule or the Clinical Laboratory Fee Schedule. However, HHS' 2016 rule implementing PAMA's mandates defined applicable labs as those with a unique National Provider Identifier (NPI). Healthcare providers use NPIs to bill Medicare.

Conflict arose because hospital laboratories, including those offering lab outreach services, don't usually have their own NPIs. Independent labs are far more likely to have a unique NPI, thus they were more likely to report payment data to CMS under PAMA.

By comparison, "Almost every hospital laboratory uses the hospital's NPI to bill Medicare, so many of those labs were not required to report payments rates for outreach lab testing under PAMA," Lovitch said. That led to an under-represented sampling of hospital lab payment data compared to independent labs.

"[HHS] admitted at oral argument that it did not even know how many outreach laboratories had NPIs, and it has never disputed ACLA's argument that the number is low," the appeals court ruling noted.

Clinical Lab Test Prices

CMS set reimbursement payments based on the information it received from clinical laboratories. However, commercial lab companies—because of the deeply-discounted lab test prices they have in their contracts with private insurers for high volume lab tests—often receive less reimbursement amounts than hospital labs. Over time, under the PAMA mandate, substantial Medicare price cuts hurt hospital lab outreach labs and smaller lab companies that primarily serve Medicare beneficiaries in smaller towns and rural areas.

Laboratory leaders will note that should SALSA pass in Congress, the final disposition of the ACLA's lawsuit becomes irrelevant. Until then, the legal pressure from the case will continue. TDR

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Tactics to Standardize Point-of-Care Testing

At big hospitals and health systems, thousands of operators may be performing point-of-care tests

Jeanne Mumford

CEO SUMMARY: *Managing point-of-care testing (POCT) at a multi-hospital health system like Johns Hopkins Medicine (JHM) often means overseeing thousands of nurses and staff members who perform such tests. Lessons learned at JHM in standardizing POCT, training staff, and maintaining quality results were shared at last spring's Executive War College.*

POINT-OF-CARE TESTING (POCT) CONTINUES TO EXPAND. At the same time, mergers and acquisitions bring formerly separate hospitals and clinical laboratories under a single health system's banner. These developments often trigger inefficiencies and inconsistencies in the operation and management of a far-flung POCT program.

Baltimore-based **Johns Hopkins Medicine** (JHM) experienced that exact dilemma and learned certain lessons that other health system laboratories and hospitals—regardless of size—can use to help standardize POCT and ensure accurate, reproducible results.

"Clinical laboratories that want to get a better handle on their point-of-care testing endeavors can learn from what Hopkins has done and adjust it for their own approach," said Jeanne Mumford, Pathology Manager for POCT at JHM. Mumford presented at April's *Executive War College Conference for Laboratory and Pathology Management* in a session titled, "Standardizing Point-of-Care Testing and Harmonizing Workflows Between Hospitals and Ambulatory Locations."

During her 22 years of laboratory experience—12 years working with POCT—Mumford recognized that the following factors help smooth out aspects of this testing:

- Multidisciplinary collaborations within and beyond the hospital can overcome workflow inefficiencies.
- Standardized POCT processes and equipment are essential to achieve more consistency in how staff use these tests.
- Middleware technology can link disparate analyzers and laboratory information systems (LIS) to streamline the production of POCT results.

Challenges at Johns Hopkins

The lab team at Johns Hopkins Medicine faced most of the same POCT challenges that confront other hospital and health system laboratories. Johns Hopkins is a large hospital system, which from a lab operations perspective can sometimes be a detriment because many different processes are used.

"Geography is one of our biggest challenges at Johns Hopkins because we have five hospitals in the Baltimore and Washington, D.C., region," Mumford

noted. "In addition, we have dozens of ambulatory sites delivering primary care and specialty care throughout Maryland and into Northern Virginia."

JHM also has a partnership to run the **Johns Hopkins All Children's Hospital** in St. Petersburg, Fla. Serving multiple sites is complicated because each has its own staff and systems in place.

"At each site, different members of the clinical team do POCT," she explained. "These are multidisciplinary teams that include certified nursing assistants, medical assistants, licensed practical nurses, and physician assistants, among other professionals. In addition, we have more than 40 point-of-care testing sites across Maryland, Northern Virginia, and the Washington D.C. areas where we oversee testing."

Legacy POC Test Systems

At most of its sites JHM has some integrated instruments, but not all are interfaced to the central laboratory information system, Mumford said. "For example, we have a tear osmolarity vendor that provides us with a legacy instrument that's been in our system for longer than I have. And that system was never meant to connect to the other parts of our system. Therefore, when we use it, we run it as a manual test," she noted.

"We also have a variety of manual tests that many health systems run in their physicians' offices or even in their laboratory settings as a reference test," she told attendees at the conference. *(See sidebar on page 11, "Interfaced, Non-Interfaced POCT at Johns Hopkins," for further details.)*

To deal with these challenges, the POCT team at JHM undertook several critical steps, any of which other hospital laboratories could emulate. Among the most effective is using "guests" to help convey to staff the importance of consistency in POCT approaches and discuss what works, Mumford said.

JHM hosts monthly meetings with commercial labs and internal core labs, she explained. During these meetings, support staff from the commercial or core labs explain how other healthcare systems have solved problems they encounter with POCT and how JHM may be able to apply those same lessons.

Point-of-Care Coordinators

Point-of-care coordinators, which Mumford referred to as POCCs, also can conduct monthly or quarterly meetings with testing personnel, unit managers, and those who train the testing personnel and managers.

Regular and frequent meetings with nurse administrators to outline problems and solutions also can improve POCT workflows and results, she added. Of course, daily huddles on as many units and floors as possible help ensure that all professional staff involved in POCT are consistently following standardized procedures the lab has implemented for POCT, she noted.

A further way to improve efficiency in POCT: Invite lab vendor representatives to participate in training for staff, Mumford suggested.

"You can bring in vendor reps to your sites to perform on-site training to help your staff complete your competency checklist," she said. "Keep in mind that vendor reps are likely to have a good rapport with your POCT staff and often reach out to lab managers several times a year to offer their support."

Standardized Testing

Standardizing POCT and related processes can bring about more efficiency. Such goals are not always easy to accomplish, particularly in larger healthcare systems, but Mumford said the effort is worth it.

JHM followed a three-step process to standardize POCT:

STEP 1: Standardize all testing throughout the Hopkins system. To do so, staff in the labs explain the most efficient and patient-centric procedures that they use when conducting POCT. In this way,

they teach clinical best practices to those doing the testing at the point of care.

"To do that, I oversee all point-of-care tests, requests, and field studies," Mumford explained. "We work very closely with all the local lab directors, administrative teams, and their point-of-care coordinators at each hospital."

STEP 2: Establish a single structure for improving the quality of patient care. "We have a huge healthcare system, but you can scale this down to any size medical laboratory or system, as long as you have a tiered approach to decision-making," she said.

For example, JHM has committees for patient safety and quality, an ambulatory quality council, and the **Armstrong Institute for Patient Safety and Quality**, which coordinates patient safety efforts in the Hopkins system.

POCT Committees

"On our committees, we have deputy directors for nursing and for every scope of care across medicine," she added. "One thing we do is ask which point-of-care devices work best and which ones can we integrate into our system."

STEP 3: Standardize equipment and processes as much as possible. If a health system is vast, doing so may not be feasible, but aim to tackle as much as you can, Mumford said.

"I have six hospitals, which means I have six procedures for glucose testing," she commented. Those various processes piggybacked from legacy systems each hospital had in place when JHM acquired that facility.

"For example, when we acquired a hospital in the suburbs outside of Washington D.C., that hospital had a blood gas solution that they used for many years before Hopkins came along," she added. "They don't do any blood gases in their core lab. All their blood gases for the entire campus are performed at the point of care.

Interfaced, Non-Interfaced POCT at Johns Hopkins

HERE IS A LIST of point-of-care tests and devices that are interfaced and non-interfaced at Johns Hopkins Medicine:

Interfaced tests/devices

- ACT-LR, ACT Plus
- Blood gases
- Creatinine
- Glucose, whole blood
- HbA1c
- Hgb
- INR
- O2 Saturation
- SARS-CoV-2 only and 4PLEX molecular
- Urinalysis
- Urine HCG

Non-Interfaced tests/devices

- Fecal occult blood
- pH
- PPM (multiple)
- Rapid HCV
- Rapid HIV 1/2 antibody
- Urine HCG
- SARS AG
- SARS-CoV-2 PCR
- Specific gravity
- Strep A
- Tear osmolarity
- Urine drug screen

"One size does not fit all, and that's okay," she concluded. To offset these conflicts, JHM contracts with two lab vendors that offer good pricing. "Those two vendors can supply us with everything we need. We tell them the metrics we're trying to improve, such as time to treatment, time to discharge, or length of stay."

In 2010, JHM began a years-long journey to implement a new electronic health record (EHR) system. Medical laboratory

representatives from JHM visited many hospital systems across the country that had various EHR systems.

"Once we selected our EHR, we took inventory of all the LIS systems and medical records we had in place and formulated a plan to implement our new IT infrastructure across the system," Mumford reported.

"We started this process 12 years ago, and in 2022 we might be finishing the final leg. To do that, we will be bringing in an LIS to the All Children's Hospital in Florida," she added.

The inventory showed that JHM had POCT instruments that were not interfaced throughout the system. This is a normal finding at any healthcare system that is growing and partnering with other hospitals, and for JHM, it has been bearable thanks to a piece of technology called middleware.

Use of Middleware

Middleware provides a method of communication between applications that would otherwise not have any way to exchange data, such as with software tools and databases, according to *TechTarget*. IT departments in healthcare should be familiar with middleware.

"At Hopkins, we all connect to a single middleware product, which means the middleware is the hub that gives us the connectivity we need to make the system work throughout all six hospitals and all ambulatory sites," Mumford explained.

"Our middleware product allows us to have a daily, weekly, monthly, and ad hoc workflow," she continued. "That allows us to standardize practices, such as accounting for instrument connectivity."

Medical laboratories that are evaluating their POCT processes should consider the best practices from across the health system and adopt what works best in their facilities.

What is feasible at JHM may not work for every other lab or hospital, Mumford acknowledged. But the approaches are solid and can be used regardless of a facility's size or complexity.

"Just because my strategies are based on a healthcare system that is highly complex and diverse does not mean that these strategies will not help you if you're working in a smaller institution or even a larger institution," Mumford observed. **TDR**

Contact Jeanne Mumford at 443-287-8543 or jmumfor3@jhmi.edu.

Efforts to Standardize Glucose Monitoring

One way to understand the complexity of the Johns Hopkins Medicine (JHM) health system is to consider the numbers: at JHM there are 2,677 inpatient hospital beds, more than 50 ambulatory sites with glucose testing, more than 11,700 glucose operators, and 14 point-of-care coordinators (POCCs).

"Across the world, glucose is the bread and butter of point-of-care testing," explained Jeanne Mumford, Pathology Manager for point-of-care testing (POCT) at JHM. "There are always questions asked on the POCT listservs: 'What is the magic formula for determining how many POCCs you need based on how much work you have?' for example. While I don't know the answer to this question, I would argue that 14 POCCs across our system still aren't enough to support our ever-growing and expanding needs. Several point-of-care experts in my network are working on establishing a formula. Maybe we'll have a decent guideline soon."

Standardizing glucose monitoring is a significant challenge and has a big payoff. "It's worth every penny in the millions that we've spent standardizing systems in general," she declared. "I say that because in the process of taking care of patients in all of our institutions, regardless of the size of the POCT program, we know that laboratory testing plays a critical role in establishing safe and effective patient care."

Pathology Update

Shortage of Pathologists a Factor in Adoption of Digital Pathology

Within the United States, it is now recognized that the demand for surgical pathologists exceeds the available supply. There are more vacant positions than qualified applicants to fill them.

The question yet to be answered is when this shortage of pathologists will have a negative impact on the pathology profession's ability to return accurate, timely results to referring physicians. To date, for example, there are no public news stories about cancer patients in this country waiting weeks or months for the results of their biopsies.

That is not the case in the United Kingdom, however. As early as 2017, the severe shortage of histopathologists in that country's **National Health System** (NHS) was triggering news stories about large numbers of cancer patients waiting as much as six months to learn the results of their biopsies.

The shortage of histopathologists in the United Kingdom was a major reason why, in 2020, the NHS announced a £50 million (US$59 million) initiative to develop a national digital pathology network. It is establishing several pathology centers of excellence across the country.

UK's Pathologist Shortage

The goal is to shorten average turnaround time for pathology cases so that cancer patients are not waiting months for the diagnosis that is needed to start their treatments. One way that digital pathology can enable this is by making it fast and easy for pathologists in any region to be assigned cases, do the analysis, and report the results.

Here in the United States, it was primarily pathologists in academic centers that were the first to adopt and use digital pathology. This started in the mid-2000s. Digital pathology systems enabled academic pathology groups to contract with pharmaceutical companies and drug developers to read digital images in support of drug research and clinical trials.

Academic center adoption of digital pathology also had another consequence. For the past 15 years, nearly all pathology residents and fellows were trained almost exclusively with digital images. This means that a large number of pathologists practicing today were trained with digital pathology tools.

Factors Favoring Digital Path

Thus, what may be about to occur in the pathology profession is a "perfect storm" where the inadequate supply of pathologists versus the growing demand favorably changes the economics of digital pathology.

This will happen as digital pathology vendors demonstrate how their digital pathology systems increase the productivity of individual pathologists, allowing them to sign out more cases without compromising quality and accuracy.

As this happens, it will illustrate the economic principle that increased demand encourages an increase in supply. In this case however, it won't be a big increase in the supply of pathologists in the U.S. Rather, it will be the substitution of digital pathology as the tool that increases the productivity of individual pathologists, allowing them to close the supply-demand gap. TDR

2021 Rankings of the World's Top 12 IVD Corporations

WHILE THERE WAS SOME JOCKEYING FOR NEW positions, *in vitro* diagnostics (IVD) manufacturers remain entrenched in their market based on THE DARK REPORT'S 2021 ranking of the Top 12 IVD Companies.

COVID-19 testing demand led to strong IVD growth in 2021. The top 12 firms took in $85 billion in annual revenue compared to our 2020 ranking, when the top 11 companies earned $61.3 billion.

There are shifts of note: **Abbott Laboratories** jumped to No. 2, while **Danaher** jumped five places to No. 4 based on strong sales. Also, **PerkinElmer** landed on our list.

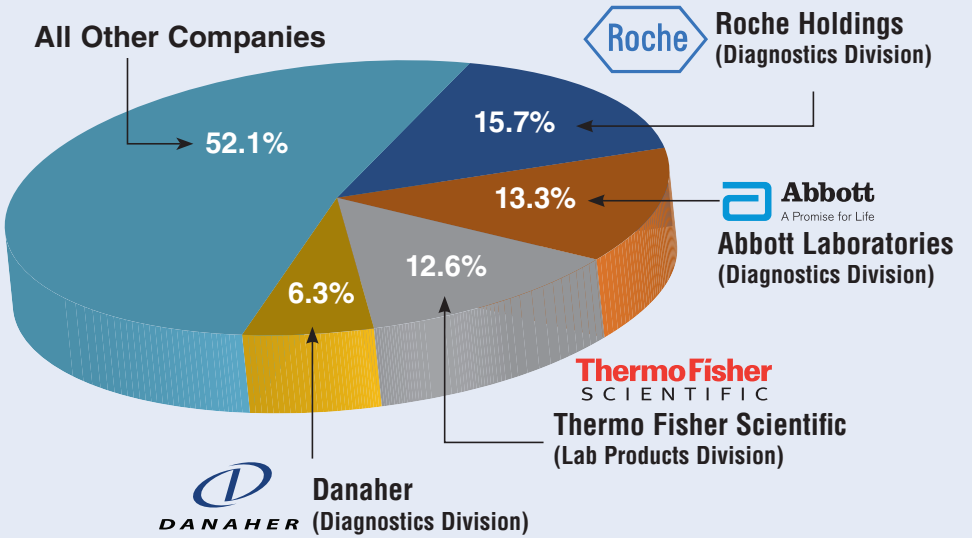
Finally, at No. 12 is **Ortho Clinical Diagnostics**, which in December 2021 was acquired by **Quidel**. Quidel narrowly missed the 2021 list, but in the future, the combined company could hit the top five.

Top 12 IVD Companies by Global Revenue in 2021 (in billions)

IVD Corporation	2021 revenue	Cumulative revenue	Percent of market	Cumulative percent of market	2020 prior rank	
1. Roche Holdings–Diagnostics Division *Basel, Switzerland, founded 1896*	$18.4	$18.4	15.7%	15.7%	1	
2. Abbott Laboratories–Diagnostics Division *Abbott Park, Ill., founded 1888*	$15.6	$34.0	13.3%	29.1%	3	▲
3. Thermo Fisher Scientific–Lab Products Div. *Waltham, Mass., founded 1956*	$14.8	$48.8	12.6%	41.7%	2	▼
4. Danaher–Diagnostics Division *Washington, D.C., founded in 1969*	$7.4	$56.2	6.3%	48.0%	9	▲
5. Becton Dickinson–Life Sciences Division *Franklin Lakes, N.J. founded 1897*	$6.5	$62.7	5.6%	53.6%	4	▼
6. Siemens Healthineers–Diagnostics Division *Erlangen, Germany, founded 1896*	$5.4	$68.1	4.6%	58.2%	5	▼
7. bioMérieux *Marcy-l'Étoile, France, founded 1963*	$3.4	$71.5	2.9%	61.1%	6	▼
8. Hologic–Diagnostics Division *Marlborough, Mass., founded 1985*	$3.0	$74.5	2.6%	63.7%	10	▲
9. (tie) Bio-Rad Laboratories *Hercules, Calif., founded 1952*	$2.9	$77.4	2.5%	66.2%	8	▼
9. (tie) PerkinElmer–Diagnostics Division *Waltham, Mass., founded 1937*	$2.9	$80.3	2.5%	68.6%	N/A	▲
11. Sysmex *Hyōgo, Japan, founded 1968;*	$2.7	$83.0	2.3%	68.5%	7	▼
12. Ortho Clinical Diagnostics *Raritan, N.J., founded 1939*	$2.0	$85.0	1.7%	70.2%	11	▼
Total Market Share Top 12 IVD Firms	$85.0	$85.0	72.6%	72.6%		
Market Share, Other IVD Firms	$32.0	$32.0	27.4%	27.4%		
Total Global IVD Revenue in 2021 (est.)	**$117.0**	**$117.0**	**100.0%**	**100.0%**		

Source: Company documents, news reports, financial analysts' reports.

Four IVD Companies Make up 48% of Market



- Roche Holdings (Diagnostics Division)
- Abbott Laboratories (Diagnostics Division)
- Thermo Fisher Scientific (Lab Products Division)
- Danaher (Diagnostics Division)
- All Other Companies

GLOBAL SALES OF IVD PRODUCTS WERE ESTIMATED to be $117.0 billion in 2021, an increase of 57.9% from the prior year. COVID-19 testing was a major factor in the performance of the IVD industry during 2021.

Roche Diagnostics, Abbott Laboratories, Thermo Fisher Scientific, and Danaher—the top four companies on THE DARK REPORT'S ranking of IVD manufactures—collectively hold 48% of market share in the IVD industry. This illustrates the domination of the "big four" compared to smaller players.

Abbott seized additional IVD market share in 2021, achieving $7.7 billion in global COVID-19 testing-related sales alone. As a result, it moved up to second on the list in 2021 from third in 2020 and has narrowed the gap between itself and Roche, the world's global IVD leader.

In fact, Bruce Carlson, Senior Vice President at **Kalorama Information** in Arlington, Va., said during April's *Executive War College Conference on Laboratory and Pathology Management* that Abbott hired about 1,200 people during the pandemic who were dedicated to COVID-19 test development.

"Abbott was positioned for COVID and grabbed it. They got in there and are now nearly tied [with Roche] in market share," Carlson said.

Regulatory Update

Clinical Laboratories Face 20% Increase in CLIA Fees

CHANGES HAVE BEEN PROPOSED to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that would raise fees by 20% for clinical laboratories and amend certain testing personnel qualifications.

The **American Hospital Association** (AHA) has objected to the latter change.

The proposal was published in the *Federal Register* on July 26. According to the federal **Centers for Medicare and Medicaid Services** (CMS), the rule, if finalized, would do the following, among other changes:

- Institute a 20% across-the-board increase on existing fees.
- Establish a biennial increase of CLIA fees for follow-up surveys, substantiated complaint surveys, and revised certificates.
- Revise personnel regulations under CLIA to address obsolete regulations and incorporate changes in technology.

$22.5 Million Annual Increase

With the 20% increase in fees, and an additional increase to account for inflation, CMS expects the CLIA program to raise $15.8 million. Additional proposed fees would account for another $6.7 million, bringing the total amount to $22.5 million in added revenue each year.

"We believe this would stabilize the CLIA program and allow us to use the inflation factor for future biennial increases," CMS wrote in the *Federal Register*.

In a separate fact sheet on the proposed rule, the agency said that, without the fee increases, the CLIA program will no longer be financially self-supporting by the end of fiscal year 2023.

The proposed rule seeks to add doctoral, master's, and bachelor's degrees in nursing to qualify testing personnel for high and moderate complexity testing. CMS pointed to point-of-care testing as a standard that illustrates the evolving nature of testing personnel requirements.

Nurse Qualifications Debated

"We recognize that in many healthcare systems, nurses perform the majority of the point-of-care testing in many different scenarios (for example, bedside, surgery centers, end-stage renal disease facilities)," CMS wrote. "We do not have any reason to believe that nurses would be unable to accurately and reliably perform moderate and high complexity testing with appropriate training and demonstration of competency."

CMS acknowledged that it has received blowback from some in the healthcare industry regarding prior statements supporting nursing degrees within CLIA.

The AHA has taken umbrage with the testing personnel proposal."The types of laboratory tests classified by CMS as high complexity require a level of knowledge, training, and result interpretation that we believe exceeds the typical nurses training—even at the doctoral and master's [degree] levels," the AHA wrote in a letter to CMS.

The comment period on the proposal was scheduled to close on Aug. 25, but there were requests for CMS to extend that period by an additional 30 days to allow more time for comments from the clinical lab industry. TDR

Lab Market Update

Public Laboratory Companies Eye More Lab Outreach Acquisitions

Companies want to get back to base business as COVID-19 test volumes fall, according to earnings reports

Publicly-traded clinical laboratory companies released second quarter 2022 financial reports that confirmed a softening demand for COVID-19 tests, even as their base business revenues grew compared to last year.

While continuing to address ongoing needs for SARS-CoV-2 testing, company leaders said during earnings calls that they are prioritizing the following business areas:

- Acquiring hospital laboratories.
- Growing relationships with retail sites.
- Stepping up at-home test offerings to consumers.
- Expanding oncology testing and companion diagnostics.

Here is an overview of results and priorities shared by leading publicly-traded laboratory companies.

LABCORP: Focus on Acquisitions, Consumer Tests, Oncology

At **Labcorp** in Burlington, N.C., Q2 revenue was down amid a decrease in COVID-19 testing, but base business revenue went up. Moving forward, the company said it is prioritizing its base business, including the acquisition of hospital laboratories.

Labcorp announced:

- Q2 revenue was $3.7 billion, down from $3.8 billion in Q2 2021.
- Revenue for the first six months of 2022 was $7.6 billion, down 5.1% from $8 billion in the first six months of 2021.
- Diagnostics revenue in Q2 earned $2.26 billion, down 4.7% from $2.37 billion Q2 2021.
- Q2 COVID-19 testing revenue went down 42% compared to Q2 2021, with requisition volume down 2.7%
- Diagnostics base business revenue grew 3.9% compared to Q2 2021.

During the Labcorp earnings call, an analyst asked about balancing more testing from retail pharmacies. Chairman and CEO Adam Schechter noted challenges in retail settings and reaffirmed Labcorp's priorities for growth.

"We've seen more of our business move to the retail sector, where it challenges our margins a bit. Margin right now for PCR testing is about 60%. And we see the retail sector as an opportunity," he commented. "But frankly, we are focused on our base business. We're really focused on the hospital and local laboratory acquisitions that are before us."

Labcorp has a "strong pipeline of health system and regional acquisition possibilities," Schechter said. "We acquired select outreach business assets and agreed to provide ongoing technical support to **Prisma Health's** [South Carolina] hospital laboratories. We completed our acquisition of select clinical outreach business assets from **AtlantiCare** in New Jersey. We reached an agreement to acquire the clinical outreach business and related assets of **RWJBarnabas Health**, also in New Jersey."

The RWJBarnabas deal, announced on Aug. 23, involved New Jersey's largest

academic health system. The agreement, the cost of which was not disclosed, affects all lab outreach services in the system. RWJBarnabas does not list lab test statistics in its financial documents, but the system runs 15 hospitals and sees two million outpatients per year.

Labcorp's other priorities include expanding home testing offerings and oncology diagnostics.

Quest Diagnostics®

QUEST: STRONG RETAIL PRESENCE, PLANS FOR OUTREACH EXPANSION

Quest Diagnostics in Secaucus, N.J., increased base business revenue, even as COVID-19 test earnings decreased.

"We believe demand for COVID-19 molecular testing will continue into 2023," Steve Rusckowski, Chairman, and outgoing CEO, told investors during an earnings call.

"We also continued to ramp our investments to accelerate growth in the base business, particularly in the areas of advanced diagnostics and direct-to-consumer testing," said Jim Davis, CEO-elect, in a news release.

Quest shared the following results:

- Q2 revenue was $2.4 billion, down 3.8% from Q1 2021.
- Q2 base revenue brought in $2.1 billion, up 2.9% from Q1 2021.
- COVID-19 testing revenue was $355 million in Q2, down 31% from Q2 2021 and 41% compared to Q1 2022.
- Revenue-per-test-requisition declined 2.6% year over year, and requisition volume dropped 1.4%.

Half of Quest's COVID-19 test revenue in Q2 came from retail channels. Quest operates about 6,000 COVID-19 patient access sites, which include its retail relationships with **CVS**, **Rite Aid**, and **Walmart**, and patient service centers.

In response to an analyst's inquiry about spending, Davis explained that the company's priorities for 2023 included investments in advanced diagnostics and direct-to-consumer testing.

"We continue to see growth in direct-to-consumer testing," he added. "We saw strong growth from testosterone, comprehensive metabolic panels, and Lyme disease [tests]."

The company's merger and acquisition opportunities remain appealing, according to Davis. "We are in late-stage discussions with several hospital health systems on the purchase of their laboratory outreach businesses," Davis noted.

BioReference LABORATORIES

BIOREFERENCE: PLAN FOR GROWTH WHILE STAFF CUTS REDUCE COSTS

BioReference Laboratories (part of **OPKO Health**) in Elmwood Park, N.J., announced its Q2 revenue was down significantly year over year as it also shared a plan to improve growth.

Data shared in an earnings call included:

- Q2 revenue was $186.8 million, down from $397.2 million in Q2 2021 due to decreased COVID-19 testing volumes.
- The company performed one million COVID-19 tests in Q2, down from 2.1 million in Q1 2022 and three million in Q2 2021.

Jon Cohen, Director, and Executive Chairman at BioReference, said in an earnings call that the company is carrying out a three-pronged strategy to improve margins: cutting costs; pursuing investments in oncology, women's health, and urology; and creating a more efficient organizational structure.

The cost cutting included a massive staff reduction. "At the peak of COVID, we had nearly 8,000 employees at BioReference, and by the end of July [2022], our employee count has been reduced to 3,600 employees, including reductions of approximately 700 associates in June and July," Cohen said. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Interesting things may be unfolding in the genetic testing marketplace. In the past few weeks, at least two high-profile genetic testing companies announced major layoffs. First was **Invitae**, a genetics testing company in San Francisco. At the end of July, it announced plans to eliminate 1,000 employees over the next year, *SFGATE* reported. That is one-third of the company's roster. A CEO shuffle soon followed, with Kenneth Knight taking the helm to streamline business operations.

MORE ON: *Layoffs*

The second genetic testing company to announce layoffs was **Sema4** in Stamford, Conn. It will eliminate 250 staff members (about 13% of its workforce) as part of restructuring to save money. The company will also shutter a clinical lab in Branford, Conn., at the end of the year, according to Sema4. The closure is a result of Sema4 exiting the somatic tumor testing business. It is believed that low reimbursement for genetic tests is a factor in the financial struggles at these two companies and a factor in the layoffs.

LIGHTHOUSE LAB SERVICES ON INC. 5,000 LIST

Lighthouse Lab Services in Charlotte, N.C., ranked at No. 999 on *Inc.*'s list of the 5,000 fastest growing private companies in the U.S. in 2022. Lighthouse had 653% revenue growth from 2018 to 2021, according to *Inc.*, making it the second fastest growing health services company in its home state.

LITTLE SUCCESS IN FILLING OPEN LAB JOBS

The number of people in the U.S. employed in medical and diagnostic laboratories remained flat from May 2002 through July 2022. Numbers posted by the federal **Bureau of Labor Statistics** showed there were 314,000 lab workers on payrolls as of July 2022, up just 800 people from May—a 0.26% increase. More than 9,000 med tech jobs remained open in the U.S. as of Aug. 26, according to **Indeed**.

TRANSITIONS

- Jon Cohen, MD, is retiring from his roles as Executive Chairman and CEO at **BioReference Laboratories** in Elmwood Park, N.J., and Senior Vice President and Director at parent company **OPKO**. Craig Allen, President, and Chief Operating Officer, has been appointed Interim CEO.

- George Cardoza is the new CEO at **AccuraGen** in San Jose, Calif. Cardoza previosly worked at **NeoGenomics** Laboratories in Fort Myers, Fla., and at **Quest Diagnostics**.

- Erik Ranheim, MD, PhD, has been named the chair of **University of Wisconsin School of Medicine and Public Health's** Department of Pathology and Laboratory Medicine. Ranheim has been there for two decades.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 19, 2022.

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