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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Special New Year's Report:

Lab Execs Share Outlook for 2025

For an inside look at what may be in store for the clinical lab industry this year, *Laboratory Economics* interviewed the top executives at a diverse group of 12 lab companies. Consensus trends identified include 1) the transition to digital pathology combined with AI is underway at nearly all of the nation's largest labs; smaller labs (offput by the high cost) are moving more slowly; 2) the employee shortage persists, especially for pathologists and histotechs; 3) inflation remains a problem—price increases for employee health insurance and professional liability insurance are rising by 10-15%; and 4) well-managed hospital outreach labs and independent labs can successfully compete with the national labs.
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Lawsuit Alleging Iowa Pathology Monopoly Dismissed

A federal judge has dismissed a lawsuit alleging that Iowa Pathology Associates (IPA-Des Moines) conspired to maintain a monopoly for pathology services in central Iowa (see *LE*, November 2024). The suit was filed in May 2024 in U.S. District Court for the Southern District of Iowa by four dermatopathologists—Drs. Tiffani Milless, Caitlin Halverson, Renee Ellerbroek, and Jared Abbott—who last year established competing Goldfinch Laboratory (Urbandale, IA).
Details on page 2.

LDT Lawsuit Decision Expected Soon

Danielle Sloane

The Food and Drug Administration (FDA) filed its closing brief on December 23 in the federal court case over the regulation of laboratory-developed tests (LDTs). Lawsuits filed by ACLA and Association for Molecular Pathology (AMP) are seeking summary judgment to have the LDT final rule thrown out. The current briefing schedule suggests that a decision on the combined lawsuits from U.S. District Court Judge Sean Jordan could come as early as next month, notes Danielle Sloane, healthcare regulatory attorney at Bass Berry & Sims PLC (Nashville).
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LDT LAWSUIT DECISION EXPECTED SOON (*cont'd from p. 1*)
Sloane notes that Judge Jordan is a conservative judge appointed by Trump in 2019 during his first term as President. Overall, Sloane believes there is a good chance—but no guarantee—that he will rule in favor of ACLA/AMP and the LDT final rule will be struck down.

Based on what was agreed to in the accelerated briefing schedule, Sloane believes that Judge Jordan's summary judgment decision could come as early as February, but the judge is not necessarily committed to issuing his ruling in that timeline so it remains uncertain as to whether or not there will be a decision before May 6—-when the FDA's first stage of LDT regulation becomes effective.

Furthermore, Sloane says, if the decision is unfavorable to the FDA, there seems to be more of a chance that a Trump FDA would choose not to appeal it. Sloane notes that during his first term, Trump's Department of Health and Human Services (HHS) had taken the position that FDA does not have the authority to regulate LDTs.

What about the possibility of re-introducing legislation, such as the VALID Act, to regulate LDTs? Sloane suggests that new legislation increasing FDA regulatory oversight of LDT seems less likely in light of the new Trump administration's aims to reduce regulatory burdens in combination with a Republican majority in both houses of Congress. The new Trump administration, including his nominated HHS Secretary, Robert F. Kennedy Jr., and FDA Commissioner, Marty Makary, MD, "seem to have other priorities based on their public comments to date, such as the pharmaceutical industry, food safety and vaccine policy, although it's hard to predict this administration," adds Sloane.

LAWSUIT ALLEGING IOWA PATHOLOGY MONOPOLY DISMISSED (*cont'd from page 1*)
The lawsuit alleged that since 2021, IPA pressured its pathologists to sign employment agreements that include a no-compete clause. At the time, the four IPA-employed pathologists, who would later depart and form Goldfinch, refused to sign the agreement. The lawsuit claims the agreement was not intended to prohibit the use of confidential corporate information and was instead aimed at maintaining IPA's monopoly on pathology services.

IPA denied any wrongdoing and filed a motion to have the case dismissed. U.S. District Judge Rebecca Goodgame Ebinger recently granted the motion after finding that Goldfinch failed to define a geographic market in which patients had no other source for pathology services. "Even assuming central Iowa is where the defendants draw a sufficiently large portion of their business, Goldfinch has not sufficiently alleged a plausible reason why potential referral sources cannot practicably turn to alternative sources outside central Iowa," the judge ruled.

Two More Lawsuits Still Pending
The monopoly lawsuit followed a still-pending lawsuit filed by IPA against the four Goldfinch dermatopathologists in late 2022 that is in the final stages of litigation. That lawsuit seeks to block Goldfinch from soliciting IPA clients or using IPA information, and alleges the dermatopathologists were "flagrantly, rampantly and disloyally working against" IPA's interests even before they left IPA (see *LE*, January 2023).

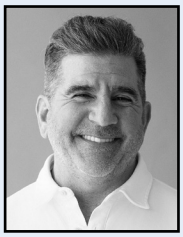
A bench trial in that case was held last month, but the court has yet to issue a decision.

Separately, two of the dermatopathologists—Milless and Halverson—have filed a discrimination lawsuit against IPA, alleging they were paid $200,000 to $350,000 annually, which they claim was far less than what some of the less qualified male doctors were paid.

A trial in that case is scheduled for August 2025.

12 EXECUTIVE PERSPECTIVES ON THE 2025 OUTLOOK FOR LABS (*cont'd from p. 1*)

Sonic Healthcare USA (Austin, TX) is in the process of digitizing its dermatopathology division. "It's our highest priority and will help us deal with the pathologist shortage," says Chief Executive Officer, **Cory A. Roberts, MD, MBA**. Sonic gained an integrated digital pathology solution (image management+AI+LIS) for dermatopathology through its acquisition of Pathology Watch (Murray, UT) in January 2024. Pathology Watch has the system in place at its three dermpath labs and Sonic is in the process of installing scanners and implementing the system at its 10 dermpath practices, according to Roberts.



Cory A. Roberts, MD, MBA

Sonic has a total of 7,500 employees in the United States, including over 380 pathologists of which 70 are dermatopathologists.

Sonic also has plans to digitize its prostate biopsy cases and add AI tools developed by Franklin.ai, a joint venture with Harrison.ai (Sydney, Australia).

Over the past year, Sonic has integrated the management and sales teams of its clinical lab and anatomic pathology services across the country into four geographic regions (West/Southwest, Midsouth, Northeast and Pacific/Hawaii). The new structure has lowered costs and allowed Sonic to sell its clinical/AP test services to hospital and physician office clients as a unified package, notes Roberts.

New test introductions at Sonic include ThyroSeq (licensed from UPMC), a next-gen sequencing test used to determine whether a thyroid nodule is malignant or benign. The test is being performed at a new 21,000-square-foot NGS lab (Rye Brook, NY) opened by Sonic last year.

Sonora Quest Laboratories (Phoenix) grew its operating margin by more than 15% in 2024 by increasing revenue (~$450 million per year), driven by an increase in the number of tests per requisition and a shift in the test mix toward more specialized tests, according to President and CEO **Dave Dexter**.

Sonora Quest, which has 3,900 employees, performs more than 100 million tests per year, primarily at its labs in Phoenix, Tucson and Yuma. Sonora Quest is a Laboratory Sciences of Arizona subsidiary and a joint venture between Banner Health and Quest Diagnostics.

Dave Dexter

Dexter says that one area of growth is the development of physician-owned laboratories (POLs). Sonora Quest now has more phlebotomists in physician offices than in its stand-alone PSCs. Sonora Quest has also developed a "hybrid" lab with VillageMD, focusing on value-based primary care. The lab is housed within Sonora Quest's 250,000-square-foot core lab but serves as a separate entity managed and staffed by VillageMD.

"Other POLs that we have built and manage for other corporate customers are stand-alone operations, some of which we staff and some that we don't," says Dexter. Sonora Quest has several POLs planned, focusing on kidney care, oncology, and other specialties.

In addition, Sonora Quest continues to work toward full digital pathology, which is operational at three hospital sites where more than 1,000 slides are scanned daily. To date, Sonora Quest has surpassed 500,000 total slides scanned. Once the transition is complete, the company will scan approximately 1.5 million slides annually.

Two other components of Sonora Quest's "digital transformation" are moving all software applications to the cloud and partnering with Cedar, a healthcare billing company, to do digital billing, which has improved collections.

Like other labs, Sonora Quest has made some changes to recruit and retain staff, which is incredibly challenging given that Arizona has a growing high-tech industry that offers competitive wages. In 2024, Sonora Quest made a significant "equity adjustment," increasing base pay for approximately 1,100 phlebotomists. In 2025, similar adjustments are planned for medical laboratory scientists and technicians.

Dexter believes managing Sonora Quest's workforce will be one of his biggest challenges in 2025. "The expectations of Gen Z are completely different from those of Gen X or Baby Boomers. What matters most to them is flexible scheduling and quick feedback," says Dexter. "In 2025, we will focus on equipping leaders with effective skill sets to manage multi-generational teams."

Mayo Clinic (Rochester, MN) continues to make progress in its transition to digital pathology, according to **Mayo Clinic Laboratories'** President and Chief Executive Officer **William Morice, MD, PhD**. More than 50% of its surgical pathology cases, including 100% of dermatology cases, on the Mayo Clinic Rochester campus are now being digitized and interpreted by pathologists via computer monitor.

William Morice, MD, PhD

Mayo Clinic employs over 180 staff pathologists and PhD laboratory scientists. It's using Leica/Aperio GT450 scanners with the Sectra digital pathology system. Mayo Clinic processes a total of roughly two million slides per year from its internal Mayo Clinic practice and outside clients.

In addition, Morice says that Mayo recently completed digitizing its archive of 12 million glass slides using Pramana scanners.

Morice says that Mayo is working with outside vendors and also internally developing AI applications for anatomic pathology. Initially, Mayo is expected to use AI for managing its digitized cases and directing them to the right subspecialist. Mayo is also working on AI algorithms for clinical diagnostics, including breast and prostate cancer cases.

Mayo Clinic Laboratories, which performed approximately 26 million tests in 2024, typically adds 80-100 new tests to its menu every year. Historically, Mayo developed most of its new tests internally. New test introductions include a urine assay (SORD testing) that screens for peripheral neuropathy and a metagenomics assay that can identify more than 1,000 pathogenic organisms in cerebrospinal fluid.

Recently, Morice says that Mayo Clinic Laboratories has begun partnering with more outside diagnostic test developers to help bring their new tests to the clinical market. For example, Mayo Clinic Laboratories has partnered with Progentec Diagnostics, which has developed a blood test for managing systemic lupus erythematosus. In addition, Mayo Clinic Laboratories has added Alzheimer's tests developed by C2N Diagnostics to its test menu in addition to its own Alzheimer's test (p-Tau217).

ACL Laboratories (West Allis, WI) grew its test volume by approximately 10% to more than 60 million tests last year, according to President **Dan Mumm**. Growth was fastest (up 14%) in the southeast (NC, SC, GA & AL), especially in the Charlotte area. Growth in the Midwest (Il & WI) was in the 3-5% range.

ACL Labs is an independent lab company owned by Advocate Health (Charlotte, NC), which includes 69 hospitals in the Midwest and southeast.

Dan Mumm

Mumm says that ACL Labs is in the process of finalizing its vendor selection for whole-slide-imaging scanners that will be installed at core histology labs in Milwaukee, Chicago, Charlotte and at Atrium Health Wake Forest Baptist (Winston-Salem, NC) by year's end. An RFP for image management software is set to go out soon. The goal is to have ACL's 205 affiliated pathologists transition to digital pathology within the next three years. Using enterprise-

wide slide scanners and image management software will simplify the eventual application of AI for case management, referrals and consults, and clinical diagnostic tools, notes Mumm.

ACL Labs is also seeking to consolidate its instrument/reagent contracts as they come up for renewal. It's currently in the process of installing an enterprise-wide blood culture solution using bioMerieux's Virtuos.

ACL Labs also plans to consolidate its reference testing lab contracts, currently held by ARUP Labs (Midwest region) and Labcorp (southeast region) within the next two years. In the meantime, ACL Labs will be opening a new lab for whole genome/exome sequencing at its Rosemont core lab (just outside of Chicago) this spring. ACL Labs also recently insourced pharmacogenomic testing for cancer drugs (e.g., DPYD genotyping) as well as noninvasive prenatal testing (NIPT).

Longer term, Mumm says ACL Labs is considering ways to provide lab testing to rural and urban patients that don't have easy access to doctor's offices and/or patient services centers. Possible solutions include collecting specimens in anticipation of future lab orders, after patients have traveled long distances for care and may have great difficulty coming back. In addition, Advocate Health is providing mobile health clinics, and considering including lab, pharmacy, and radiology services in the future.

ARUP Laboratories (Salt Lake City, UT), which has nearly 4,750 employees, continues to consolidate its instrument platforms to gain efficiencies and offset inflationary pressure, notes Chief Executive **Andy Theurer**. All mass spectrometers, for example, have been consolidated in a single lab from which all the diverse types of tests using this methodology are performed.

Andy Theurer

ARUP is a national reference lab enterprise of the University of Utah's Department of Pathology, which employs 110 pathologists.

Theurer anticipates that the University of Utah Division of Medical Laboratory Sciences' new Advanced Practice Clinical Laboratory Training Center will open this May. The center will double the number of new MTs trained by University of Utah each year from 40 to 80. ARUP hopes to hire nearly all new MTs trained at the center.

ARUP first installed a new digital pathology and AI system for ova and parasite testing in 2019. The system, developed in partnership with Techcyte, has doubled the productivity of ARUP's microbiology technologists. In addition, Theurer says that the University of Utah's Department of Pathology is planning to install new digital pathology scanners within the next 12-18 months. Thereafter, it will be able to hire additional pathologists outside of Utah to perform digital interpretations.

ARUP has a test menu of more than 3,200 tests and typically adds 50-100 new tests each year. Recent test additions include a bird flu (H5N1) test, a rapid acute myeloid leukemia targeted therapy mutation panel and an Alzheimer's disease biomarker test on cerebral spinal fluid, with a second AD biomarker test that can be performed on blood planned this spring.

Finally, Theurer says that ARUP has developed a blood management data visualization software tool that uses historical data to estimate how many units of blood transfusion patients might need, based on their preoperative characteristics. The tool helps physicians prevent adverse events that can occur during transfusion, such as volume overload or hemolytic reactions. It also helps prevent unnecessary waste of valuable blood products, saving money for the laboratory and health system. ARUP plans to offer this software tool to clients this year.

Alverno Laboratories (Hammond, IN), which fully implemented digital pathology seven years ago, scans between 1.2 million and 1.5 million slides per year and is now looking to replace its

early technology with more up-to-date scanners, according to Chief Executive **Sam Terese**. Alverno currently provides services to about 100 pathologists.

Alverno is also working with Ibex Medical Analytics (Brookline, MA.) to use AI to improve testing for prostate, breast and gastric cancers. In addition, Alverno is looking at other uses for digital-AI, such as in cytology, microbiology and hematology.

Sam Terese

Alverno, a joint venture between Franciscan Alliance and Ascension Illinois, operates over 30 hospital laboratories and provides testing to over 2,500 physician offices, freestanding urgent care facilities and research organizations. The lab currently has almost 2,000 employees and performs 15-16 million billable tests each year.

In 2024, Alverno experienced staff vacancies between 20% and 30%, but a newly implemented program has brought the vacancy rate to less than 10%. The new program, called N.O.W. (Need a Career? Opportunity Awaits With Alverno!), offers a variety of opportunities for multiple degree levels that can offer an accelerated path to a new lab career.

One area that remains difficult is retention of phlebotomists as there is a lot of competition in the Chicago area, notes Terese. "We offer phlebotomy training and have affiliations with multiple programs," he says. "Phlebotomists aren't hard to find, they're hard to keep."

In terms of inflation, the biggest price increases have been in insurance, particularly cyber-insurance, which has increased about 20%, says Terese.

Orion Laboratories (Baton Rouge, LA) processed approximately 600,000 lab claims (2.4 million tests) in 2024 and is already on track to double that amount in 2025, according to CEO **David Slaughter**. He started Orion with his wife Rachael (who is President) in a garage office at the back of his home in 2016.

Initially, Orion focused on providing phlebotomy and specimen pickup services. Orion opened a 3,000-square-foot laboratory in 2019 and then moved into a bigger 32,000-square-foot facility in early 2024. Orion currently employs 75 FTEs, has a clinical lab test menu of 515 tests, and provides services to 240 hospitals, nursing homes and physician office sites throughout Louisiana. In addition, the company has a subsidiary, Orion Therapeutics, that serves as a third-party sample tester for the state's medical marijuana program.

David Slaughter

Slaughter says Orion only has one sales rep (Rachael) and that growth is being fueled primarily by word-of-mouth from existing clients. Orion has benefited from its quick turnaround time and the fact that there are no major hospital outreach labs in the Baton Rouge area. Franciscan Missionaries of Our Lady Health System (FMOLHS) sold its outreach lab business to Labcorp in 2020.

Orion's biggest challenges include gaining in-network status with national health plans (e.g., Aetna and Cigna). In addition, Slaughter notes that inflation, particularly for employee health insurance and professional liability insurance, is a concern.

Orion added 45 tests to its menu last year (all FDA cleared test kits), including ABO Grouping and Rho(D) Typing, post-vasectomy semen analysis, mycoplasma genitalium PCR, and Herpes Simplex 1/2 (HSV) PCR. Slaughter says Orion is holding off on adding new laboratory-developed tests to its menu because of new FDA regulation.

Advanced Pathology Associates (APA-Rockville, MD) currently has three of its pathologists using digital pathology to sign out their cases. Another three pathologists will convert to digital by March 30 and then the final three by September 30, according to **Nicolas Cacciabeve, MD**, Managing Member.

Slide scanning is being performed at a freestanding central histology lab, Capital Choice Pa-

thology Lab (Silver Spring, MD), owned by Adventist HealthCare. APA provides medical and administrative directorship at the central histology lab, which has four scanners (two Philips Ultrafast Intellisite and two Roche 600 scanners) and processes 29,000 cases and 160,000 slides annually.

Nicolas Cacciabeve, MD

Cacciabeve believes that digital pathology improves pathologist productivity by 10-12% through better organization and assignment of cases, and quicker and more ergonomically friendly pathologist interpretations.

However, Cacciabeve says that the greatest productivity increases (30-50% improvement) will come from the application of AI to digitized images. AI applications will be developed and implemented more quickly than most expect driven by forthcoming studies that show AI-assisted diagnoses are more accurate (sensitivity improvement from not missing a single fragment of cancer cells) and more precise (improved inter-observer agreement and intra observer reproducibility among pathologists). Over time, digital pathology coupled with AI-assisted interpretations will become the standard of care, predicts Cacciabeve.

In terms of challenges, Cacciabeve points to the shortage of pathologists and rising salaries. APA currently has two pathologist job openings. "Pathologists coming out of fellowships are asking for salaries that someone with 5-10 years of experience would expect…This has been one of the most pronounced disruptions in salary structure that I have seen in over 30 years as practicing pathologist and employer."

APA has 20 employees, including nine pathologists and four pathologists' assistants. The group provides medical director and lab management services to three Adventist HealthCare hospitals and its central histology lab, plus two hospitals in the University of Maryland Healthcare System. In addition, Cacciabeve says that APA will soon hire a dermatopathologist to serve local dermatology practices.

Wisconsin Diagnostic Laboratories (WDL - Milwaukee), which performs more than 8.5 million tests each year, recently opened a new molecular genomics laboratory in partnership with the Medical College of Wisconsin's Department of Pathology, according to President **Steve Serota**. Initially, the new lab will offer 15 molecular tests, but Serota anticipates having 45 molecular tests by the end of the first quarter.

Steve Serota

WDL, which is owned by Froedtert Health System, has 550 employees and serves 57 hospitals, 750 long-term care facilities and 380 physician practices primarily in Wisconsin and Northern Illinois. Froedtert merged with ThedaCare Health in early 2024. Lab leadership has been centralized, but the physical locations have not changed. Because ThedaCare operated in northern Wisconsin, and Froedtert operates in southern Wisconsin, there was no need to close any labs, according to Serota.

In late 2023, WDL launched Atalan, a platform that connects physicians and hospitals with clinical laboratories across the country.

"Atalan is a tech enabled clinical partnership platform that allows academic and affiliated laboratories to partner together to use each other's reservoirs of capacity and collaborate on innovation," explains Serota. "The idea behind it is to lower the commercial barriers to market entry for hospital- and affiliated laboratories so they can offer their tests to partners in non-contiguous geographies."

Test ordering and results are connected digitally using a centralized hub to support LIS-to-LIS integrations while decreasing the demand on already-taxed information technology teams.

For example, if a lab has only one subspecialist pathologist in a given area and that person takes time off, the lab can now send the subspecialty testing to another lab in the network. Serota says this reciprocal relationship benefits all network partners and, most importantly, patients.

Currently, there are three participating partners in Atalan: Froedtert Health in Wisconsin, South County Health in Rhode Island and TriCore Reference Laboratories in New Mexico. Serota hopes to add another six to eight partners by the end of 2025.

"We see Atalan as a way for WDL to both to expand our outreach and to partner in the development and validation of new assays, while creating a platform to spur cooperation and innovation within the laboratory industry as a whole."

WDL expects to add 125 tests to its menu this year. Currently, WDL offers about 2,700 tests, including more than 500 LDTs. Serota is hopeful that there will be some compromises reached on FDA regulation of LDTs.

Due in part to Froedtert's merger with ThedaCare, WDL expects to see growth of 10% to 15% in 2025, with test revenues exceeding $12 million. The lab is continuing to expand its local outreach business as well, with a particular focus on federally qualified health centers.

Joe Song, Chief Executive of **Associated Pathology Medical Group** (APMG-Los Gatos, CA), says that his group is helping to pay the education expense of its lab assistants to become histotechnologists. There's a shortage of histotechs in California and it's difficult to hire staff from outside the state. Potential new employees get sticker shock given the high cost of living in the San Francisco area, notes Song. For example, small homes in the Bay Area are selling for an average of more than $1 million and one-bedroom apartments rent for $3,000 per month.

Joe Song

To offset inflationary pressure, Song says that APMG is seeking to lock in longer-term contracts (5-6 years) with instruments and reagent vendors.

Song says that APMG has also had some success in carving out higher reimbursement rates from health insurers for specific anatomic pathology test codes.

New test additions for 2025 at APMG will include one-swab testing for women's health panels (e.g., bacterial vaginosis, chlamydia/gonorrhea, trichomonas, etc.).

With 84 employees, including nine pathologists, four hospital contracts and a full-service histology lab, APMG is one of the largest independent pathology groups in northern California.

Joint Venture Hospital Laboratories (JVHL-Allen Park, MI), a hospital outreach laboratory network serving health plans throughout Michigan as well as northern Ohio and Indiana, has grown to include more than 120 hospital members serving 5.6 million covered lives under 28 regional and national health plan agreements. JVHL network members perform more than 20 million tests per year under the network's health plan agreements, according to Chief Executive **John Kolozsvary**.

Kolozsvary says that JVHL has a tremendous opportunity to leverage its strategic partnerships and data analytics to advance population health and other chronic disease initiatives. For example, JVHL recently completed a data mining project with the National Kidney Foundation to look at population health trends in kidney disease and is looking for additional opportunities to provide analytics to health plans. JVHL is also seeking to expand its footprint in utilization management and is actively working toward

John Kolozsvary

accreditation from the National Commission on Quality Assurance.

Kolozsvary notes that hospital laboratories in Michigan are faced with the same staffing challenges as other labs across the country and have responded with wage scale adjustments and recruitment incentives. To further network members' recruitment efforts, JVHL hired a laboratory professionals recruitment coordinator to complement their recruitment activities. These efforts to date have included workforce education sessions with hospital human resources and laboratory leaders, training program directors and participation in high school career fairs.

Kolozsvary is acutely aware that commercial labs are approaching hospital and health system members for a variety of business relationships, including sale of their outreach labs. "Selling a hospital laboratory program could certainly solve some short-term financial needs, but much more should be considered as part of the evaluation process," he says. "These items include organization structure of the lab, potential for alternate business and reimbursement models, impact on test turnaround time, patient satisfaction, the value of the longitudinal medical record, and referring physician loyalty, just to name a few."

JVHL constantly keeps an eye on leakage of lab testing to commercial laboratories, says Kolozsvary. Besides the risk of fragmenting care, there is also the risk of health plan members' exposure to increased cost sharing or balance billing for out-of-network services.

JVHL is owned by four health systems: Corewell East (Beaumont Health), McLaren Health Care, Michigan Medicine (University of Michigan) and Trinity.

Staffing shortages, especially for histotechnologists, are the biggest challenge facing the lab industry today, according to **Tony Bull**, former System Administrative Officer, Pathology and Laboratory Medicine at **Medical University of South Carolina** (Charleston, SC).

Tony Bull

MUSC Health includes 11 hospitals and 18 labs with 720 lab employees. Staffing shortages are being intensified by test volume growth. MUSC Health processed 9.1 million tests in the year ended June 30, 2024, and is expected to reach 10.1 million tests in the current fiscal year, according to Bull.

The remedy for understaffing is new technology and automation in areas like microbiology and the histology department. For example, Bull notes that three Philips UFS300 scanners have been in use at its flagship hospital in Charleston since 2020 and has transitioned its gastroenterology cases to digital pathology. MUSC Health is working to expand digital pathology into additional subspecialties (renal, cardiovascular, some placentas) and across the system.

MUSC Health insourced roughly two million tests per year from its owned physician clinics in 2021. Previously this test volume had been processed by an out-of-state commercial lab. As a result, Bull says that turnaround times improved an average of 1-2 days, depending on the test.

Bull notes that vendors have been pushing hard for price increases on supplies, reagents and analyzers as contracts have come up for renewal. However, MUSC has been able to leverage its increased size to keep prices flat to slightly lower.

Finally, MUSC recently expanded its DNA testing capabilities by adding a Genomadix Cube rapid analyzer for CYP2C19 testing to identify patients who are unable to metabolize blood-thinner clopidogrel (Plavix), as well as adding CYP3A5 testing for determining tacrolimus doses for transplant patients.

Note: Tony Bull resigned from his position at MUSC effective December 31, 2024.

Billing CPT 81479 Requires Additional Documentation

Clinical laboratories that bill for a molecular pathology procedure for which there is no specific code must use CPT 81479 (unlisted molecular pathology procedure). However, because this code has a high denial rate (75% to 80%), billers should be sure to include enough documentation to support the claim, advises Clarisa Blattner, Senior Director, Revenue and Payor Optimization, for XiFin Inc. (San Diego). [Note: In some cases, payers require pre-authorization for use of 81479.]

When billing 81479, include a description of the testing performed and any relevant medical records, says Blattner. If the claim is denied, the payer will likely ask for other documentation to be sent.

According to the Center for Medicare and Medicaid Services ("Billing and Coding: Molecular Pathology and Genetic Testing," A58917), when billing Medicare for CPT code 81479, the specific gene being tested must be entered in block 80 (Part A for the UB04 claim), box 19 (Part B for a paper claim) or electronic equivalent of the claim.

"Failure to include this information on the claim will result in Part A claims being returned to the provider and Part B claims being rejected," says CMS. "In addition, medical records may be requested when 81479 is billed. The medical record must clearly identify the unique molecular pathology procedure performed, its analytic validity and clinical utility and why CPT code 81479 was billed."

A number of private payers have adopted Medicare's MolDX Program's requirement that labs obtain a Z-code through Palmetto's Diagnostics Exchange (DEX) for their molecular tests. The DEX Z-Code identifier is a unique 5-character alpha-numeric code associated with certain molecular diagnostics tests that is used by some payers as an adjunct to non-specific CPT codes.

Current participating payers in the DEX Z-Code program include United Healthcare (Medicare Advantage and Commercial), Optum Care (Medicare Advantage) and Humana (Medicare Advantage). Other payers that participate in the DEX program include Medical Mutual of Ohio, Fallon Health and BlueCross BlueShield of North Carolina.

More information on the DEX Z-Code program is available here.

Versant Buys Avero Diagnostics

Versant Diagnostics (Grapevine, TX) has acquired the anatomic pathology business of Avero Diagnostics (aka Northwest Pathology). Avero has a total of 131 employees, including eight pathologists, and operates a histology lab in Bellingham, WA (90 miles north of Seattle). Avero has subspecialties in dermatopathology, hematopathology and GI/GU, and provides medical directorship oversight for Peace Health, Skagit Valley Medical Center and a number of smaller hospitals in the Pacific Northwest. Avero President Ryan Fortna, MD, PhD, has become Regional Managing Director for Versant.

Versant was founded by Ven Aduana, MD, Jim Billington and Brian Carr in 2021 (see *LE*, November 2021). Versant was funded with $100 million (both equity and debt) from Iron Path Capital (Nashville, TN).

Versant has now acquired nine pathology practices with a combined 65 pathologists.

Versant Diagnostics Acquisition History

Acquisition Date	Laboratory Name	# Pathologists
Dec-24	Avero Diagnostics/Northwest Pathology (Bellingham, WA)	8
May-24	Associate Pathologists (Joliet, IL)	4
Oct-23	Dahl-Chase Pathology (Bangor, ME)	15
May-23	PRW Laboratories (Charlottesville, VA)	8
Jun-22	Pathology Consultants of Chicago (Chicago, IL)	1
Jun-22	Elgin Laboratory Physicians (Elgin, IL)	1
Oct-21	Alliance Pathology Consultants (Elk Grove Village, IL)	15
Oct-21	Addison Central Pathology (Chicago, IL)	12

Source: *Laboratory Economics*

Labcorp to Acquire MAWD Pathology Group Assets

Labcorp has agreed to buy MAWD Pathology Group's clinical and women's health testing businesses. MAWD Pathology, an independent laboratory in Lenexa, KS, will continue to provide anatomic professional and technical pathology services. The transaction is expected to close in early 2025.

Labcorp Completes Purchase of Ballad Health Outreach Lab

Labcorp has completed its acquisition of the clinical lab outreach business of Ballad Health (Johnson City, TN). Ballad (formerly Wellmont Health Systems/Mountain States Health Alliance) will continue to operate its inpatient and emergency department lab, as well as its anatomic pathology services to hospital-based practices. Ballad has 20 hospitals and a large multi-specialty physician practice that covers Northeast Tennessee, Southwest Virginia, Northwest North Carolina and Southeast Kentucky.

Recent Labcorp Hospital Outreach Lab Acquisitions

Date	Acquisition Target (location)	Purchase Price ($ millions)
Dec-24	Ballad Health outreach lab (Johnson City, TN)	NA
Apr-24	Baystate Health outreach lab (Springfield, MA)	$120.2
Apr-24	Providence California Medical Group Labs (Northern California)	$54.9
Nov-23	Legacy Health outreach lab (Portland, OR)	$107.7
Sep-23	Tufts Medicine outreach lab (Boston, MA)	$157.0
Jun-23	Providence Health Oregon outreach lab (Portland, OR)	$110.0
May-23	Jefferson Health outreach labs (Philadelphia, PA)	$110.2

Source: Labcorp

Lab Stocks Jump 103% In 2024

Twenty-five lab stocks increased by an unweighted average of 103% in 2024. Overall, 11 lab stocks rose and 14 fell. The top-performing lab stock in 2024 was GeneDx, up an incredible 2,695%. Quest Diagnostics increased by 9% and Labcorp was up 1%. In comparison, the S&P 500 Index rose by 23% last year.

Company (ticker)	Stock Price 12/31/24	Stock Price 12/29/23	2023 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
GeneDx (WGS)	$76.86	$2.75	2,695%	$2,110	$267	7.9
Natera (NTRA)	158.30	62.64	153%	20,450	1,532	13.3
Interpace Biosciences (IDXG)	2.70	1.08	150%	63	45	1.4
Exagen (XGN)	4.10	1.99	106%	74	56	1.3
CareDx (CDNA)	21.41	12.00	78%	937	313	3.0
Veracyte (VCYT)	39.60	27.51	44%	2,810	425	6.6
Castle Biosciences (CSTL)	26.65	21.58	23%	493	312	1.6
Guardant Health (GH)	30.55	27.05	13%	4,190	692	6.1
Quest Diagnostics (DGX)	150.86	137.88	9%	23,160	9,539	2.4
NeoGenomics (NEO)	16.48	16.18	2%	2,330	644	3.6
Labcorp (LH)	229.32	227.29	1%	25,450	12,713	2.0
Opko Health (OPK)	1.47	1.51	-3%	1,100	711	1.5
Tempus AI (TEM)	33.76	37.00	-9%	5,320	640	8.3
Sonic Healthcare (SHL.AX)*	27.01	32.08	-16%	16,850	8,970	1.9
Biodesix (BDSX)	1.53	1.84	-17%	254	66	3.9
Exact Sciences (EXAS)	56.19	73.98	-24%	12,160	2,692	4.5
Psychemedics (PMDI)	2.24	2.96	-24%	13	20	0.7
Myriad Genetics (MYGN)	13.71	19.14	-28%	1,290	824	1.6
Fulgent Genetics (FLGT)	18.47	28.91	-36%	-244	278	NA
23andMe (ME)**	3.25	18.27	-82%	29	193	0.2
Aspira Women's Hlth (AWH)	0.71	4.08	-83%	12	9	1.3
ProPhase Labs (PRPH)	0.76	4.52	-83%	47	13	3.7
Biocept (BIOCQ)	0.00	0.04	-100%	5	NA	NA
Invitae (NVTAQ)	0.00	0.63	-100%	1,250	NA	NA
DermTech Inc. (DMTKQ)	0.00	1.75	-100%	15	16	0.9
Totals & Averages			**103%**	**$120,169**	**$40,970**	**2.9**

*Sonic Healthcare's figures are in Australian dollars **23andMe had a 1-for-20 reverse stock split on Oct. 16, 2024.
Source: *Laboratory Economics* from SeekingAlpha.com

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