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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

FDA Rule on LDTs is Dead… For Now

A district court ruling overturning the FDA's final rule on lab-developed tests (LDTs) likely means the rule is dead for good, with one caveat: The Trump administration has 60 days from the date of the decision to appeal the ruling. Sources tell *Laboratory Economics* they don't believe the administration will appeal.

Judge Sean Jordan

On March 31, 2025, Judge Sean Jordan of the U.S. District Court for the Eastern District of Texas vacated the FDA's final rule in its entirety, remanding the matter to Health and Human Services Secretary Robert F. Kennedy Jr.

"An appeal would have to be a core priority for the FDA to engage, and I don't see that. With the cutbacks on staff, there has to be prioritization within the agency. It's a bandwidth problem," according to Kyle Faget, a partner with the law firm of Foley and Lardner (Boston).

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Proscia Raises $50 Million to Fund Growth

Digital pathology software developer Proscia (Philadelphia) has raised $50 million in a Series C fundraising round led by Insight Partners (New York City). Proscia has now raised a total of $130 million since being formed in 2014. Proscia CEO David West says the new funds will be used to help continued expansion. Last year, Proscia doubled its client base to 100 pharmaceutical companies and pathology labs in the U.S. and Europe.

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How Will Tariffs Affect Lab Budgets?

Instruments, reagents and supplies typically comprise 20-30% of the average laboratory's budget. President Trump's substantial new import tariffs have the potential to raise these costs, adding to the existing pressure from rising employee salaries and benefits. However, the impact of tariffs on domestic labs may be muted given that most of the largest IVD vendors operate manufacturing plants inside the U.S., according to Michael Farmer, Principal at the IVD market research firm McEvoy & Farmer (New York City).

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HOW WILL TARIFFS AFFECT LAB BUDGETS? (*cont'd from page 1*)

Products assembled and/or manufactured at U.S.-based plants are not subject to the new tariffs, although imported component parts are getting hit with tariffs ranging from 10% to as high as 145% (China). These tariffs (aka import taxes) are paid by the importing company who will try to pass on the cost by hiking prices to their customers.

Farmer notes that the world's largest IVD manufacturer, Roche Diagnostics (Basel, Switzerland), has its North American headquarters and a major manufacturing plant in Indianapolis. Roche also owns manufacturing plants in Branchburg, NJ (Roche Molecular Systems), and Tucson, AZ (Ventana Medical Systems).

Similarly, Farmer says that Danaher's Beckman Coulter division is headquartered in California and has a major manufacturing plant in Indianapolis.

In addition, Farmer notes that Abbott Diagnostics is headquartered in the Chicago area and owns several plants in Illinois. However, Abbott does have tariff risk because it manufactures most of its core lab instruments in Singapore (10% tariff).

"The key question for laboratory instruments and reagents assembled in the U.S. is, how much do they rely on imported foreign parts, especially electronic components shipped from China, Taiwan or Singapore?" says Farmer.

Global IVD Sales by Vendor ($ millions)

IVD Companies	Headquarters	Worldwide Diagnostic Revenue 2024	Worldwide Diagnostic Revenue 2023	% Chg
Roche Diagnostics	Switzerland & Indianapolis, IN	$16,617	$16,764	-0.9%
Danaher Dx	Brea, CA	9,787	9,577	2.2%
Abbott Diagnostics	Abbott Park, IL	9,341	9,988	-6.5%
Siemens Healthineers Dx	Erlangen, Germany & Malvern, PA	4,837	4,959	-2.5%
Thermo Fisher Specialty Dx	Waltham, MA	4,512	4,405	2.4%
BioMerieux Clinical Dx	Marcy-l'Etoile, France	3,692	3,394	8.8%
Becton Dickinson IDS	Franklin Lakes, NJ	3,679	3,624	1.5%
Sysmex	Kobe, Japan	3,171	2,821	12.4%
QuidelOrtho	San Diego, CA	2,783	2,998	-7.2%
Werfen	Barcelona, Spain	2,320	2,308	0.5%
Mindray IVD	Shenzhen, China & Mahwah, NJ	2,093	1,731	20.9%
Hologic Dx	Marlborough, MA	1,782	1,880	-5.2%
Agilent Dx	Santa Clara, CA	1,651	1,755	-5.9%
Bio-Rad Labs Dx	Hercules, CA	1,538	1,489	3.3%
Revvity Dx	Waltham, MA	1,502	1,459	2.9%
DiaSorin	Saluggia, Italy	1,286	1,258	2.2%
QIAGEN	Hilden, Germany	749	698	7.3%
Total for 17 companies		$71,340	$71,108	0.3%
Worldwide IVD Market		$89,175	$88,885	0.3%

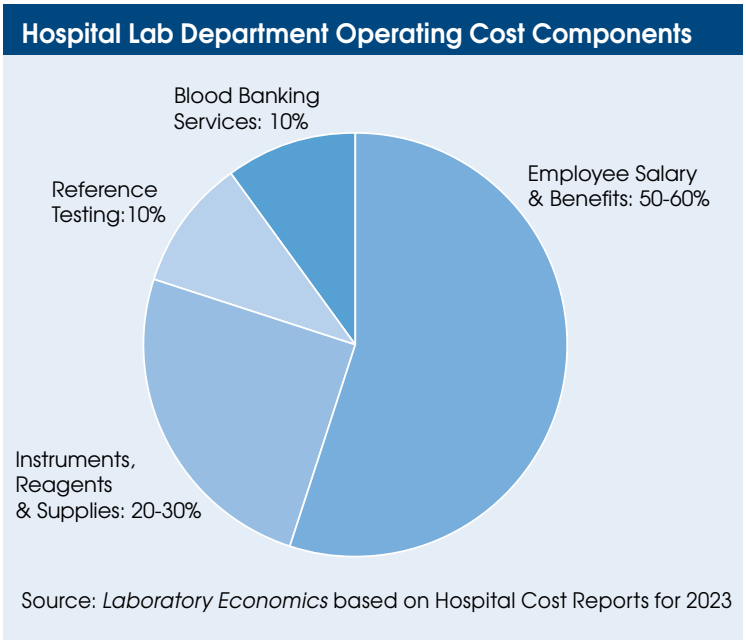
Source: *Laboratory Economics* from company reports, Nephron Research and UBS Equity Research

Among the IVD vendors that could be hurt the most from tariffs is Sysmex (Kobe, Japan), which manufactures its hematology analyzers in Japan (10% tariff with potential hike to 24%) and India (10% with potential hike to 26%). Farmer notes that Sysmex does have a reagent manufacturing plant in Mundelein, IL.

Other IVD vendors that could get squeezed by U.S. tariffs include Werfen (Barcelona, Spain), QIAGEN (Hilden, Germany) and DiaSorin (Saluggia, Italy), according to Farmer.

Retaliatory Tariffs are the Greatest Risk for IVD Vendors

Meanwhile, Bruce Carlson, President of the market research firm Eye on IVD (New York City), says that the majority of IVD instruments and reagents are manufactured in the United States. As a result, the biggest risk to IVD companies is retaliatory tariffs.



For example, China, one of the fastest-growing lab markets in the world, imposed new 125% tariffs on U.S. products effective April 11.

Carlson says that instrument and reagent sales to U.S.-based labs represent roughly 40% ($36 billion) of the total worldwide IVD market. The other 60% ($53 billion) of the market is comprised of Europe, Japan, China, Canada, etc. As a result, American-based IVD manufacturers have more to lose than their foreign counterparts in the event of a worldwide trade war.

Tariffs Biggest Impact Could Be on Consumables

Larry Worden, Principal at IVD Logix (Dallas, TX), believes that import tariffs could have their greatest impact on low-tech laboratory consumables such as glass slides, test tubes, pipettes, gloves and gowns. In addition, he notes that tariffs may increase the cost of paper forms and packaging supplies (i.e., paper, cardboard and plastic containers).

Worden estimates that import tariffs could raise lab operating budget costs by an average of 2-3%. For example, if the average lab spends 25% of its budget on instruments, reagents and supplies, and if half of the lab supply budget (12.5%) is hit by 20% tariffs, that would result in a 2-3% overall cost increase.

Worden notes that labs are already struggling with post-pandemic employee wage and benefit pressures.

Tariffs will also be felt in lab capital budgets. To offset these cost pressures, labs might delay capital investments in new instrument lines.

Finally, Worden notes that the inflationary pressure might lead more health systems to outsource more of their lab testing to either Quest Diagnostics or Labcorp.

Spotlight on BayCare Laboratories

Donna Lynch

BayCare Health System (Tampa, FL), which includes 16 hospitals in Florida, has almost 1,200 lab employees that perform a total (inpatient/outpatient/outreach) of more than 14 million tests per year. BayCare Laboratories operates core labs at St. Joseph's Hospital (Tampa - 1,354 beds), Morton Plant Hospital (Clearwater – 689 beds) and Winter Haven Hospital (Winter Haven – 455 beds). *Laboratory Economics* recently spoke with BayCare's Donna Lynch, Vice President of Laboratory Services, on a range of topics.

Can you describe the clinical laboratory outreach business at BayCare?
BayCare currently performs a total of 3.6 million nonpatient outreach tests per year, which grew by 8.5% in 2024. About 50% of our outreach test volume comes from BayCare Medical Group, which employs 495 physicians at 213 outpatient clinics throughout West Central Florida. The other half comes from non-affiliated physician clients, clinics, surgery centers, and nursing homes.

BayCare has 27 patient service centers (PSCs) and employs over 100 couriers. A 28th PSC is planned to open next year at a new 45,000-square-foot medical office building being constructed in Manatee County. BayCare also anticipates opening its 17th hospital (154 beds) in Manatee County in 2028.

Our outreach growth is the result of fast turnaround times and quality of service at our PSCs, including short wait times.

BayCare's outreach growth is also benefiting from growth in the health system as well as population growth in Florida. Note: The population of the Tampa-St. Petersburg-Clearwater MSA grew by 1.8% per year between 2020 and 2024 to reach 3.4 million, according to the U.S. Census Bureau. That's more than double the overall U.S. population growth rate of 0.7% per year.

Who provides anatomic pathology services to BayCare's outreach labs?
We contract for professional services with three different pathology groups (Associated Pathologists, Pathology Associates and Clearwater Pathology Associates).

In addition, we've started to evaluate whole-slide scanners and digital pathology software. We plan to implement slide-scanning within the next year at Morton Plant Hospital.

What are some of the tests you've insourced in the past 12 months?
Our primary reference lab is Labcorp. We recently added myeloproliferative neoplasm panel (MPN) to help diagnose rare blood cancers.

We also added a PCR test for Candida auris for quicker detection of yeast infections that can cause severe illness. Candida auris is a particular concern for hospitals and nursing homes because it can spread easily among patients, especially those who are already sick or have weakened immune systems. Bringing this test in-house has helped us trim 24-48 hours off turnaround time.

In addition, we modified the critical ranges for a separate CBC with diff, specifically for our ordering hematologists and oncologists. The tighter range eliminates unnecessary after-hour calls to these specialists.

We have a total of 42 LDTs on our test menu. We were prepared to meet the proposed FDA regulations for LDTs, but were glad to see ACLA prevail in its lawsuit.

Vanderbilt Takes First Step into Digital Pathology

The pathology lab at Vanderbilt University Medical Center (VUMC-Nashville, TN) has installed its first high throughput scanner and has begun digitizing its vast archive of glass slides. This is the first step toward plans for enabling VUMC's 100 practicing pathologists to utilize digitized slides images & AI for clinical diagnostics. The multi-year project is being led by Fedaa Najdawi, MD, Medical Director of Informatics and Digital Pathology at VUMC. Dr. Najdawi joined VUMC in September 2024 following four years as Director of Pathology at the artificial intelligence software developer PathAI (Boston, MA).

Fedaa Najdawi, MD

Where does VUMC stand in its rollout of digital pathology?
VUMC recently installed its first high throughput scanner in our new 110,000-square-foot core laboratory located approximately five miles north from VUMC's main Nashville campus. Initially we will focus on scanning the millions of glass slides held in our archive. Our goal is to scan a total of 500,000 slides over the next three years. These digitized slide images will be used for educational purposes and research for the development of new diagnostics and therapies.

Which type of scanners are being used?
We're using Pramana's SpectralHT four-head system with a robotic arm for automated slide handling. This system is capable of processing 480 slides per run and we're planning two runs per day. We're also using Pramana's whole slide image viewer. In addition, we are evaluating various AI-enhanced software platforms for image management.

When do you anticipate using digital pathology for clinical diagnostics?
VUMC's histology lab and 100 practicing pathologists will begin scanning and interpreting digitized slide images for primary diagnosis within the next few years.

What benefits do you expect from using digital pathology for clinical diagnostics?
Number one, improved efficiency and turnaround time from a reduction in the need to physically transport glass slides; 2) better case management in terms of more-easily prioritizing urgent cases and getting cases to the right sub-specialty pathologists; and 3) improved collaboration and second opinions for complex cases. Finally, digital pathology is also a necessary first step toward applying AI.

What's the future of AI in the practice of anatomic pathology?
First let me say that human expertise is irreplaceable. At the same time, I expect that AI will slowly and fundamentally reshape the practice of pathology. I anticipate a hybrid model where AI tools are used by pathologists, rather than replace pathologists. For example, AI can be integrated into the slide scanning process for quality control--detecting a variety of artifacts like annotations, debris, broken coverslips and bubbles. It can also be used for quantitative analysis, including IHC scoring and tumor marker grading. Ultimately, I expect AI to help create integrated patient case reports, including results from digital pathology, molecular diagnostics and radiology.

PROSCIA RAISES $50 MILLION TO FUND GROWTH (*cont'd from page 1*)

Proscia's Concentriq software platform helps pathologists and scientists view and manage digitized slide images.

Recent new clients include CellNetix Pathology & Laboratories (Seattle), HNL Lab Medicine (Allentown, PA) and Fimlab (the largest lab in Finland). Proscia's clinical customers diagnosed 2.4 million patients on Concentriq in 2024.

West says that Proscia is on track to double its client base to more than 200 worldwide clients within the next 12-18 months. Proscia currently has 100 employees and is seeking to hire 25 more people (e.g., software engineers, sales reps and client service) in the next few months.

West notes that over the past 18 months, nearly every large pathology lab in the U.S. has begun the transition to digital pathology. The expected return on investment will come from the application of AI tools to raise pathologist productivity. Digital pathology and the potential to read slides from home can also be used as an enticement to help labs hire pathologists.

However, West believes the growing pipeline of new cancer treatments that rely on digital pathology and AI may become the biggest motivator. For example, he notes that AstraZeneca and Roche Tissue Diagnostics are co-developing a companion diagnostic for Daiichi Sankyo's drug (datopotamab deruxtecan) for patients with non-small cell lung cancer. The test uses AI on digitized slide images to help determine which NSCLC patients can benefit from datopotamab deruxtecan. "As new AI-directed precision therapeutics come to market in the next few years, labs will have no choice but to adopt digital pathology," according to West.

ARUP Labs to Digitize Hematopathology Archive

ARUP Laboratories (Salt Lake City, UT) has installed three Pramana SpectraHT scanners at its Institute for Research and Innovation and plans to begin scanning its archive of bone marrow biopsies. ARUP, which employs 16 hematopathologists, is aiming to digitize 75,000 bone marrow slides within the next few months, according to David Ng, MD, Medical Director of Hematologic Flow Cytometry and Applied Artificial Intelligence.

Ng notes that bone marrow biopsy cases are complex and difficult to scan. The Pramana SpectraHT scanners were chosen because they are faster and capable of higher magnification (40x to 100x) than most other digital scanners (typically 40x).

Ng says that ARUP's data scientists will utilize semi-supervised learning models to develop AI tools to perform cellular counts and morphology analysis of digitized bone marrow images. These tools will initially be used for research purposes only, including for the development of new drugs and diagnostic tests. Over time, ARUP may develop laboratory-developed tests that utilize digital pathology and AI for clinical interpretation of bone marrow biopsies.

PathAI Adds 4 New Lab Clients

PathAI (Boston, MA) has added four new lab clients that will adopt its AISight digital pathology image management system. PathAI now has a total of 64 lab clients in the U.S.

The four new lab clients include:

- **Annapath Pathology Services** (Bowie, MD), a surgical pathology lab with specialties in gastrointestinal, genitourinary and dermatopathology based in the Mid-Atlantic region and now expanding nationwide.
- **Pathology Group of Louisiana** (Baton Rouge, LA), an independent pathology group with 15 pathologists across Texas and Louisiana.
- **Peninsula Pathologists Medical Group** (South San Francisco, CA), an independent pathology practice with nine pathologists serving Northern California.
- **SigmaCore** (San Antonio, TX), a pathology practice management company specializing in anatomic pathology and hematopathology.

PathAI has raised a total of $255 million since being founded in 2016. Major backers include Labcorp, Kaiser Permanente, Merck and Bristol-Myers.

FDA RULE ON LDTS IS DEAD … FOR NOW (*cont'd from page 1*)

The American Clinical Laboratory Association (ACLA) filed the lawsuit on May 29, 2024, seeking to have the rule, issued May 6, 2024, thrown out. The Association for Molecular Pathology (AMP) also filed a lawsuit, and the two lawsuits were later consolidated.

In the judgment in favor of the plaintiffs, the court stated that: "the text, structure and history of the Food Drug and Cosmetic Act [FDCA] and the Clinical Laboratory Improvement Amendments [CLIA] make clear that the FDA lacks the authority to regulate laboratory-developed test services."

Kyle Faget

Throughout its opinion, the court outlines its disagreement with the FDA's expansion of its authority and interpretation of the definition of 'device' and the agency's overall interpretation of its authority to regulate LDTs under the FDCA, according to Foley and Lardner attorney Kyle Faget. The court emphasized that "devices" under the FDCA "are tangible, physical products, not intangible test services performed as in-house diagnostic tests developed, validated, and performed by trained professionals within a single clinical lab" and that Congress specifically addressed the regulation of clinical labs and their services through CLIA, an independent statutory framework under the Centers for Medicare & Medicaid Services (CMS).

In its opinion, the court defines LDTs as "a methodology or process by which a laboratory generates biochemical, genetic, molecular or other forms of clinical information about a patient specimen for use by the treating physician. Each laboratory uses its own unique knowledge of the protocols, performance characteristics and means of analysis to develop such methodologies and processes."

The court emphasized that LDTs are offered as services. Unlike a drug or device, which is a manufactured and packaged article of commerce with user instruction, an LDT-developed test service is a proprietary methodology performed only by the developing laboratory, the ruling states.

"That service generates information from test results and transmits that information to the ordering physician," the court writes. "The testing services are not sold as a kit, and the protocol is not transferred in any manner to other laboratories, hospitals or other facilities outside the developing laboratory entity. No physical product is sold, and no article of personal property is transferred such that title passes from one party to another."

The first compliance deadline under the final rule was supposed to have been May 6, 2025. On that date, labs were to have implemented medical device reporting systems and complaint file management requirements. As a result of the March 31 court decision, the rule and its deadlines are no longer in effect.

"The court's ruling ensures that clinical laboratories can continue to focus on their primary mission – offering innovative and reliable diagnostics that save and improve the lives of million of patients every day," said ACLA President Susan Van Meter in a statement.

Appeal Unlikely

An appeal by the Trump administration is unlikely, says Faget. "We are in an environment of deregulation as opposed to regulation," she explains.

Jonathan Genzen, MD, PhD, Chief Medical Officer with ARUP Laboratories (Salt Lake City), agrees that an appeal probably will not be forthcoming.

"It seems unlikely given many of the administration's regulatory positions, but the court's opinion does raise additional questions about the extent of FDA's authority over software and other things," he says. "I don't think an appeal is the most streamlined way to get that particular authority, but there probably will be an opportunity for the FDA to express its opinion on the rule."

Jonathan Genzen, MD, PhD

The court's decision in this case does raise additional questions that need to be clarified, notes Genzen. For example, what happens to LDTs that were previously cleared or approved by the FDA since the court said the FDA doesn't have jurisdiction over LDTs?

In addition, there may be cases where a lab may want to submit an LDT to the FDA for review, either for billing purposes or for other reasons, says Genzen, but if the FDA does not have jurisdiction over these tests, will there be pathways for the review?

Next Steps

Assuming the Trump administration does not appeal the court ruling, Congress could attempt to address some of the open-ended questions regarding interstate commerce and the FDA's authority over items such as software used in LDTs.

Lawmakers could revisit the idea of establishing just which agency has jurisdiction over LDTs as they tried to do in between 2020 and 2023 with the Verifying Accurate Leading-Edge IVCT Development (VALID) Act. VALID would have created a new regulatory pathway, separate from both drugs and devices, for FDA premarket review and the regulation of LDTs. That bipartisan measure, which failed to advance, would have established a federal regulatory framework for the oversight of LDTs.

Genzen says there may be other conversations about setting up a regulatory structure similar to what VALID would have done, but he doubts that the agency would be able to administer such a regulatory system, particularly given recent cuts.

"I personally think there may be an opportunity for more discussion on a CLIA-centric regulatory approach that would achieve many of the same goals but be done so in a much more cost-effective and efficient way," he says.

For now, however, Genzen believes there is little desire in Congress to address the issue of LDT oversight. "There is focus on many other things at the national level right now that have extreme national importance and the issue of LDTs, at least in the short term, may not have to be resolved quickly," he says.

Faget agrees. "I don't think Congress will get involved because we are entering a world of deregulation and there does not exist uniform agreement as to whether FDA should regulate in this space on both sides of the aisle….It could be revisited by future administrations, but short of Congressional action, I don't see this going anywhere."

Publicly Traded Lab Revenue Jumps 8% in 2024; bioAffinity Up 270%

On a combined basis, 25 publicly traded labs reported a revenue increase of 8.3% to $31.5 billion in full-year 2024 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Revenue growth was fastest at **bioAffinity Technologies** (San Antonio, TX), up 270% to $9.4 million. boAffinity operates a CLIA-certified lab (dba Precision Pathology Services) in San Antonio. The company markets a laboratory-developed test that is branded CyPath Lung (PLA 0406U; Medicare rate: $760). CyPath Lung is a flow cytometry test with five markers used to help detect lung cancer in patients at high risk for the disease.

Natera (Austin, TX) increased its revenue by 57% to $1.7 billion. Natera operates CLIA-certified labs in Austin, TX and San Carlos, CA that specialize in genetic testing. Natera processed approximately 3.1 million tests in 2024, up 23% from 2.5 million tests in 2023.

Castle Biosciences (Friendswood, TX) increased its revenue by 51% to $332 million. Castle operates CLIA-certified labs in Phoenix and Pittsburgh. Its highest volume test is DecisionDx-Melanoma (CPT 81529; Medicare rate: $7,193), which helps to stratify risk for patients with stage I-III cutaneous melanoma.

Revenue Growth at 25 Publicly-Traded Lab Companies ($000)

Company	Full-Year 2024	Full-Year 2023	Reported Change	Pro Forma Change
Labcorp (lab testing only)	$10,144,300	$9,415,100	7.7%	4.2%
Quest Diagnostics	9,872,000	9,252,000	6.7%	3.0%
Sonic Healthcare USA	1,270,130	1,282,831	-1.0%	3.0%
Opko/BioReference Labs	480,667	515,275	-6.7%	1.5%
Total, 4 National/Clinical Labs	**$21,767,097**	**$20,465,206**	**6.4%**	**3.5%**
Exact Sciences	2,758,867	2,499,766	10.4%	10.4%
Natera	1,696,911	1,082,571	56.7%	56.7%
Myriad Genetics	837,600	753,200	11.2%	11.2%
Guardant Health	739,016	563,948	31.0%	31.0%
Tempus AI	693,398	531,822	30.4%	30.4%
NeoGenomics	660,566	591,643	11.6%	11.6%
Veracyte	445,764	361,051	23.5%	23.5%
CareDx	333,785	280,324	19.1%	19.1%
Castle Biosciences	332,069	219,788	51.1%	51.1%
GeneDx	305,450	202,566	50.8%	50.8%
Fulgent Genetics	283,470	289,213	-2.0%	-2.0%
23andMe	219,638	299,489	-26.7%	-26.7%
Adaptive Biotechnologies	178,957	170,276	5.1%	5.1%
Personalis	84,614	73,481	15.2%	15.2%
Biodesix	71,323	49,087	45.3%	45.3%
Exagen Inc.	55,641	52,548	5.9%	5.9%
Interpace Biosciences	46,926	40,036	17.2%	17.2%
bioAffinity Technologies	9,362	2,532	269.7%	269.7%
Aspira Women's Health	9,182	9,154	0.3%	0.3%
ProPhase Labs	6,770	34,984	-80.6%	-80.6%
Oncocyte Corp.	1,881	1,503	25.1%	25.1%
Total, 21 Specialty/Genetic Labs	**$9,771,190**	**$8,108,982**	**20.5%**	**20.5%**
Grand Total, All 25 Lab Companies	**$31,538,287**	**$28,574,189**	**10.4%**	**8.3%**

*Pro forma change is estimated by Laboratory Economics after adjustments for acquisitions.
[1]Sonic Healthcare USA revenue is for the 12 months ended June 30, 2024, at constant exchange rate of 1 Australian Dollar equal to 0.61 U.S. Dollar. 223andMe revenue is for the 12 months ended March 31, 2024.
Source: *Laboratory Economics* from company reports

Quest Diagnostics Highlights "Co-Lab" Division

Quest Diagnostics has rebranded its hospital professional lab services division as Collaborative Lab Solutions (Co-Lab). Quest's Co-Lab provides supply chain management and outsourced lab testing services to health systems. Over the past five years, Quest's Co-Lab division has grown by an annual average of 22% to reach $800 million of revenue in 2024.

At Quest's March 19 Investor Day Conference in New York City, Chief Executive Jim Davis said that the company's biggest impediment to growth in a particular metropolitan statistical area (MSA) is health systems that employ a high percentage of local doctors. Health systems use EMRs (Epic, Cerner, etc.) that require their employed physicians to electronically order tests from affiliated hospital-based labs, according to Davis. Most employed doctors can only use an outside independent lab by using paper requisition forms. "As a company and through our trade association, we're gonna put a lot more pressure on this issue because we believe all doctors should have electronic access to any lab that they want to use," said Davis.

Regarding hospital outreach lab acquisitions, Davis said, "Our goal is to get an anchor client [in an MSA] and then grow from there….Once you've established a presence, there are physicians in other health systems that will order from you, even if it requires a paper req."

LifeLabs Workers Go On Rotating Strike for Higher Wages

About 1,200 unionized employees at LifeLabs (Toronto, Canada) have been on rotating strikes since February 16. Instead of a full strike, workers at some LifeLabs locations are walking off the job to picket a few days each week. On April 7, for example, four of 10 locations in or near downtown Vancouver were closed.

The union wants Quest Diagnostics, which owns LifeLabs, to agree to higher wages and increased staffing in a new collective bargaining agreement. Quest acquired LifeLabs for CAN $1.35 billion (USD $1 billion) in August 2024 (see *LE*, July 2024).

LifeLabs operates five primary labs and over 350 PSCs in British Columbia, Ontario and Saskatchewan that perform 140 million tests per year.

The BC General Employees' Union, or BCGEU, has been in negotiations on a new contract for LifeLabs employees since the previous contract expired in March 2024.

BCGEU President Paul Finch contends that LifeLabs' wages are below the rates by hospitals. For example, he says that medical technologists with five years of experience make CAN $40.70 (USD $28.98) at LifeLabs, compared with CAN $45.81 (USD $32.62) at a hospital, according to Finch.

The union also wants LifeLabs to hire more staff to reduce employees' workload.

A spokesperson for LifeLabs said in a statement that the company "respects the negotiation process and employees' right to pursue their interests…. As a designated essential service, LifeLabs will continue to operate, however, some patient services centers are subject to rotating temporary closures. We will do everything in our control to minimize the disruption this creates for our customers and clients."

Physician Office Labs Face Billing Challenges for PCR-Based Tests

High reimbursement and CLIA-waived status for PCR-based respiratory panels (CPT 87633: 12-25 targets) have made these tests attractive for many POLs, according to Jerry Tavolino, Chief Information Officer at the consulting firm CodeMap (Chicago). CPT 87633-QW is payable by Medicare at $416.78 in 2025.

However, Tavolino notes that most payers – including Medicare and private payers – have strict coverage requirements for these panels. As a result, many claims for expanded respiratory panels get denied when submitted by POLs. In fact, 99% of the claims submitted for CPT 87633-QW to Medicare Part B carriers were denied in 2023.

For example, Novitas's Local Coverage Determination for respiratory panel testing (L38916) specifically states that panels that test for more than five respiratory pathogens in a Part B outpatient setting such as a POL are considered not medically reasonable and necessary. Private payers typically follow Medicare when establishing their own coverage requirements, adds Tavolino.

Tavolino says that POLs also face challenges when billing for PCR-based tests for chlamydia and gonorrhea. POLs with a CLIA Certificate of Waiver must use the QW modifier to indicate they are performing a waived test, but there are cases when a code with a QW modifier is not recognized on the Medicare CLFS.

For example, the FDA has granted many PCR-based chlamydia trachomatis/neisseria gonorrhoeae (CT/NG) combination tests and their individual analytes CLIA-waived complexity. The corresponding CPT codes and Medicare rates for these tests are as follows:

- CPT 87491: Chlamydia trachomatis, amplified probe technique: $35.09
- CPT 87591: Neisseria gonorrhoeae, amplified probe technique: $35.09

However, neither 87491 nor 87591 are recognized on the CLFS with a QW. To bypass this, CMS issued Transmittal R11082CP, instructing Medicare contractors to allow use of CPT code 87801-QW for CT/NG tests. "My advice to POLs is to make sure you understand the coding before you start offering a test," concludes Tavolino.

NeoGenomics Picks Tony Zook as CEO

NeoGenomics Inc. announced that Tony Zook, age 64, has assumed the role of CEO. Zook has been a member of the company's Board of Directors since 2023. He succeeds Chris Smith, age 62, who will continue in an advisory role to support the transition.

23andMe Files for Chapter 11 Bankruptcy

DNA testing firm 23andMe (San Francisco) filed for bankruptcy protection in Missouri federal court on March 23. Co-founder and CEO, Anne Wojcicki, has resigned. The company will now attempt to sell itself under the supervision of a court. 23andMe plans to continue operating throughout the sale process and that there "are no changes to the way the company stores, manages, or protects customer data."

Founded in 2006, 23andMe went public in 2021 but it never made a profit. Accumulated losses were $2.35 billion as of December 31, 2024.

23andMe's largest unsecured creditors include Labcorp's National Genetics Institute (owed $1.2 million), digital marketing firm Jellyfish (owed $382,544), Blue Shield of California (owed $339,925), Kaiser Foundation Health Plan (owed $205,155) and Power Digital Marketing (owed $194,506).

Lab Stocks Down 16% YTD

Twenty-four lab stocks are down an unweighted average of 16% year to date through April 11. In comparison, the S&P 500 Index is down 9%. Guardant Health has risen 43%; Adaptive Biotechnologies, up 32%; and GeneDx, up 26%. Labcorp is down 3% on the year and Quest Diagnostics is up 9%.

Company (ticker)	Stock Price 4/11/25	Stock Price 12/31/24	2025 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos.	Enterprise Value/ Revenue
Guardant Health (GH)	$43.71	$30.55	43%	$5,890	$739	8.0
Adaptive Biotechnologies (ADPT)	7.94	6.00	32%	1,150	179	6.4
GeneDx (WGS)	96.63	76.86	26%	2,690	306	8.8
Tempus AI (TEM)	42.12	33.76	25%	7,310	693	10.5
Oncocyte Corp. (OCX)	2.78	2.38	17%	75	2	39.2
Quest Diagnostics (DGX)	163.99	150.86	9%	24,890	9,872	2.5
Exagen (XGN)	4.26	4.10	4%	78	56	1.4
Fulgent Genetics (FLGT)	19.00	18.47	3%	-238	284	-0.8
Opko Health (OPK)	1.42	1.47	-3%	1,030	713	1.4
Labcorp (LH)	221.46	229.32	-3%	24,380	13,009	1.9
Natera (NTRA)	148.04	158.30	-6%	19,230	1,697	11.3
Sonic Healthcare (SHL.AX)*	24.80	27.01	-8%	16,170	9,330	1.7
CareDx (CDNA)	18.81	21.41	-12%	810	334	2.4
Veracyte (VCYT)	31.80	39.60	-20%	2,240	446	5.0
Exact Sciences (EXAS)	44.45	56.19	-21%	9,990	2,759	3.6
Castle Biosciences (CSTL)	19.70	26.65	-26%	295	332	0.9
Myriad Genetics (MYGN)	8.00	13.71	-42%	769	838	0.9
Personalis (PSNL)	3.28	5.78	-43%	148	85	1.7
NeoGenomics (NEO)	9.32	16.48	-43%	1,420	661	2.1
Interpace Biosciences (IDXG)	1.35	2.70	-50%	10	47	0.2
ProPhase Labs (PRPH)	0.31	0.76	-59%	37	7	5.4
23andMe (MEHCQ)	1.15	3.25	-65%	12	209	0.1
Biodesix (BDSX)	0.53	1.53	-65%	115	71	1.6
Aspira Women's Hlth (AWH)	0.10	0.71	-86%	5	9	0.5
Totals & Averages			**-16%**	**$118,504.7**	**$42,675.2**	**2.8**

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

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About the Author

Jondavid Klipp is president and publisher of ***Laboratory Economics LLC***, an independent market research firm focused on the business of laboratory medicine. Prior to founding ***Laboratory Economics*** in April 2006, Mr. Klipp was managing editor at Washington G-2 Reports. During his seven-year employment with G-2, he was editor of Laboratory Industry Report and Diagnostic Testing & Technology Report. Prior to joining G-2, Mr. Klipp was an HMO analyst at Corporate Research Group in New Rochelle, New York, and a senior writer in the equity research department at Dean Witter in New York City.

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