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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Labs See Artificial Intelligence as Biggest Opportunity

A plurality of lab executives (45%) believe that the application of AI represents a big opportunity for their lab over the next 3-5 years, according to an exclusive survey conducted by *Laboratory Economics*. Other big opportunities cited include "economies of scale from lab consolidation" and "lowering vendor contract costs/prices."

More survey results on pages 3-4.

What are the biggest opportunities for labs in the next 3-5 years?*

Application of AI	45%
Economies of scale from lab consolidation	39%
Lowering vendor contract costs/prices	38%
Improved billing & collection	37%
Digital pathology	35%
Increased productivity from lab automation	31%
Expanding test menu	27%
Gaining market share in our geographic market	27%
Gaining access to more in-network insurance contracts	15%

*Survey participants were asked to select their three biggest opportunities

Source: *Laboratory Economics* Survey (March 2025; n=104)

Ruling in LDT Lawsuit Could Come in April

An attorney representing the American Clinical Laboratory Association (ACLA) says he is "cautiously optimistic" that a Texas judge will rule in favor of ACLA in its lawsuit challenging the FDA's authority to regulate lab-developed tests (LDTs). The Association for Molecular Pathology (AMP) is also a party to the lawsuit.

Judge Sean Jordan in the Eastern District of Texas heard oral arguments in the lawsuit on February 19. The argument lasted about three hours and included a number of questions by the judge. "The fact that he allowed the hearing to last that long indicates that he recognized that this is an important case," said Ashley Parrish, a partner with King & Spalding and the attorney representing ACLA. Parrish gave an update on the lawsuit during ACLA's annual meeting on February 27 in Washington, DC.

Citing the May 6 compliance date for Stage 1 of the LDT rule, both ACLA and AMP asked Judge Jordan to issue his ruling expeditiously. The judge said he would issue a decision as soon as possible, said Parrish, noting that April is a real possibility. *Cont'd on page 2.*

Contents

HEADLINE NEWS
Labs See Artificial Intelligence as Biggest Opportunity 1, 3
Ruling in LDT Lawsuit Expected Soon ... 1-2

REGULATION & ENFORCEMENT
PAMA Reform a Priority 2
More Private Payers to Use DEX Registry for Molecular Tests 2
The Pros and Cons of Self-Disclosure 10

EMPLOYEE COMPENSATION
Lab Employee Costs are Fastest-Growing Expense 4
Labcorp Workers Vote to Unionize at Providence Portland 4
UVMC Lab Workers Vote for Union 4
No End in Sight for Lab Personnel Shortage 5

DIGITAL PATHOLOGY
A Slow Start for Digital Pathology Add-On Codes 6

MERGERS & ACQUISITIONS
LabX Buys Dark Report 8
Quest to Buy Spectra Labs 8
EmeritusDX Acquires PathMD 8
Labcorp to Buy BioReference's Cancer Testing Business 9
NeoGenomics Buys Pathline 9

TOXICOLOGY
Payer Policies for Toxicology 11

FINANCIAL
Comparing Productivity at Labcorp, Quest and BioReference 7
Lab Stocks Down 11% YTD 12

RULING IN LDT LAWSUIT COULD COME IN APRIL (*cont'd from page 1*)
The first phase of the rule requires laboratories to have certain policies and procedures in place to begin handling complaints, filing Medical Device Reports and reporting corrections and removals. On August 22, 2024, the FDA held a webinar to outline the requirements of Stage 1 and another webinar on Stage 2 requirements was scheduled for late February, but since the new administration took office, the webinar page has been taken down from FDA's website.

While it is unclear just what position the new administration will take on the LDT rule, which was issued under President Biden's administration, the Department of Justice counsel strongly defended the rule throughout the hearing. However, the DOJ counsel did ask to be allowed to submit a brief on the question of the remedy in the event of an adverse ruling.

ACLA and AMP have asked the court to vacate the final rule. If the court does so, the rule essentially would be dead (subject to any appeal by the government). However, it is possible that the court could accept the government's request to grant a narrower remedy, said Parrish.

PAMA Reform a Priority of Senate Finance Committee
Reform of the Protecting Access to Medicare Act (PAMA) is a top priority for lawmakers on the Senate Finance Committee, according to staff members who spoke at the ACLA annual meeting.

"There is joint recognition that PAMA is not working the way it was intended," said Conor Sheehy, a senior health policy advisor on the committee. "This is a nonpartisan issue. There is a shared goal of trying to find a path forward that works for stakeholders and is financially feasible. We are working with ACLA on a legislative solution."

In fact, a new bill to reform PAMA is expected to be introduced within the next several weeks, according to Elyse Oveson, Chief of Advocacy Operations at ACLA.

Past efforts to reform PAMA permanently have been unsuccessful although Congress has delayed implementation of PAMA's Medicare reimbursement cuts to the Clinical Lab Fee Schedule for five straight years (2021-2025).

Although PAMA reform is a priority, it is also competing with other priorities of the Senate Finance Committee, including executive confirmation hearings and approval of the federal budget for fiscal year 2025.

More Private Payers to Use DEX Registry for Molecular Tests
The Diagnostic Exchange (DEX) registry used by Palmetto GBA to track and determine coverage of molecular diagnostic procedures is likely to be adopted by more private payers, according to Gabriel Bien-Willner, MD, who heads Palmetto's Molecular Diagnostics Program (MolDX). MolDX is used by Medicare administrative contractors (MACs) in seven jurisdictions across 28 states, as well as several private payers. Bien-Willner gave an update on the program during the ACLA meeting.

United Healthcare became the first private payer to adopt the DEX registry for its Medicare Advantage and certain commercial plans in 2024. The registry is also used by Humana Medicare Advantage, Optum Care Medicare Advantage, Medical Mutual of Ohio, Fallon Health and Blue Cross and Blue Shield of North Carolina. Bien-Willner expects the program will continue to expand to additional private payers.

Under the DEX program, clinical labs register their molecular diagnostic tests and are assigned a Z-Code after successfully passing a technical assessment from MolDX. Currently, there are more than 20,000 molecular diagnostic tests in the registry, says Bien-Willner, who notes that the program evaluates between 1,600 and 4,000 tests every year.

LABS SEE ARTIFICIAL INTELLIGENCE AS BIGGEST OPPORTUNITY (*cont'd from page 1*)
In addition to analyzing digitized slide images, survey participants said that AI could potentially be used to optimize staff scheduling, reduce errors in the preanalytical phase of testing and for billing and payment processing (e.g., invoice creation, fraud detection, data analysis, etc.).

The survey also asked lab executives what they saw as the biggest challenges they would face over the next 3-5 years. The top answer was declining reimbursement (cited by 74%). Declining reimbursement has been the top concern since *LE* conducted its very first survey back in 2007.

The next biggest challenges are rising employee salaries and benefit costs (cited by 43%) and technical staffing shortages (cited by 39%).

"Wages for staff are increasing rapidly in our region. The large hospitals and union hospitals are able to pay much more than the community hospitals. This makes it difficult for us to hire and retain qualified staff," according to a hospital lab director from California.

"Staffing continues to be a major concern. The struggle is to find qualified candidates with the declining number of accredited programs," said a hospital lab director from Massachusetts.

Surprisingly, only 13% of survey respondents selected "FDA regulation of laboratory developed tests" as their biggest challenge. However, the implications of FDA regulation were not lost on lab directors and pathologists from academic medical centers.

"The fate of the FDA's LDT rule will heavily influence the fate of many labs," according to a pathologist from an academic medical center in Ohio.

"FDA LDT regulation will impose a significant burden on labs," noted a lab director from an academic medical center in South Carolina.

What are the biggest challenges that labs and pathology groups will face over the next 3-5 years?*

	2025	*2023*	*2021*	*2020*	*2019*	*2016*
Declining reimbursement	74%	80%	83%	81%	82%	89%
Rising employee salaries & benefit costs	43%	NA	NA	NA	NA	NA
Technical staff shortages	39%	52%	45%	34%	28%	21%
Rising inflation/supply costs	35%	NA	NA	NA	NA	NA
Budget pressure/pressure to lower costs	25%	NA	NA	NA	NA	NA
Pathologist shortages	15%	7%	6%	3%	11%	6%
Competition from large commercial labs	13%	29%	30%	28%	42%	36%
Exclusion from managed care contracts	13%	35%	33%	44%	47%	45%
FDA regulation of laboratory developed tests	13%	NA	NA	NA	NA	NA
Increased expenses for information technology	13%	10%	9%	14%	14%	13%
Difficulty/expense of adding new molecular/genetic tests	9%	11%	9%	6%	14%	12%
Prior authorization test order requirements	5%	31%	21%	38%	28%	13%
The Covid-19 pandemic	0%	0%	12%	27%	NA	NA

*Survey participants were asked to pick their top three challenges

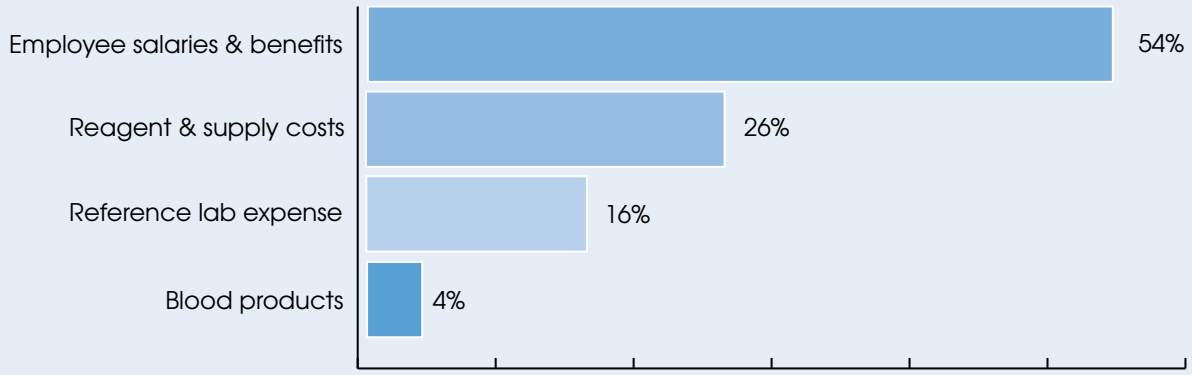
Source: *Laboratory Economics* Surveys (March 2025, October 2023, December 2021, October 2020, July 2019 and August 2016—no comparable *LE* surveys were conducted in 2017, 2018, 2022 and 2024)

Survey Demographics: The survey was e-mailed to approximately 20,000 laboratory executives and pathologists in early March 2025. A total of 104 surveys were completed. Among the respondents, 48 were from health system/hospital-based labs, 20 from local or regional independent labs, 14 from national pathology or lab companies, 10 from pathology groups, six from in-office pathology labs, and six from "other" labs.

Lab Employee Costs Are Fastest-Growing Expense

Fifty-four percent of surveyed lab executives said that "employee salaries & benefits" are the fastest-growing expense in their lab budget, according to the most recent *Laboratory Economics* Survey (March 2025; n=104). The next most frequently cited expense was "reagent & supply costs" (26%), followed by "reference lab expenses" (16%). Surveyed lab executives said rising expenses were coming in the face of growing test volumes. Test volumes grew by an average of 8% in 2024 (median=7%) and are expected to grow by an average of 9% in 2025 (median=6%), according to survey respondents.

What is the fastest-growing expense in your lab budget?



Source: *Laboratory Economics Survey* (March 2025; n=104)

Labcorp Workers Vote to Unionize at Providence Portland

A group of 114 medical technologists and technicians working for Labcorp at Providence Portland hospital have voted to unionize. The tally was 79-23 in favor of joining the Oregon Federation of Nurses and Health Professionals (OFNHP) on February 19, according to the National Labor Relations Board.

Labcorp acquired Providence Oregon's outreach laboratory business and select assets in Oregon for $110 million effective August 2023. As part of the agreement, Labcorp provides certain clinical lab testing services to Providence's Portland-area hospitals.

"Since the transition with Labcorp, we've noticed an increase in workload, an increase in expectations, and more of a focus on volume and throughput," according to Allister Brister-Smith, a Laboratory Services Team Lead at Labcorp's Halsey Street lab, which is the worksite that voted to unionize.

Providence Portland is the second location in Oregon where Labcorp workers have voted to unionize. More than 400 Labcorp employees working at Legacy hospitals also joined OFNHP in May 2024. They are currently negotiating their first contract.

University of Vermont Medical Center Lab Workers Vote for Union

On February 18, 143 medical technologists, histotechnologists and histotechnicians at University of Vermont Medical Center (Burlington) voted to unionize. The vote count was 103-5 in favor of joining the Vermont Federation of Nurses and Health Professionals (VFNHP), Local 5221, according to the National Labor Relations Board. VFNHP now represents over 3,000 nurses and technical professionals at the University of Vermont Medical Center.

No End in Sight for Lab Personnel Shortage

Outside of declining reimbursement, the single greatest risk that the lab industry faces today is a growing shortage of personnel that is putting upward pressure on labor expenses at nearly all clinical and anatomic pathology labs. The shortage of lab workers has been a well-known concern for at least the past 20 years. Data from the Bureau of Labor Statistics (BLS-Washington, DC) and the National Accrediting Agency for Clinical Laboratory (NAACLS-Chicago) shows that the demand for medical laboratory scientists and technicians will continue to far outstrip the supply of new workers in the coming years.

There are approximately 335,000 medical laboratory scientists and technicians working in the U.S. today, according to BLS. On average, about 24,000 job openings are projected each year over the next decade. Most of those openings are expected to result from the need to replace lab workers who are retiring.

On the supply side, NAACLS program graduates totaled 8,662 in 2023, including 4,189 medical laboratory scientists and 2,638 medical laboratory technicians. During the five-year period from 2018-2023, the overall number of NAACLS program graduates has fallen by an average of 0.5% per year.

Over the five-year period, the number of pathology assistant graduates grew the fastest—up 8.8% per year to reach 204 in 2023.

The number of new phlebotomists fell the most—down 8.5% per year to 1,146 program graduates in 2023.

Simple economics indicate that rising salaries and benefits and/or massive productivity improvements will be needed to balance the growing gap between the demand for lab employees (~24,000 annually) and the new supply (~8,700 annually).

The most significant barriers to expanding the number of new medical laboratory scientists and technicians is the number of student applicants and lab facilities available for clinical rotations, according to Marisa James, Chief Executive Officer of NAACLS.

NAACLS Program Graduates Per Year

Program Type	*Grad 2023*	*Grad 2022*	*Grad 2021*	*Grad 2020*	*Grad 2019*	*Grad 2018*	*5-Year CAGR*
Cytogenetic	15	17	15	30	23	30	-12.9%
Diagnostic Molecular Science	73	73	77	89	88	163	-14.8%
Histotechnician	344	360	314	294	365	363	-1.1%
Histotechnologist	48	62	59	52	57	63	-5.3%
Medical Laboratory Assistant	5	10	12	38	47	33	-31.4%
Medical Laboratory Scientist	4,189	4,162	4,114	3,964	3,899	3,772	2.1%
Medical Laboratory Technician	2,638	2,663	2,844	2,848	2,932	3,159	-3.5%
Pathology Assistant	204	204	153	154	151	134	8.8%
Phlebotomist	1,146	1,208	1,120	1,158	1,421	1,783	-8.5%
Total	**8,662**	**8,759**	**8,708**	**8,627**	**8,983**	**9,500**	**-1.8%**

Source: National Accrediting Agency for Clinical Laboratory (NAACLS)

A Slow Start for Digital Pathology Add-On Codes

Utilization of 13 new Category III digital pathology add-on codes for surgical pathology technical services was less than 1% in 2023, according to an *LE* analysis of Medicare Part B carrier claims data. The 13 add-on codes (0751T-0763T) became effective January 1, 2023, to allow CMS to monitor the usage of digital pathology. CMS is looking for widespread use of digital pathology before it moves the new codes to Category I and assigns Medicare reimbursement rates.

However, it's a Catch-22 situation because many labs won't invest in digital pathology until the cost of digitizing glass slides is reimbursed. Furthermore, most private insurers won't reimburse for digital pathology without formal Medicare coverage and payment rates.

In total, the 13 add-on codes recorded Medicare Part B volume of 52,137 in 2023. These codes could potentially have been reported for up to 14.3 million Part B pathology technical services, indicating an overall usage rate of only 0.36%.

For example, submitted Part B volume for the add-on code 0753T was 37,619 in 2023. This code is used in conjunction with technical services for CPT 88305 (Level IV, surgical pathology), which had submitted volume of 10.3 million indicating a usage rate of 0.37%.

Robert Tessier, Founder and Panelist on the Panel of National Pathology Leaders (Woodbridge, CT), believes that the utilization of the new add-on codes could be severely undercounted. He notes that hospital-based labs are charging anywhere between $0.01 and $5 for the new codes. Either way, he says that every hospital billing system eliminates charges that are below their threshold, which is often in the range of $5-10. As a result, Tessier believes that a high percentage of add-on code utilization is not being sent to third party payers, including Medicare. Furthermore, he notes that since they are not Category I billable codes, there may be a block on reporting the new Category III digital pathology add-on codes to Medicare as well.

Another 30 Category III digital pathology add-on codes (0827T-0856T) for cytopathology, FISH and other pathology technical services were introduced effective January 1, 2024. However, utilization data for these new codes is not yet available.

Medicare Part B Utilization of Digital Pathology Add-On Codes in 2023

Test Codes	Short Description	Submitted Part B Digital Path Add-On Services	Submitted Part B Services for Related Category I CPT Code*	Digital Pathology Percentage Utilization
0751T/88302	Digitization of slides for level II, surgical pathology	45	6,104	0.74%
0752T/88304	Digitization of slides for level III, surgical pathology	1,106	283,240	0.39%
0753T/88305	Digitization of slides for level IV, surgical pathology	37,619	10,253,329	0.37%
0754T/88307	Digitization of slides for level V, surgical pathology	469	41,051	1.14%
0755T/88309	Digitization of slides for level VI, surgical pathology	82	2,270	3.61%
0756T/88312	Digitization of slides for special stain, Group 1	2,249	907,696	0.25%
0757T/88313	Digitization of slides for special stain, Group 2	1,145	726,214	0.16%
0758T/88314	Digitization of slides for histochem special stain	1	20,290	0.00%
0759T/88319	Digitization of slides for special stain, Group 3	0	1,673	0.00%
0760T/88342	Digitization of slides for immunohistochem, initial stain	2,761	1,019,168	0.27%
0761T/88341	Digitization of slides for immunohistochem, each add'l stain	4,236	974,985	0.43%
0762T/88344	Digitization of slides for immunohistochem, each multiplex stain	1,921	96,603	1.99%
0763T/88360	Digitization of slides for morphometric analysis, tumor IHC	503	219874	0.23%
	Grand Totals	**52,137**	**14,332,623**	**0.36%**

*Includes submitted test volumes for TC-only and global test services. Excludes PC-only test volumes.
Source: *Laboratory Economics* from CodeMap.com

Comparing Productivity at Labcorp, Quest Diagnostics and BioReference for 2024

On a weighted basis, three publicly traded lab companies collected average revenue of $47.83 per requisition in 2024. Average collected revenue per test was an estimated $13.67.

The three companies—Labcorp, Quest Diagnostics and OPKO's BioReference Labs—generated a weighted average of $207,459 in revenue per employee in 2024. The average number of requisitions and tests processed per employee per year were 4,337 and 15,180, respectively. These figures are based on the total number of FTEs at the three companies, including all administrative, couriers, sales and marketing, and lab technical staff.

Overall, the three companies received an average of 43.5% of their revenue from private healthcare insurers (Aetna, BCBS, Cigna, etc.), 31.6% from client payers (hospitals, physicians, etc.), 11.7% directly from patients, 8.8% from Medicare (CLFS & PFS) and 2% from Medicaid fee-for-service.

Productivity Stats at Quest Diagnostics, Labcorp and BioReference for 2024

2024 Financials	*Labcorp**	*Quest*	*BioReference*	*Combined*
Total Lab Testing Revenue 2024	$10,144,300,000	$9,872,000,000	$480,667,000	$20,496,967,000
Operating Income 2024	$1,606,300,000	$1,346,000,000	-$24,125,000	$2,928,175,000
# Employees**	49,000	47,500	2,300	98,800
Employee Efficiency				
Avg. Annual Revenue per Employee	$207,027	$207,832	$208,986	$207,459
Avg. Annual Operating Income per Employee	$32,782	$28,337	-$10,489	$29,637
Requisition Stats				
Est'd Annual Requisitions 2024	205,000,000	217,000,000	6,500,000	428,500,000
Est'd Avg. Revenue per Requisition	$49.48	$46.25	$73.95	$47.83
Est'd Avg. Operating Income per Requisition	$7.84	$6.20	-$3.71	$6.83
Est'd Avg. Reqs Processed per Employee	4,184	4,568	2,826	4,337
Test Stats				
Est'd Annual Test Volume 2024***	717,500,000	759,500,000	22,750,000	1,499,750,000
Est'd Avg. Revenue per Test	$14.14	$13.21	$21.13	$13.67
Est'd Avg. Operating Income per Test	$2.24	$1.77	-$1.06	$1.95
Est'd Avg. Tests Processed per Employee	14,643	15,989	9,891	15,180
Billing Stats				
Accounts Receivable	1,259,300,000	$1,304,000,000	$106,215,000	$2,669,515,000
Est'd Bad-Debt % (pre-ASC 606)	4% - 5%	4% - 5%	5% - 10%	4.5%
Days in AR	45	48	81	48
Revenue by Payer				
Private Patients	12.8%	11.0%	3.3%	11.7%
Medicare CLFS	8.0%	8.0%	12.0%	8.1%
Medicare PFS	0.4%	1.0%	2.6%	0.7%
Medicaid (fee-for-service)	1.9%	2.0%	2.5%	2.0%
Client Payers (physicians, hospitals, etc.)	30.8%	33.0%	19.4%	31.6%
Private Healthcare Insurers	46.2%	40.0%	60.2%	43.5%
Other	0.0%	5.0%	0.0%	2.4%

*Data is for Labcorp's lab testing business only. **Full-time equivalents (part-time employees are counted as ½ FTE)

***Test volume stats assume an average of 3.5 tests per requisition.

Source: Company reports and *Laboratory Economics'* estimates

LabX Acquires The Dark Intelligence Group

The Dark Intelligence Group (TDIG-Austin, TX) announced on March 13 that it has sold all its assets to LabX Media Group (Ontario, Canada). The sale includes all TDIG products, including *The Dark Report* newsletter and annual conference *The Executive War College*. TDIG was founded in 1995 by its CEO Robert Michel, age 74, who will serve as an advisor to LabX to ensure a smooth transition as he starts his path to retirement.

Quest to Buy Certain Assets of Spectra Laboratories

Quest Diagnostics is acquiring select assets of Spectra Laboratories (Rockleigh, NJ) from its owner Fresenius Medical Care (Bad Homburg, Germany) for an undisclosed purchase price. Spectra provides lab testing services to end-stage renal disease (ESRD) patients—primarily serving the 200,000+ annual patients who get treatment at Fresenius's 2,624 kidney dialysis clinics in the United States.

Spectra owns two major CAP-accredited labs—Rockleigh, NJ and Southaven, MS—each more than 200,000 square feet. Quest is not acquiring these labs, which will likely be shut down after the deal is finalized. Instead, Quest will serve the Fresenius clinics and patients through its existing network of labs. Quest says that its labs will be able to serve Fresenius during lower-volume daytime hours.

Spectra performs roughly 70 million lab tests per year that are reimbursed primarily from a bundled payment from traditional and privately managed Medicare and Medicaid plans. The bundled payment covers all ESRD-related services, including lab tests, on a monthly basis. Following the close of the transaction, Fresenius is expected to pay Quest for lab testing services on a capitated per-patient per-month basis under a long-term agreement.

More than 800,000 people in the U.S. receive dialysis, which requires periodic lab testing to manage the disease. Spectra's high-volume tests include routine hematology tests (e.g., complete blood counts) and chemistry tests (e.g., A1c, uric acid, creatinine, iron studies, etc.). Another important component of ESRD testing is specialized water testing. The water used in the treatment of dialysis patients must be regularly tested for contaminants and bacteria. Dialysis-related water testing will be a new service added to Quest's test menu.

Other large ESRD testing labs include Ascend Clinical LLC (Sunnyvale, CA), owned by Eurofins Scientific, DaVita Labs (Deland, FL), owned by DaVita Inc., and the DCI Laboratories (Nashville, TN), owned by the not-for-profit Dialysis Clinic Inc.

EmeritusDX Acquires PathMD

Emeritus Medical Technology (Lake Forest, CA), which does business as EmeritusDX, has acquired PathMD Inc. (Los Angeles, CA). PathMD is an anatomic pathology lab focused on urology, gastroenterology and dermatology clients.

PathMD was founded by urologist Kiarash Michel, MD, and gastroenterologist Siamak Tabib, MD, in 2012. PathMD's CAP-accredited technical lab and most of its 35-40 employees are expected to join EmeritusDX's new 10,000-square-foot CAP-accredited lab in Lake Forest (46 miles south of Los Angeles).

EmeritusDX was formed by lab industry veterans Robert Embree and Jason Allchin in 2021 (see *LE*, June 2021).

Haverford Healthcare Advisors (Radnor, PA) provided advisory services to PathMD in connection with the transaction.

Labcorp to Acquire BioReference's Cancer Testing Business

Labcorp has agreed to pay up to $225 million to buy select assets of the anatomic pathology and cancer-related clinical testing business of BioReference Health (Elmwood Park, NJ), a wholly owned subsidiary of OPKO Health (Miami, FL). The purchase price includes $192.5 million in cash plus up to $32.5 million in an earnout based on performance.

Labcorp will be acquiring certain customer accounts and operating assets that currently generate approximately $85-$100 million in annual revenue. BioReference's anatomic pathology division does business under the brand name GenPath Oncology with high volumes in hematopathology and flow cytometry testing. The full purchase price is equal to roughly 2.25x annual revenue (i.e., $225 million/$100 million=2.25x).

Labcorp had previously acquired BioReference's clinical lab testing business (outside of New York/New Jersey) for $238 million in September 2024.

After the deal is completed, BioReference's operations will include its clinical lab testing business in New York and New Jersey and its 4Kscore prostate cancer test, which have combined annual revenue of $300 million.

NeoGenomics Buys Pathline in New Jersey

NeoGenomics (Ft. Myers, FL) has acquired Pathline LLC (Ramsey, NJ) for an undisclosed amount. Pathline has a total of approximately 135 employees, including seven full-time pathologists, and operates a full-service CAP-accredited lab in Ramsey (a suburb of New York City). Pathline was founded in 2009 and offers a full menu of anatomic pathology services, including hematopathology and flow cytometry testing, to hospitals, cancer centers and physician practices. *Laboratory Economics* estimates that Pathline has annual revenue in the range of $20-40 million.

Pathline (aka Histopathology Services) was sold to the private equity firm Tower Arch Capital (Salt Lake City, UT) in 2015 and then sold to another investment firm, Monroe Capital (Chicago), in 2019.

NeoGenomics is expected to keep the Pathline laboratory in operation. The Northeast has historically been an underpenetrated region for NeoGenomics. "We have deeper penetration rates in areas where we have close proximity to a lab like in California, Florida and Texas…. Pathline will further enhance our ability to support oncologists, healthcare institutions and patients in the Northeast region," according to Warren Stone, Chief Commercial Officer at NeoGenomics.

The Pathline deal represents NeoGenomics' first acquisition since buying liquid-biopsy-developer Inivata Ltd. (Cambridge, England) for a value of $520 million in June 2021.

Separately, NeoGenomics reported a net loss of $79 million for 2024 compared with a net loss of $88 million in 2023; revenue increased by 12% to $661 million.

The Pros and Cons of Self-Disclosure: Q&A With Karen Lovitch


Karen Lovitch

The Department of Justice (DOJ) in the last couple of years has actively incentivized companies to voluntarily self-disclose potential civil and criminal violations. *Laboratory Economics* recently spoke with Karen Lovitch, Chair of Mintz Levin's Health Law Practice and Health Care Enforcement Defense Practice (Washington, DC), about the pros and cons of self-disclosure.

What actions has the DOJ taken recently to encourage self-disclosure?

In 2023, on the criminal side, the DOJ issued a revised Corporate Enforcement Policy, the United States Attorneys' Office Voluntary Self-Disclosure Policy and a safe harbor policy for voluntary self-disclosure made in connection with mergers and acquisitions. They generally incentivize companies to self-disclose potential misconduct, participate in investigations and take corrective action as soon as possible. If the DOJ is satisfied that you have done those things, then it likely will decline to prosecute. But the catch, at least on the criminal side, is you have to disclose something the government doesn't already know about.

Also in 2024, on the criminal side, DOJ published its Whistleblower Awards Pilot Program, which provides monetary awards to whistleblowers who bring original information to DOJ about certain crimes that it doesn't already know about, including federal healthcare fraud offenses not covered by the False Claims Act (FCA). However, the report has to lead to a forfeiture that nets more than $1 million for the government. This program puts pressure on companies to make quick self-disclosures because they are racing against employees who may report misconduct first.

On Sept. 23, 2024, the DOJ's Criminal Division revised its Evaluation of Corporate Compliance Programs guidance, which puts further pressure on companies to ensure their compliance function is effective in application, thus maximizing the chance that a company will become aware of, and subsequently self-report, criminal misconduct.

On the civil side, back in 2019, the DOJ updated the Justice Manual to encourage voluntary self-disclosure and remediation in FCA cases. While the policy is not specific about the benefits of self-disclosure for the company reporting, settlements over the past few years seem to show that the government is inclined to lower the multiplier used to determine damages.

Under the FCA, the government can impose up to treble damages. So, if you have $1 million in false claims, you might have to pay up to $3 million. In cases settled without a self-disclosure, DOJ typically seeks a multiplier of 2x. But most recent settlements involving a self-disclosure seem to involve a 1.5x multiplier, so the DOJ is rewarding self-disclosure by applying a lower multiplier.

What are the advantages of self-disclosure on the civil side?

In a self-disclosure involving potential kickbacks, DOJ may be willing to consider a favorable alternative to calculating single damages. This approach is consistent with the OIG's self-disclosure protocol, which states that the OIG might calculate single damages based on the amount of the kickback that was paid instead of the amount of Medicare claims payments that were received. For example, if a lab disclosed that it gave a physician group $100,000 of free equipment, and the physician group referred $1 million in federal healthcare program business to the lab, the OIG will consider the single damages to be $100,000 instead of $1 million (and then would apply the multiplier to that number).

Do you advise clinical labs to self-disclose a violation once they become aware of it?

Labs have to work with their legal counsel and weigh the costs and benefits of self-disclosure. For example, if it's not 100% clear that you have a legal violation, you may choose not to disclose. In some cases, you may have to make admissions of fact in a settlement agreement, and you would have to be prepared to do that.

Payer Policies for Toxicology Testing Present Challenges

Clinical labs are continuing to experience challenges related to various payer policies, especially for toxicology urine drug screening, according to Dyana Williams, Director of Revenue Cycle Management Operations at Lighthouse Lab Services (Charlotte, NC). "For every test panel that can be billed, there is some kind of special guidance—whether at the federal or private-payer level," she explains.


Dyana Williams

While Medicare established national coverage determinations (NCDs) and local coverage determinations (LCDs), private payers may have coverage policies based on these federal determinations but with key differences.

Keeping up with the various coverage policies and setting up either front-end edits or back-end appeal policies can be difficult for labs, who may have multiple payers. "There is no easy solution," says Williams. "There will be administrative burdens on the front end and/or on the back end."

For example, under Medicare, one presumptive drug testing code and one definitive drug testing code may be billed once per patient per day (A56915, effective 10/01/2024). All services/procedures performed on the same day for the same beneficiary by the physician/provider should be billed on the same claim. However, despite the guidance, claims are often denied, says Williams.

"Even though Medicare indicates that's how the claims should be submitted, we frequently see payers deny those claims because they don't like seeing a presumptive and definitive test billed simultaneously without clear justification in the ordering provider's clinical notes," she explains.

To further complicate things, there also may be different frequency limitations amongst payers and across different geographic reasons to limit reimbursement only for presumptive tests versus definitive tests since definitive tests should be used less often. Most payers use a risk assessment to determine the appropriate testing frequency with higher-risk patients (e.g., those on high-dose opioid therapy) typically requiring more frequent testing than low-risk patients.

In addition, coverage requirements may vary depending on where testing is performed, says Williams. Some payers may allow limited payment for toxicology testing in an independent or hospital-owned lab but might not cover it in a physician office laboratory. Williams notes that there are a number of tools available to help keep up to date with payer policies, such as Policy Reporter, which provides real-time policy alerts.

Meanwhile, the latest available data from CMS shows that the average Medicare Part B carrier denial rate for seven key toxicology codes was 14.9% in 2023. This compares with average denial rates of 5-10% for routine clinical lab tests (e.g., comprehensive metabolic panel, lipid panel, TSH, Vitamin D, etc.).

Medicare Part B Stats for Key Toxicology Test Codes in 2023

CPT	Short Description	Submitted	Denied	Denial Rate	Allowed
80305	Presumptive drug class screening	612,401	108,781	17.8%	$6,336,183
80306	Presumptive drug class screening	13,149	4,368	33.2%	$150,453
80307	Presumptive drug class screening	2,367,259	347,021	14.7%	$125,367,403
G0480	Definitive drug test(s), 1-7 classes	769,775	126,265	16.4%	$73,050,311
G0481	Definitive drug test(s), 8-14 classes	526,602	76,178	14.5%	$70,316,295
G0482	Definitive drug test(s), 15-21 classes	642,758	75,573	11.8%	$112,563,902
G0483	Definitive drug test(s), 22+ classes	696,688	98,702	14.2%	$147,266,871
	Grand Totals	**5,628,632**	**836,888**	**14.9%**	**$535,051,418**

Source: *Laboratory Economics* from CodeMap.com

Lab Stocks Down 11% On the Year

Twenty-four lab stocks have fallen an unweighted average of 11% year to date through March 12. In comparison, the S&P 500 Index is down 6%. Oncocyte has jumped 59% YTD, Guardant Health is up 41% and Tempus AI is up 35%. Quest Diagnostics and Labcorp are up 10% and 3% respectively.

Company (ticker)	Stock Price 3/12/25	Stock Price 12/31/24	2025 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
Oncocyte Corp. (OCX)	$3.79	$2.38	59%	$107	$1	152.9
Guardant Health (GH)	43.10	30.55	41%	5,820	739	7.9
Tempus AI (TEM)	45.50	33.76	35%	7,860	693	11.3
Adaptive Biotechnologies (ADPT)	7.62	6.00	27%	1,100	179	6.1
Opko Health (OPK)	1.78	1.47	21%	1,270	713	1.8
GeneDx (WGS)	92.08	76.86	20%	2,560	306	8.4
Quest Diagnostics (DGX)	166.42	150.86	10%	25,160	9,872	2.5
Labcorp (LH)	236.83	229.32	3%	25,670	13,009	2.0
Fulgent Genetics (FLGT)	17.48	18.47	-5%	-284	284	-1.0
Sonic Healthcare (SHL.AX)*	25.36	27.01	-6%	16,440	9,330	2.0
Natera (NTRA)	144.50	158.30	-9%	18,750	1,697	11.0
CareDx (CDNA)	18.92	21.41	-12%	816	334	2.4
Exact Sciences (EXAS)	46.35	56.19	-18%	10,350	2,759	3.8
Exagen (XGN)	3.33	4.10	-19%	60	56	1.1
Veracyte (VCYT)	30.96	39.60	-22%	2,170	446	4.9
Myriad Genetics (MYGN)	10.41	13.71	-24%	988	838	1.2
Castle Biosciences (CSTL)	19.63	26.65	-26%	293	332	0.9
Personalis (PSNL)	3.82	5.78	-34%	197	85	2.3
NeoGenomics (NEO)	10.23	16.48	-38%	1,530	661	2.3
ProPhase Labs (PRPH)	0.45	0.76	-41%	40	13	3.1
23andMe (ME)	1.77	3.25	-46%	29	209	0.1
Biodesix (BDSX)	0.78	1.53	-49%	151	71	2.1
Interpace Biosciences (IDXG)	1.13	2.70	-58%	57	45	1.3
Aspira Women's Hlth (AWH)	0.14	0.71	-80%	2	9	0.3
Totals & Averages			**-11%**	**$121,136**	**$42,678**	**2.8**

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

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