Jondavid Klipp, Editor, jklipp@laboratoryeconomics.com

Volume 20, No. 6 June 2025

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

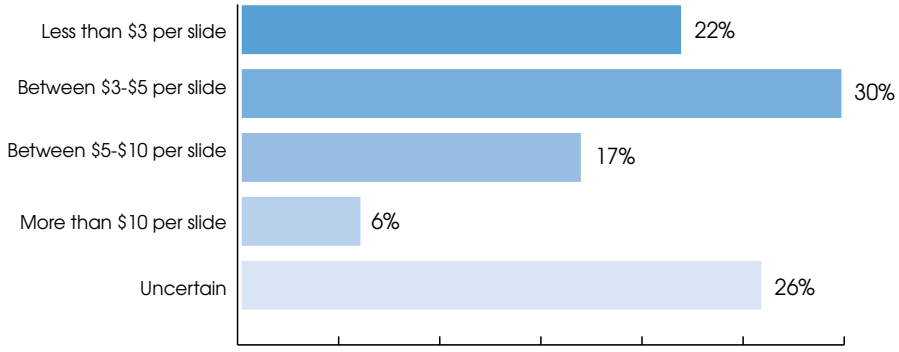
The Outlook for Medicare CLFS Rates

Without legislative action, Medicare rates for nearly 800 lab tests will be cut by up to 15% effective January 1, 2026. "A lot of labs have become complacent after five straight years of Medicare CLFS rate freezes," says Mark Birenbaum, Executive Director of the National Independent Lab Association (St. Louis, MO). "But they need to start thinking about the potential for rate cuts next year." *Full details on pages 3-4.*

How Much Does Digital Pathology Cost?

The pace of adoption of digital pathology for primary clinical diagnosis is accelerating, according to the latest *LE Digital Pathology Survey* (May 2025; n=120). The speed bump to even faster adoption is the fact that digitizing slides is an added cost that is not reimbursed. A plurality of surveyed labs and pathologists (30%) estimate that the all-in cost to digitize a slide is $3-5. *More survey results on pages 5-6.*

What is Your Estimated Cost to Digitize a Slide?*



*Includes scanning, image management software and storage

Source: *LE Digital Pathology Survey* (May 2025; n=120)

Caris Seeks Up to $423 Million from IPO

Caris Life Sciences (Irving, TX) has filed paperwork to raise as much as $423 million through an initial public offering (IPO) of 23.5 million shares at $16 to $18 each. Caris specializes in molecular profiling of solid biopsies as well as blood-based cancer tests. Caris has already raised a total of $1.9 billion from private equity and debt investors since 2018, including $168 million raised in April. Revenue growth is strong at Caris (up 50% YOY in 1Q25). However, the company has accumulated losses totaling $2.6 billion since being formed in 2008. *More details on page 2.*

Contents

CARIS SEEKS UP TO $423 MILLION FROM IPO (*cont'd from page 1*)
BofA Securities, J.P. Morgan, Goldman Sachs and Citigroup are the lead underwriters for the offering. Caris plans to use the IPO proceeds to fund operating expenses and capital expenditures. The money will also help pay for costs related to restricted stock units (RSUs) granted to Caris executives and directors, according to the IPO prospectus.

Caris operates two CAP-accredited labs in Phoenix—one lab for solid tissue testing (66,000 sq. ft.) and another for blood-based testing (35,500 sq. ft.). Caris is also building a third major lab in Irving, Texas (100,000+ sq. ft.). In addition, Caris has a 59,000-square-foot R&D laboratory in Tempe, Arizona that is utilized for research and drug discovery work. Caris has installed 50 of Illumina's NovaSeq sequencing systems at its labs as of March 2025.

The company has a total of 1,700 employees, including a sales and marketing staff of 270 and nearly 50 PhDs and MDs.

The company's flagship testing products include Caris MI Cancer Seek, which analyzes DNA and RNA from tissue specimens. MI Cancer Seek was cleared by the FDA in late 2024 as a companion diagnostic to help identify cancer patients, including breast, colorectal, melanoma, NSCLC, etc., who may benefit from treatment with the targeted therapies. MI Cancer Seek is reimbursed by Medicare through PLA code 0211U at $8,455.

In addition, Caris Assure (PLA 0485U; MolDx rate of $3,649) is a blood-based molecular profiling LDT that was launched in the first quarter of 2024 for cancer therapy selection.

Caris's testing services help doctors select high-priced cancer drugs such as Keytruda ($191,000 per year) for melanoma, NSCLC and head and neck cancer.

Caris reported a net loss of $102.6 million in the three months ended March 31, 2025, versus a net loss of $111 million in the same period a year earlier; revenue increased by 50% to $120.9 million. Revenue from Medicare patients represents more than 50% of total revenue at Caris.

Caris was founded by its Chairman and CEO David Halbert, age 69, through the acquisition of Molecular Profiling Institute (MPI) in 2008. Halbert's previous experience includes CEO of the pharmacy benefit manager AdvancePCS Inc. (acquired by CareMark in 2004 for $7.5 billion).

Competitors of Caris include Roche's Foundation Medicine, Guardant Health and Tempus AI, as well as academic medical centers such as Memorial Sloan Kettering Cancer Center and New York Presbyterian-Weil Cornell.

Caris Life Sciences Financials ($000)

	First-Quarter 3/31/2025	First-Quarter 3/31/2024	% Chg	Full-Year 2024	Full-Year 2023	% Chg
Molecular profiling revenue	$114,081	$73,233	55.8%	$349,115	$278,748	25.2%
Pharma R&D revenue	6,834	7,444	-8.2%	63,145	27,380	130.6%
Total revenue	120,915	80,677	49.9%	412,260	306,128	34.7%
Total cost & operating expenses	178,867	172,902	3.4%	669,382	625,679	7.0%
Loss from operations	-57,952	-92,225	NA	-257,122	-319,551	NA
Net loss to shareholders	-102,581	-111,028	NA	-378,257	-462,527	NA
Accumulated losses	-$2,599,865	-$2,498,838	NA	-$2,498,838	-$2,144,950	NA
Total case volume (in thousands)	47.3	36.5	29.6%	172.6	136.9	26.1%

Source: Caris IPO registration statement

THE OUTLOOK FOR MEDICARE CLFS RATES (*cont'd from page 1*)
Birenbaum says that NILA is working with the American Clinical Laboratory Assn. to introduce a new "PAMA-fix" bill within the next month or two. Any new bill would seek to delay the scheduled Medicare CLFS rate cuts for 2026 and ensure that hospital lab rates are correctly represented in future private-payer payments surveys and rate calculations.

It's too late to get a PAMA-fix into the Big Beautiful Bill currently being debated in the Senate. The hope is that a PAMA-fix could get inserted into a major government funding or healthcare policy bill at the end of the year. But this will be a tough hill to climb, and time is running short.

Here's an outline of three possible scenarios:

Scenario 1: PAMA Proceeds as Scheduled by Law
The first PAMA survey, which was based on private-payer lab rates from 2016, resulted in three straight years (2018-2020) of 10% cuts to most lab tests on the Medicare CLFS. A second PAMA survey and additional rate cuts were then frozen for five straight years (2021-2025).

Under current law, Medicare CLFS rates for approximately 800 lab tests will be reduced by up to 15% on January 1, 2026. See table on page 4.

In addition, the second PAMA survey is scheduled to begin on January 1, 2026. Independent labs, hospitals and large POLs are required to submit their private-payer volumes and reimbursement rates from the period January 1, 2019 to June 30, 2019 to CMS by March 31, 2026. CMS will use this data to calculate new median private-payer rates to set the Medicare CLFS for 2027-2029.

Scenario 2: A PAMA-Fix is Introduced and Passed into Law
Despite widespread support from both Democrats and Republicans, the last PAMA-fix bill SALSA (H.R. 2377/S. 1000) failed to get passed into law. The culprit was cost. The Congressional Budget Office (CBO) had projected that passing SALSA into law would cost $6 billion over 10 years. A separate analysis by ACLA had estimated the cost at less than $3 billion.

ACLA is now crafting a new PAMA-fix proposal and seeking supporters to introduce it. A simpler and less costly alternative to SALSA is what's needed.

There is little argument that current PAMA law pertaining to labs is unworkable. In particular, it will be nearly impossible for most hospital labs to dig up their private-payer volume and payment data from 2019 and report it to CMS, notes Josh Kramer, Managing Partner at the laboratory IT company Leap Consulting Group (Teaneck, NJ). Kramer says that many hospitals have gone through system upgrades and changes since 2019 and these hospitals may not have historical claims data readily available from legacy systems. In addition, PAMA does not allow hospitals to ignore paper claims data. And smaller hospitals may not have detailed lab data from paper claims loaded in their systems at all, according to Kramer.

A new PAMA-fix bill will need to include a mechanism (e.g., statistical sampling) to ensure that the higher rates paid to hospital labs are accurately surveyed and included in CLFS rate calculations.

Scenario 3: CLFS Remains Frozen and PAMA is Delayed Another Year
In previous scoring of one-year delays in PAMA payment cuts and reporting, the CBO assumed that private payers were adjusting their lab test reimbursement rates for inflation. Based on this assumption, the CBO concluded that the suspension of PAMA would result in cost savings. The CBO is no longer assuming private payer inflation updates. As a result, another one-year PAMA delay is unlikely to be scored to provide savings and thus unlikely to be passed into law.

Medicare CLFS Rates to Drop by Average 8.5% in 2026

Rate cuts of up to 15% for nearly 800 tests on the Medicare CLFS are scheduled to take effect on January 1, 2026. This will result in an overall average drop in Medicare fee-for-service payments of 8.5% for most clinical labs, according to an *LE* analysis of the top 25 CLFS tests by Medicare Part B carrier allowed charges.

Among the lab tests that face the maximum 15% rate cut are CPT 87798 (Detect agent not otherwise specified by PCR), CPT 80061 (Lipid panel), CPT 87481 (Candida by PCR) and CPT 87801 (Detect agent, multiple organisms, by PCR).

Importantly, scheduled Medicare rate cuts may also influence other payers, including Medicaid and most commercial insurance plans that tie their lab test rates to a percentage of the Medicare CLFS.

Scheduled Medicare Rate Changes for 25 Key Tests

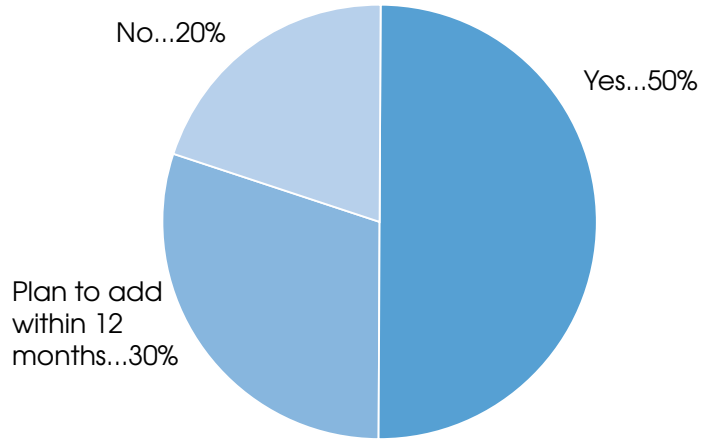
Code	Description	Medicare Part B Carrier Allowed Charges (2023)	2025 Medicare Rate	PAMA Survey Weighted Median	Scheduled Medicare Rate for 2026	% Chg
81528	Colorectal screen (Cologuard)	$307,230,047	$508.87	$508.87	508.87	0.0%
87798	Detect agent NOS by PCR	295,634,919	35.09	29.83	29.83	-15.0%
80053	Comprehensive metabolic panel	285,701,579	10.56	9.08	9.08	-14.0%
84443	Thyroid stim hormone (TSH)	233,445,081	16.80	14.87	14.87	-11.5%
80061	Lipid panel	232,313,225	13.39	11.23	11.38	-15.0%
85025	Complete cbc w/auto diff wbc	203,780,093	7.77	6.88	6.88	-11.5%
82306	Vitamin D 25 hydroxy	185,044,047	29.60	26.37	26.37	-10.9%
G0483	Drug test def 22+ classes	147,266,871	246.92	NA	246.92	0.0%
83036	Glycosylated hemoglobin (A1C)	136,551,060	9.71	8.50	8.50	-12.5%
80307	Drug test(s), presumptive	125,367,403	62.14	NA	62.14	0.0%
81455	Targeted genomic seq analysis	121,188,883	2,919.60	2,919.60	2,919.60	0.0%
G0482	Drug test def 15-21 classes	112,563,902	198.74	NA	198.74	0.0%
81519	Oncology breast mRNA	97,051,916	3,873.00	3,873.00	3,873.00	0.0%
G0480	Drug test def 1-7 classes	73,050,311	114.43	NA	114.43	0.0%
83970	Assay of parathormone	71,319,998	41.28	36.76	36.76	-10.9%
G0481	Drug test def 8-14 classes	70,316,295	156.59	NA	156.59	0.0%
87481	Candida by PCR	69,258,797	35.09	29.25	29.83	-15.0%
82607	Vitamin B-12	67,799,007	15.08	13.43	13.43	-10.9%
84153	PSA total	58,792,910	18.39	16.38	16.38	-10.9%
87150	DNA/RNA amplified probe	53,920,814	35.09	30.10	30.10	-14.2%
84439	Free thyroxine	47,938,183	9.02	8.03	8.03	-11.0%
80048	Basic metabolic panel	44,735,174	8.46	8.06	8.06	-4.7%
82728	Assay of ferritin	44,469,987	13.63	12.13	12.13	-11.0%
87801	Detect agent mult by PCR	38,142,423	70.20	59.22	59.66	-15.0%
81162	BRCA1&2 seq & full dup/del	12,459,068	1,824.88	1,615.81	1,615.81	-11.5%
	Total for 25 tests	**$3,135,341,993**				**-8.5%**

Source: *Laboratory Economics* from CMS

HOW MUCH DOES DIGITAL PATHOLOGY COST? (*cont'd from page 1*)

Fifty-percent of surveyed pathology groups and labs reported having digital slide scanners in place for analyzing patient specimens. Another 30% said they plan to add a system within 12 months, according to the *LE Digital Pathology Survey*.

Does your pathology group/laboratory use digital pathology to analyze patient slides?



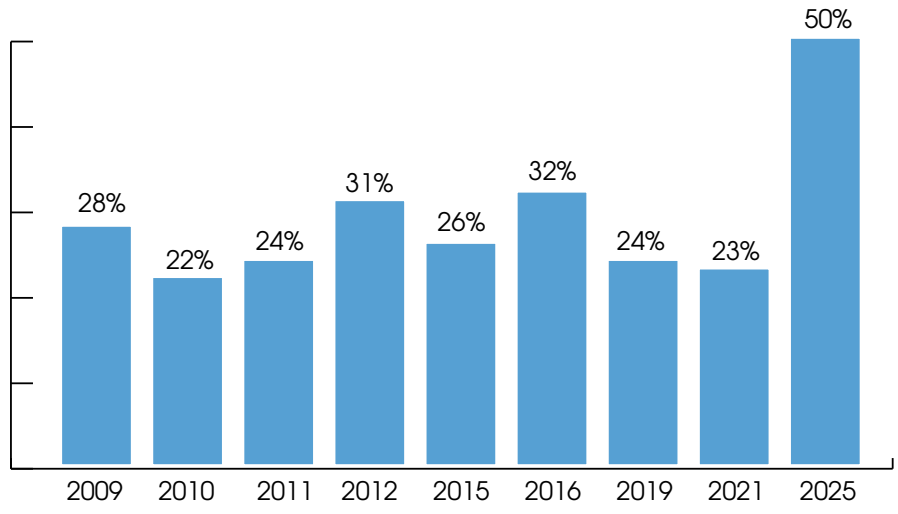
Source: *LE Digital Pathology Survey* (May 2025; n=120)

These survey results overstate current digital pathology utilization. However, when compared with our previous surveys, the trend toward higher adoption is undeniable. In previous surveys (2009-2021), 22%-33% of respondents reported using digital pathology.

"I would like to begin to transition to digital slides within the next 5 years. I believe it will be difficult in the future (~10 years) for any pathology practice to be competitive without the use of digital pathology," according to a practice administrator from North Carolina.

"Our pathology group is small and trying to cover three facilities. If they could remote read and review slides, it would mean less driving in traffic and easier to cover for each other," commented a hospital-based pathologist.

Percentage of Labs that Report Using Digital Pathology



Source: *LE Digital Pathology Surveys:*2009-2012, 2015, 2016, 2019, 2021 & 2025

"Our group wants to add, but cost and staffing issues are a hindrance," said a practice manager from Arkansas.

"The drawback is the desire for people to work from home when they also have CP responsibilities. I question one's work ethic if that's how they want to work," noted a pathologist from a hospital in North Carolina.

"Until AI is more mature, digitization of slides is a wasteful distraction," said a pathologist from Kentucky.

The biggest market for digital pathology at labs is currently in primary clinical diagnosis (cited by 50% of survey respondents). Other uses of digital pathology include second opinions and/or consultations (49%) and education and/or training (45%). In addition, the latest survey showed that utilization for remote frozen section interpretations (33%) has jumped from previous surveys.

What do you use digital pathology for?*

	2025	2021	2019	2016
Primary clinical diagnosis	50%	44%	6%	20%
Second opinions and/or consultations	49%	50%	40%	50%
Education and/or training	45%	69%	34%	54%
Remote frozen section interpretations	33%	13%	0%	0%
Archiving specimens	29%	31%	14%	19%
HER2 scoring	21%	75%	57%	56%
ER/PR scoring	19%	50%	43%	35%
Contract research for clinical trials	15%	13%	3%	13%
Photography of autopsies	5%	13%	5%	0%

*Survey respondents were able to select multiple answers

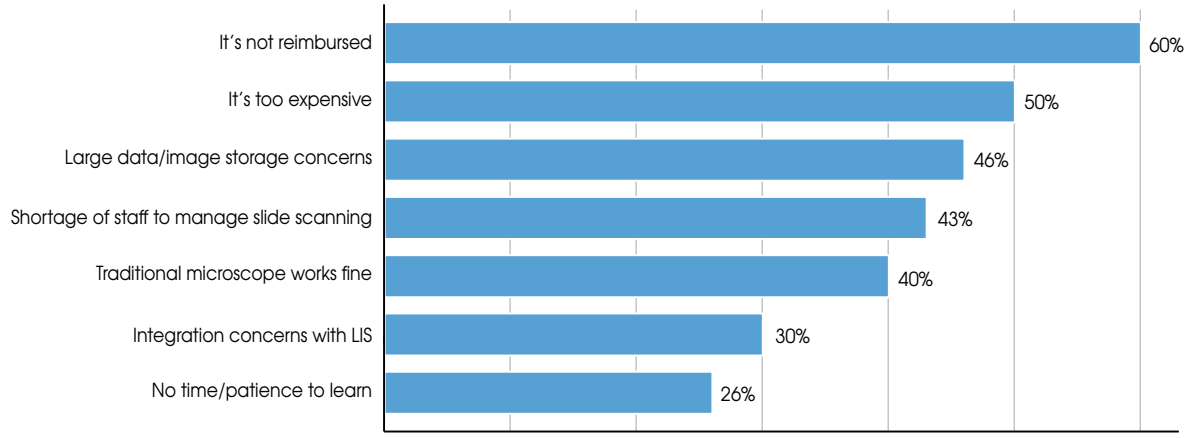
Source: *LE Digital Pathology Surveys:* 2016, 2019, 2021 & 2025

The main barriers to greater adoption of digital pathology are the lack of reimbursement (60%) and the perception that it's too expensive (50%).

Survey respondents also cited large data/image storage concerns (46%). Digitized pathology slides must be in color and require multiple levels of focus up and down through the section. The result is extremely large computer files and expensive storage costs.

Pathology groups and labs are hoping that AI-based decision-support tools that boost pathologist productivity and reduce errors will provide an ROI on their digital pathology investment.

Barriers to Adoption of Digital Pathology



Source: *LE Digital Pathology Survey* (May 2025; n=120)

Survey Demographics: The survey was e-mailed to approximately 5,000 pathology groups, independent labs and hospitals in late May 2025. A total of 120 surveys were judged usable, yielding a response rate of 2.4%. Among the respondents, 46 were from local or regional independent pathology groups and labs, 37 from hospital-based pathology groups or labs, 16 from academic medical center-based pathology groups, 10 from national pathology or lab companies and 11 from physician-office-based labs.

Big Beautiful Bill Includes Inflation Updates for Pathology Rates

House Republicans passed the One Big Beautiful Bill Act (OBBBA-H.R. 1) on May 22. The OBBBA includes provisions to link Medicare Physician Fee Schedule payments to the Medicare Economic Index (MEI). The bill is a big step toward providing pathologists and pathology labs with annual inflation updates to their Medicare rates. Below is a summary of *LE's* interview with CAP Governor A. Joe Saad, MD, on what potential MEI inflation updates will mean for pathologists and pathology labs.

A. Joe Saad, MD

What kind of inflation updates are included in the BBB?
The year one increase (effective January 1, 2026) would hike the Medicare PFS conversion factor by 75% of MEI. This would be quite acceptable.

For 2027 and onwards the conversion factor would be raised by 10% of the MEI. This falls far short of expectations and would further strain the entire Medicare population's access to high quality care. So, there is still work to be done, but it does change the mindset in Congress to consider further future increases.

[For the sake of comparison, the MEI increased by 4.6% in 2024 and by 3.5% in 2025. In 2026, the MEI is expected to increase by 2.3%, so this would mean a 1.7% increase in physician payments.]

What is the estimated cost of implementing MEI inflation updates?
The Congressional Budget Office (CBO) has estimated this provision will cost about $8.9 billion to the Medicare physician payment system over a 10-year budget window.

Who were some of the supporters of MEI-linked increases to the conversion factor?
The CAP is very appreciative of our advocates in Congress, especially our physician colleagues, who were able to win increases to Medicare payments through tough negotiations in a very difficult and divisive budget battle. Notable supporters have included Representatives Raul Ruiz, MD (D-CA), Ami Bera, MD (D-CA), Mariannette Miller-Meeks, MD (R-IA) and former Rep. Larry Bucshon, MD (R-IN).

Wasn't the 2.8% cut to the conversion factor for 2025 highly unusual? What happened?
Yes. In recent years, Congress has always acted to mitigate Medicare PFS cuts. Congress was initially poised to provide relief for the 2.8% cut in December 2024 through a continuing resolution (CR) that almost passed the House but was derailed at the last minute. Ultimately, the CR passed in December, and another CR passed in March, but both failed to mitigate the cuts. It was a huge disappointment, but we are now focused on the future. There is reason to be optimistic given the precedent H.R. 1 will set.

Would MEI inflation adjustments help to offset potential adjustments to the CF due to sequestration cuts?
Yes. MEI inflationary updates would be an important factor in adjusting the conversion factor and reversing the downward payment spiral. In recent years, the CF has decreased, in large part, from implementation of the new E&M code (G2211) and sequestration cuts. This is triggered by budget neutrality, which has yet to be addressed by Congress. The MEI inflationary updates are definitely a positive development and will provide benefit.

What is the current status of the One Big Beautiful Bill Act (H.R. 1)?
H.R. 1 is now in the hands of the Senate. The Senate definitely wants to make adjustments and put their own markers down for further negotiation. Several fiscally conservative senators are concerned about costs and increases to the federal deficit. Some want further cuts to Medicaid. Many on both sides are concerned about cuts to healthcare, especially Medicaid, which could increase the number of uninsured by millions.

No Appeal Filed by FDA in LDT Lawsuit Loss

The FDA has not filed an appeal to a recent U.S. District Court decision that eviscerated the agency's final rule for regulation of lab-developed tests (LDTs). The 60-day window for the FDA to appeal the ruling ended on May 30. Furthermore, it's unlikely that the current Trump Administration is going to move forward on comprehensive LDT regulation, notes Sheila Walcoff, JD, Chief Executive at the regulatory consulting firm Goldbug Strategies (Gaithersburg, MD). And without the threat of comprehensive LDT regulation, there is no incentive for federal legislation either (i.e., no VALID Act), adds Walcoff.

Sheila Walcoff, JD

"This decision should finally conclude the FDA's unwarranted and overreaching attempts to assert regulatory authority over LDTs," said Jane Gibson, President of the Association for Molecular Pathology (AMP), in a statement. AMP, along with the American Clinical Lab Assn. (ACLA), were among the groups that sued the FDA seeking to overturn its final rule giving it the authority to regulate LDTs (see *LE*, June 2024).

"I anticipate that the FDA will now move to enforce in areas where its authority is clear and the risk to patient health is high," says Walcoff. "The FDA held back on enforcement actions over the last few years because of its anticipated LDT regulatory structure."

Walcoff notes that the U.S. District Court's definition of "LDT services" is narrower than the industry's common understanding of LDT. This could certainly impact the enforcement approach the FDA takes in this Administration and beyond.

U.S. District Court Judge Sean Jordan defined LDTs as "in-house diagnostic tests developed, validated, and performed by trained professionals within a single clinical laboratory."

Consequently, Walcoff believes that third-party lab test developers and anyone else manufacturing or distributing products labeled RUO/IUO may be "low hanging fruit" for FDA enforcement action.

FDA Warning Letter on RUO Reagents Could Signal New Trend

A recent warning letter from the FDA to a manufacturer of research use only (RUO) reagents shows one way that the agency might try to indirectly regulate LDTs, according to Steven Gonzalez, an associate with Hyman Phelps & McNamara (Washington, DC) and a contributor to the FDA Law Blog.

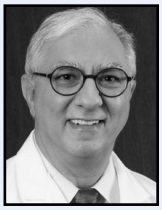
The warning letter to German IVD company DRG Instruments GmbH states that FDA has determined the company's RUO-labeled assay is being marketed for clinical diagnostic use. Some of the claims that the FDA has cited as being for diagnostic use include, "Simple and patient-friendly measurement of hormone profiles" and "Can be performed also by patients."

The FDA issued the letter on March 31, 2025, but did not post it on its website until May 27, 2025. It is only one of two warning letters that the FDA has sent related to RUO-labeled products in the last five years.

"Because LDTs for clinical diagnostic use can sometimes include RUO-labeled components, FDA may look to increase its scrutiny of these components as a means of tightening its control of the inputs to LDTs," says Gonzalez.

If a clinical laboratory is using an RUO reagent in one of its tests, it may find that the reagent could be harder to get in the future if RUO manufacturers feel they need to police how their customers use their products to avoid FDA enforcement, says Gonzalez.

Spotlight Interview with UTMB's Michael Laposata



Michael Laposata, MD, PhD

The University of Texas Medical Branch laboratory, located in Galveston, performs more than 4.5 million laboratory tests per year and is launching a new "Diagnostic Center" to aid clinicians in the selection of diagnostic tests and in the personalized interpretations of test results. *Laboratory Economics* recently spoke with Michael Laposata, MD, PhD, Chairman of UTMB's Department of Pathology, about lab-developed tests, the Diagnostic Center and the role of artificial intelligence in healthcare.

How many pathologists work at UTMB? How many total employees in the laboratory?
We have 20 anatomic pathologists, 10 clinical pathologists (some are PhDs) and 30 additional scientists in the pathology department who do research almost exclusively, making a pathology department of 60 faculty and 377 people who work at the technical level. We have four hospital-based clinical labs, including a core lab in Galveston that performs all of our anatomic pathology services.

What are your thoughts on the FDA's LDT rule being overturned?
It's a huge relief to have the rule vacated. There were many times during the pandemic where we had to modify Covid tests on the fly because variants kept changing. If we had to wait for FDA approval for each of these changes, it would have taken months each time. This would have meant that the FDA would be regulating me as a doctor as though I were a medical device. It was preposterous.

How many LDTs does the University of Texas Medical Branch offer?
More than a dozen. But as a doctor, there are times when I am modifying tests as I go to get information about a diagnosis. For example, as an expert in bleeding and clotting disorders, I might say mix half normal plasma with half of the patient's plasma, when it is not a defined test.

Does UTMB use digital pathology?
Yes, we are using it for 100% of our cases. We are also using AI to review every slide for the organs and tissues which have validated AI programs from Ibex Medical Analytics. We started using it for prostate biopsies last fall and for breast biopsies shortly after. It is incredible. All tumor sites light up as bright red, yellow is "I'm not sure" and blue is normal. This allows our pathologists to focus their time on areas that need the most scrutiny. Digital pathology and AI have improved our ability to detect tumors when they are more likely to be curable.

What are the biggest drawbacks to digital pathology?
When it's used correctly, none. But you can't just do digital pathology alone. You also need to do H&E with it. Pathology residents still need to be trained in how to read H&E slides so that the pathologist and the AI programs each provide essential diagnostic expertise.

Where will the application of artificial intelligence be most useful to pathologists?
It goes beyond anatomic pathology. AI can help doctors figure out which tests to order. In our Diagnostic Center, the doctor can type in the signs and symptoms of a patient and AI can narrow down the differential diagnosis and recommend which tests to offer. We, as pathologists, are making ourselves valuable for achieving the correct diagnosis rapidly for any patient of any kind.

Does UTMB have any new initiatives underway?
We received a $9 million grant a year and a half ago and used it to develop the John Sealy Diagnostic Center here at UTMB. We help providers figure out which tests to order, how to interpret results and how to manage patients. This service is offered for both tissue-based and liquid-based diagnosis, involving all tests that we perform in our pathology lab. We are planning to expand this service, first throughout Texas, and then to other states.

Lab Industry Needs to Make the Case for Z Codes for UTI Panels

PCR-based testing for urinary tract infections (UTIs) can be more accurate, detect a wider range of pathogens and provide faster results than traditional urine cultures. Despite this, no MolDx-Z codes have been issued for any UTI PCR panels and very few for any PCR panel above five targets, according to Jon Harol, President of Lighthouse Lab Services (Charlotte).

"There needs to be a good data case made, and as an industry, we have yet to meet the standard that MolDx is looking for," says Harol, who notes that PCR-based testing is more expensive than cultures, so it's reasonable for MolDx to want to see strong clinical utility before it starts paying for UTI PCR panels.

Harol says the industry is working to develop a playbook to demonstrate clinical utility of PCR UTI panels so they can be assigned Z codes, which he says will be transformative for the clinical lab industry.

MolDx, which is run by Palmetto GBA, has been adopted by three other Medicare administrative contractors (MACs): CGS, Noridian and WPS. Altogether, the program provides uniform policies for 28 states. In these regions, a Z code is required for reimbursement under Medicare.

While MolDx historically has been used by federal payers, there is increasing adoption by commercial payers. The remaining MACs are likely to adopt the MolDx program, predicts Michael Sprintz, DO, founder and CEO of Cellarian, who advises labs to prepare now for MolDx. Cellarian is a health information technology company based in Texas.

"It's better to get ahead of it than get left behind," says Sprintz, who explains that labs mistakenly assume that having a Z code and a technical assessment will result in automatic payment. "Those are not enough," he says. "They are just the first barriers to coverage."

Having a Z code and a positive TA means your test is registered and you have coverage, but it doesn't automatically mean you'll get paid, explains Sprintz. The third requirement for payment is medical necessity.

Denials often stem from lack of documentation proving medical necessity, not just coding errors, he says. Medical necessity documentation must adequately describe the patient's clinical story in a way that clearly justifies the need for the ordered test.

Common reasons for denials include missing clinical rationale (why this test, for this patient, at this time?); templated or generic notes; lack of connection between symptoms, history and ordered test; and inconsistency between the lab order and documentation.

"Doctors don't have time to document effectively, which means you as the lab are chasing clinicians," says Sprintz. Appeals cost time and money, and the success rate is poor without thorough documentation. In addition, lack of visibility into the appeals process limits consistent strategic response.

NJ Medicaid Saves $100+ Million from Toxicology Test Limits

The New Jersey Office of the State Comptroller (NJOSC) reports that the state's Medicaid program has saved $102 million in the last four years (April 2021 through April 2025) due to policy changes that reduced unnecessary drug tests.

NJOSC says that its audit of Ammon Analytical Laboratory (Linden, NJ) found that Ammon used "blanket" or one-size-fits-all drug test requisition forms, subjecting all patients to the same battery of tests regardless of individual medical needs. The audit also found that Ammon and its ordering substance abuse providers would commonly request a medically unnecessary "definitive" test as the initial test, bypassing the lower cost "presumptive" test. NJOSC found that other toxicology labs had adopted the same wasteful practices.

As a result, the New Jersey Medicaid program implemented a number of restrictions:

- Eliminated the billing of three definitive drug test panels: G0481 (Definitive drug test, 8-14 classes), G0482 (Definitive drug test, 15-21 classes) and G0483 (Definitive drug test, 22+ classes).
- Prohibited definitive testing for G0480 (Definitive drug test, 1-7 classes) when initial presumptive screening tests (CPT 80305-80307) were negative.
- No more than 10 patient encounters may be billed for presumptive drug testing per rolling 30 days.

Approximately 260 independent labs participate in New Jersey's Medicaid program. From April 2021 through April 2025, these labs received Medicaid payments totaling $172 million for drug testing services. Without the policy changes, NJOSC says that spending would have been $102 million higher.

LifeLabs Reaches 3-Year Deal with 1,200 Striking Workers

Quest's LifeLabs (Toronto, Canada) and the BC General Employees' Union representing about 1,200 workers have reached a deal ending roughly 10 weeks of rotating strikes (see *LE*, April 2025). The union says that the deal includes wage increases of about 11.3% to 20% over the agreement's three-year term ending March 31, 2027.

The contract puts the lab workers pay "at parity" with public-sector wages in the deal's second year. The agreement also includes "critical changes to address workload and overtime issues," and the union says that LifeLabs removed sick-pay concessions it wanted from workers.

The two sides had been without a contract since April 2024 and the union voted in November to authorize strikes.

LifeLabs operates five primary labs and over 350 PSCs in British Columbia, Ontario and Saskatchewan that perform 140 million tests per year. Quest acquired LifeLabs for CAN $1.35 billion (USD $1 billion) in August 2024 (see *LE*, July 2024).

States Sue to Block Sale of 23andMe

Twenty-seven states and the District of Columbia have filed a lawsuit in bankruptcy court seeking to block the sale of personal genetic data by 23andMe (San Francisco) without customer consent. 23andMe owns raw genetic code, from 15 million people that is paired with data on each person's physical appearance and their family tree. Regeneron Pharmaceuticals has offered to buy the company for $256 million, while co-founder and former CEO Anne Wojcicki has bid $305 million. 23andMe filed for Chapter 11 bankruptcy in Missouri federal court in March (see *LE*, April 2025).

Lab Stocks Down 3% YTD

Twenty-four lab stocks are down an unweighted average of 3% year to date through June 13. In comparison, the S&P 500 Index is down 2%. Tempus AI has jumped 111%, Exagen is up 74% and Adaptive Biotechnologies is up 72%. Quest Diagnostics is up 19% and Labcorp is up 14%.

Company (ticker)	Stock Price 6/13/25	Stock Price 12/31/24	2025 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
Tempus AI (TEM)	$71.28	$33.76	111%	$12,980	$803	16.2
Exagen (XGN)	7.12	4.10	74%	168	57	3.0
Adaptive Biotechnologies (ADPT)	10.32	6.00	72%	1,560	190	8.2
23andMe (MEHCQ)	5.49	3.25	69%	120	190	0.6
Guardant Health (GH)	49.29	30.55	61%	6,710	774	8.7
Quest Diagnostics (DGX)	180.21	150.86	19%	26,620	10,158	2.6
Labcorp (LH)	261.12	229.32	14%	28,090	13,177	2.1
Fulgent Genetics (FLGT)	20.69	18.47	12%	-181	292	NM
Oncocyte Corp. (OCX)	2.65	2.38	11%	48	4	12.7
Natera (NTRA)	165.34	158.30	4%	21,780	1,831	11.9
Personalis (PSNL)	6.01	5.78	4%	390	86	4.6
Sonic Healthcare (SHL.AX)*	26.89	27.01	0%	17,180	9,330	1.8
Exact Sciences (EXAS)	53.52	56.19	-5%	11,850	2,828	4.2
Opko Health (OPK)	1.33	1.47	-10%	1,120	689	1.6
CareDx (CDNA)	18.59	21.41	-13%	834	346	2.4
GeneDx (WGS)	64.57	76.86	-16%	1,800	330	5.5
Castle Biosciences (CSTL)	18.75	26.65	-30%	286	347	0.8
Veracyte (VCYT)	26.44	39.60	-33%	1,830	463	3.9
ProPhase Labs (PRPH)	0.33	0.76	-57%	28	6	4.8
NeoGenomics (NEO)	7.07	16.48	-57%	1,160	672	1.7
Myriad Genetics (MYGN)	5.03	13.71	-63%	529	831	0.6
Interpace Biosciences (IDXG)	0.77	2.70	-71%	6	48	0.1
Biodesix (BDSX)	0.29	1.53	-81%	88	75	1.2
Aspira Women's Hlth (AWHL)	0.08	0.71	-88%	4	9	0.4
Totals & Averages			**-3%**	**$134,823**	**$43,538**	**3.1**

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor Harrison Klipp, Data Analyst