

LABORATORY *E* ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Final 2025 MPFS Cuts Pathology Rates by 2.5%

The Final Medicare Physician Fee Schedule (MPFS) for 2025 reduces professional rates paid to pathologists by an average of 2.5%, while technical fees paid to pathology labs will fall by approximately 2.7%. These cuts are primarily due to a 2.8% reduction in the final 2025 conversion factor to 32.3465. The rate cuts will become effective January 1, unless Congress intervenes with an end-of-year legislative fix.

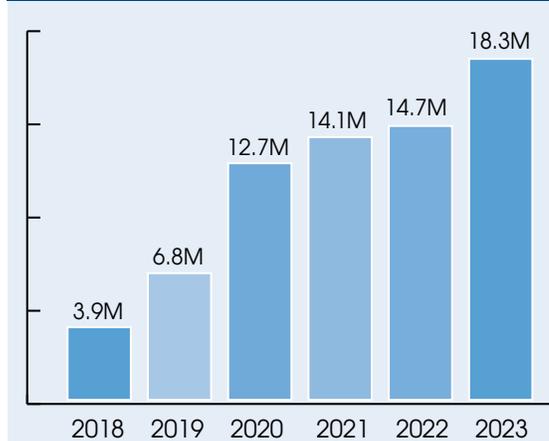
Full details on page 11.

PCR-Based Microbiology Tests Continue to Lead in Growth

PCR-based microbiology testing (excluding Covid) continues to be the fastest-growing test segment, according to the latest data from CMS. During the five-year period from 2018-2023, Medicare Part B carrier allowed claims for PCR-based tests grew by 36% per year to reach 18.3 million tests. The growth in PCR testing has occurred despite Part B claim denial rates that average nearly 20%.

Full details on page 5.

Medicare Part B Allowed Test Volume for PCR-Based Microbiology Tests*



*Includes 37 test codes for PCR-based testing (excludes Covid tests and panels)

Source: *Laboratory Economics* from CMS

What's Behind the GeneDx Stock Boom?

Shares of GeneDx (Stamford, CT) have skyrocketed by more than 2,600% this year to reach an enterprise value of \$2.1 billion (see page 12). The company, formerly named Sema4, had been in severe financial distress only about one year ago. However, a massive restructuring and new focus on highly priced whole exome/genome testing for pediatric/rare disease has led GeneDx to the brink of profitability.

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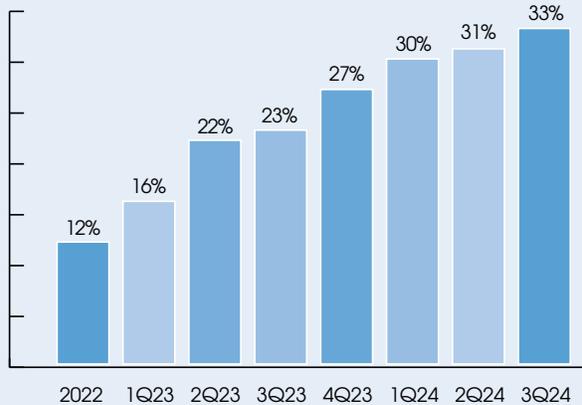
- Lab Stocks Up 108% YTD 12



WHAT'S BEHIND THE GENEDX STOCK BOOM? (cont'd from page 1)

Opko Health (Miami, FL) sold GeneDx (Gaithersburg, MD) to Sema4 for \$364 million in April 2022. Sema4 then shut down its Connecticut lab operations in 2022 and 2023, and focused its business on the acquired GeneDx lab in Gaithersburg (just north of Washington, DC). In addition, GeneDx President Katherine Stueland became CEO of the combined company which changed its name to GeneDx in January 2023.

Over the past two years, GeneDx has incentivized its 50+ sales reps to concentrate on whole exome/genome testing for pediatric/rare disease. The company has eliminated hundreds of single and multi-gene tests from its menu and is instead promoting next-gen sequencing (NGS) tests to pediatric neurologists and specialists.

GeneDx: Whole Exome/Genome Testing as % of Total Test Volume

Source: GeneDx

For example, GeneDx's XomeDx uses NGS to analyze the protein-coding regions of approximately 20,000 genes to identify genetic changes that may be the underlying cause of a child's neurodevelopmental disorder (e.g., developmental delay, intellectual disability and autism) or unexplained epilepsy. This test is billed under CPT 81415; Medicare rate is \$4,780.

Whole exome/genome testing represented 33% (19,262 tests) of GeneDx's overall volume (59,029 tests) in the three months ended September 30, 2024. GeneDx currently collects an average of \$3,115 in revenue

per whole exome/genome test (after accounting for an average denial rate of 45%). In comparison, GeneDx collects an average of only \$430 per test on its other volume (primarily chromosomal microarrays and hereditary cancer testing).

At the recent Piper Sandler Health Care Conference, GeneDx's Stueland said that whole exome/genome testing can help speed diagnosis and stop endless specialist visits and mismanagement of undiagnosed disease. GeneDx's goal is to perform NGS testing to every newborn at birth.

GeneDx has accumulated \$1.4 billion in losses since being founded in 2000 by scientists from the National Institutes of Health. Wall Street analysts expect the company to report its first-ever profit in the fourth quarter of 2024.

GeneDx Financial Results (\$ millions)

	2024*	2023	2022	2021	2020
Revenue	\$267.2	\$202.6	\$234.7	\$212.2	\$179.3
EBITDA	-38.8	-142.9	-439.7	-429.9	-213.7
Net Loss	-83.5	-175.8	-549.0	-245.4	-241.3
Accumulated Losses	-1,357.9	-1,300.2	-1,124.4	-575.4	-330.1
Total Debt	116.1	119.8	77.1	11.0	45.0
Cash & ST investments	116.5	130.1	123.9	400.6	108.1
# Employees	910	1,000	1,100	1,200	872

*Trailing 12 months ended September 30, 2024

Source: SEC filings for GeneDx

Profits Remain Elusive for Most Genetic Testing Labs

Despite high revenue growth, bottom-line profits are uncommon for most publicly traded genetic testing lab companies. Barriers to profitability include high sales and marketing expenses which average roughly 35-40% of revenue at genetic testing lab companies. In addition, payer denial rates average more than 25% for most genetic test claims.

Fifteen genetic testing lab companies recorded combined losses of \$2.1 billion for the latest 12-month period ended Sept. 30, 2024. Accumulated losses at these companies now total \$22.2 billion. Among the 15 publicly traded companies analyzed are three that declared bankruptcy within the past year: DermTech, Invitae Corp. and Biocept Inc.

Tempus AI (Chicago) reported a net loss of \$800.7 million on revenue of \$640.4 million for the latest 12 months ended Sept. 30, 2024. The company has accumulated \$2.1 billion in losses since being formed in 2015.

Guardant Health (Palo Alto, CA) had a net loss of \$512.4 million on revenue of \$692.3 million; accumulated losses total \$2.5 billion since inception in 2012.

Natera (Austin, TX) had a net loss of \$214.7 million on revenue of \$1.5 billion; accumulated losses total \$2.5 billion since being founded in 2004.

Only two of the publicly traded genetic testing lab companies recorded profits over the 12-month period ended Sept. 30, 2024. Castle Biosciences (Friendswood, TX) recorded net income of \$6.1 million on revenue of \$311.9 million and Interpace Biosciences (Parsippany, NJ) had net income of \$4.7 million on revenue of \$44.9 million.

Latest Financial Results at Genetic Testing Lab Companies (\$ millions)

Company	Net Income for Latest 12 mos. to Sept. 30, 2024	Accumulated Losses Since Inception	Year Founded
Tempus AI	-\$800.7	-\$2,137.8	2015
Guardant Health	-512.4	-2,467.2	2012
Natera	-214.7	-2,514.1	2004
Exact Sciences	-214.0	-3,633.4	1995
Myriad Genetics	-116.0	-714.3	1991
Personalis Inc.	-91.4	-533.6	2011
GeneDx	-83.5	-1,357.9	2000
Biodesix	-43.8	-454.2	2005
Aspira Women's Health	-14.8	-530.0	1993
Veracyte	-9.3	-449.1	2008
Interpace Biosciences	4.7	-244.4	1986
Castle Biosciences	6.1	-209.7	2008
DermTech	Filed for Chapter 11 bankruptcy in June 2024	-443.9	1995
Invitae Corp.	Filed for Chapter 11 bankruptcy in Feb. 2024	-6,169.9	2010
Biocept Inc.	Filed for Chapter 7 bankruptcy in Oct. 2023	-309.2	1997
Total for 15 companies	-\$2,089.8	-\$22,168.7	

Source: *Laboratory Economics* from Securities & Exchange Commission 10Q filings

Spectrum Healthcare Partners Rolling Out Digital Pathology Services

Spectrum Healthcare Partners (South Portland, ME) has begun providing digital pathology interpretations to its hospital clients in New England. Spectrum is a physician-owned multi-specialty group that was formed in 1996 as a result of a merger amongst Northeast Anesthesia, Maine Pathology Associates and Radiology Associates of Maine. Spectrum's pathology division includes 23 pathologists and 11 pathology assistants who provide professional interpretations to 14 hospitals in Maine and New Hampshire. Here's a summary of our interview with Bilal R. Ahmad, MD, MBA, Chair of Spectrum's Digital Pathology Innovation and Compliance Committee.



Bilal R. Ahmad, MD

Where does Spectrum stand in its rollout of digital pathology for clinical diagnostics?

Our first whole slide imaging hospital client, Central Maine Medical Center (Lewiston, ME), installed its first high throughput scanner and our pathologists began digital sign outs last month. CMMC has 250 beds and processes about 100,000 slides per year. Spectrum has two full-time pathologists based at CMMC.

A second client, NorDx (Portland, ME), will be installing its first scanner at its flagship Maine Medical Center (Portland, ME) within a few months followed by several more at its central location in Scarborough. MMC has 700 beds and NorDx processes more than 450,000 slides per year. Spectrum has 12 full-time pathologists based at MMC.

Initially, slide scanning at both hospital sites will focus on prostate, breast and gastrointestinal biopsies. Our goal is to convert to 100% digital sign outs within the next 12 months.

Which type of scanners are being used?

We're using Pramana's SpectralHT scanners which can digitize one slide every few minutes. We chose Pramana because it has unique volumetric scanning technology that produces highly detailed fused z-stack images at the tile level with built-in quality assurance. In addition, we're using Proscia's image management software and Microsoft Azure for cloud-based image storage.

How are you handling intra-operative frozen sections?

We recently installed four PreciPoint iO:M8 digital live microscopes at several NorDx labs for remote interpretations of frozen sections and rapid on-site evaluation (ROSE) of cytologic preparations.

What is your estimated average cost to digitize a slide?

Somewhere in the range of \$5-7 per slide, including labor, scanning, image management and storage.

What factors led Spectrum to shift to digital pathology?

Pathologist and PA shortages are a big issue in Maine and New Hampshire. Post-pandemic burn-out and fatigue have led some older pathologists to accelerate their timetable for retirement or enter into modified work plans. But the potential for digital sign outs from home is enticing some of our retirement-age pathologists to continue working three or four days per week. It's also a big draw as we compete to hire new pathologists and PAs.

What are some other benefits of switching to digital pathology?

A major portion of our return on investment (ROI) will come from the application of AI. We anticipate applying AI initially to prostate core biopsies. AI should help raise pathologist productivity in detecting and grading tumors and may also eliminate the need for a second review of all negative cases. Ultimately, pathologists using AI will have a big advantage (e.g., accuracy, productivity and turnaround time) over those that cling to the microscope.

What's the outlook for reimbursement of digitizing slides?

It's irrelevant. Some pathology groups are waiting for Medicare to set reimbursement for the CPT Category III add-on codes, but this could take years. You'll be left behind if you wait too long. Start small, iterate and get involved now.

PCR-BASED MICROBIOLOGY TESTS LEAD IN GROWTH (*cont'd from page 1*)

The fastest-growing PCR-based test is CPT 87150 (culture typing), which went from 16,211 Medicare Part B allowed services in 2018 to 1.539 million in 2023 (149% per year). CPT 87150 is most commonly ordered to help diagnose urinary tract infections. Labs performing the highest volume of CPT 87150 include Patients Choice Laboratories of Indiana (Indianapolis), Laboratory of Florida (Tampa) and Alpha Medical Laboratory (Tulsa, OK).

The second fastest-growing test was a CPT 87634 (RSV), which grew by 137% per year to reach 126,458 Part B tests in 2023. Labs performing the highest volume of CPT 87634 include Ultra Medical Lab (Torrance, CA), GMI Laboratories (North Hollywood, CA) and Yellowstone Labs (Dallas, TX).

CPT 87498 (enterovirus) grew by 130% per year to reach 73,390 Part B tests in 2023. Labs performing the highest volume of CPT 87498 include Ultra Medical Lab, GMI Laboratories and Yellowstone Labs.

The highest-volume PCR-based test is CPT 87798 (infectious agent detection by PCR, not otherwise specified). CPT 87798 grew by 49% per year to reach 8.429 million Part B tests in 2023. Labs performing the highest volume of CPT 87798 include SilverPath Inc. (Bluebell, PA), Ultra Medical Lab and MedArbor Diagnostics (Bristol, PA).

Top 20 Fastest-Growing PCR Tests by Medicare Part B Carrier Allowed Volume (2018-2023)

CPT Code	Description	2023 Medicare Part B Volume	2018 Medicare Part B Volume	5-Year CAGR*
87150	Culture typing by PCR	1,539,019	16,211	149%
87634	RSV by PCR	126,458	1,701	137%
87498	Enterovirus by PCR	73,390	1,134	130%
87541	Legionella pneumophila by PCR	132,960	6,575	82%
87631	Respiratory virus 3-5 targets by PCR	152,664	8,192	80%
87481	Candida by PCR	1,985,374	186,596	60%
87556	Mycobacteria tuberculosis by PCR	61,135	7,229	53%
87551	Mycobacteria by PCR	33,197	3,939	53%
87651	Strep A by PCR	524,338	62,851	53%
87532	Herpes virus-6 by PCR	33,567	4,475	50%
87798	Detect agent NOS by PCR	8,429,395	1,165,255	49%
87640	Staph A by PCR	614,347	88,922	47%
87506	Gastrointestinal pathogen 6-11 targets	33,865	5,469	44%
87641	Staphylococcus aureus, methicillin resistant	387,992	63,903	43%
87653	Strep B by PCR	592,828	98,073	43%
87500	Vanomycin by PCR	481,933	84,336	42%
87801	Detect agent, multiple organisms	549,119	111,652	38%
87529	Herpes simplex virus (HSV) by PCR	201,379	46,061	34%
87502	Influenza virus by PCR	278,007	82,313	28%
87511	Gardnerella vaginalis by PCR	71,754	25,010	23%
	Total for Top 20 PCR Tests	16,302,721	2,069,897	51%
	Grand Total for All PCR Tests	18,318,325	3,902,406	36%

*CAGR (Compound annual growth rate)

Source: Medicare Part B Carrier Data, 2018-2023

The Enforcement Outlook for Labs and Pathologists in 2025

With a new administration set to take office on January 20, 2025, it's likely that federal enforcement priorities will shift in the coming year. *Laboratory Economics* recently spoke with Hope Foster, an attorney with Mintz Levin (Washington, DC) about what might change in 2025. Foster regularly defends clinical labs in cases involving false claims and other alleged violations of law and assists in the development of lab compliance programs.



Hope Foster, Esq.

What will the healthcare industry enforcement look like under the Trump Administration?

It may look at least somewhat different than it does now, given the President Elect's campaign which suggests that his administration will be more pro-business than the Biden Administration. In addition, I presume that we will have all new U.S. attorneys and leaders at the Justice Department. They will have priorities and policies of their own, and they will likely not mirror those of the Biden administration.

However, the changes in enforcement will probably be less significant than in other areas of regulation and oversight. This is likely as administrations tend to see alleged fraud the same way. Neither political party tends to be interested in condoning conduct that is seen as allegedly fraudulent, and I do not think that the Trump Administration will be any more interested in seeing people take money from the federal health programs than other presidents have been.

Nonetheless, it will be interesting to see what happens with the False Claims Act and its qui tam provisions, as much of the federal enforcement agenda is driven by the types of cases that whistleblowers bring against providers on behalf of the United States. Thus, we will be watching whether the Trump Justice Department joins in the same types and number of cases brought by whistleblowers under the Biden Administration.

What is your outlook on FDA regulation of lab-developed tests under the Trump Administration?

I think the ACLA and AMP lawsuits will be successful and that the LDT rule will not be implemented. A Trump Administration would be unlikely to appeal a court decision that went against the FDA. Labs developing LDTs will likely be happy about this prediction; IVD companies will probably not be.

What should labs and pathologists be mindful of in terms of compliance issues in 2025?

An issue that is likely to attract attention is the use of artificial intelligence (AI). There are questions about when you use AI, what it applies to, how you manage privacy issues, what current laws, if any, apply to it, and what, if anything, they require. AI is important to labs and pathologists. If I were running a lab compliance program, I would look closely at AI's use, especially in algorithms used in test development. If my lab used AI, I would be actively seeking a dialogue with federal agencies to understand what they believe my AI obligations are.

Another issue that I have been dealing with, and that I would urge labs to be thinking about, is consumer protection and compliance with the federal and state laws that govern this area. One of the three federal agencies that are responsible for consumer protection is the Federal Trade Commission (FTC). The FTC has been focusing more on healthcare. I don't know whether its emphasis on consumer protection and healthcare will continue under President Trump, as we do not yet know who the FTC Chairman will be.

We will be looking carefully at the nominee once he or she is named, and we will be considering what we think this individual will do in leading the FTC. But if we see consumer protection ini-

tiatives decline at the federal level, I think we'll see increasing activity at the state level where there is already a lot of activism.

Despite the Eliminating Kickbacks in Recovery Act (EKRA), many labs are continuing to employ commission-based sales representatives. What advice do you have for labs related to EKRA?

I have heard the same thing although I have no personal knowledge about whether this is true. When my clients ask, I work to help them design non-commission-based compensation plans. These plans vary depending on what the lab is like and how they want to reward people. I look for ways of not paying based on referrals. I consider methods for rewarding the types of behaviors you want to incentivize, including compliance.

There have not been many enforcement actions brought under EKRA. Those EKRA cases that have been brought seem, based on what has been made public about them, to have involved alleged violations that appeared to be pretty egregious. But I should add, based on my own experience, that public descriptions of these kinds of cases may not jibe with either what the defendant's conduct was or what the defenses were.

The Federal Trade Commission in April banned noncompetes, but that ban was recently overturned by a district court. What do you think will happen with noncompete agreements?

Noncompetes tend to be business deals, not deals that are regulated. They are contractual issues. Typically, the only time that a governmental entity gets involved is when a court is asked to enforce a noncompete agreement. I would expect that the Trump Administration will nominate judges who are business friendly, so they are likely to enforce contractual provisions.

Texas Lab Owner Charged for \$79 Million Testing Fraud

O sman Syed, 34, the owner and operator of BioDX Labs (Coppell, TX) has been charged for his alleged role in a respiratory pathogen panel testing fraud scheme. Syed is accused of causing BioDX to submit more than \$79 million in fraudulent claims to Medicare and Texas Medicaid for tests that were not provided or were not medically necessary, according to the U.S. Department of Justice (DOJ).

Syed allegedly used the personal identifying information of a physician without the physician's knowledge or consent, according to the DOJ. The unknowing physician had no prior relationship with the patients for whom test were ordered.

To conceal that BioDX did not perform the tests as billed, Syed falsely represented that the company used reference labs to perform its testing. He allegedly laundered the proceeds of the scheme by transferring substantial sums to bank accounts abroad, including accounts in China, Hong Kong, Turkey, Greece and Switzerland. The government has seized more than \$15 million in cash in connection with the charges.

Syed is charged with three counts of healthcare fraud, conspiracy to engage in money laundering and three counts of money laundering. If convicted, he faces up to 10 years in prison on each count.



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Q&A with NYSCLEP Director Beverly Rauch

In its final rule on lab-developed tests (LDTs), the FDA established partial discretion for LDTs that are approved by the New York State Department of Health’s Clinical Laboratory Evaluation Program (NYSCLEP). LDTs approved by NYSCLEP are exempt from the FDA’s premarket review process, but they are still subject to the FDA’s phaseout of enforcement discretion for other requirements, including medical device reporting requirements, registration class-based listing and labeling and quality system requirements.



Beverly Rauch

Assuming that the final rule sticks, clinical labs that develop LDTs may need to decide whether to seek approval from the FDA or from NYSCLEP. *Laboratory Economics* recently submitted questions about NYSCLEP’s approval of LDTs to Beverly Rauch, MS, director of the program. Here’s a summary of her answers:

Has NYSCLEP seen an increase in applications for LDTs so far this year?

Comparing the number of LDT submissions between this year and last year, there is an 11% increase in submissions overall from January to September 2024.

How many LDTs does NYSCLEP approve each year?

This answer requires a bit of explanation and familiarity with our LDT Review Policy. Incoming LDT submissions are assigned a risk level by a board of subject matter experts. This risk level determines the approval status of the submission and if further review is required.

NYSCLEP Risk Levels

Category	Submission Required	Initial Approval	Review Required	Review Priority
High	Yes	None	Yes	High ¹
Moderate	Yes	Conditional ^{2,3}	Yes	Medium
Low	Yes	Full ^{2,3}	No ⁴	---
Clinical Trial	Yes	N/A ^{2,4}	No ⁴	---
Not Evaluated	Yes	N/A ^{2,4}	N/A ⁴	---

¹Submissions for laboratories pending a permit or permit category are automatically assigned High Risk, except for packages that qualify for Clinical Trials or Not Evaluated status; ²Provided the laboratory holds the appropriate permit category; ³The NYSCLEP reserves the right to withhold approval at its discretion; ⁴The NYSCLEP reserves the right to review all applications at its discretion.

Source: Source: NYS Dept. of Health/NYSCLEP

The table below lists LDT approval status by year. Note that this data does not include any LDTs that have been withdrawn from review by the laboratory. It must also be noted that due to the significant time required to complete an LDT review, approval granted in any given year likely reflects some submissions from a prior year. A total of 587 LDTs were approved by NYSCLEP in 2023.

Annual LDT Approvals by NYSCLEP

Approval Status	2023	2022	2021	2020	2019
Approved after review	322	338	481	320	384
Approved without review	182	225	282	345	262
Conditionally Approved	83	52	42	37	72
Total Tests Approved	587	615	805	702	718

Source: NYS Dept. of Health/NYSCLEP

Does NYSCLEP have an increased budget to handle any expected increase in LDT applications?

The annual operating costs for NYSCLEP are approximately \$14 million. This operating cost includes the costs associated with the review of the LDT submissions; the specific cost of LDT review cannot be broken out.

Do you have any concerns about NYSCLEP’s ability to handle LDT applications?

I cannot opine on this question.

Has the Food and Drug Administration offered any help in terms of resources?

The State Health Department and the Food and Drug Administration do not share resources.

What are the costs for labs seeking NYSCLEP clearance for an LDT?

There is no fee specific to the review of an LDT. The costs are currently incorporated into permit and reference system fees paid by permitted laboratories. Fees are determined in accordance with NYS Public Health Law Section 576 and Subpart 58-3 of Title 10 of the New York Codes, Rules and Regulations. Additional information on fees can be found on CLEP’s Laboratory Fees page [here](#).

How long does an average NYSCLEP approval take from the time an LDT application is submitted?

An LDT submission that undergoes a full review (e.g., assigned High Risk) is measured in months, not weeks, and more than one round of review may be required. An average cannot be calculated, as there are too many variables involved in the LDT review process. The length of the review depends on the complexity of the assay, the quality and organization of the data presented, the volume in a particular technical reviewer’s queue, etc. Laboratories are advised to follow the submission checklists available on our [Test Approval Page](#) under the section entitled “Making a Submission” to ensure their LDT submission is appropriately organized. If we experience an increase in LDT submissions, it is highly likely that the time to get approval will increase.

Recent NYSCLEP Test Approvals

Laboratory/ Manufacturer	Test Name	Description	Approval Date
Biota Laboratory	BIOTA-ID	Urine NGS assay for urinary tract infections (UTIs).	Nov-24
Aspira Labs Inc.	OvaWatch	Blood test intended to assess the risk of ovarian cancer.	Oct-24
NeoGenomics	Neo Comprehensive Solid Tumor	Tissue-based (FFPE) NGS assay for 14 cancer types.	Oct-24
NeoGenomics	NeoType DNA & RNA Lung	Tissue-based (FFPE) NGS assay for lung cancer.	Oct-24
Next Bio-Research Services	EpiSwitch Checkpoint inhibitor Response Test (CiRT)	A blood-based PCR test to identify likelihood of response to an immune checkpoint inhibitor (ICI) therapy.	Oct-24
Sysmex Inostics	RAS-RAF-SEQ	Blood test for five genetic mutations associated with cancer (approved for clinical trial use only).	Sep-24
Applied DNA Sciences	TR8 PGx	A cheek-swab test that analyzes 120 genetic targets to help predict how a patient may respond to a wide range of medications.	Jun-24

Source: NYS Dept. of Health/NYSCLEP

FormaPath Plans to Launch Automated Tissue Biopsy Grossing System

FormaPath (Ithaca, NY) continues to beta test its nToto automated tissue biopsy grossing system with plans for commercial launch in the summer of 2025. nToto was developed by FormaPath in collaboration with Mayo Clinic Rochester's Advanced Diagnostics Laboratory and Division of Anatomic Pathology. Below is a summary of our discussion with FormaPath CEO, Ted Snelgrove.



Ted Snelgrove

When was FormaPath founded?

FormaPath (formerly Parker Isaac Instruments) was founded by our Chief Technology Officer Alex Bodell in 2016. Bodell is a mechanical engineer with BS and MSE degrees from Johns Hopkins University. I joined FormaPath in March 2022 to help raise funds and prepare the company for commercialization. FormaPath currently has a team of 12, with HQ in Ithaca (central New York State).

How much has FormaPath raised to date?

We've raised a total of \$3.8 million to date, primarily from high-net-worth individuals who have an understanding of the medical space. We're currently in the early funding stages of a Series A round.

Can you describe the nToto system?

It's a desktop system, designed to be the first step in an emerging automated workflow for tissue biopsy specimens that combines robotics and computer vision to transfer biopsies from capped jars to tissue cassettes. nToto also generates specimen images, with measurements and text descriptions to create an electronic gross report for each specimen container, via integration with the local laboratory information system (LIS).

How big is nToto and what is its throughput?

It has the same footprint as a standard grossing bench (3.5 ft wide x 2 ft deep), and only 2 ft high. The specimen intake tray allows for "hands-free" automated grossing of 24 jars per hour (or 150+ jars per eight-hour shift). The finishing step for each container is a gross report with loaded cassettes ready for paraffin embedding and sectioning.

What is the relationship between FormaPath and Mayo Clinic?

In 2023, our engineers began to jointly develop nToto with Mayo Clinic's Department of Laboratory Medicine and Pathology, under the direction of Joaquin Garcia, MD, Chair of Anatomic Pathology. This joint development was possible through the support and engagement of Mayo Clinic's Advanced Diagnostics Laboratory and Process Innovation Through Automation Lab.

What is the target market for nToto, and have you set a price yet?

Details are still coming together as the manufacturing plans are at an early stage, and pricing will depend on the final value proposition. Our initial target market will be any histology lab processing more than 24,000 tissue specimen jars per year.

Does FormaPath's technology have other applications?

Yes. We're also developing a high-throughput version of nToto that can process 600 jars per eight-hour shift. And we see the potential for nToto to streamline initial processing of urine specimen containers at toxicology labs as well, which could be a huge market for us.

Does FormaPath have other partnerships in mind?

Yes. Aside from our research collaborations with academic centers that are helping us develop our new tools, we are open to partnering with larger lab equipment developers who might want to engage in a co-marketing deal to help us accelerate the nToto commercialization effort, especially for ex-US markets.

FINAL 2025 MPFS CUTS PATHOLOGY RATES BY 2.5% (*cont'd from page 1*)

The American Medical Association (AMA) and other physician groups are lobbying for the bipartisan Medicare Patient Access and Practice Stabilization Act of 2024 (HR 10073), which would stop the conversion factor cut and instead result in a 4.7% increase. However, barring last-minute legislative action, the following changes will become effective January 1, 2025.

Surgical Pathology

The global rate for CPT 88305 (Level IV, tissue exam) will drop by 2.8% to \$69.54 in 2025; professional interpretation down 2.8% to \$34.93; technical component also down 2.8% to \$34.61.

The global rate for CPT 88307 (Level V, tissue exam) will decline by 3.3% to \$278.18; professional interpretation down 2.8% to \$76.66; technical down 3.4% to \$201.52.

Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) has been finalized to increase by 3% to \$109.01; professional interpretation down 2.8% to \$32.67; technical up 5.7% to \$76.34.

The global rate for CPT 88341 (IHC, each additional stain) will rise by 3.2% to \$93.48; professional interpretation down 1.6% to \$26.52; technical up 5.3% to \$66.96.

Special Stains

The global rate for CPT 88312 (Special stains, group 1) will decline by 3.7% to \$108.36; professional interpretation down 2.8% to \$24.91; technical down 3.9% to \$83.45.

The global rate for CPT 88313 (Special stains, group 2) will decrease by 4% to \$79.57; professional interpretation down 2.8% to \$11.32; technical down 4.2% to \$68.25.

Final Medicare Rate Changes for Key Pathology Codes for 2025

CPT Code	Description	Final 2025	Final 2024	% Chg
88305-Global	Tissue exam by pathologist	\$69.54	\$71.57	-2.8%
88305-26	Tissue exam by pathologist	34.93	35.95	-2.8%
88305-TC	Tissue exam by pathologist	34.61	35.62	-2.8%
88307-Global	Level V, tissue exam by pathologist	278.18	287.60	-3.3%
88307-26	Level V, tissue exam by pathologist	76.66	78.89	-2.8%
88307-TC	Level V, tissue exam by pathologist	201.52	208.71	-3.4%
88312-Global	Special stains, group ¹	108.36	112.51	-3.7%
88312-26	Special stains, group ¹	24.91	25.63	-2.8%
88312-TC	Special stains, group ¹	83.45	86.88	-3.9%
88313-Global	Special stains; group ²	79.57	82.89	-4.0%
88313-26	Special stains; group ²	11.32	11.65	-2.8%
88313-TC	Special stains; group ²	68.25	71.24	-4.2%
88341-Global	Immunohistochemistry (Add'l stain)	93.48	90.54	3.2%
88341-26	Immunohistochemistry (Add'l stain)	26.52	26.96	-1.6%
88341-TC	Immunohistochemistry (Add'l stain)	66.96	63.58	5.3%
88342-Global	Immunohistochemistry (1st stain)	109.01	105.85	3.0%
88342-26	Immunohistochemistry (1st stain)	32.67	33.62	-2.8%
88342-TC	Immunohistochemistry (1st stain)	76.34	72.23	5.7%

¹ Payments based on the 2025 conversion factor of 32.3465; ² Payments based on the 2024 CF of 33.2875

Source: *Laboratory Economics* from CMS

Lab Stocks Up 108% YTD

Twenty-five lab stocks have risen by an unweighted average of 108% year to date through December 13. In comparison, the S&P 500 Index is up 27% year to date. GeneDx is holding on to massive gains, up 2,643% YTD. Exagen is up 190% and Natera is up 166%. Labcorp is up 2% and Quest Diagnostics is up 12%.

Company (ticker)	Stock Price 12/13/24	Stock Price 12/29/23	2024 Price Change	Enterprise Value (\$ millions)	Revenue for Trailing 12 mos. (\$ millions)	Enterprise Value/Revenue
GeneDx (WGS)	\$75.43	\$2.75	2,643%	\$2,070	\$267	7.4
Exagen (XGN)	5.78	1.99	190%	103	56	1.8
Natera (NTRA)	166.55	62.64	166%	21,530	1,532	14.1
Interpace Biosciences (IDXG)	2.76	1.08	156%	66	45	1.5
CareDx (CDNA)	22.86	12.00	91%	1,050	313	3.4
Veracyte (VCYT)	43.22	27.51	57%	3,190	425	7.5
Castle Biosciences (CSTL)	28.87	21.58	34%	563	312	1.8
Guardant Health (GH)	34.76	27.05	29%	4,730	692	6.8
Quest Diagnostics (DGX)	155.00	137.88	12%	23,740	9,539	2.5
Tempus AI (TEM)	41.00	37.00	11%	6,620	640	10.3
NeoGenomics (NEO)	17.73	16.18	10%	2,520	644	3.9
Opko Health (OPK)	1.59	1.51	5%	1,200	711	1.7
Labcorp (LH)	232.01	227.29	2%	25,670	12,713	2.0
Sonic Healthcare (SHL.AX)*	28.02	32.08	-13%	17,402	8,970	1.9
Exact Sciences (EXAS)	61.25	73.98	-17%	13,330	2,692	5.0
Myriad Genetics (MYGN)	14.43	19.14	-25%	1,360	824	1.7
Biodesix (BDSX)	1.34	1.84	-27%	219	66	3.3
Fulgent Genetics (FLGT)	19.58	28.91	-32%	-190	278	NA
Psychemedics (PMDI)	1.70	2.96	-43%	16	20	0.8
23andMe (ME)**	0.17	0.91	-81%	32	193	0.2
Aspira Women's Hlth (AWH)	0.75	4.08	-82%	12	9	1.3
ProPhase Labs (PRPH)	0.74	4.52	-84%	39	18	2.2
Invitae (NVTAQ)	0.00	0.63	-100%	1,250	482	2.6
Biocept (BIOCQ)	0.00	0.04	-100%	5	NA	NA
DermTech Inc. (DMTKQ)	0.00	1.75	-100%	15	16	0.9
Totals & Averages			108%	\$126,540	\$41,457	3.0

*Sonic Healthcare's figures are in Australian dollars **23andMe had a 1-for-20 reverse stock split on Oct. 16, 2024

Source: *Laboratory Economics* from SeekingAlpha.com

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U.S. Laboratory Reference Testing: Market Profile & Trends • 2024-2027

Featuring:

Exclusive findings from our first national survey of the \$6 billion reference testing market.

Market & financial intelligence you can use to evaluate your send-out testing relationships, how much you pay for referral work, plus how to save hundreds of thousands of dollars on reference testing expenses.

Most hospital and independent lab directors and managers are acutely aware of the volume and cost trends for referred tests at their own facilities, but have scant access to reliable and comprehensive information on what's happening in the broader marketplace.

Don't be left in the dark. Managing reference lab expenses requires more than blind faith and market hunches. Even the odds when you negotiate your next reference lab contract by arming yourself with the latest facts in this invaluable, easy-to-read market research report.

Inside, you'll find:

- National pricing data on the top 200 most frequently referred tests
- Benchmarking data on average referral volume and costs by lab size and type
- Which tests your peers aim to bring in-house over the next 12 months
- How national reference labs are rated by service, turnaround time, price and overall best value
- An analysis of the new FDA LDT regulations and how they will affect the reference testing market

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The Laboratory Economics Difference

Over the past 10 years, reference testing expenses paid to the major national reference testing laboratories (ARUP Laboratories, Labcorp, Mayo Clinic Labs and Quest Diagnostics) has been a small operating cost (averaging between 4-8%) in most lab budgets that grew roughly 5-7% per year. Historically, there has always been a general equilibrium between the number of tests that hospitals and independent labs were bringing in-house and the number of new tests that the national reference labs were introducing to the market.

But that equilibrium is now being upset by new FDA regulations for laboratory-developed tests (LDTs). Complying with these regulations will raise the cost of performing existing LDTs. In addition, the introduction of new LDTs by hospitals and independent labs is being curtailed due to the lengthy and costly requirements of premarket review. As a result, send-out test volumes are increasing.

The U.S. Laboratory Reference Testing: Market Profile & Trends 2024-2027 has been written to help laboratories make more informed decisions regarding the tests they refer out, the prices they pay and how changes in referral and contracting processes might cut costs.

OUR RESEARCH METHODOLOGY

The U.S. Laboratory Reference Testing: Market Profile & Trends 2024-2027 includes data gathered the old-fashioned way—through primary research. The estimates and market analysis in this report have been built from the ground up. Our proprietary reference testing survey combined with extensive interviews with commercial lab executives, hospital lab directors, and respected consultants form the basis of this report. And no stone has been left unturned in our examination of Medicare test volume and expenditure data, hospital cost reports, Securities & Exchange Commission filings and non-profit company tax reports.

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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