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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

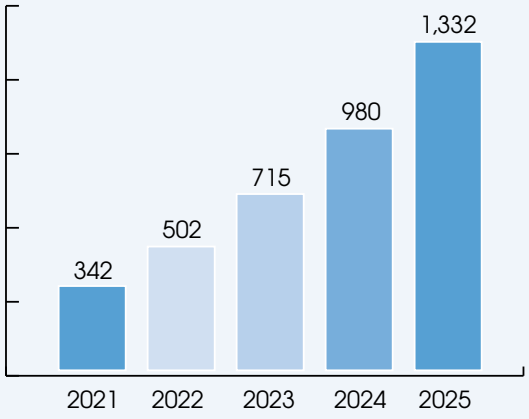
How Much Would the RESULTS Act Cost?

Lab industry lobbyists are anxiously waiting for the Congressional Budget Office (CBO) to estimate the cost of the RESULTS Act. A low CBO score would improve the odds that the bill is included as part of larger healthcare legislation expected to be passed by year's end or in January. A high CBO score (or no score at all) would kill the chances of getting the RESULTS Act passed. Without new legislation, scheduled Medicare CLFS rate cuts and PAMA survey reporting requirements will take effect on February 1, 2026. *Full details on page 5.*

MRD Testing Volume Surges 36%

The U.S. clinical market for tissue and blood-based assays that detect minimal residual disease (MRD) rose by 36% to reach 1.3 million tests in 2025, according to estimates from *Laboratory Economics*. The market leaders are Natera's Signatera (est'd 760,000 tests in 2025) and Adaptive Biotecnologies' ClonoSEQ (est'd 106,000 tests). The remaining 35% of the market is held by more than 20 other MRD tests. And the fight for market share should get a whole lot more competitive now that Quest Diagnostics has launched its Haystack MRD Baseline and Monitoring tests. *Full details on pages 3-4.*

Annual U.S. MRD Test Volume (in thousands)



Source: *Laboratory Economics'* estimates based on test volume data from Natera and Adaptive Biotechnologies

Abbott to Pay Whopping $23 Billion for Exact Sciences

This is the biggest acquisition in the history of laboratory testing services. Abbott Labs has agreed to pay Exact Sciences' shareholders $105 a share in cash, a roughly 50% premium to Exact's share price prior to the deal's announcement. The deal places a market value of $21 billion on Exact and an enterprise value (EV) of $23 billion (including ~$2 billion in assumed net debt). The EV works out to be 7.5x Exact's revenue of $3.1 billion and 213x its EBITDA of $108 million for the trailing 12 months ended September 30, 2025. *Continued on page 2.*

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ABBOTT TO PAY WHOPPING $23 BILLION FOR EXACT SCIENCES (*cont'd from page 1*)
Abbott anticipates that the acquisition will be completed in mid-2026. Abbott will finance the transaction with a combination of cash on hand and debt financing. Abbott says it was attracted to Exact's revenue growth, which averaged 16% per year between 2022-2025. In comparison, Abbott grew its revenue by an average of only 1% per year over the same period. Abbott expects that Exact will be dilutive to its earnings in 2026 and 2027 and then become accretive in 2028 and beyond.

Exact's key tests include its Cologuard and Cologuard Plus stool tests for colorectal cancer screening and its Oncotype DX Breast Recurrence Score test for predicting the likelihood of breast cancer recurrence.

During a November 20 conference call, Abbott CEO Robert Ford said that Exact would operate within Abbott's diagnostics division. Minimal cross-selling opportunities exist because sales reps tend to focus on one specific product when calling on primary care offices, according to Ford. He expects to achieve only about $100 million in annual pre-tax cost savings at Exact by 2028. Ford said the rationale for the acquisition was mostly focused on tapping into Exact's high revenue growth.

Exact Sciences at a Glance

Chairman & CEO	Kevin Conroy (age 58)
Total employees	7,000
Sales & marketing employees	1,300
Total annual test volume	5+ million
Revenue (12 mos. 9/30/25)	$3.1 billion
EBITDA (12 mos. 9/30/25)	$108 million
Net loss (12 mos. 9/30/25)	-$987 million
Accumulated losses	-$4.6 billion
Main labs	Madison, WI & Redwood City, CA

Sources: Exact Sciences and SEC filings

PAMA Rate Survey Risk
Like nearly all labs, Exact faces the risk of scheduled Medicare rate cuts in 2026 plus a new PAMA rate survey that could lead to rate cuts in 2027-2029. Exact's two main tests Cologuard (CPT 81528; Medicare rate: $509) and Oncotype DX Breast Recurrence Score (CPT 81519; Medicare rate: $3,873) are not subject to rate cuts in 2026. However, Exact will have to report its private payer payment rates and volumes from 2019 to CMS for both tests by April 30, 2026. CMS will use this data to set new reimbursement rates for 2027-2029.

Top 10 Biggest Lab Deals in U.S. History ($ millions)

Date	Buyer	Target	Purchase Price	Acquired EBITDA	Price/ EBITDA	Acquired Revenue	Price/ Revenue
Pending	Abbott Laboratories	Exact Sciences	$23,000	$108	213.0	$3,082	7.5
Jul-18	Roche Holding	Foundation Medicine	5,300	NA	NA	153	34.6
Nov-19	Exact Sciences	Genomic Health	2,469	57	43.3	452	5.5
May-07	Quest Diagnostics	AmeriPath	2,000	119	16.8	752	2.7
Aug-99	Quest Diagnostics	Smithkline Beecham Clinical Labs	1,187	158	7.5	1,590	0.7
Aug-24	Quest Diagnostics	LifeLabs	1,053	166	6.3	700	1.5
Feb-03	Quest Diagnostics	Unilab	1,000	NA	NA	425	2.4
Aug-15	Opko Health	BioReference Labs	950	121	7.9	900	1.1
Apr-95	Labcorp	Roche Biomedical Labs	950	NA	NA	730	1.3
Nov-05	Quest Diagnostics	LabOne	947	68	13.9	500	1.9

Source: *Laboratory Economics*

MRD TESTING VOLUME SURGES 36% (*cont'd from page 1*)
MRD testing is the fastest-growing segment within molecular oncology testing. The U.S. MRD testing market was estimated at approximately $2 billion in 2025, up 36% from 2024.

MRD testing uses highly sensitive procedures (i.e., next-gen sequencing, polymerase chain reaction (PCR) and/or flow cytometry) to detect very small amounts of cancer cells that may remain in the body after treatment. These cells have the potential to come back and cause a relapse in patients. MRD testing typically involves a baseline test followed by monitoring tests every three months to check on a patient's progress.

Currently there are more than 20 different MRD tests on the U.S. market (or near launch).

Natera's Signatera pan-cancer liquid biopsy test is by far the most widely used MRD test on the clinical market today. The Signatera MRD assay was launched for research use only in 2017, followed by a clinical launch in 2019. An estimated 760,000 Signatera tests were processed generating revenue of more than $1 billion in 2025. Signatera is reimbursed by Medicare through PLA code 0340U at a reimbursement rate of $3,920. Signatera's average selling price (ASP) across all payers is ~$1,200.

Adaptive Biotechnologies' ClonoSEQ is a next-gen sequencing based assay used on blood and bone marrow samples to detect and measure minimal residual disease in patients with certain types of blood cancers (multiple myeloma, Acute lymphoblastic leukemia (ALL), etc.). Adaptive Biotechnologies markets ClonoSEQ through its direct salesforce of 65 reps. An estimated total of 106,000 ClonoSEQ tests were processed generating revenue of more than $150 million in 2025. ClonoSEQ is reimbursed by Medicare through PLA code 0364U at a reimbursement rate of $2,007. ClonoSEQ's ASP across all payers is ~$1,300.

Labcorp entered the MRD test market through the acquisition of **Personal Genome Diagnostics (PGDx)** in early 2022. Labcorp's PGDx elio tissue complete test is the first and only FDA-cleared tumor profiling kitted test. It is reimbursed by Medicare through PLA code 0250U at a reimbursement rate of $2,920.

In addition, Labcorp markets the PGDx elio plasma focus Dx. It is reimbursed by Medicare through PLA code 0562U at a newly finalized reimbursement rate of $598 for 2026. CMS established this rate by crosswalking to CPT 81455. Labcorp had hoped this test would be crosswalked to PLA 0388U to get a higher rate of $3,500.

Labcorp also gained MRD tests through the acquisition of Invitae in late 2024. These included the PCM Tissue Profiling and MRD Baseline Test (PLA 0306U; Medicare rate: $3,878) and the PCM MRD Monitoring Test (PLA 0307U; Medicare rate: $794).

Quest Diagnostics entered the MRD test market through the acquisition of **Haystack Oncology** in 2023. In late 2024, Quest began marketing the Haystack MRD Baseline (PLA 0560U; Medicare rate: $3,878) and Haystack MRD Monitoring (PLA 0561U; Medicare rate: $794) liquid biopsy tests. The initial focus is on monitoring colon cancer patients with plans to expand into head and neck, breast and lung cancers. In addition, Quest is seeking FDA clearance of its Haystack MRD test platform, which has been granted the FDA's Breakthrough Device Designation.

NeoGenomics recently received a favorable court ruling that dismissed competitor (Natera) patent litigation against its RaDaR ST MRD Assay. In addition, RaDaR has received MolDX approval for head and neck and breast cancers. As a result, NeoGenomics expects to begin marketing RaDaR early next year. NeoGenomics already has a flow cytometry MRD test (Myeloma MRD Flow Panel) on the clinical market.

Guardant Health says its fastest-growing oncology test is Guardant Reveal, a blood-based MRD test used to monitor colorectal, breast and lung cancer treatment. Reveal was launched in the clinical market in early 2021. It is reimbursed by Medicare through PLA code 0569U at a gapfill rate of $1,640. The ASP for Reveal across all payers is between $600 and $700.

Lucence Health (Palo Alto, CA), which was founded by its CEO Min-Han, MBBS, FRCP, PhD, in 2016, has developed a blood-based MRD testing technology under the brand name LiquidHALLMARK. LiquidHALLMARK, which is performed at Lucence's CLIA-certified and CAP-accredited lab in Palo Alto, targets genes that are commonly associated with 15 cancers, including lung, breast and colon cancer. In early 2025, Lucence struck a deal to have **Mayo Clinic Labs** help commercialize LiquidHALLMARK in the United States.

ARUP Laboratories uses a variety of testing methods, including flow cytometry for MRD testing, which offers faster turnaround time (1-3 days) and lower cost (<$400) compared with MRD testing via next-gen sequencing. Also, MRD testing using flow cytometry does not require sequencing of the original tumor.

Sample of MRD Tests

Test Code	Test Name	Lab Name	Medicare Rate 2026	Code Effective Date
0569U	Guardant Reveal	Guardant Health	$1,640	7/1/2025
0560U	Haystack MRD Baseline	Quest Diagnostics	3,878	7/1/2025
0561U	Haystack MRD Monitoring	Quest Diagnostics	794	7/1/2025
0571U	LiquidHALLMARK ctDNA and ctRNA	Lucence Health	2,920	7/1/2025
0539U	PredicineCARE Assay	Predicine Inc.	3,289	4/1/2025
0467U	UroAmp MRD	Convergent Genomics	1,519	7/1/2024
0364U	clonoSEQ Assay	Adaptive Biotechnologies	2,007	4/1/2023
0356U	NavDx	Naveris Inc.	1,800	1/1/2023
0340U	Signatera	Natera	3,920	10/1/2022
0306U	PCM Tissue Profiling and MRD Baseline Test	Labcorp/Invitae	3,878	4/1/2022
0307U	PCM MRD Monitoring Test	Labcorp/Invitae	794	4/1/2022
0250U	PGDx elio tissue complete	Labcorp/Personal Genome Diagnostics	2,920	7/1/2021
0562U	PGDx elio plasma focus Dx	Labcorp/Personal Genome Diagnostics	598	7/1/2021
0171U	MyMRD NGS Panel	Laboratory for Personalized Molecular Medicine	1,519	4/1/2020
88184x1, 88185x11 & 88188x1	Myeloma MRD Flow Panel	NeoGenomics	394	NA
81479	RaDaR ST	NeoGenomics	NA	NA
88184x1, 88185x9 & 88188x1	Chronic Lymphocytic Leukemia MRD by Flow Cytometry	ARUP Laboratories	348	NA
NA	Oncodetect	Exact Sciences	NA	NA
NA	FoundationOne Tracker	Foundation Medicine	NA	NA
NA	FlexOMx Lab	Foundation Medicine	NA	NA
NA	Precise MRD	Myriad Genetics	NA	NA

Source: *Laboratory Economics* from CMS and CodeMap.com

HOW MUCH WOULD THE RESULTS ACT COST? (*cont'd from page 1*)

CBO analysts previously used the Consumer Price Index (CPI) as a proxy to estimate lab test rate changes. That measurement showed that freezing CLFS rates appeared to save Medicare money.

However, the CBO has changed its forecasting model and now estimates that pushing off scheduled cuts to the CLFS will add to the deficit, instead of saving tax dollars.

For example, the CBO estimated that the recent 30-day delay in Medicare CLFS rate cuts and data reporting will cost the government $49 million over 10 years (see *LE*, November 2025). Under the old CBO forecasting model, delaying rate cuts had always been scored as saving money.

This change means that passing the RESULTS Act into law or getting another delay in CLFS rate cuts will be very difficult, but not impossible.

RESULTS Act Adds Support of 11 More Reps

The RESULTS Act now has the support of 48 members of the House (up from 37 members last month) and two Senators (unchanged). Sixteen supporting Reps. are members of the House Committee on Energy and Commerce, which has a total of 54 members and represents the best path for moving the bill forward.

Potential Scenarios for CLFS Reimbursement Rates

ACLA President Susan Van Meter says that there are three potential pathways for getting PAMA relief passed into law.

1) Congress is currently debating extending the enhanced Affordable Care Act (ACA) premium tax credits set to expire December 31, 2025, which would prevent premium hikes for roughly 22 million enrollees in Obamacare health plans. The RESULTS Act could potentially be inserted into this legislation.
2) Separate healthcare bill that extends pandemic-era Medicare flexibilities, such as telehealth services, past their current expiration of January 30, 2026, is expected to be introduced early next year. The RESULTS Act could be packaged into this legislation.
3) If unable to pass the RESULTS Act, then another short-term delay will be sought.

Meanwhile, there is precious little time to get any new healthcare bill passed into law this year. Congress is scheduled to go on break starting December 19 and won't return to Washington until January 6.

No New Guidance from CMS

CMS has not yet posted the new Medicare CLFS for February 1 – December 31, 2026. These rates will be posted here by early January, according to CMS. In the meantime, final Medicare rate determinations for new test codes can be found here.

CMS has not posted any new guidance for labs regarding the next PAMA survey other than to update the reporting period.

The next private-payer payment data reporting period for labs will be from February 1, 2026—April 30, 2026, and will be based on the original data collection period of January 1, 2019 through June 30, 2019.

More information on which labs must report and for which test codes can be found here.

Failure to report could result in a penalty of up to $10,000 per day, although CMS never fined any non-reporting labs after the first PAMA survey was completed in 2017.

What is the Future of Artificial Intelligence in Digital Pathology?

As more pathology groups and health systems adopt digital pathology, artificial intelligence (AI) is poised to become an important tool to aid in diagnostics. *Laboratory Economics* recently spoke with Lee Cooper, PhD, Director of the Institute for Artificial Intelligence in Medicine and a professor of pathology and toxicology at Northwestern University Feinberg School of Medicine, about the future of AI in digital pathology.

Lee Cooper

How is AI being used for clinical diagnostics in cancer detection?
There are commercial tools that focus on detection of breast and prostate cancer. Paige Prostate and Ibex Breast are two tools that are approved for clinical use in either the United States or in Europe. These tools help pathologists identify cancer in whole-slide H&E images with the goals of improving accuracy and efficiency.

What about the kind of AI tools that you are working on?
Like many academic institutions, we are using institutional data to develop similar tools that might be used in the clinic one day and to study the impact on quality and efficiency. Academic institutions have rich data resources and often machine learning experts to collaborate with. Not every institution is willing to deal with the regulatory issues and challenges in operationalizing internally developed models though.

How widespread is use of AI in diagnostics?
It is still limited. Most of the activity is in tools for cancer detection. There will be more adoption in the next five years though. One of the challenges is reimbursement. There are also challenges in implementation, even for commercial tools. You need to have digital imaging and image management software, as well as experts to validate and monitor these systems. Currently, that is mostly exclusive to academic centers. Some studies have shown that benefits of AI are not as significant for pathologists with subspecialist training compared to a general pathologist who might practice in a smaller setting, so there is some mismatch between who benefits from using the tools and who has the capabilities to deploy them.

How is AI being used for research into cancer treatment?
At Northwestern, we're interested in the tumor microenvironment and how immune cells and other non-cancer cells interact with one another and with the tumor. A lot of our work is to develop tools to measure these patterns and improve our ability to predict clinical outcomes and treatment response. There are more tools now that focus on prognosis. I think that's one area where AI can add value to a pathologist by measuring latent patterns that cannot currently be captured by visual grading. For example, with ArteraAI for prostate, you send a slide and receive a prognostic score that can help to stratify patient risk and guide treatment.

What is the cost of storing a typical digitized slide with a cloud service for a year?
The file for a typical slide is around 1 gigabyte. Archival cloud storage could cost from one cent to seven cents per gigabyte per year, depending on the provider. There is a tradeoff, though, between archive cost and time and cost to recall that data in the future. For pathology, that is not a serious problem though, as even though all slides need to be stored, most will never be accessed again as time goes on. That allows use of inexpensive "cold storage."

What about storing these images at your institution? Is that even feasible?
It can be unrealistic to store these locally. In some cases, we are talking about storing files for one million or more slides per year. I should also mention that an advantage of cloud storage is that this storage is connected to an extremely large computer that you can use on a "pay as you go" basis which can be helpful for using AI or performing research with your data.

Do you see any technologies that would eliminate the need to create a pathology slide?
Yes, there are some interesting technologies like a microCT machine offered by 3DHISTECH. There are also innovative microscopy techniques like Light Sheet. These both allow nondestructive and volumetric imaging of tissue specimens. This is only used in research right now. These mostly provide structural information which can be really helpful, but they cannot reliably infer the molecular information provided by an immunohistochemical stain.

Will AI will replace or greatly reduce the need for pathologists' interpretations?
No, I don't. Humans and machines have very complementary strengths. AI could liberate pathologists from labor intensive and time-consuming tasks like counting objects. Machines can do this work reproducibly and exhaustively. Instead of counting just in a limited area, machines can count everything. That's not something that humans can do, and it's arguably not like a good use of their intelligence.

Machines are also good at identifying latent patterns in tissue that are hard for pathologists to reliably score. That's another example of where machines may have some edge, but you will always need pathologists to deal with rare cases that machines cannot handle. That is an area where human intelligence is still relatively powerful.

AI can also improve efficiency. There will be systems that help with workflow optimization, such as triaging cases for review and balancing cases across a group of pathologists so that one pathologist doesn't get all the hard cases. With an aging population, there's going to be increased demand for pathologist services. AI can help make pathologists more efficient, which should help meet that demand.

What do you think are the limitations of AI in clinical diagnostics?
What we call pre-analytical variability remains a big challenge for AI. This manifests in differences in how images look due to tissue sectioning, fixation, staining – all of those things that go into producing the slide and image. Pathologists are pretty good at compensating for these differences, but it can be terribly confusing for AI software. To overcome that, you currently need very large, diverse data sets for training AI, so that's still a weakness.

Anonymous $50 Million Gift Given to UW Lab Program

An anonymous donor has given a gift estimated to exceed $50 million to the University of Washington (UW) Medicine's Medical Laboratory Science program. The donation, announced on December 1, 2025, will cover in-state tuition for the two quarters of full-time clinical rotations during an MLS student's senior year. This translates to a saving of approximately $8,000 to $10,000 per MLS student. The gift will enable the program to expand its enrollment from its current 70 students to 100 over the next 10 years. The donor, a Washington state resident who wished to remain anonymous but had a prior relationship with the program, also requested that students celebrate the announcement with burgers from a Seattle chain, Dick's Drive-In Restaurant. [Note: It's hard to believe, but this is a true story.]

Medicare Clawbacks Threaten Survival of Some PCR Labs

Some labs that perform multiplex PCR testing for urinary tract infections (UTIs) are facing millions of dollars in clawbacks from audits conducted by Novitas and UHC Advantage. While Novitas and UHC Advantage have reimbursed UTI PCR panels in the past, they now say they will only pay for one unit of CPT 87801 (Infectious agent detection by PCR, multiple organisms) regardless of test complexity or number of organisms being tested.

Novitas processes Medicare claims in jurisdiction H (AR, CO, LA, MS, NM, OK and TX) and jurisdiction L (Delaware, DC, MD, NJ, PA and northern Virginia). UHC Advantage, which has 8.4 million members, is the nation's largest Medicare Advantage plan.

Novitas began clawing back UTI PCR payments about six months ago without giving public notice that its policy had changed, according to Ashley Zarling, Founder and Principal of Precision Billing Solution (Williston, North Dakota). At issue, she says, is a conflict between American Medical Association coding rules, which state that each organism tested by PCR should receive a separate CPT code and Novitas' interpretation of National Correct Coding Initiative (NCCI), which is that an entire panel should receive one code.


Ashley Zarling

In 2022, MolDx, a program under Medicare that establishes coverage and reimbursement for molecular diagnostic tests, issued a local coverage determination (LCD) requiring that any PCR tests that target more than one pathogen be defined as a panel. However, this LCD does not apply to Novitas, which is not under the MolDx jurisdiction.

Zarling notes that historically, Unified Program Integrity Contractors (UPIC) auditors in the Novitas jurisdiction have reviewed labs' methodology, testing, CPTs and records and never found issue with the coding. "We have years of passed audits for Novitas," she says. "This is why we are so firm that they are interpreting NCCI Chapter 10 to say multiple units cannot be billed, whereas the NCCI policy states that there can be multiple units. If Novitas would like to change their interpretation, they should update their policies first and not hit labs retrospectively."

Zarling is organizing a coalition of clinical labs to seek a clearer policy on billing for PCR UTI panels. She is hoping they can convince Medicare to align its policy with AMA guidance or to secure a local or national coverage determination establishing coverage and documentation requirements for UTI testing by PCR. Ultimately, she would like to see a new panel-specific CPT or PLA code for PCR UTI panels to remove any ambiguity.

PCR Testing for UTIs

In the past five years, PCR testing for UTIs has become more common among the elderly who are at high-risk for sepsis, such as those who are homebound, catheterized or have kidney issues that cause multiple UTIs. Many labs perform this using their own lab-developed tests. Unlike culture testing for younger,

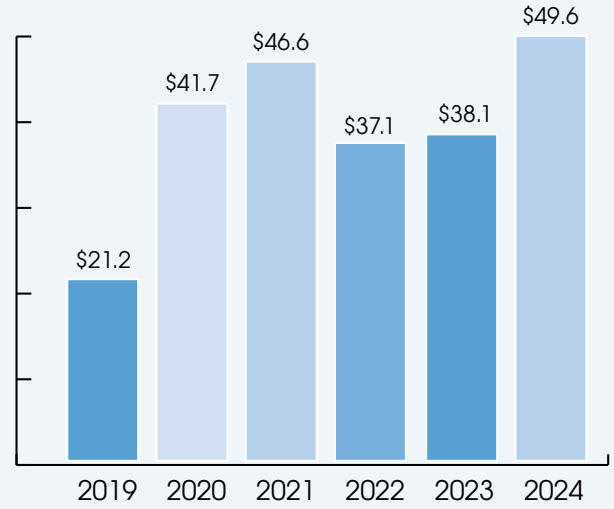
healthier patients, PCR testing for UTIs has a much faster turnaround and can test for polymicrobial infections with results in as few as 24 hours. In addition, the results include an antibiotic gene profile, enabling more accurate antibiotic prescriptions.

"There have been more PCR tests for UTIs in the elderly since more studies have come out about the reduction in septic hospitalization," Zarling tells Laboratory Economics. "One facility reported a 4% reduction in hospitalizations in six weeks as a result of PCR testing."

Recent audits by UPIC have resulted in Medicare clawing back millions of dollars that it had paid for PCR UTI testing. Zarling says one lab she works with is on the hook to repay $2.9 million in payments while another owes more than $1 million. These types of clawbacks threaten the viability of many specialty labs, she says.

The difference in Medicare payment for one unit of 87801 versus multiple units is significant. Medicare reimburses CPT 87801 at a national rate of $70.20, which is well below the cost of running high-complexity panels, notes Zarling. A PCR UTI panel billed with separate codes had previously been reimbursed at more than $600.

Medicare Part B Allowed Payments for CPT 87801 ($ millions)



Source: *Laboratory Economics*

During the five-year period from 2019-2024, Medicare Part B carrier allowed payments for CPT 87801 increased by an average of 18.5% per year to reach $49.6 million. High-volume labs billing for 87801 include CAP Diagnostics (dba Pathnostics - Lake Mary, FL), Altru Diagnostics (Houston, TX), Laboratory of Florida (Tampa, FL), Concord Life Sciences (Houston, TX) and Bakotic Pathology Associates (Tampa, FL).

Puts Elderly at Risk

Precision Life Sciences (Olive Branch, MS) is one of those labs that may be forced to close if Medicare reimbursement for a multiplex panel drops from more than $600 to $70, according to Andrew Wiseman, Founder and CEO. Precision is one of two labs in Mississippi that serve long-term care facilities. Between clawbacks from Novitas and UHC, Precision is now on the hook to repay about $1.4 million. Wiseman is appealing the request for recoupment.

Andrew Wiseman

"We're a small lab with about $6 million in annual revenue," he says. "We can't afford to pay back $1.4 million. If we go out of business, there will be only one lab in the state serving long-term care facilities."

Lack of rapid PCR testing for long-term care residents with UTIs could be deadly, explains Wiseman, who notes that a compromised senior with an infection can become septic in as little as 24 hours. Wiseman says he is frustrated by the lack of clarity from Novitas and UHC, especially since both of the organizations have been reimbursing for multiplex PCR UTI panels for years.

Ruling Provides Clarity on Labs' Reliance on Doctors' Orders

In what is considered a significant win for the lab industry, a recent ruling by the U.S. Court of Appeals for the First Circuit provides reassurance to clinical laboratories that they can rely on doctors' order to show that a test is reasonable and necessary.

The court on Dec. 1, 2025, upheld a district court ruling issued in January 2025 in the case of *U.S. ex rel OMNI Healthcare v. MD Spine Solutions LLC, et al*. The lower court had dismissed all counts in a whistleblower lawsuit filed by OMNI Healthcare, saying there was not enough evidence that MD Labs knowingly submitted false claims to Medicare.

In its ruling, the lower court held that "a laboratory cannot and is not required to determine medical necessity but rather is permitted to rely on the ordering physician's determination that the laboratory tests billed to Medicare are medically necessary."

Danielle Tangorre

In upholding that decision, the appellate court said, "we don't see how it's 'natural, ordinary and reasonable' to put labs on the hook for doctors' professional decisions, barring some other chicanery at play."

In fact, the appellate court warns that accepting OMNI Healthcare's litigation position could lead to dangerous consequences if labs begin to second-guess providers' orders or delay care to avoid FCA liability. Of significance, this is the first time an appellate court has ruled on the issue of medical necessity of laboratory testing and false claims.

According to Danielle Tangorre, an attorney with Robinson+Cole (New York City), which represented MD Labs, the decision "affirms the unique role of a laboratory and brings greater clarity to the collaborative responsibilities between laboratories and ordering providers concerning medical necessity."

Qui Tam Action Brought in 2018

The case, which is discussed in greater detail in the February 2025 issue of *Laboratory Economics*, began in 2018 when OMNI Healthcare (Melbourne, FL) brought a qui tam action against MD Labs (Reno, NV) and its owners, Denis Grizelj and Matthew Rutledge. OMNI alleged that the defendants violated federal False Claims Act (FCA) and state laws by submitting false claims for medically unnecessary urinary tract infection (UTI) PCR tests.

Craig Deligdish, MD, owner of OMNI, sent around 600 samples to MD Labs for PCR UTI testing between 2017 and 2019, some of which were billed to government health programs. According to the lower court, Deligdish changed the requisition orders without his staff's knowledge to order PCR UTI testing from MD Labs even when the provider had selected a bacterial urine culture (BUC), a less expensive test.

Implications for Laboratory Compliance Practices

While the ruling clarifies that labs can generally rely on a doctor's order to show that the test is "reasonable and necessary," Tangorre notes that labs continue to have responsibilities to ensure compliance when submitting claims to Medicare and to avoid potential allegations of violations of the FCA. For example, labs should review their marketing materials to make sure they are not over-promising on testing or misleading providers and should also review their requisition forms to ensure there are options for testing. Overall, labs should not promote or influence providers to order testing that they know is medically unnecessary. As has been highlighted in the voluntary compliance guidance from the Office of Inspector General from 1998, labs should also be mindful of custom profiles and standing orders to ensure that ordering providers are making individual determinations regarding medical necessity of the testing for the patient.

Labcorp to Buy Parkview Health Outreach Lab Assets

Labcorp has agreed to acquire select outreach lab assets from Parkview Health (Fort Wayne, IN) for an undisclosed amount. The deal is expected to be finalized in early 2026.

Parkview is northeast Indiana's largest employer with about 17,500 workers. The healthcare system includes 15 hospitals and nearly 300 physician offices in northeast Indiana and northwest Ohio. Parkview reported a net gain of $165.1 million in 2024, down from $250.8 million in 2023; total revenue was up 9.2% to $3.1 billion. Parkview derived 47% of its revenue from Medicare and Medicaid and 23% from Anthem BCBS.

The Labcorp agreement applies only to non-emergency outreach laboratory services. Labs located inside Parkview hospitals will continue to serve patients with emergency and acute care needs.

"By partnering with Labcorp, a global leader in laboratory services, our patients will have broader access to cost-effective, high-quality laboratory services," according to Ray Dusman, MD, President of Physician and Clinical Enterprise at Parkview.

Parkview's largest clinical outreach lab is based at Parkview Regional Medical Center (Fort Wayne, IN) with estimated annual revenue of $18 million. Laboratory Economics estimates that Parkview's total clinical lab outreach business generates revenue of roughly $30 million per year.

In 2022, Indiana's attorney reached a $2.9 million overbilling settlement with Parkview, which stemmed from allegations that staff at multiple hospital locations were using improper revenue codes for blood-clotting tests to get paid more Medicaid dollars.

The State of Indiana had alleged that between January 1, 2017 and March 1, 2021, Parkview submitted claims to Indiana Medicaid for the treatment of Medicaid managed care members at its Anticoagulation Therapy Units. Parkview billed those claims under revenue code 760 (Specialty Services – General). The State of Indiana alleged that those claims should have been submitted under the lower-paying revenue code 510 (Clinic – General).

Parkview contended that the medical claims are related to a complex area of Medicaid billing and denied it knowingly engaged in wrongdoing.

Parkview Health Outreach Lab Stats

Hospital Name	*Location*	*Total Staffed Beds*	*Total Medicare CLFS Payments for 2024*	*Total Est'd Outreach Lab Revenue for 2024**
Parkview Regional Medical Center	Fort Wayne, IN	894	$2,019,052	$18,171,468
Parkview Whitley Hospital	Columbia City, IN	58	360,072	3,240,648
Parkview Noble Hospital	Kendallville, IN	31	263,728	2,373,552
Parkview DeKalb Hospital	Auburn, IN	48	263,224	2,369,016
Parkview Huntington Hospital	Huntington, IN	36	262,080	2,358,720
Parkview Bryan Hospital	Bryan, OH	55	160,632	1,445,688
Parkview Ortho Hospital	Fort Wayne, IN	37	8,231	74,079
Grand Total All Parkview Hospitals		1,159	$3,337,019	$30,033,171

*Estimated clinical lab outreach revenue from all payers

Source: CMS Hospital OPPS files and LE estimates

Lab Stocks Up 31% YTD

Twenty-five lab stocks have increased an unweighted average of 31% year to date through December 13. In comparison, the S&P 500 Index is up 16%. Guardant Health has jumped 234%, Adaptive Biotechnologies is up 158% and Insight Molecular is up 119%. Quest Diagnostics has risen 21% and Labcorp is up 15%.

Company (ticker)	Stock Price 12/13/25	Stock Price 12/31/24	2025 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
Guardant Health (GH)	$102.07	$30.55	234%	$13,900	$903	15.4
Adaptive Biotechnologies (ADPT)	15.44	6.00	158%	2,350	253	9.3
Insight Molecular/Oncocyte (IMDX)	5.22	2.38	119%	134	4	30.4
Tempus AI (TEM)	70.61	33.76	109%	13,140	1,105	11.9
GeneDx (WGS)	151.51	76.86	97%	4,340	402	10.8
Exact Sciences (EXAS)	101.50	56.19	81%	20,790	3,082	6.7
Exagen (XGN)	7.11	4.10	73%	154	64	2.4
Personalis (PSNL)	8.77	5.78	52%	670	69	9.7
Fulgent Genetics (FLGT)	27.14	18.47	47%	54	316	0.2
Natera (NTRA)	231.95	158.30	47%	31,170	2,117	14.7
Castle Biosciences (CSTL)	38.63	26.65	45%	877	344	2.6
Caris Life Sciences (CAI)	26.76	21.00	27%	7,220	649	11.1
Quest Diagnostics (DGX)	182.56	150.86	21%	26,370	10,850	2.4
Labcorp (LH)	264.18	229.32	15%	27,900	13,765	2.0
Veracyte (VCYT)	42.84	39.60	8%	3,060	495	6.2
23andMe (MEHCQ)	3.50	3.25	8%	84	175	0.5
CareDx (CDNA)	20.56	21.41	-4%	891	358	2.5
Opko Health (OPK)	1.38	1.47	-6%	1,040	642	1.6
Sonic Healthcare (SHL.AX)*	23.19	27.01	-14%	15,960	9,650	1.7
NeoGenomics (NEO)	11.85	16.48	-28%	1,780	709	2.5
Myriad Genetics (MYGN)	7.21	13.71	-47%	739	825	0.9
Interpace Biosciences (IDXG)	1.40	2.70	-48%	7	42	0.2
Aspira Women's Hlth (AWHL)	0.34	0.71	-52%	13	9	1.4
Biodesix (BDSX)	7.85	30.60	-74%	120	80	1.5
ProPhase Labs (PRPH)	0.11	0.76	-86%	13	5	2.5
Totals & Averages			**31%**	**$172,776**	**$46,913**	**3.7**

*Sonic Healthcare's figures are in Australian dollars

Source: Laboratory Economics from SeekingAlpha.com