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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

CAP Lobbies for 6.6% Medicare Rate Hike

The College of American Pathologists (CAP), as well as the American Medical Association (AMA), are lobbying Congress to pass a bill that would hike Medicare payments to pathologists and other physicians by 6.6%. The potential rate hike would become effective April 1, and would more than offset the 2.8% rate cut that took effect January 1, 2025.
More details on page 11.

Supreme Court to Rule on Coverage of Preventive Screening Tests

The Supreme Court on Jan. 10, 2025, agreed to hear a challenge to whether the screening services recommended by the U.S. Preventive Services Task Force (USPSTF) must be covered at no charge to patients under the Affordable Care Act (*Becerra v. Braidwood Management*). The court will hear arguments in this case sometime in its current term (most likely in April).

The case has big implications for clinical labs as the covered preventive services include high-volume cholesterol and diabetes testing, as well as screening for sexually transmitted diseases. Other covered services include cancer screenings (e.g., colorectal and cervical cancer screening), bone density screening and HIV screening.

If the court rules that these screenings do not have to be covered at zero cost to patients, the number of people receiving these testing services would likely decline.
Full analysis on pages 5-6.

Favorable Ruling for MD Labs in False Claims Case Is Big Win for Lab Industry

U.S. District Judge Patti Saris has dismissed all counts in a whistleblower lawsuit filed by OMNI Healthcare against MD Spine Solutions LLC (dba MD Labs). The decision is significant because it tested theories of liability that the government has used for years in False Claims Act (FCA) prosecutions, related to medical necessity of testing and the payment of commissions to independent contractor marketers, according to Danielle Tangorre, an attorney with Robinson+Cole (New York) who represented MD Labs.
Full details on pages 2-3.

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FAVORABLE RULING FOR MD LABS IN FALSE CLAIMS CASE (*cont'd from page 1*)
OMNI Healthcare (Melbourne, FL) initially brought a qui tam action against MD Labs (Reno, NV) and its owners, Denis Grizelj and Matthew Rutledge, in 2018. OMNI alleged that the defendants violated the federal FCA and state laws by submitting false claims for medically unnecessary urine drug tests and urinary tract infection (UTI) PCR tests.

In late 2021, the U.S. Department of Justice reached a $12-16 million settlement with MD Labs and its owners that resolved the allegations related to medically unnecessary urine drug tests (see *LE*, November 2021). The government declined to pursue the UTI PCR test allegations. Even so, OMNI filed an amended complaint in April 2022 to pursue these remaining allegations on its own. Judge Saris's recent decision was related to the UTI PCR test allegations.

The Background
MD Labs is an independent CAP-accredited clinical lab that began performing UTI testing around 2017. The standard test for UTIs has historically been the bacterial urine culture (BUC), but MD Labs used PCR-based testing for either 17 or 19 pathogens that could cause UTIs. Some requisition forms only allowed the physician to select the entire 17- or 19-pathogen panel, while others enabled physicians to customize the panel to test for specific pathogens.

OMNI, a multispecialty practice in Brevard County, Florida, owned by Craig Deligdish, MD, sent around 600 samples to MD Labs for PCR UTI testing between 2017 and 2019, some of which were billed to government health programs. When an OMNI provider determined that a particular laboratory test was warranted, the provider would select the test in the patient's electronic medical record, and a medical assistant would complete a requisition form.

Deligdish instructed his staff to order PCR UTI testing from MD Labs even when the provider had selected a BUC test for the patient. He did so in order to substantiate OMNI's FCA claims against MD Labs, according to the court. All the PCR UTI testing that MD Labs performed for OMNI patients resulted from this switch.

MD Labs Sales Force
During the relevant period, MD Labs used both employees and independent contractors to promote its PCR UTI testing to providers. These sales representatives received commissions based on the revenue generated from the tests ordered. MD Labs trained and managed its sales representatives identically whether they were employees or independent contractors. In 2018, Deligdish and others at OMNI discussed PCR UTI testing with multiple independent-contractor sales representatives from MD Labs. There is no evidence that any sales representative offered or paid inducements to providers.

MD Labs sought legal advice about its use of independent-contractor sales representatives in late 2016 and early 2017, and in 2021, following a court ruling, MD Labs reconfigured its sales force to use solely employees.

The Amended Whistleblower Complaint
OMNI's amended complaint focusing on alleged medically unnecessary PCR UTI testing included claims under the Anti-Kickback Statute (AKS) and the Eliminating Kickbacks in Recovery Act (EKRA). It also advanced three new sets of allegations in support of its FCA claims: 1) that MD labs entered into independent-contractor service agreements in which it paid compensation for referrals; 2) that MD Labs routinely did not balance bill patients; and 3) that MD Labs submitted claim forms to healthcare programs listing diagnosis codes that differed from those on the requisition forms.

MD Labs first moved to dismiss the amended complaint, which was granted in part with respect to the new AKS and EKRA claims and that the claim forms had false diagnosis codes. After discov-

ery, the defendants moved for summary judgment on the remaining claims. Ultimately, the court determined that no reasonable jury could conclude that the defendants knew they were submitting claims for PCR UTI testing that was medically unnecessary and that no reasonable jury could find that the submission of claims for PCR UTI testing resulted from any alleged AKS violation, including any commission-based payments to independent contracts. The court granted summary judgment in favor of the defendants and dismissed the entire case with prejudice on January 6.

Grizelj and Rutledge, owners of MD Labs, say their decisive court victory marks a significan milestone for the company. They have filed a motion to be reimbursed for legal fees that is now in the hands of Judge Saris. They note that OMNI and its owner Dr. Deligdish are serial whistleblowers and are likely to seek an appeal.

What Does This Mean for Labs?
To learn more about the significance of this ruling, *Laboratory Economics* recently spoke with Danielle Tangorre, who represented MD Labs.


Danielle Tangorre, JD

Why is the ruling in OMNI vs. MD Labs significant for the lab industry?
It really addresses a few theories and is counter to a lot of the settlements we've seen in the last year and a half. One of the issues was whether the PCR UTI testing in this case lacked medical necessity. The court found that the testing on its face did not lack medical necessity. It found it was reasonable for the lab to rely on the physician order and to assume that tests ordered were medically necessary because there was also no conduct by the lab that suggested that the lab had actual knowledge of a lack of medical necessity or showed reckless disregard in its practices in promoting or marketing its tests. For labs that are offering newer types of testing that may not be as mainstream or lack coverage decisions by Medicare, the simple lack of an LCD or NCD does not mean it is not a covered service by Medicare but is decided on a case-by-case basis.

The next half of the decision is really what's counter to recent settlements—allegations that the lab paid commissions to independent contractors. OMNI alleged this violated the AKS and that the commissions were illegal and thus were a false claim.

The court said commissions paid to contractors weren't automatically illegal under the AKS, which turns on intent. The court found that there was no improper or undue influence by the sales and marketing reps, or what I call the "plus factors." This is an important aspect given the rise in settlements in the laboratory field related to payment of commissions under the AKS.

It's not a per se violation if you pay commissions to independent contractors—you have to look at all factors and conduct. For labs that may choose to pay commissions, it's not necessarily the death knell that some of the settlements we've seen indicate.

Please explain the "but-for" standard adopted by the judge in this case.
In this decision, Judge Saris adopted a stringent "but-for" standard. Essentially, the judge found that no reasonable jury could find that the submission of claims for UTI PCR testing hinged or resulted from the payment of commission-based payments to independent contractors and its alleged violation of the AKS.

What lessons can labs take from this ruling?
Labs can look at this ruling and take a few lessons: 1) Medical necessity—the judge reaffirmed that labs can rely on the ordering provider's determination that ordered tests are medically necessary, and 2) Commissions—paying commissions to independent contractors is not per se illegal. Other factors must be considered in making an assessment and labs should review such practices and past practices in light of this ruling.

Geneoscopy Raises $100M+ for Launch of Colorectal Cancer Screening Test


Andrew Barnell

Geneoscopy (St. Louis, MO) is gearing up for commercial launch of its proprietary ColoSense test, a stool RNA test for colorectal cancer screening. Geneoscopy plans to launch ColoSense later this year. Below is a summary of our discussion with Geneoscopy CEO Andrew Barnell.

When was Geneoscopy founded?
Geneoscopy was founded by my sister Erica Barnell, MD, PhD in 2015. Dr. Barnell obtained her MD/PhD degrees from Washington University School of Medicine with her PhD in Molecular Genetics and Genomics. I joined Geneoscopy in 2017 to help raise funds and prepare the company for commercialization. Geneoscopy currently has 50 employees, with its HQ and CAP-accredited lab in St. Louis.

How much has Geneoscopy raised to date?
We've raised a total of $150 million to date, including $105 million from a Series C funding round in January. The Series C was led by Bio-Rad Laboratories; others included Labcorp, Petrichor, Morningside Ventures and Lightchain Capital.

Can you describe the ColoSense test?
The technology behind ColoSense, in particular the ability to isolate human RNA from stool samples, was developed by Dr. Barnell. She is the lead author on all patents related to ColoSense, which does not owe royalties or licensing fees to any outside organizations.

The ColoSense test includes an analysis of 8 RNA markers along with a Polymedco iFOBT test and one demographic feature (smoker status), which are combined to generate a score. That score is either positive or negative, identifying patients who potentially have colorectal cancer or precancerous adenomas. If a patient tests positive, they are advised to get a colonoscopy.

Analyzing RNA (as opposed to the DNA-methylation techniques) provides a consistent sensitivity profile for all average-risk patients from the youngest to the older population.

What is the sensitivity of ColoSense?
ColoSense received FDA clearance in May 2024. Studies filed to support our FDA application showed that ColoSense had obtained 93% sensitivity for detecting colorectal cancer and 45% sensitivity for advanced adenomas in average-risk individuals. The negative predictive value for ColoSense is 94.4%, meaning that if a patient has a negative test, there is a 94.4% chance that they don't have colorectal cancer or advanced adenomas.

Where is the testing performed?
All testing is performed at our 11,000-square-foot laboratory in St. Louis. We're in the process of expanding this lab to 25,000 square feet.

How will you market ColoSense?
We signed a multi-year marketing agreement with Labcorp in late 2023. Labcorp will market our test to primary care physicians, gastroenterologists and Ob/Gyns and bill for all test orders it originates. Geneoscopy will ship sample collection kits to patients. The turnaround time for test results is an expected 10-14 days after our lab receives the sample.

What is the reimbursement rate for ColoSense?
ColoSense is reimbursed by Medicare through proprietary laboratory analysis (PLA) code 0421U at a rate of $508.87.

SUPREME COURT TO RULE ON COVERAGE OF SCREENING TESTS (*cont'd from page 1*)
In the original case, Braidwood Management v. Becerra, a few individuals and businesses challenged the constitutionality of the ACA's preventive benefit coverage guarantee for nearly all privately insured Americans. The plaintiffs argued that covering benefits such as pre-exposure prophylaxis to reduce the likelihood of getting HIV infection (PrEP) and contraceptives violates their religious beliefs.


Richard Hughes IV

Beyond claiming a violation of their beliefs under the Religious Freedom Restoration Act (RFRA), plaintiffs challenged the benefits on constitutional grounds, arguing that the process used for appointing the expert panels that recommended the ACA's benefits package was flawed and, therefore, the recommendations cannot be enforced.

In 2022, the trial court sided with the plaintiffs on one of the expert panels, the USPSTF, but rejected their arguments regarding the other two—the Health Resources and Services Administration (HRSA) and the Advisory Committee on Immunization Practices (ACIP). This effectively saved the ACIP's vaccine recommendations and the HRSA recommendations for women's and children's health, including coverage of contraceptives.

However, the court found that USPSTF members were unconstitutionally appointed and also found merit in the plaintiff's RFRA claims. Based on this conclusion, the court vacated all recommendations adopted after the ACA was enacted in 2010 (including its recommendations on maternal health, HIV prophylaxis and cancer prevention).

On June 21, 2024, the 5th Circuit Court of Appeals affirmed the district court's ruling that the ACA's requirement to cover at no cost services recommended by the USPSTF is unconstitutional. However, the court did not issue a nationwide injunction, limiting the immediate effects of the ruling to the plaintiffs.

Former Secretary of Health and Human Services Xavier Becerra appealed the decision to the U.S. Supreme Court, which on January 10, 2025, agreed to hear the case.

Severability Analysis
Richard Hughes IV, an attorney in Epstein Becker and Green's Health Care and Life Sciences Practice (Washington, DC), expects the Supreme Court to hear oral arguments in the case in April and to rule in late June or early July.

"This is a very significant case," says Hughes. "All screenings with A or B rating that currently have to be covered by Medicare and Medicaid and private health plans are at risk. If the court rules that these services do not have to be covered without charge, the question becomes what would payers be willing to cover? There could be restrictions on services or out-of-pocket costs."

If the high court follows prior precedent, it will engage in a "severability analysis," separating out the "problematic language" and letting the statute survive, says Hughes.

"That's what they've done in the past," he explains, citing United States v. Arthrex, in which seven of the nine justices disagreed on the merits of the case but ultimately severed the language that created the constitutional problem. "If they take a scalpel instead of a sledgehammer and really look at the problematic language, everything could be resolved and coverage requirements would remain in place."

The language at issue reads: "All members of the task force [USPSTF] … and any recommenda-

tions made by such members, shall be independent and, to the extent practicable, not subject to political pressure." Bainbridge argued that this language prevents the Secretary of Human Services from overseeing the recommendations of the USPSTF, thus creating a constitutional problem.

If the Supreme Court does not sever the language and upholds the appeals court ruling, coverage of preventive services screening would be uneven across the country, says Hughes. Payers could refuse to cover screening services or could implement age restrictions or prior authorization requirements.

"This is the first major challenge to the preventive services provision of the ACA," he says, adding that this case comes at a time when the Supreme Court is re-evaluating the role of experts in the government. Because preventive services screening is one of the more popular provisions of the ACA, Hughes thinks it is unlikely the court will rule that the services should not be covered.

More Than 100 Labcorp Employees in Portland Seek Union Election

Nearly 120 Labcorp workers at the Providence Laboratory Services core lab in Portland filed their intention to unionize on January 29. The workers will vote on whether or not to join the 6,000-member Oregon Federation of Nurses and Health Professionals (OFNHP) on February 19.

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

The voting workers will include full-time and part-time medical technologists, lab technicians and specimen accessioners. Excluded from voting are couriers and managerial employees.

"We decided to unionize because we want to ensure a stable, well-trained, well-staffed medical laboratory is available to our community. By unionizing we can have a strong voice for our patients and ourselves, ensuring a positive future for healthcare in this region," says Allister Brister-Smith, a Laboratory Services Team Lead at the core lab.

OFNHP and the workers are represented by the law firm Youtz & Valdez P.C. (Albuquerque, NM). Labcorp is being represented by Blank Rome LLP (Philadelphia, PA).

The upcoming union vote follows OFNHP's successful effort to unionize over 400 Labcorp workers at the acquired clinical lab outreach business of Legacy Health (Portland) in May 2024 (see *LE*, June 2024). Labcorp purchased the clinical lab outreach business of Legacy Health for $108 million in November 2023.

The national shortage of lab employees combined with union efforts targeting large regional labs has resulted in a growing number of pro-union votes across the country in the past 18 months.

Recent Labs Voting to Unionize

Vote Tally Issued Date	Laboratory Name & Location	No. of Eligible Voters	Votes for Labor Union	Votes Against
Pending	Labcorp/Providence (Portland, OR)	120	NA	NA
9/25/2024	Northwell Health Laboratories (Lake Success, NY)	867	502	113
5/3/2024	Labcorp/Legacy (Portland, OR)	435	311	43
3/6/2024	Tempus AI (Chicago, IL)	353	243	38
12/20/2023	Northwell Health Laboratories (Little Neck, NY)	146	100	31
10/11/2023	Quest Diagnostics (Tucker, GA)	52	29	17
7/28/2023	Trinity Health Outpatient Labs (Ann Arbor, MI)	67	29	20

Source: National Labor Relations Board

Labcorp Reports Full-Year 2024 Financial Results

Labcorp (Burlington, NC) reported net income of $746 million for the full-year 2024, up 79% from $418 million in 2023. Labcorp's overall revenue increased by 7% to $13 billion in 2024. Revenue from Labcorp's lab testing business increased by 7.7% to $10.1 billion in full-year 2024, including roughly 3-4% growth from acquisitions. On February 6, Labcorp held a conference call with analysts and investors. Here are some comments on a few key topics from CEO Adam Schechter and CFO Julia Wang.

Acquisitions and Hospital Lab Deals

Labcorp spent $839 million of cash on 10 acquisitions in 2024. Its biggest deals included certain assets of Invitae ($241 million) and BioReference Health ($238 million). Labcorp also purchased the clinical lab outreach business of Baystate Medical Center ($120 million) and Sonic's California clinical lab business ($98 million).

Schechter said that Labcorp continues to look for hospital outreach labs and regional independent labs to acquire. Labcorp is seeking acquisitions that are accretive to profits in the first year and earn back cost of capital in 2-3 years.

Hospital Lab Management Agreements

Labcorp recently signed an agreement with Inspira Health (Vineland, NJ) to manage the daily operations of the health system's three hospital labs: Inspira Medical Center Vineland (345 beds), Inspira Medical Center Elmer (286 beds) and Inspira Medical Center Mannington (113 beds).

In addition, Labcorp will serve as the primary lab for the Inspira Medical Group, which includes 175 physicians and advanced practice providers working at 17 primary care practices and 8 urgent care locations in Southern New Jersey.

Inflation

"A big part of our inflation is cost of people and we've assumed 3-3.5% inflation [for 2025]. As we look at our labor, it actually got better in 2024 than it was prior, particularly our turnover rate, so I feel like we're in a pretty good place," said Schechter.

Estoteric Testing

Labcorp's esoteric testing volume grew faster than routine in 2024. Schechter said that Labcorp is seeing its fastest growth in oncology, women's health, neurology and autoimmune disease.

Labcorp Financial Summary ($ millions)

	2024	2023	% Chg
Total revenue	$13,008.9	$12,161.6	7.0%
Labcorp Diagnostics	10,144.3	9,415.1	7.7%
Biopharma Lab Services	2,922.6	2,774.2	5.3%
Operating cash flow	1,585.8	1,327.7	19.4%
Capital expenditures	489.9	453.6	8.0%
Free cash flow	1,095.9	874.1	25.4%
Pretax income	959.5	568.9	68.7%
Net income	746.0	418.0	78.5%
Diluted EPS	$8.84	$4.77	85.3%
Est'd number of requisitions	190.2	180.8	5.2%
Est'd revenue per requisition	53.39	52.09	2.5%
# Employees	69,000	67,000	3.0%
Avg. revenue per lab employee	$188,535	$181,516	3.9%

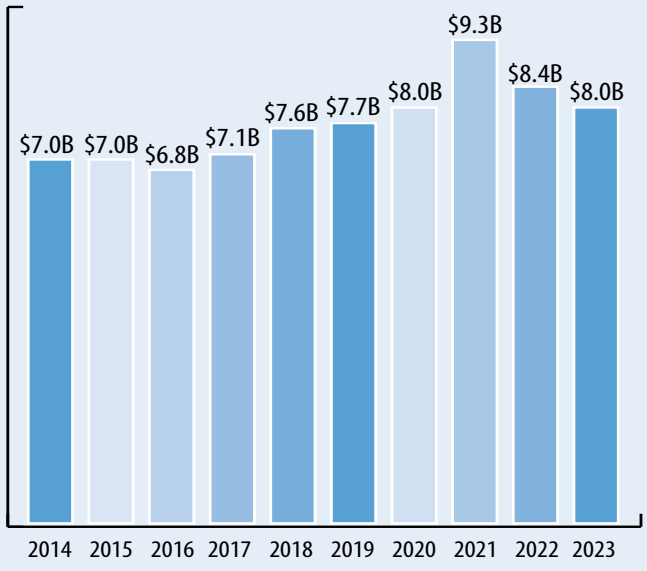
Source: Labcorp and *LE*'s estimates for number of reqs and average revenue per req.

Recent new test introductions include an H5 bird flu molecular test to aid in the diagnosis of human infection with H5 bird flu and a companion diagnostic assay to identify gastric cancer patients eligible for a targeted treatment—VYLOY (zolbetuximab-clzb)—for people with advanced cancer of the stomach.

OIG Report Shows 5% Drop in CLFS Spending

Medicare Part B spending on clinical lab fee schedule (CLFS) tests, including payments to independent labs, physician offices and hospitals, fell by 5% to $8 billion in 2023, according to the latest OIG review of CLFS payments. Total CLFS payments declined in 2023 because of significantly lower Covid-19 test volumes. Over the nine-year period from 2014 through 2023, overall Medicare Part B CLFS spending increased at an average annual rate of 1.5%.

Overall Medicare Part B Spending on CLFS Tests



Source: OIG analysis of Medicare Part B Spending on Lab Tests (December 2024)

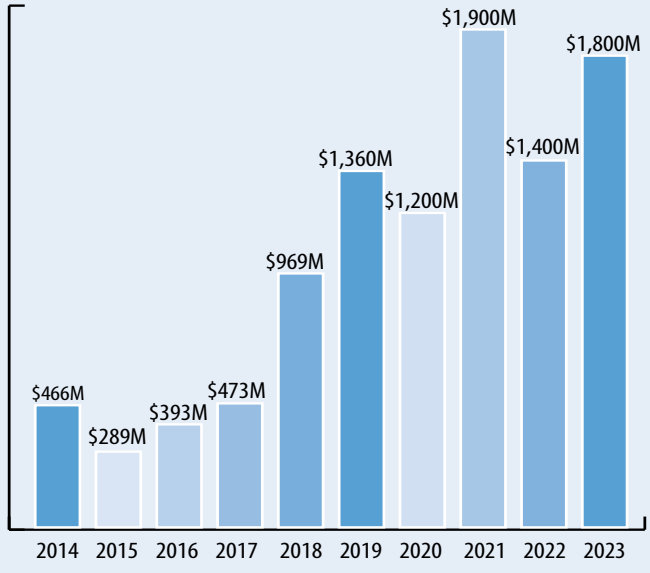
Genetic Testing

Medicare Part B spending on genetic tests increased to $1.8 billion in 2023, up 32% from $1.4 billion in 2022. Genetic tests, including molecular pathology tests, multianalyte algorithmic assays, genomic sequencing procedures, and proprietary lab analysis tests, accounted for 23% of Medicare Part B spending for all CLFS tests in 2023. The average payment per genetic test was approximately $750 in 2023. Over the nine-year period from 2014 through 2023, Medicare Part B spending on genetic tests increased at an annual rate of 16%.

The Top 25 CLFS Tests

The OIG report highlighted the top 25 tests in 2023, which represented 50% of Medicare payments for all lab tests paid under the CLFS. The top three tests (CPT 80053, 80061 & 84443) were routine chemistry tests.

Medicare Part B Spending on Genetic Tests



Source: OIG analysis of Medicare Part B Spending on Lab Tests (December 2024)

The fastest-growing test by volume was CPT 87637 (Covid-19/influenza A&B/RSV test panel), which jumped by 526% to ~700,000 tests in 2023.

Medicare volumes also increased for CPT 81455 (genomic sequence analysis panel for cancer), which grew by 59% to ~100,000 tests ($145.2 million); CPT 81542 (mRNA gene expression of 22 genes in prostate tumor tissue), up 37% to 19,000 tests ($71.7 million); and CPT 87798 (infectious agent detection by DNA or RNA), up 32% to 8.5 million tests ($292.4 million).

Top 25 Clinical Lab Tests by Medicare Part B Spending for 2023

CPT Code	Description	2023 Part B Volume (millions)	2022 Part B Volume (millions)	Volume Change 2022-2023	Medicare CLFS Rate for 2023	Total Medicare Spending for 2023 (millions)
80053	Comprehensive metabolic panel	38.6	38.6	0%	$10.56	$405.1
80061	Lipid panel	25.3	25.6	-1%	13.39	355.2
84443	Thyroid stimulating hormone (TSH)	19.2	19.2	0%	16.80	316.0
81528	DNA-based colorectal cancer screening	0.6	0.5	13%	508.87	301.0
87798	Infectious agent detection by DNA or RNA	8.5	5.8	32%	35.09	292.4
85025	Complete blood cell count	36.5	36.9	-1%	7.77	282.3
82306	Vitamin D-3 level	8.7	8.9	-2%	29.60	250.9
83036	Hemoglobin A1C level	18.4	18.4	0%	9.71	176.0
81455	Genomic sequence analysis panel for cancer (51 or greater genes)	0.1	0.0	59%	2,919.60	145.2
G0483	Drug test, definitive, 22+ classes	0.6	0.7	-13%	246.92	145.1
80307	Testing for presence of drug	2.1	2.3	-8%	62.14	129.1
U0003	Covid-19, nucleic acid, high-throughput	1.6	2.9	-83%	75.00	115.0
G0482	Drug test, definitive, 15-21 classes	0.6	0.7	-9%	198.74	110.5
0242U	Gene analysis of 55-74 genes	0.02	0.0	31%	5,000.00	104.8
87637	Covid-19/influenza A&B/RSV test panel by amplified probe	0.7	0.1	526%	142.63	103.6
83970	Parathyroid hormone	2.6	2.6	1%	41.28	103.1
81519	Breast cancer gene expression	0.03	0.0	2%	3,873.00	94.7
82607	Vitamin B-12	6.2	5.9	5%	15.08	91.9
0241U	Cepheid Covid-19/influenza A&B/RSV test panel	0.6	0.6	-1%	142.63	79.9
80048	Basic metabolic panel	9.3	9.7	-4%	8.46	79.4
G0480	Drug test, definitive, 1-7 classes	0.7	0.7	-4%	114.43	77.8
87635	Covid-19, Amplified probe technique	1.5	1.8	-17%	51.31	76.4
84153	Total PSA	4.2	4.2	0%	18.39	76.2
81542	mRNA gene expression of 22 genes in prostate tumor tissue	0.0	0.0	37%	3,873.00	71.7
G0481	Drug test, definitive, 8-14 classes	0.5	0.5	-1%	156.59	70.5
	Total for top 25 tests	**187.1**	**186.4**	**0.4%**		**$4,053.8**

Source: OIG analysis of 2022-2023 Medicare Part B spending on clinical lab tests.
Payment rates are from 2023 CLFS.

Quest Reports Full-Year 2024 Financial Results

Quest Diagnostics reported net income of $871 million for full-year 2024, up 2% from $854 million in 2023. Quest's overall revenue increased by 6.7% to $9.9 billion, with acquisitions contributing roughly 3.7% to revenue growth. Quest's average revenue per requisition rose by 1.3% to an estimated $44.24 per req. A summary of key topics discussed by CEO Jim Davis and CFO Sam Samad on a January 30 conference call follows.

Hospital Outreach Lab Acquisitions

Quest completed its $180 million acquisition of the outreach lab business of University Hospitals (Cleveland, OH) at the end of December. Davis said that Quest typically pays about 3.5 times annual revenue for hospital outreach lab acquisitions.

Davis noted that health systems are getting 2x to 3x the reimbursement rates that Quest is paid. After an outreach lab acquisition is completed, private-payer rates are transitioned to Quest's lower fee schedule over a period of two to three years. Quest's acquisition strategy is currently mostly focused on hospital outreach labs, according to Davis.

Direct-to-Consumer Testing

Davis said that Quest's direct-to-consumer [DTC] testing service, Questhealth.com, grew its revenue by 40% to reach just over $60 million in 2024. The Questhealth.com menu now includes 135 different tests.

Pricing Pressure

Quest is getting out of certain capitated contracts in California that are unprofitable. In addition, Davis said there is some price pressure on hospital reference testing contracts. During the pandemic period (2020-2023), most hospitals didn't send out RFPs for reference testing contracts. "So, we're seeing an uptick in RFPs, and there's price pressure in that segment," noted Davis.

Haystack MRD Test

Quest spent much of last year validating its Haystack MRD blood test for early detection of minimal residual disease in solid tumor cancer patients. Quest provided Haystack MRD testing to 75 academic medical centers and community oncology practices on a non-revenue basis last year. Quest is now seeking to move those customers into commercial arrangements. Quest acquired Haystack Oncology for $392 million in June 2023.

LDT Regulation

Quest is spending $30 million to modernize its IT infrastructure, as well as to comply with the first phase of FDA regulations of laboratory-developed tests (LDTs) that takes effect May 6.

Meanwhile, oral arguments for the ACLA-AMP lawsuit contesting LDT regulation are scheduled for February 19. Davis believes a decision on the case will come in March or April.

Quest Diagnostics Financial Summary ($ millions)

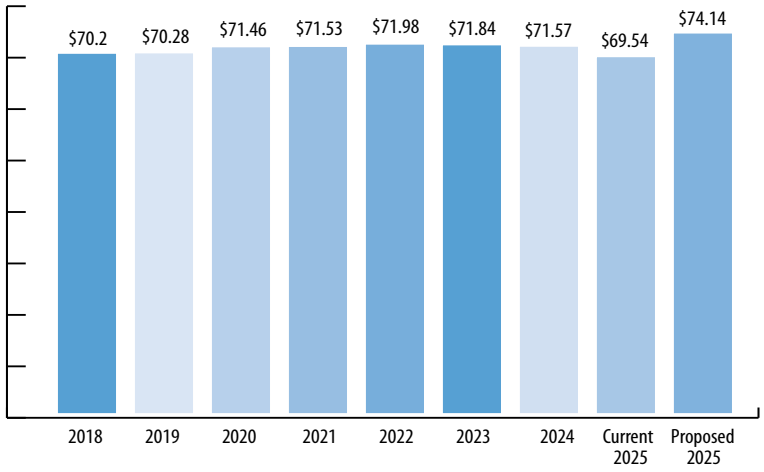
	2024	2023	% Chg
Total revenue	$9,872	$9,252	6.7%
Operating cash flow	1,334	1,272	4.9%
Capital expenditures	425	408	4.2%
Free cash flow	909	864	5.2%
Pretax income	1,175	1,130	4.0%
Net income	871	854	2.0%
Diluted EPS	7.69	$7.49	2.7%
Est'd number of requisitions	217.9	206.5	5.5%
Est'd revenue per requisition	$44.24	$43.67	1.3%
# Employees	55,000	49,500	11.1%
Avg. revenue per employee	$179,491	$186,909	-4.0%

Source: Quest Diagnostics and *LE*'s estimates for number of reqs and average revenue per req.

CAP LOBBIES CONGRESS FOR 6.6% MEDICARE RATE HIKE (*cont'd from page 1*)

The bipartisan bill is called the Medicare Patient Access and Practice Stabilization Act of 2025 (H.R. 879). This bill would raise the conversion factor (CF) used to set Medicare rates for all physicians by 6.6% to $34.49 effective April 1. It would reverse the 2.8% payment cut that took effect on January 1, while also granting a payment adjustment for inflation plus a bump to reflect the lower CF in effect during the first quarter of 2025.

Medicare Global Reimbursement Rate for CPT 88305 (unadjusted national fee)



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

With the federal government facing a March 14 funding deadline, the best opportunity for passage is for this bill to be packaged with a larger spending bill to keep the government open, CAP President Donald Karcher, MD, tells Laboratory Economics. He says that the House could certainly pass it as a standalone bill because representatives have overwhelmingly supported similar Medicare payment increases for physicians in the past. But getting it through the Senate by itself would be challenging.

In addition to CAP and AMA, dozens of other physician groups support the bill, including the Medical Group Management Association (MGMA), the California Medical Association and the American Society for Clinical Pathology (ASCP).

The bill was introduced by Rep. Greg Murphy (R-NC) on January 31 and currently has 49 cosponsors (25 Republicans/24 Democrats).

If passed into law, Medicare Physician Fee Schedule reimbursement for CPT 88305 (Level IV, tissue exam) would rise by 6.6% to a global rate of $74.14 from its current rate of $69.54. The Medicare rate hike would impact other pathology services as well as influence the rates paid by Medicaid and private health insurance plans.

Physician groups argue that a rate hike is needed to offset inflationary pressures. CMS has estimated that the Medicare Economic Index (MEI), a cumulative measure of the individual costs of running a practice, will increase by 3.5% this year after a 4.6% increase in 2024.

Lab Stocks Down 2% So Far in 2025

Twenty-four lab stocks have fallen an unweighted average of 2% year to date through February 12. Tempus AI has jumped 119%, Guardant Health is up 49%, and Adaptive Biotechnologies is up 26%. Quest Diagnostics is up 9% and Labcorp is up 5%.

Company (ticker)	Stock Price 2/12/25	Stock Price 12/31/24	2025 Price Change	Enterprise Value ($ millions)	Revenue For Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
Tempus AI (TEM)	$73.88	$33.76	119%	$11,640	$640	18.2
Guardant Health (GH)	45.38	30.55	49%	6,020	692	8.7
Adaptive Biotechnologies (ADPT)	7.55	6.00	26%	1,080	179	6.0
CareDx (CDNA)	23.96	21.41	12%	1,070	313	3.4
Opko Health (OPK)	1.64	1.47	12%	1,220	711	1.7
Natera (NTRA)	172.73	158.30	9%	22,250	1,532	14.5
Quest Diagnostics (DGX)	164.35	150.86	9%	24,740	9,872	2.5
Oncocyte Corp. (OCX)	2.51	2.38	5%	43	1	61.3
Exagen (XGN)	4.32	4.10	5%	78	56	1.4
Labcorp (LH)	241.15	229.32	5%	25,880	13,009	2.0
Castle Biosciences (CSTL)	27.85	26.65	5%	527	312	1.7
Veracyte (VCYT)	40.38	39.60	2%	2,880	425	6.8
Sonic Healthcare (SHL.AX)*	27.01	27.01	0%	16,850	8,970	1.9
Myriad Genetics (MYGN)	13.09	13.71	-5%	1,230	824	1.5
GeneDx (WGS)	70.97	76.86	-8%	1,950	267	7.3
Exact Sciences (EXAS)	51.06	56.19	-9%	11,080	2,692	4.1
Fulgent Genetics (FLGT)	16.22	18.47	-12%	-313	278	-1.1
NeoGenomics (NEO)	13.78	16.48	-16%	1,990	644	3.1
Personalis (PSNL)	4.66	5.78	-19%	232	88	2.7
23andMe (ME)	2.47	3.25	-24%	47	209	0.2
Biodesix (BDSX)	0.94	1.53	-39%	168	66	2.6
Interpace Biosciences (IDXG)	1.25	2.70	-54%	57	45	1.3
Aspira Women's Hlth (AWH)	0.31	0.71	-56%	5	9	0.6
ProPhase Labs (PRPH)	0.28	0.76	-63%	36	13	2.8
Totals & Averages			**-2%**	**$130,761**	**$41,846**	**3.1**

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

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