Jondavid Klipp, Editor, jklipp@laboratoryeconomics.com Volume 20, No. 11 November 2025

LABORATORY ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## Anthem to Impose 10% Out-of-Network Penalty

Effective Jan. 1, 2026, Anthem will impose a 10% administrative penalty on hospitals that use OON providers for commercial members. The new policy could disrupt relationships between hospitals and some pathology groups and labs, says William Baus, Founder of Lab Revenue Navigator (Carrollton, TX). The policy will apply in 11 states and may result in network termination for non-compliant facilities. Emergency and pre-approved OON care are exempt from this penalty, according to the announcement. Anthem also warns hospitals not to balance-bill health plan members for the 10% penalty when utilizing OON providers.

*William Baus*

*Cont'd on page 6.*

## Medicare CLFS Rate Cuts Delayed 30 Days

The new continuing resolution to fund the government through January 30, 2026, includes provisions that will delay scheduled Medicare CLFS rate cuts and PAMA survey reporting requirements through that date. The short-term delay will give the lab industry a few more weeks to lobby for a long-term PAMA fix (RESULTS Act: H.R. 5269/S. 2761)—*see below.*

## RESULTS Act Adds Support of 15 More Reps.

The RESULTS Act now has the support of 37 members of the House (up from 22 members last month) and two Senators (unchanged). Twelve supporting Reps. are members of the House Committee on Energy and Commerce, which has a total of 54 members and represents the best chance for moving the bill forward. The lab industry is now waiting for the Congressional Budget Office (CBO) to estimate the cost of the bill. "Getting a score from CBO is hugely important and would show progress from a legislative perspective," notes Erin Morton, Washington Representative for the National Independent Laboratory Association (NILA) and Partner at CRD Associates (Washington, DC).

*Erin Morton*

*More details on page 2.*

## Contents

**RESULTS ACT ADDS SUPPORT OF 15 MORE REPS.** (*cont'd from page 1*)
Morton says that the government shutdown did not hinder the lab industry's ability to lobby for the RESULTS Act. "We have still been on the Hill talking to legislators about the importance of passing the bill. In fact, NILA's Clinical Laboratory Coalition leaders converged on the Hill this past Thursday [November 13] during which members met with Senators and Representatives to discuss the bill."


*Susan Van Meter*

Similarly, ACLA President Susan Van Meter says that throughout the government shutdown, ACLA has continued to lobby members in both the House and Senate. The goal is to get provisions of the RESULTS Act inserted into a bigger healthcare bill expected to be introduced in the next few weeks, according to Van Meter.

In an October 30 letter, more than 30 provider groups, including the American Hospital Association and the American Medical Association, urged House and Senate leaders to support the RESULTS Act. The RESULTS Act would freeze Medicare CLFS rates through 2028 and revamp the way that future rates are calculated (see *LE*, September 2025).

Without new legislation, Medicare CLFS rate cuts of up to 15% for roughly 800 lab tests will take effect on January 30, 2026. In addition, independent labs, hospital outreach labs and large POLs will be required to report their private-payer volume and payment data from 2019 for approximately 1,500 lab test codes starting February 1 through April 30, 2026. CMS will use this data to determine Medicare CLFS rates for 2027-2029. In addition, there is legitimate concern that private payers could use the results from the next private-payer survey as justification to lower their lab rates.

Despite growing support in the House, "The RESULTS Act is not gonna be an easy one to pass," according to Sam Samad, Chief Financial Officer at Quest Diagnostics. Speaking on an October 21 conference call, Samad said that if the scheduled Medicare CLFS rate cuts do go into effect, Quest will suffer about $100 million in lost revenue and profits in 2026. Samad said that Quest would offset a portion of this loss through cost cutting.

On an October 28 conference call, Labcorp CEO Adam Schechter said, "With everything that's happening right now, including the shutdown…. It's very hard to handicap whether or not we'll see that happen [passage of the RESULTS Act] by the end of the year." The scheduled Medicare rate cuts would lower Labcorp's top and bottom lines by $100 million for 2026. Labcorp is aiming to reduce this potential loss by $25 million through cost cutting.

**CBO Scoring is Key**
The CBO has not yet estimated the cost of the RESULTS Act. The previous Medicare CLFS reform bill, Saving Access to Laboratory Services Act (SALSA), had been estimated to cost Medicare approximately $6 billion over 10 years. This cost estimate was the primary reason the bill did not pass. Under federal "pay-as-you-go" (PAYGO) budgetary rules, Congress needs to offset new spending with either tax increases or cuts in other programs.

**Revised CBO Forecasting Model**
The 30-day delay in Medicare CLFS rate cuts and data reporting will cost the government $49 million over 10 years, according to estimates from the CBO. In prior years, the CBO had always scored delays as saving money under the mistaken assumption that private insurance companies were adjusting the rates they pay labs by annual inflation (as measured by the Consumer Price Index). However, the CBO updated its forecasting model earlier this year to correct this error. As a result, longer-term delays as well as the RESULTS Act will have higher cost estimates and thus will be harder to pass into law.

# BillionToOne Raises $314 Million in Upsized IPO

BillionToOne Inc. (Menlo Park, CA) completed its initial public offering (IPO) on November 6, raising $314 million in gross proceeds. The company priced its IPO at $60 per share, above the initially proposed range of $49 to $55 per share (see *LE*, October 2025).

At the IPO price of $60 per share, BillionToOne was valued at a market cap of $2.75 billion. However, by the end of its first day of trading on November 6, its shares were up 82% to $109 giving it a market cap of $5 billion.

The IPO was managed by J.P. Morgan, Piper Sandler, Jefferies and William Blair.

After deducting sales commissions and IPO costs, BillionToOne will receive net proceeds of nearly $300 million. BillionToOne intends to use the IPO proceeds for research and development initiatives, technology development, working capital and operating expenses.

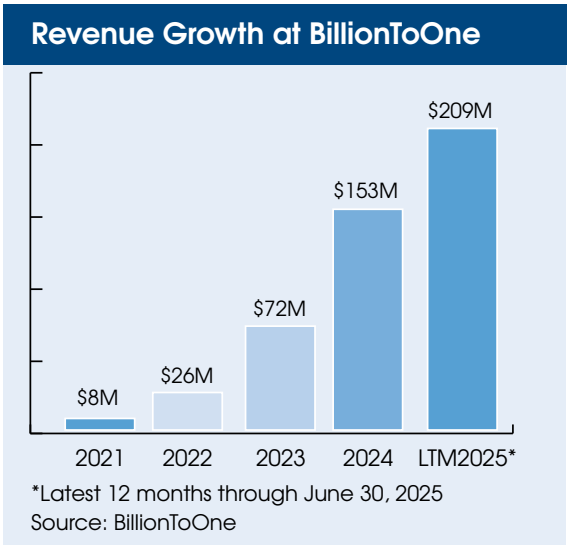
BillionToOne, which has 620 employees, operates a 36,000-square-foot CLIA-certified lab in Menlo Park, CA, and a second 90,000-square-foot lab in Union City, CA. It is also constructing a new 220,000-square-foot lab in Austin, TX, that is expected to open in 2028.

Its patented technology can detect a single DNA letter of a single DNA molecule out of a total of 3 billion in a human genome (thus the company's name)—helping it determine if a developing baby is at risk of serious disease from one maternal blood sample. BillionToOne launched a prenatal blood test (branded UNITY Fetal Risk Screen) to analyze risk of cystic fibrosis, sickle cell disease and spinal muscular atrophy in 1999. The current CLFS rate established for the UNITY test (PLA 0489U) is $1,154.

In 2023, BillionToOne launched two pan-cancer liquid biopsy tests: Northstar Select (PLA 0487U; $2,920), which is used to guide therapy selection, and Northstar Response (PLA 0486U; $1,644), which quantifies the amount of cancer at the single molecule level without requiring a tissue biopsy.

In addition, BillionToOne is developing a tissue-free, pan-cancer minimal residual disease (MRD) test that it expects to launch commercially as an LDT in 2026.

Chief Executive Oguzhan Atay, PhD, age 37, a Turkish immigrant with a doctorate in systems biology from Stanford University, cofounded BillionToOne in 2016. At a price of $109 a share, Atay's stake in the company (including shares and vested options) is worth approximately $340 million. Cofounder David Tsao, PhD, 36, the company's Chief Technology Officer, holds a stake worth nearly $325 million.




BillionToOne reported a net loss of $4.2 million for the six months ending June 30, 2025, versus a net loss of $15.2 million for the same period a year earlier; revenue increased by 82% to $125.5 million. The company processed 508,000 tests (average revenue per test of ~$411) in the 12 months ended June 30, 2025. BillionToOne has accumulated total losses of $286 million since being founded in 2016.

# Final Medicare PFS Hikes Pathology Rates by 0.6%

Global rates for high-volume surgical pathology services (e.g., CPT 88305, 88307, 88341, 88342, etc.) will be raised by an average of approximately 0.6% next year under the Final Medicare Physician Fee Schedule (MPFS) for 2026 (released on November 10, 2025). The small rate hike is the result of ~3.3% increase in the conversion factor offset by a negative ~2.5% "efficiency adjustment" to work relative value units (RVUs) for pathology and most surgical specialties.

Below we highlight the final Medicare rates for several key pathology codes for 2026. Medicare rates are critical not only because Medicare is the largest payer for pathology services, but also because most commercial insurance plans as well as Medicaid programs baseline their rates to the Medicare Physician Fee Schedule.

**Surgical Pathology-CPT 88305**
The global rate for CPT 88305—the highest volume pathology code—is being raised by 0.9% to $70.14 in 2026. The professional rate for 88305 will increase by 0.4% to $35.07, while the technical component will increase by 1.3% to $35.07.

**Immunohistochemistry**
The global rate for CPT 88342 (IHC, first stain procedure) is increasing by 1.4% to $110.56; professional interpretation up 0.2% to $32.73; technical component up 1.9% to $77.82.

The global rate for CPT 88341 (IHC, additional slide) will increase by 1.1% to $94.52; professional interpretation up 0.8% to $26.72; technical component up 1.3% to $67.80.

**Prostate Biopsies**
Global reimbursement for HCPCS code G0416 (prostate needle biopsy) is being hiked by 1% to $358.06 in 2026. The professional rate for G0416 will increase by 0.3% to $167.34, while the technical component will increase by 1.7% to $190.72.

**Special Stains**
The global rate for CPT 88312 (Special stains, group 1) will increase by 1.4% to $109.89; professional interpretation up 0.6% to $25.05; technical up 1.7% to $84.84.

The global rate for CPT 88313 (Special stains, group 2) will increase by 2% to $81.16; professional interpretation up 0.4% to $11.36; technical up 2.3% to $69.81.

**FISH Testing**
Global reimbursement for CPT 88120 (FISH-manual, 3-5 probes) is being raised by 0.3% to $544.10. The professional rate is being cut by 0.4% to $54.44, while the technical component will increase by 0.4% to $489.66.

Global reimbursement for CPT 88121 (FISH-computer-assisted, 3-5 probes) is being raised by 0.5% to $395.47. The professional rate is being cut by 0.4% to $45.43, while the technical component will rise by 0.7% to $350.04.

**Flow Cytometry**
Flow cytometry will see the highest Medicare rate increases in 2026. Technical rates for CPT 88184 (TC for 1st marker) will rise by 7.7% to $81.50, while rates for CPT 88185 (TC for each additional marker) are going up by 4.8% to $23.05. The professional rate for CPT 88187 (interpretation of 2-8 markers) is being raised by 3.2% to $35.40.

## Final Medicare Rates for Key Pathology Codes in 2026

| CPT Code | Short Description | Final 2026* | Final 2025** | Proposed Rate |
|---|---|---|---|---|
| 88120-Global | FISH-manual, 3-5 probes | $544.10 | $542.45 | 0.3% |
| 88120-26 | FISH-manual, 3-5 probes | 54.44 | 54.67 | -0.4% |
| 88120-TC | FISH-manual, 3-5 probes | 489.66 | 487.79 | 0.4% |
| 88121-Global | FISH-computer assisted, 3-5 probes | 395.47 | 393.33 | 0.5% |
| 88121-26 | FISH-computer assisted, 3-5 probes | 45.43 | 45.61 | -0.4% |
| 88121-TC | FISH-computer assisted, 3-5 probes | 350.04 | 347.72 | 0.7% |
| 88184-TC only | Flow cytometry/1st marker | 81.50 | 75.69 | 7.7% |
| 88185-TC only | Flow cytometry/each add'l marker | 23.05 | 22.00 | 4.8% |
| 88187-26 only | Flow cytometry, read 2-8 | 35.40 | 34.29 | 3.2% |
| 88188-26 only | Flow cytometry/read 9-15 | 58.45 | 58.22 | 0.4% |
| 88189-26 only | Flow cytometry, read 16 & greater | 78.83 | 79.25 | -0.5% |
| 88304-Global | Level III, tissue exam by pathologist | 41.08 | 41.4 | -0.8% |
| 88304-26 | Level III, tissue exam by pathologist | 10.35 | 10.67 | -3.0% |
| 88304-TC | Level III, tissue exam by pathologist | 30.73 | 30.73 | 0.0% |
| 88305-Global | Tissue exam by pathologist | 70.14 | 69.54 | 0.9% |
| 88305-26 | Tissue exam by pathologist | 35.07 | 34.93 | 0.4% |
| 88305-TC | Tissue exam by pathologist | 35.07 | 34.61 | 1.3% |
| 88307-Global | Level V, tissue exam by pathologist | 278.90 | 278.18 | 0.3% |
| 88307-26 | Level V, tissue exam by pathologist | 76.82 | 76.66 | 0.2% |
| 88307-TC | Level V, tissue exam by pathologist | 202.08 | 201.52 | 0.3% |
| 88309-Global | Level VI, tissue exam by pathologist | 413.84 | 415.33 | -0.4% |
| 88309-26 | Level VI, tissue exam by pathologist | 134.61 | 135.21 | -0.4% |
| 88309-TC | Level VI, tissue exam by pathologist | 279.23 | 280.12 | -0.3% |
| 88311-Global | Decalcify tissue | 19.71 | 19.73 | -0.1% |
| 88311-26 | Decalcify tissue | 11.36 | 11.64 | -2.4% |
| 88311-TC | Decalcify tissue | 8.35 | 8.09 | 3.2% |
| 88312-Global | Special stains, group 1 | 109.89 | 108.36 | 1.4% |
| 88312-26 | Special stains, group 1 | 25.05 | 24.91 | 0.6% |
| 88312-TC | Special stains, group 1 | 84.84 | 83.45 | 1.7% |
| 88313-Global | Special stains; group 2 | 81.16 | 79.57 | 2.0% |
| 88313-26 | Special stains; group 2 | 11.36 | 11.32 | 0.4% |
| 88313-TC | Special stains; group 2 | 69.81 | 68.25 | 2.3% |
| 88331-Global | Pathology consult during surgery | 97.53 | 97.69 | -0.2% |
| 88331-26 | Pathology consult during surgery | 57.78 | 58.22 | -0.8% |
| 88331-TC | Pathology consult during surgery | 39.75 | 39.46 | 0.7% |
| 88341-Global | Immunohistochemistry (Add'l stain) | 94.52 | 93.48 | 1.1% |
| 88341-26 | Immunohistochemistry (Add'l stain) | 26.72 | 26.52 | 0.8% |
| 88341-TC | Immunohistochemistry (Add'l stain) | 67.80 | 66.96 | 1.3% |
| 88342-Global | Immunohistochemistry (1st stain) | 110.56 | 109.01 | 1.4% |
| 88342-26 | Immunohistochemistry (1st stain) | 32.73 | 32.67 | 0.2% |
| 88342-TC | Immunohistochemistry (1st stain) | 77.82 | 76.34 | 1.9% |
| G0416-Global | Prostate biopsy, any method | 358.06 | 354.52 | 1.0% |
| G0416-26 | Prostate biopsy, any method | 167.34 | 166.91 | 0.3% |
| G0416-TC | Prostate biopsy, any method | 190.72 | 187.61 | 1.7% |
| **Overall Unweighted Average for Global Rates** | | | | **0.6%** |

Note: Rates presented in table are national non-facility rates (unadjusted for geographic locations)
*Payments based on final conversion factor for CY2026 of 33.4009
**Payments based on final conversion factor of 32.3465 for CY2025
Source: *Laboratory Economics* from CMS and College of American Pathologists

**ANTHEM TO IMPOSE 10% OUT-OF-NETWORK PENALTY** (*cont'd from page 1*)
According to Anthem, the new policy helps protect members from unexpected costs that arise when receiving care from nonparticipating care providers in the facility-based setting. Anthem officials also have said this move is in response to concerns about the misuse of the No Surprises Act's independent dispute resolution process.

But groups representing anesthesiologists, radiologists and emergency physicians are pushing back. In a Nov. 5 letter sent to the CEO of Elevance, which owns Anthem, three medical groups said the policy is deeply flawed and operationally unworkable.

"It effectively shifts Elevance's network adequacy obligations onto facilities, holding them financially liable to the contracting status of independent physician groups – an area over which they have no control or infrastructure to manage," they wrote. "Hospitals will be forced to compel independent providers to join Elevance's network under unfavorable terms leading to a risk of worsening financial instability and the loss of clinicians."

Baus says the penalty is most likely to apply to in-network hospitals that send specimens to OON reference labs and bill under the facility or a facility using an OON pathology group for in-house specimens. As a result, facilities are more likely to refer to in-network providers, such as Labcorp or Quest, which is exactly what Anthem is trying to accomplish, he says.

"These kinds of tactics will likely push facilities to be more cautious about using out-of-network providers," says Baus. He advises pathology groups that are currently out of network to consider seeking credentialing with Anthem. "In many markets, it's not inherently difficult for pathologists to apply for in-network status, although some regions may be closed with Anthem's common response that 'your specialty is adequately represented in our network.' When that happens, facilities can—and often do—advocate for the inclusion of their preferred pathology groups." Baus adds that the real challenge is determining whether Anthem's reimbursement rates make participation financially viable.

"Hospitals may challenge the policy—whether through contract disputes, regulatory complaints, or even legal arguments—as they evaluate how the penalty affects their use of out-of-network providers," says Baus.

The penalty will apply to facilities in Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, Ohio and Wisconsin, according to Anthem. Baus doesn't expect the policy to appear in all Anthem states. Some Anthem plans operate under different regulatory environments, contracting structures, or levels of operational flexibility, which may make the penalty harder to implement.

# OmniPathology Expanding Menu and Going Digital

*Mohammad Kamal, MD*

OmniPathology (Pasadena, CA), which specializes in gastrointestinal pathology and molecular diagnostics, operates out of a 9,600-square-foot lab located just north of Los Angeles. The lab recently took its first step toward digital pathology. *Laboratory Economics* spoke with Founder and CEO Mohammad Kamal, MD.

**How much has OmniPathology changed since we last talked in 2020?**
We are still at about 20 employees, including six pathologists. Gastrointestinal pathology testing continues to be our flagship product. In the last year we have grown by 106% over the previous year in terms of volume. Our current volume is about 6,000 CPT codes per month in pathology. [see *LE*, March 2020]

Our molecular volumes have also increased – more than double this year over the previous year. We were very active with Covid testing from the very start of the pandemic. Now we aren't doing much Covid testing, but we are doing a lot of molecular testing for sexually transmitted diseases, respiratory and gastrointestinal tract infections.

We have also developed a swab test for oropharyngeal human papillomavirus (HPV), to be used as a screening tool for HPV-related oropharyngeal cancer, a rapidly increasing cancer worldwide. Our approach is based on a simple fact that persistent HPV infection is linked to cancer development.

**How many molecular tests do you offer?**
Between sexually transmitted infections, respiratory and gastrointestinal panels, we cover approximately 60 organisms obtained from several specimen types such as cervical, anal, oropharyngeal, nasopharyngeal, urine and stool. For pathology, in addition to GI, we do gynecological, head and neck, dermatology and prostate. We also perform GYN and non-GYN cytology.

**What geographic areas do you serve?**
We serve California exclusively. There are so many restrictions to be able to bill for services from other states. We recently signed an agreement with Delta Laboratories in Saudi Arabia to offer our oropharyngeal HPV test to their patients. We are also finalizing a consultation relationship to provide Delta with GI pathology second opinion service using digital pathology. This is the first of many similar partnerships we are planning to have with labs in different parts of the world.

**What are your plans for digital pathology?**
I believe digital pathology is the future. We're not looking at it for just primary diagnoses, but we also want to see it create opportunities in research and clinical trials through partnerships with pharma. We have a wealth of pathology data that once digitized will be of tremendous value. For the digital scanner, we are starting with one Leica Aperio GT450. Gestalt's PathFlow is the software tool our pathologists will use to review the slides and to collaborate with other pathologists. We expect to be fully digital by the end of the year.

**Are you still involved in research and clinical trials?**
We are preparing to publish our data on the oropharyngeal HPV test by the end of the year. That's one research opportunity that we are very excited about. We expect to have conversations about clinical trials once our digital pathology program is fully implemented.

**What are your strategies for expanding as you go forward?**
Oropharyngeal HPV testing is one of the areas we are focused on. We are expecting that gynecologists and primary care physicians will order this test. We are also in the process of getting more dentists onboard. This is in line with the American Dental Association modifying its guidelines for oral cancer screening to include oropharyngeal cancer.

# Labs Still Reporting Minimal Utilization of Digital Pathology Add-On Codes

Thirteen Category III add-on codes (0751T-0763T) became effective January 1, 2023, and another 30 add-on codes (0827T-0856T) were introduced effective January 1, 2024. These 43 codes are being used by CMS to monitor the usage of digital pathology. CMS is looking for widespread use of digital pathology before it moves the new codes to Category I and assigns Medicare reimbursement rates. However, utilization of 43 new digital pathology add-on codes was only 1.1% in 2024, according to an analysis of Medicare Part B carrier claims data.

In total, the 43 add-on codes recorded Medicare Part B volume of 179,892 in 2024. These codes could potentially have been reported for up to 16.4 million Part B pathology technical services, indicating an overall usage rate of only 1.1%.

"Because the new digital pathology add-on codes currently offer neither reimbursement nor mandatory reporting, they're difficult for labs to prioritize," says Josh Kramer, Managing Partner at Leap Consulting Group (Teaneck, NJ), which helps labs go digital. Most labs are focused on optimizing slide scanning, case routing, and pathologist review to make digital workflows more efficient. Without a clear financial or regulatory incentive, billing automation for digital pathology is a lower priority. Once digital pathology software vendors can automatically integrate these add-on codes into laboratory information systems (LISs), reported adoption of the these codes should increase significantly, according to Kramer.

In the meantime, CMS is unlikely to consider an upgrade to permanent Category I status and national payment until it sees significant utilization of these add-on codes. Furthermore, most private insurers won't reimburse for digital pathology without formal Medicare coverage. As a result, pathology labs investing in digital pathology must earn a return on investment (ROI) by employing AI tools to analyze digitized slide images and raise pathologist efficiency.

**Medicare Part B Utilization of Digital Pathology Add-On Codes in 2024**

| Test Codes | Short Description | Submitted Part B Digital Path Add-On Services 2024 | Submitted Part B Pathology Services for Related Category I CPT Code 2024* | Digital Pathology Percentage Utilization |
|---|---|---|---|---|
| 0753T/88305 | Digitization of slides for level IV, surgical pathology | 117,593 | 10,407,471 | 1.13% |
| 0760T/88342 | Digitization of slides for immunohistochemistry, initial stain | 17,068 | 1,048,588 | 1.63% |
| 0756T/88312 | Digitization of slides for special stain, Group 1 | 10,923 | 940,300 | 1.16% |
| 0761T/88341 | Digitization of slides for immunohistochemistry, each add'l stain | 9,696 | 1,027,038 | 0.94% |
| 0757T/88313 | Digitization of slides for special stain, Group 2 | 9,038 | 711,719 | 1.27% |
| 0762T/88344 | Digitization of slides for IHC, each multiplex stain | 5,779 | 104,096 | 5.55% |
| 0752T/88304 | Digitization of slides for level III, surgical pathology | 3,565 | 289,443 | 1.23% |
| 0830T/88112 | Digitization of slides for cytopathology | 2,531 | 304,487 | 0.83% |
| 0763T/88360 | Digitization of slides for morphometric analysis, tumor IHC | 1,626 | 240,301 | 0.68% |
| 0754T/88307 | Digitization of slides for level V, surgical pathology | 804 | 42,165 | 1.91% |
| 0853T/88377 | Digitization of slides for morphometric analysis, in situ hybridization | 193 | 55,121 | 0.35% |
| 0846T/88350 | Digitization of slides for immunofluorescence | 182 | 110,724 | 0.16% |
| | All other digital pathology add-on codes | 894 | 1,123,930 | 0.08% |
| | Grand Totals | 179,892 | 16,405,383 | 1.10% |

*Includes submitted test volumes for TC-only and global test services—excludes PC-only test volumes.

Source: Laboratory Economics from CodeMap.com

# Medi-Cal Expands Coverage for Six Whole-Genome Sequencing Tests

Effective Nov. 1, 2025, Medi-Cal will cover six whole-genome sequencing tests that previously had only limited coverage. The coverage changes affect the 14.7 million people enrolled in California's Medi-Cal program.

Previously, these six codes were covered only for neonatal populations in inpatient settings. While some of the tests now have frequency limits, as well as a treatment authorization request (TAR) requirement, there is no age or place-of-service restriction, according to Clarisa Blattner, Senior Director, Revenue and Payor Optimization for XiFin Inc. (San Diego).

The covered codes are:

- 0340U: Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-gen sequencing of the patient's tumor and germline DNA; Medicare rate $3,590.
- 81228: Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number variants, comparative genomic hybridization microarray analysis; Medicare rate $900.
- 81229: Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and single nucleotide polymorphisms (SNP) variants, comparative genomic hybridization microarray analysis; Medicare rate $1,160.
- 81425: Genome (e.g., unexplained constitutional or heritable disorder syndrome); sequence analysis; Medicare rate $5,031.
- 81426: Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (eg, parents, siblings); Medicare rate $2,710.
- 81427: Genome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence; Medicare rate $2,338.

California was one of the first states in the nation to cover rapid WGS for critically ill infants under Medi-Cal, beginning Jan. 1, 2022. There are 30 states, plus Puerto Rico, with limited coverage for WGS testing under Medicaid, but none is as extensive as California, says Blattner. She believes it is likely that other states will follow California's example.

Genetic testing labs, especially those that perform neonatal and pediatric testing, are likely to see an increase in testing as a result of the expanded coverage. Because there are no age limitations on the WGS tests now covered by Medi-Cal, the number of tests performed could increase substantially. Southern California, which has the highest concentration of Medi-Cal participants, also includes major genomic hubs, including Rady's Children's Hospital, UCLA, Children's Hospital of Los Angeles and Loma Linda University Medical Center, all of which stand to benefit from the expanded coverage. Independent labs that may benefit include Baylor Genetics, GeneDx and Natera Inc.

According to Blattner, rapid trio WGS is most often used for critically ill infants with unexplained disease while standard WGS in adults is used for rare disease diagnosis, hereditary cancer/cardiac risk assessment and pharmacogenomics.

While Medi-Cal has not yet posted reimbursement rates for the expanded coverage, Blattner notes that Medicare payment ranges from $900 for cytogenomic analysis (CPT 81427) to $10,451 for rapid trio WGS (CPT 81425 & 81426 x2).

# The Top 25 Medi-Cal FFS Laboratories in 2024

California Medi-Cal fee-for-service (FFS) payments to labs and pathologists fell by 23% to reach $172.7 million in calendar-year 2024, according to data from the California Department of Health Care Services (DHCS). The decline was due to reduced Covid-19 testing and a reduction in the number of members in traditional FFS plans. These FFS payments do not include lab expenses for Medi-Cal managed care plans, which are paid on a capitated basis and negotiate their own rates with their contracted providers. As of October 2023, Medi-Cal served 14.7 million members, including 14 million in managed care plans and 726,321 in traditional fee-for-service.

The largest Medi-Cal lab provider is **Quest Diagnostics**, which received $23.3 million of Medi-Cal FFS payments in 2024, down 3.2% from 2023, according to data from the California DHCS.

**The Genetic Disease Screening Program** (GDSP) of the California Department of Public Health was the second largest, with $19.9 million, down slightly from $20 million in 2023. The Genetic Disease Screening Program provides prenatal and newborn testing services to Medi-Cal recipients.

**BillionToOne** (Menlo Park, CA) was the fastest-growing Medi-Cal lab. BillionToOne received $2.2 million, up 35% from $1.6 million in 2023.

### Top 25 Medi-Cal FFS Laboratories in CY 2024

| *Laboratory* | *CY 2024 Reimbursements Paid (FFS Only)* | *CY 2023 Reimbursements Paid (FFS Only)* | *% Chg* |
|---|---|---|---|
| Quest Diagnostics | $23,305,537 | $24,087,235 | -3.2% |
| CDPH Genetic Disease Branch | 19,941,191 | 19,956,575 | -0.1% |
| Planned Parenthood | 18,126,893 | 18,808,488 | -3.6% |
| Labcorp | 6,964,468 | 8,829,791 | -21.1% |
| Gentech Laboratories | 6,516,593 | 7,079,203 | -7.9% |
| Childrens Hospital of Los Angeles | 3,648,475 | 3,545,543 | 2.9% |
| Regents of the University of CA/UCLA Outreach | 3,408,166 | 4,401,182 | -22.6% |
| Natera Inc. | 3,327,935 | 3,786,517 | -12.1% |
| BillionToOne Inc. | 2,201,987 | 1,629,442 | 35.1% |
| Dignity Health | 2,179,543 | 2,574,498 | -15.3% |
| Latara Enterprise (dba Foundation Laboratory) | 1,824,028 | 2,113,566 | -13.7% |
| Rady Children's Hospital | 1,808,237 | 1,804,442 | 0.2% |
| City of Hope Helford | 1,790,204 | 1,936,181 | -7.5% |
| Family Planning Associates | 1,786,468 | 1,480,238 | 20.7% |
| CHLAMG-Pathology | 1,569,154 | 1,457,930 | 7.6% |
| Golden Star Labs | 1,479,608 | NA | NA |
| Santa Clara Medical Center | 1,464,006 | 2,369,579 | -38.2% |
| Loma Linda University | 1,374,617 | 1,466,005 | -6.2% |
| Kaiser Foundation Hospital | 1,238,664 | 1,144,902 | 8.2% |
| Lucile Salter Packard | 1,139,659 | 939,383 | 21.3% |
| National Labs Inc. | 1,127,937 | NA | NA |
| County of San Bernardino | 1,092,410 | 1,189,664 | -8.2% |
| UC Davis Medical Center | 1,042,674 | 1,084,956 | -3.9% |
| Alameda Health System | 1,012,724 | 1,279,787 | -20.9% |
| Primex Clinical Labs | 1,009,413 | 2,027,159 | -50.2% |
| Total for Top 25 | $110,380,593 | $114,992,266 | -4.0% |
| 300+ other labs | $62,310,803 | $108,225,702 | -42.4% |
| **Grand Total, all Medi-Cal Labs** | **$172,691,397** | **$223,217,968** | **-22.6%** |

Source: California Dept. of Health Care Services

# Labcorp to Buy Empire City Labs for $250 Million

Labcorp has agreed to purchase select clinical lab assets of Empire City Laboratories (ECL-Brooklyn, NY).

ECL, which has 200+ employees, operates a CLIA-certified lab in Brooklyn that serves the greater New York City area. ECL is a routine testing lab—its highest volume tests include (CBC, comprehensive metabolic panels, A1C, lipid panels, etc.). Estimated annual revenue at ECL is $50-75 million. ECL was founded in 2005 by CEO Steve Nisan and COO Michael Nisan.

The purchase price for the transaction is up to $250 million, including $165 million payable at closing and up to $85 million of additional consideration contingent on performance. The transaction is anticipated to close in the first quarter of 2026.

Labcorp operates a major regional lab in northern New Jersey where ECL's test volumes could potentially be consolidated.

# Laboratory Alliance of Central New York

Under a separate deal, Labcorp has agreed to acquire Laboratory Alliance of Central New York (LACNY-Liverpool, NY) for an undisclosed amount. LACNY is an independent, for-profit, clinical and anatomic pathology laboratory that serves the Syracuse area.

LACNY, which has 300+ employees, is the exclusive provider of laboratory services for St. Joseph's Health and Crouse Health. It also provides laboratory services for the majority of physician practices in Central New York.

Crouse Health (Syracuse, NY) is the sole owner of LACNY, having acquired 100% ownership interest in January 2024. Before this change, the lab was co-owned by Crouse Health and St. Joseph's Health.

LACNY, which has 300+ employees, has estimated annual revenue of $25-50 million.

**Lab Acquisition Summary for 2025**

| *Date* | *Buyer* | *Target* | *Purchase Price ($ mill)* |
|---|---|---|---|
| Pending | Labcorp | Empire City Laboratories (Brooklyn, NY) | $250 |
| Pending | Labcorp | Laboratory Alliance of Central NY (Liverpool, NY) | NA |
| Pending | Labcorp | Community Health Systems outreach labs (Franklin, TN) | 195 |
| Oct-25 | Versant Diagnostics | SouthEastern Pathology (Rome, GA) | NA |
| Oct-25 | MDxHealth | ExoDx (Waltham, MA) | 15 |
| Sep-25 | Sonic Healthcare USA | Cairo Diagnostics (White Plains, NY) | NA |
| Sep-25 | Labcorp | BioReference Lab cancer testing business (Elmwood Park, NJ) | 225 |
| Aug-25 | Quest Diagnostics | Spectra Laboratories (Rockleigh, NJ) | 34 |
| Aug-25 | TridentCare | Shoreline Diagnostics (Irvine, CA) | NA |
| May-25 | Labcorp | North Mississippi Health Services outreach labs (Tupelo, MS) | NA |
| May-25 | Labcorp | Incyte Diagnostics lab assets (Spokane Valley, WA) | NA |
| Apr-25 | Principle Health Systems | Heartland Health Laboratory (Lenexa, KS) | NA |
| Mar-25 | EmeritusDX | PathMD Inc. (Los Angeles, CA) | NA |
| Apr-25 | NeoGenomics | Pathline (Ramsey, NJ) | 8.5 |
| Feb-25 | Hims & Hers Health | Trybe Labs (Kearny, NJ) | 5.0 |
| Feb-25 | Tempus AI | Ambry Genetics (Aliso Viejo, CA) | 692 |
| Jan-25 | Labcorp | MAWD Pathology's clinical lab and women's health (Lenexa, KS) | NA |

Source: Laboratory Economics

# Lab Stocks Up 27% YTD

Twenty-five lab stocks have increased an unweighted average of 27% year to date through November 14. In comparison, the S&P 500 Index is up 14%. Insight Molecular has jumped 211%, Guardant Health is up 209% and Adaptive Biotechnologies is up 135%. Quest Diagnostics is up 24% and Labcorp is up 16%.

| Company (ticker) | Stock Price 11/14/25 | Stock Price 12/31/24 | 2025 Price Change | Enterprise Value ($ millions) | Revenue for Trailing 12 mos. ($ millions) | Enterprise Value/ Revenue |
|---|---|---|---|---|---|---|
| Insight Molecular/Oncocyte (IMDX) | $7.40 | $2.38 | 211% | $196 | $4 | 44.6 |
| Guardant Health (GH) | 94.37 | 30.55 | 209% | 12,640 | 903 | 14.0 |
| Adaptive Biotechnologies (ADPT) | 14.10 | 6.00 | 135% | 2,150 | 253 | 8.5 |
| Exagen (XGN) | 9.01 | 4.10 | 120% | 197 | 64 | 3.1 |
| Tempus AI (TEM) | 68.48 | 33.76 | 103% | 12,760 | 1,105 | 11.5 |
| GeneDx (WGS) | 128.06 | 76.86 | 67% | 3,660 | 402 | 9.1 |
| Fulgent Genetics (FLGT) | 29.10 | 18.47 | 58% | 115 | 316 | 0.4 |
| Personalis (PSNL) | 7.51 | 5.78 | 30% | 558 | 69 | 8.1 |
| Natera (NTRA) | 204.28 | 158.30 | 29% | 27,350 | 2,117 | 12.9 |
| Castle Biosciences (CSTL) | 33.45 | 26.65 | 26% | 726 | 344 | 2.1 |
| Quest Diagnostics (DGX) | 186.95 | 150.86 | 24% | 26,880 | 10,850 | 2.5 |
| Exact Sciences (EXAS) | 67.03 | 56.19 | 19% | 14,230 | 3,082 | 4.6 |
| Labcorp (LH) | 266.89 | 229.32 | 16% | 28,130 | 13,765 | 2.0 |
| Caris Life Sciences (CAI) | 23.85 | 21.00 | 14% | 6,400 | 649 | 9.9 |
| 23andMe (MEHCQ) | 3.26 | 3.25 | 0% | 77 | 175 | 0.4 |
| Veracyte (VCYT) | 39.35 | 39.60 | -1% | 2,780 | 495 | 5.6 |
| Opko Health (OPK) | 1.28 | 1.47 | -13% | 966 | 642 | 1.5 |
| Sonic Healthcare (SHL.AX)* | 21.32 | 27.01 | -20% | 15,180 | 9,650 | 1.6 |
| CareDx (CDNA) | 15.94 | 21.41 | -26% | 653 | 358 | 1.8 |
| Aspira Women's Hlth (AWHL) | 0.51 | 0.71 | -28% | 21 | 9 | 2.5 |
| NeoGenomics (NEO) | 10.34 | 16.48 | -37% | 1,580 | 709 | 2.2 |
| Myriad Genetics (MYGN) | 6.71 | 13.71 | -51% | 692 | 825 | 0.8 |
| ProPhase Labs (PRPH) | 0.28 | 0.76 | -63% | 19 | 6 | 3.5 |
| Interpace Biosciences (IDXG) | 0.98 | 2.70 | -64% | 5 | 42 | 0.1 |
| Biodesix (BDSX) | 8.00 | 30.60 | -74% | 121 | 80 | 1.5 |
| **Totals & Averages** | | | **27%** | **$158,087** | **$46,914** | **3.4** |

*Sonic Healthcare's figures are in Australian dollars

Source: Laboratory Economics from SeekingAlpha.com