

LABORATORY *e* ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

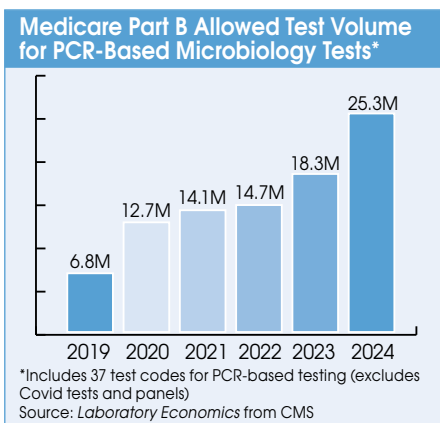
RESULTS Act Gaining Traction in House Energy & Commerce Committee

The new PAMA reform bill (RESULTS Act: H.R. 5269/S. 2761) now has the support of 22 members of the House and two Senators. Importantly, nine supporting Reps. are members of the House Committee on Energy and Commerce, which has a total of 54 members and is one of the most powerful committees in the U.S. Congress. In addition, the staff from Committee Chairman Brett Guthrie (R-KY) has requested that the Congressional Budget Office (CBO) score the bill. A CBO score (aka cost estimate) is a necessary step to move the bill forward. Despite the progress, laboratory policy expert Dennis Weissman notes that the RESULTS Act faces an uphill battle, especially given the Trump administration's focus on healthcare spending cuts. *More details on page 3.*

PCR-Based Microbiology Tests Continue to Boom

PCR-based microbiology testing (excluding Covid) continues to be the fastest-growing test segment, according to the latest data from CMS. During the five-year period from 2019-2024, Medicare Part B carrier allowed claims for PCR-based tests grew by 30% per year to reach 25.3 million tests. The growth in PCR testing has occurred despite Part B claim denial rates that average nearly 20%.

Full details on page 5.



Can Pathology Labs Waive TC Charges To Win Hospital Contracts?

The short answer is "Yes," based on a recent court decision. On September 23, a federal District Court in Tennessee dismissed a lawsuit brought by two pathologists, Jason Nolan, MD and Meiklejohn McKenzie, DO, against HCA Healthcare and a competing laboratory, PathGroup (Brentwood, TN). The pathologists were co-owners of Pathologists' Laboratory PC (PLPC) which had for decades been the exclusive anatomic pathology services provider for two HCA Hospitals (TriStar Summit Medical Center and TriStar Hendersonville Medical Center). *Cont'd on page 2.*

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CAN PATHOLOGY LABS WAIVE TC CHARGES (*cont'd from page 1*)

The trouble started when Medicare's direct payments to independent pathology labs for the technical component (TC) of anatomic pathology testing provided to hospital patients ended on July 1, 2012. This was the final step in phasing out a "grandfather" clause that had previously allowed some independent labs to bill Medicare directly for TC, or slide-prep, services to hospital patients.

Medicare would continue to reimburse pathologists directly for professional component (PC), or slide-interpretation, services. However, with the expiration of the grandfather clause, independent pathology labs that provided TC services for hospital patients could no longer directly bill traditional Medicare. Instead, they had to negotiate contracts with their hospital clients for TC payment, which generally led to lower TC reimbursement rates.

CMS warned hospitals that if they "were to condition, express or implied, the referral of physician pathology services to a clinical laboratory," on the lab's agreement to accept less than fair market for the TC, that could violate federal anti-kickback laws. The HCA hospitals complied with the new rule by agreeing to reimburse PLPC for the TC charges for traditional Medicare patients.

Meanwhile, other insurers (e.g., Medicare Advantage, TennCare and Blue Cross) continued to reimburse PLPC for TC charges for a few years after the new CMS rule went into effect. But other insurers stopped making TC payments to independent labs serving hospital patients in early 2018. Once this happened, PLPC demanded that the HCA hospitals start paying these costs instead. The HCA hospitals refused. The HCA hospitals took the position that PLPC was responsible for incurring or paying the TC charges for patients covered by other insurers.

Contract Stalemate

Negotiations ensued in 2019. The HCA hospitals offered "to negotiate a single [TC] schedule that would apply to all PLPC's anatomic pathology services, regardless of payer...calculated as a percentage of the Medicare rate." The HCA hospitals "generally considered fair market value" for the TC charges to be between 50% and 100% of the Medicare rate," whereas PLPC "suggested 80% of the Medicare rate." HCA also suggested that "PLPC consider merging with PathGroup." Ultimately, however, the HCA hospitals and PLPC could not reach an agreement for patients covered by other insurers.

Switch to PathGroup and Subsequent Lawsuit

On September 1, 2019, the two HCA hospitals each replaced PLPC with PathGroup as their new anatomic pathology provider. On November 2020, PLPC filed a whistleblower lawsuit alleging that PathGroup was willing to provide the free TC services to other insurers that HCA demanded. Furthermore, PLPC alleged that the HCA hospitals reimbursed PathGroup "for just 60% of the Medicare rate" for TC services provided to hospital patients covered by traditional Medicare. As a result, the two PLPC pathologists alleged that the HCA hospitals received an illegal kickback from PathGroup in exchange for anatomic pathology referrals. Both the United States and Tennessee declined to intervene as parties to this case.

Normal Marketplace Competition

In his September 22 ruling, District Judge Waverly D. Crenshaw, Jr., stated that the lawsuit did not cite any reason why HCA had any obligation to pay for the TC costs for Medicare Advantage and other insurer beneficiaries. What the lawsuit actually describes is "normal marketplace competition," according to Judge Crenshaw. Once other insurers stopped paying the TC charges, "the HCA hospitals simply bet on the market that they could find a lab who would cover those charges instead....When PLPC put its foot down and required the hospitals to pay the TC charges, the hospitals sent their patients to PathGroup....These business practices reflect the market functioning as expected." Judge Crenshaw granted HCA's Motion to Dismiss.

The court decision can be found here **No. 3:20-cv-00978**.

RESULTS ACT GAINING TRACTION (*cont'd from page 1*)

Without new legislation, Medicare CLFS rate cuts of up to 15% for roughly 800 lab tests will take effect on January 1, 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 by March 31, 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.

The RESULTS Act would freeze Medicare CLFS rates at current levels through 2028. It would also revamp the way that future CLFS rates (2029 and beyond) are calculated to ensure that data from highly reimbursed hospitals outreach labs are accurately represented (see *LE*, September 2025).

Meanwhile, Weissman, who heads the eponymous Dennis Weissman & Associates (Falls Church, VA), notes that the estimated cost of the RESULTS Act would fall under “PayGo” regulations and need to be offset by spending cuts or revenue increases elsewhere. “The lab industry needs a few powerful political angels on their side to help the RESULTS Act get inserted into a year-end healthcare or budget package,” notes Weissman.

Right now, the most powerful advocates of the RESULTS Act are Rep. Richard Hudson (R-NC), who introduced the bill, and E&C health subcommittee chair, Morgan Griffith (R-VA), who has expressed an interest in potentially holding a hearing on PAMA reform.

The Government Shutdown

Congressional offices remain open and most meetings will continue despite the shutdown, notes Erin Morton, Washington Representative for the National Independent Laboratory Association and Partner at CRD Associates (Washington, DC). Morton notes that NILA and 10 of its member labs lobbied their Congressional representative and staff on September 16 about the RESULTS Act. “The key is to paint a picture with specific examples of how the PAMA cuts will hurt lab service for Medicare beneficiaries,” notes Morton.

Stop Lab Cuts

Raising our collective voices on the urgent need to address pending Medicare cuts and foundational reform to PAMA to stabilize the payment system is essential to our advocacy efforts, notes ACLA President Susan Van Meter. To this end, ACLA has developed a quick and pain-free app that allows lab professionals to contact their Senate and House Representatives: <https://stoplabcuts.org/>

Key Supporters of RESULTS Act (as of October 8, 2025)

Supporters	Date Supported	Key Committees
Rep. Richard Hudson (R-NC)	9/10/2025	House Energy & Commerce
Rep. Scott H. Peters (D-CA)	9/10/2025	House Energy & Commerce
Rep. Gus M. Bilirakis (R-FL)	9/10/2025	House Energy & Commerce
Rep. Earl L. “Buddy” Carter (R-GA)	9/10/2025	House Energy & Commerce
Rep. John Joyce (R-PA)	9/10/2025	House Energy & Commerce
Rep. Troy Balderson (R-OH)	9/10/2025	House Energy & Commerce
Debbie Dingell (D-MI)	10/3/2025	House Energy & Commerce
Neal P. Dunn (R-FL)	10/3/2025	House Energy & Commerce
Jake Auchincloss (D-MA)	10/6/2025	House Energy & Commerce

Source: Congress.gov

RESULTS Act Could Give CLFS Rates a Boost

Although passage into law may be a long shot, The RESULTS Act could provide a rate hike to many routine tests on the Medicare Clinical Laboratory Fee Schedule (CLFS), according to an analysis by *Laboratory Economics*. Specifically, the inclusion of hospital outreach lab private-payer test volumes and rates would have an outsized positive impact on rate setting.

The RESULTS Act would direct CMS to use an independent, not-for-profit commercial claims database (e.g., The FAIR Health Database) to calculate weighted median private payer rates from January 1 – June 30, 2027. CMS would use this data to set Medicare rates for CLFS tests for 2029-2032. Using data from a comprehensive claims database would help ensure that higher-paid hospital outreach lab tests, representing an estimated ~20% of the total non-patient lab market, are more accurately represented in future rate calculations. Only 21 hospitals (out of a potential 3,000+ hospitals) participated in the first PAMA private-payer survey, which led to rate cuts of ~30% for most CLFS tests in 2018-2020.

Hospital outreach lab test reimbursement rates can be 5-10x higher than those paid to independent labs. The table below helps illustrate the big positive influence that including hospital outreach lab rates could have in future CMS/PAMA private payer rate surveys and Medicare CLFS rate calculations.

Hypothetical Medicare Rates Based on Blended Independent Lab and Hospital Outreach Lab Private-Payer Rates

CPT/Description	Est'd Median In-Network Independent Lab & POL Rate (80% weight)	Est'd Median In-Network Hospital Out- reach Lab Rate (20% weight)	Blended In- Network Rate*	2025 Medi- care Rate	Differ- ence**
80048/Basic metabolic panel	\$8.10	\$87.30	\$23.94	\$8.46	183%
80053/Comp metabolic panel	10.80	107.10	30.06	10.56	185%
80061/Lipid panel	13.50	51.30	21.06	13.39	57%
80307/Drug test(s), presumptive	61.20	372.60	123.48	62.14	99%
81162/BRCA1&2 seq & full dup/del	1,346.40	3,144.60	1706.04	1,824.88	-7%
81455/Targeted genomic seq	2,284.20	3,644.10	2556.18	2,919.60	-12%
81528/Colorectal screen (Cologuard)	396.00	NA	396.00	508.87	-22%
82306/Vitamin D 25 hydroxy	27.00	72.00	36.00	29.60	22%
82607/Vitamin B-12	13.50	64.80	23.76	15.08	58%
83036/Glycosylated hemoglobin (A1C)	9.00	52.20	17.64	9.71	82%
83970/Assay of parathormone	33.30	205.20	67.68	41.28	64%
84153/PSA total	13.50	94.50	29.70	18.39	62%
84443/Thyroid stim hormone (TSH)	15.30	66.60	25.56	16.80	52%
85025/Complete CBC w/auto diff WBC	7.20	68.40	19.44	7.77	150%
87798/Detect agent NOS by PCR	24.30	146.70	48.78	35.09	39%
G0483/Drug test def 22+ classes	262.80	505.80	311.40	246.92	26%
Unweighted Avg. for 16 tests					65%

*Based on 80% of In-Network Independent Laboratory & POL Rates and 20% of In-Network Hospital Outreach Laboratory Rates

**Our analysis uses a blended average (80% independents/20% hospitals) as opposed to the weighted median used by CMS/PAMA survey

PCR-BASED MICROBIOLOGY TEST VOLUME BOOM (*cont'd from page 1*)

The fastest-growing PCR-based test is CPT 87634 (RSV), which went from 5,049 Medicare Part B allowed services in 2019 to 148,837 in 2024 (97% per year). Labs performing the highest volume of CPT 87634 include Yellowstone Labs (Dallas, TX), USA Biosciences (Torrance, CA), CDR Laboratories (Doral, FL) and GMI Laboratories (North Hollywood, CA).

The second fastest-growing test was CPT 87631 (Respiratory virus 3-5 targets), which grew by 67% per year to reach 257,780 Part B tests in 2024. Labs performing the highest volume of CPT 87631 include Yellowstone Labs, HealthTrackRx (Denton, TX) and Texas Molecular Diagnostics Laboratory (Irving, TX)

CPT 87498 (enterovirus) grew by 67% per year to reach 112,784 Part B tests in 2024. Labs performing the highest volume of CPT 87498 include Yellowstone Labs, GMI Laboratories and Texas Molecular Diagnostics Laboratory.

The highest-volume PCR-based test is CPT 87798 (infectious agent detection by PCR, not otherwise specified). CPT 87798 grew by 38% per year to reach 12.7 million Part B tests in 2024. Labs performing the highest volume of CPT 87798 include SilverPath Inc. (Bluebell, PA), Yellowstone Labs and CAP Diagnostics (dba Pathnostics-Lake Mary, FL).

Top 20 Fastest-Growing PCR Tests by Medicare Part B Carrier Allowed Volume (2019-2024)

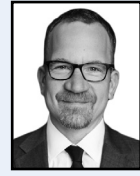
CPT Code	Description	2024 Medicare Part B Volume	2019 Medicare Part B Volume	5-Year CAGR*
87634	RSV by PCR	148,837	5,049	97%
87631	Respiratory virus 3-5 targets by PCR	257,780	19,653	67%
87498	Enterovirus by PCR	112,784	8,606	67%
87556	Mycobacteria tuberculosis by PCR	99,954	10,908	56%
87541	Legionella pneumophila by PCR	169,242	23,058	49%
87481	Candida by PCR	2,949,068	432,924	47%
87651	Strep A by PCR	721,000	115,681	44%
87506	Gastrointestinal pathogen 6-11 targets	35,375	5,685	44%
87798	Detect agent NOS by PCR	12,743,732	2,591,912	38%
87640	Staph A by PCR	875,946	202,502	34%
87653	Strep B by PCR	806,718	196,198	33%
87641	Staphylococcus aureus, methicillin resistant	486,835	123,852	31%
87150	Culture typing by PCR	1,458,096	375,045	31%
87500	Vancomycin by PCR	632,493	166,758	31%
87581	Mycoplasma pneumoniae by PCR	277,738	79,901	28%
87486	Chlamydia pneumoniae by PCR	272,342	80,724	28%
87532	Herpes virus-6 by PCR	58,268	17,711	27%
87502	Influenza virus by PCR	295,234	109,240	22%
87801	Detect agent, multiple organisms	707,923	274,081	21%
87529	Herpes simplex virus (HSV) by PCR	222,109	96,397	18%
87551	Mycobacteria by PCR	29,301	13,022	18%
87511	Gardnerella vaginalis by PCR	92,895	44,046	16%
	Total for Top 20 PCR Tests	23,331,475	4,935,885	36%
	Grand Total for All PCR Tests	25,272,101	6,784,432	30%

*CAGR (Compound annual growth rate)

Source: Medicare Part B Carrier Data, 2019-2024

HealthTrackRx Opens Major Lab at UPS Labport

HealthTrackRx (Denton, TX), which specializes in PCR testing for infectious diseases, recently opened a \$45.5 million, 40,000-square-foot lab in Louisville at UPS Labport. UPS Labport, which is located three miles away from UPS's global air hub at Louisville Muhammad Ali International Airport, leases space to lab companies and fast-tracks specimen delivery for immediate processing. *Laboratory Economics* spoke with HealthTrackRx CEO Martin Price about the new lab which opened in September.



Martin Price

How many laboratories does HealthTrackRx operate and how many employees do you have?

We operate four labs, one in Southern California, one in Dallas, our new central lab in Louisville and a lab in southern Indiana. Our team includes about 600 employees, and about 250 of these work at our Louisville lab. Together, these facilities provide a national testing capacity of more than 100,000 PCR tests per day.

Is the new laboratory at UPS Labport used only to process specimens?

We are performing full pre-analytical and analytical testing there. The majority of our patient specimens run through the Labport facility. Our goal in developing this lab was to reduce turnaround time for infectious disease testing so that clinicians could have results by the next morning, enabling them to prescribe the correct antibiotic, if needed at all, and avoid repeat visits.

We were introduced to this unique program at UPS Healthcare about 2½ years ago. UPS was looking to bring more diagnostic work to Louisville, and we became their flagship tenant at Labport. We receive specimens by 1 a.m. All processing is done overnight, and results are delivered electronically by the next morning to the 10,000 or so providers who send us samples.

How much turnaround time is saved as a result of the location of the new laboratory?

The UPS HealthCare overnight extraction program and our integrated lab at LabPort versus delivering a sample by other methods saves about a day. In testing for acute infections, which is our specialty, every minute makes a difference. The faster we can put answers in clinicians' hands, the sooner they are able to impact therapy.

We have 10,000 to 15,000 specimens delivered around the same time each night. We've been able to reduce our batch processing time from about 10 hours to under 7 hours, which allows us to get results to clinicians the next morning. At Labport we have the capacity to process 30,000 samples in under 7 hours.

What's on the test menu at the new laboratory at UPS Labport?

Our primary menu is PCR testing for respiratory, genitourinary and UTI. We also offer curated testing for wound, gastro, ear, eye. It's head to toe. If you can swab it, we can test it. We receive about 50% of our patient specimens through urgent care facilities. Our next largest call points are pediatrics, FQHCs (federally qualified health centers) and women's health. Those three make up about 85% of our customers.

What's causing the boom in PCR test volume across the United States?

The way most people have typically experienced infection detection and therapy is empiric treatment. A patient presents at a physician's office with what appears to be an infection. Most patients leave with a prescription for an antibiotic and hope it works. If they return after a few days because the antibiotic didn't work, the physician reflexes to culture and susceptibility – which can take anywhere from 3 to 14 additional days.

With PCR testing you know a definite answer, right away, and what treatment is needed to get better. This is game changing not only for the patient, but for the community.

PCR testing typically can be performed for less than \$150, often comparable to the cost of traditional cultures, and significantly less than the downstream costs of repeat urgent care visits and multiple prescriptions.

Is HealthTrackRx planning to expand further?

We are looking at where rapid intervention can make a critical therapeutic difference, such as allergy testing, blood testing and prenatal testing. We can expand capacity within our existing footprint by 3x. Currently we have about 18 test menu areas in infectious disease. We are looking at adding more tests to the menu.

What are your thoughts on the lab-developed test lawsuit win in March of this year?

It was critical for the lab industry because innovation sits in the laboratory. The only way to bring cutting-edge diagnostics to patients is through the LDT model. Being able to protect that and ensure that testing is of the highest quality is paramount. Our ability to deliver cutting-edge therapeutics would grind to halt without LDTs. Each of our labs is CLIA and CAP certified and offer a mix of both LDT and FDA-cleared testing. Beyond that, our concern is coverage policies, whether Medicare, Medicaid or commercial that have established a de facto FDA requirement for some tests. While the lawsuit was critical for the lab industry, it is not the end of the battle. Now is the time for coverage policies to keep pace with advances in technology and ensure access to timely, clinically appropriate treatment for infection.

NOTE: The American Clinical Laboratory Association (ACLA) and HealthTrackRx filed a lawsuit against the FDA challenging the Agency's May 2024, Final Rule which sought to regulate LDTs as medical devices. The U.S. District Court for the Eastern District of Texas vacated the Final Rule in its entirety in March 2025 and the FDA chose not to appeal (see *LE*, April 2025).

BillionToOne Seeks to Raise \$100 Million from IPO

BillionToOne (Menlo Park, CA) has filed with the SEC to raise up to \$100 million from an initial public offering (IPO). BillionToOne 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.

In 2019, the company launched a prenatal blood test (branded UNITY Fetal Risk Screen) that uses cell-free DNA to provide fetal risk assessment for sickle cell disease and cystic fibrosis without requiring amniocentesis. The current CLFS price 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.

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, which has 620 employees, has accumulated total losses of \$286 million since being founded in 2016.

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Northwestern Medicine Moves Toward AI in Digital Pathology

Northwestern Medicine (Chicago) has announced a strategic collaboration with PathAI (Boston) to transform pathology diagnostics through artificial intelligence (AI). *Laboratory Economics* spoke with Daniel J. Brat, MD, PhD, Chair of Pathology at Northwestern Medicine, to find out more.



Daniel J. Brat,
MD, PhD

When did Northwestern Medicine first start digitizing slides for primary clinical diagnosis?

We started in November 2024 at one of our large community-based hospitals, Northwestern Medicine Central DuPage Hospital, and then started at our academic medical center, Northwestern Memorial Hospital, which went live about a month later with gastrointestinal biopsies. We are an 11-hospital integrated academic healthcare system, and digital pathology and AI are critical for us as we see this as an important way to ensure quality, maintain standards and share cases across our system. We have scanners at most of our hospitals and are in various stages of going live, except for one. One of our hospitals in the northern suburbs is putting in a new laboratory, so they'll wait to go live with digital pathology until they're done.

Which type of scanners are you using? How many do you have?

We use Aperio GT 450s. We have 14 across our system right now, five at our central academic hospital, four at Northwestern Medicine Central DuPage Hospital, and one each at our smaller community-based hospitals.

How many pathologists are at Northwestern Medicine?

We have about 90 pathologists, including 55 at our downtown academic hospital (Northwestern Memorial Hospital).

Is this being used primarily for diagnostics or for research?

We use slide scanning for both diagnostics and research. We have a very active computational pathology group here at Northwestern Medicine, with world leaders in digital pathology and AI led by Lee Cooper, PhD, and our medical director, Jeff Goldstein, MD, PhD. We are actively engaged in many areas of research, including predicting breast cancer outcomes, prostate cancer diagnosis, and characterizing placental pathology using AI. Our more recent rollout of digital pathology and AI at each of the hospitals is for clinical diagnostic work.

What is your goal for getting all pathologists switched to digital slide reads?

We don't have a specific goal but appreciate the flexibility of virtual sign-out of cases and the future possibility of streamlining diagnostics so that pathologists will see the value of digital pathology and AI that is not always apparent to everyone.

The shift to digital pathology will be hospital-dependent, pathologist-dependent and specimen-dependent. There is a lot of variability in the types of specimens we see in pathology, and some are more challenging for efficient review by digital images. Size is an important variable. Small biopsies, such as gastrointestinal, prostate and gynecological, are fairly amenable to using digital pathology for remote sign out. Cases that have many slides for review and large tissue sections on each slide may not be reviewed as efficiently right now.

A lot has to do with the size of the images generated on each specimen. Our scans are performed 20x magnification and because of that the file size is enormous, about 4 gigabytes, and it takes a long time to visualize those images and to zoom in and out of regions of interest. Using glass slides on a microscope might be more efficient for these large cases for many pathologists. These are also the type of cases that AI will add the most value when more fully developed and implemented.

Said in another way, I think the full value of digital pathology will come with more complete integration of artificial intelligence. Until that time, I think there's going to be a lot of individual variations in preference. My goal is to provide digital pathology capabilities that allow flexibility in sign out, whether remote or on-site. I can see how that might be attractive for future recruitment where pathologists can sign out from home. When we add the viewer and management system of PathAI, I believe our workflows will be much more efficient, since their viewing system is much more user-friendly. If the image management and viewing capability is fluid and seamless, there will be many more adopters.

What percentage of your pathologists are using digital pathology now?

Only about 15 of our pathologists are using digital pathology right now, and the adoption depends on the hospital. At Northwestern Medicine Central DuPage Hospital, there are quite a few younger pathologists who were hungry to incorporate digital pathology into their practice. At our academic medical center, we only have it validated for gastrointestinal, genitourinary and placental pathology right now. We hope to implement the PathAI viewer within the next six months, and we think that will be a game changer.

Where are you storing the digital slide images (in-house system or cloud-based storage)?

We are currently using the Northwestern Medicine data center in-house. The future will potentially involve some cloud-based and some on-site. Part of the value of digital pathology is that image retrieval is much more rapid and efficient than retrieving glass slides, sometimes from a distant warehouse.

Which types of cases will you apply AI to first?

AI incorporates many capabilities. Some people think that new AI algorithms will be able to diagnose diseases based on digital images, and this may be true at some point, but we're not there yet. What it can do is provide a quality assurance function with its capability to detect very small amounts of cancer that might be missed by visual inspection. I can also imagine incorporating algorithms that can point out hot spots of interest in the images where pathologists should pay attention. There are also capabilities for quantitating IHC stains, like proliferation, HER2+, PD-L1, and other biomarkers and potentially for detecting infectious organisms in tissue.

The choice of AI algorithms will be based on improving efficiencies and accuracy of diagnosis, and those will be the algorithms we implement first. We will talk to our pathologists to determine which offerings from PathAI they feel will be most useful. Importantly, these AI algorithms do have a cost associated with them. We will move forward cautiously as we implement AI algorithms.

How do you think using digital pathology and AI will improve diagnostics?

I think it will improve our ability to share cases around our system, and it will increase our ability to maintain quality assurance with algorithms like PathAI's TumorDetect. I think getting images to pathologists will be much quicker. It will improve efficiency, it will reduce turnaround time, and it will increase quality.

Do you anticipate purchasing more scanners?

Yes. We currently don't have the capacity to scan all of our slides on a daily basis at our downtown academic medical center. We expect to get five more scanners in the near future. At this point, we're not trying to digitize everything and are scanning only those slides that will be used to sign out cases. At the academic medical center, we are taking a biopsy first approach to digital pathology and AI.

At Northwestern Medicine Central DuPage Hospital, they are using it for all types of cases. We want to have flexibility and let those pathologists who find it useful to have digital pathology at their disposal. It's all about adding value to their practice. We aren't going to force it on anyone, but I am sure that we will have more and more users as time goes by. There is definitely a generational aspect to the rollout of digital AI.

Northwestern Medicine Has Nation's Biggest Laboratory Outreach Business

Northwestern Medicine (Chicago, IL) has the nation's largest hospital-based outreach laboratory testing business based on combined Medicare Clinical Laboratory Fee Schedule and Physician Fee Schedule payments for 2024. This data focuses on pure nonpatient outreach testing and excludes hospital outpatient and inpatient testing.

Northwestern Medicine had total Medicare CLFS payments of \$33.4 million and PFS payments of \$1.7 million in 2024. Total outreach testing revenue from all payers was an estimated \$281 million. This estimate assumes that Medicare CLFS and PFS payments represent 12.5% of overall outreach testing revenue.

Northwestern Medicine hospitals operating the biggest outreach labs include Central DuPage Hospital (Winfield, IL) and Northwestern Memorial Hospital (Chicago, IL).

Top 25 Hospital-Based Outreach Laboratory Businesses in 2024

<i>Health System</i>	<i>Total Medicare CLFS Payments for 2024</i>	<i>Total Medicare Pathology PFS Payments for 2024</i>	<i>Grand Total Medicare</i>	<i>Estimated Annual Size of Laboratory Outreach Business 2024 (8 x Medicare Allowed Payment)</i>
Northwestern Medicine (Chicago, IL)	\$33,398,256	\$1,683,377	\$35,081,633	\$280,653,064
CommonSpirit Health (Chicago, IL)	27,505,565	2,717,673	30,223,238	241,785,904
Trinity Health (Livonia, MI)	24,606,669	1,885,870	26,492,539	211,940,312
Cleveland Clinic Health System (Cleveland, OH)	21,929,242	806,901	22,736,143	181,889,144
Mass General Brigham (Boston, MA)	18,856,954	2,939,705	21,796,659	174,373,272
Penn Medicine (Philadelphia, PA)	16,241,260	3,468,082	19,709,342	157,674,736
Corewell Health (Grand Rapids, MI)	18,200,580	725,113	18,925,693	151,405,544
Advocate Health Care (Charlotte, NC)	16,859,995	1,248,264	18,108,259	144,866,072
Beth Israel Lahey Health (Cambridge, MA)	16,574,934	1,236,811	17,811,745	142,493,960
AdventHealth (Altamonte Springs, FL)	17,077,785	576,645	17,654,430	141,235,440
Endeavor Health (Evanston, IL)	16,579,736	891,490	17,471,226	139,769,808
UPMC (Pittsburgh, PA)	14,946,461	1,811,901	16,758,362	134,066,896
Bon Secours Mercy Health (Cincinnati, OH)	15,317,743	438,638	15,756,381	126,051,048
University of Texas System (Dallas, TX)	7,794,269	7,683,399	15,477,668	123,821,344
University of California Health (Oakland, CA)	12,068,325	2,424,985	14,493,310	115,946,480
BJC HealthCare (Saint Louis, MO)	13,198,452	619,690	13,818,142	110,545,136
HCA Healthcare (Nashville, TN)	12,478,863	882,190	13,361,053	106,888,424
Sutter Health (Sacramento, CA)	11,402,399	1,539,856	12,942,255	103,538,040
Community Health Systems (Franklin, TN)	12,252,653	538,679	12,791,332	102,330,656
Providence (Renton, WA)	10,684,780	1,276,680	11,961,460	95,691,680
WellSpan Health (York, PA)	11,269,359	660,861	11,930,220	95,441,760
UCHealth (Aurora, CO)	11,215,583	460,548	11,676,131	93,409,048
Geisinger (Danville, PA)	11,210,510	351,240	11,561,750	92,494,000
Yale New Haven Health (New Haven, CT)	10,043,573	1,143,428	11,187,001	89,496,008
Saint Luke's University Health (Bethlehem, PA)	9,917,045	562,681	10,479,726	83,837,808
Total for Top 25 Health Systems	391,630,991	38,574,707	430,205,698	3,441,645,584
Total for All Health Systems	\$1,432,741,838	\$124,816,528	\$1,557,558,366	\$12,460,466,928

Source: *Laboratory Economics* from hospital cost reports and Medicare OPPS claims data for 2024

Sonic's Goldschmidt to Retire

Sonic Healthcare Limited (Sydney, Australia) has announced that Managing Director and Chief Executive **Dr. Colin Goldschmidt**, age 71, will retire at the company's Annual General Meeting on November 20, 2025.

Goldschmidt, who is a pathologist, has been Sonic's CEO since 1993 and has managed the company's growth from a single laboratory in Sydney to becoming the third largest medical diagnostics company in the world. Today, Sonic has annual worldwide revenue of USD \$6.4 billion and is the largest laboratory company in Australia and Europe and the third-largest full-service lab in the U.S.



Dr. Colin Goldschmidt



Dr. Jim Newcombe

Dr. Jim Newcombe, age 46, is set to become Sonic's new Managing Director and CEO. Newcombe, who is a pathologist, joined Sonic eight years ago and is currently the CEO of Douglass Hanly Moir Pathology in Sydney, Sonic's founding practice and one of its largest laboratories globally.

Versant Buys SouthEastern Pathology

Versant Diagnostics (Grapevine, TX) has acquired Southeastern Pathology (Rome, GA) for an undisclosed amount. Southeastern Pathology has a total of 48 employees, including eight pathologists, and operates a CAP-accredited laboratory in Rome, GA (about 70 miles north of Atlanta). The lab performs histology, IHC, special stains and some molecular testing in house.

SouthEastern Pathology President Frederick Swiger Jr, MD, and his partner Christopher Kligora, MD, will continue in their current roles.

Versant was founded by Ven Aduana, MD, Jim Billington and Brian Carr in 2021 (see *LE*, November 2021). Versant was funded with \$100 million (both equity and debt) from Iron Path Capital (Nashville, TN). Versant has now acquired 10 pathology practices with a combined 70+ pathologists.

Versant Diagnostics Acquisition History

Acquisition Date	Laboratory Name	# Pathologists
Oct-25	SouthEastern Pathology (Rome, GA)	8
Dec-24	Avero Diagnostics/Northwest Pathology (Bellingham, WA)	8
Aug-24	Cutaneous Pathology (Winston-Salem, NC)	2
May-24	Associate Pathologists (Joliet, IL)	4
Oct-23	Dahl-Chase Pathology (Bangor, ME)	15
May-23	PRW Laboratories (Charlottesville, VA)	8
Jun-22	Pathology Consultants of Chicago (Chicago, IL)	1
Jun-22	Elgin Laboratory Physicians (Elgin, IL)	1
Oct-21	Alliance Pathology Consultants (Elk Grove Village, IL)	15
Oct-21	Addison Central Pathology (Chicago, IL)	12

Source: *Laboratory Economics*

MDxHealth Buys ExoDx Test Business

MDxHealth (Irvine, CA) has completed its acquisition of the ExoDx business from Bio-Techne Corp. (Minneapolis, MN) for \$15 million. The acquisition includes the ExoDx Prostate IntelliScore (EPI) test and a CLIA-certified laboratory in Waltham, MA. The EPI test is a urine-based assay for early detection of high-grade prostate cancer used as an aid in deciding the need for biopsy in men with grey-zone prostate specific antigen (PSA) scores. The EPI test is reimbursed by Medicare at \$760 through the Proprietary Laboratory Analysis (PLA) code 0005U.

Lab Stocks Jump 22% YTD

Twenty-five lab stocks have increased an unweighted average of 22% year to date through October 10. In comparison, the S&P 500 Index is up 11%. Tempus AI has jumped 186%, Exagen is up 167% and Adaptive Biotechnologies is up 153%. Quest Diagnostics is up 22% and Labcorp is up 21%.

Company (ticker)	Stock Price 10/10/25	Stock Price 12/31/24	2025 Price Change	Enterprise Value (\$ millions)	Revenue for Trailing 12 mos. (\$ millions)	Enterprise Value/ Revenue
Tempus AI (TEM)	\$96.39	\$33.76	186%	\$17,310	\$952	18.2
Exagen (XGN)	10.95	4.10	167%	236	59	4.0
Adaptive Biotechnologies (ADPT)	15.17	6.00	153%	2,310	205	11.3
Guardant Health (GH)	64.22	30.55	110%	8,820	829	10.6
Caris Life Sciences (CAI)	30.48	21.00	45%	8,270	534	15.5
GeneDx (WGS)	121.72	76.86	58%	3,480	362	9.6
Insight Molecular/Oncocyte (IMDX)	3.89	2.38	63%	90	4	21.0
23andMe (MEHCQ)	3.62	3.25	11%	87	175	0.5
Quest Diagnostics (DGX)	184.07	150.86	22%	26,770	10,522	2.5
Labcorp (LH)	277.88	229.32	21%	29,060	13,483	2.2
Fulgent Genetics (FLGT)	22.51	18.47	22%	-85	303	NA
Natera (NTRA)	169.27	158.30	7%	22,410	1,964	11.4
Personalis (PSNL)	8.12	5.78	40%	590	80	7.3
Exact Sciences (EXAS)	58.34	56.19	4%	12,720	2,940	4.3
Opko Health (OPK)	1.51	1.47	3%	1,330	664	2.0
Sonic Healthcare (SHL.AX)*	21.57	27.01	-20%	15,180	9,650	1.6
Castle Biosciences (CSTL)	23.08	26.65	-13%	431	346	1.2
Veracyte (VCYT)	34.80	39.60	-12%	2,470	479	5.2
Aspira Women's Hlth (AWHL)	0.56	0.71	-21%	25	9	2.7
CareDx (CDNA)	14.39	21.41	-33%	609	341	1.8
ProPhase Labs (PRPH)	0.53	0.76	-30%	30	6	5.3
Myriad Genetics (MYGN)	7.50	13.71	-45%	778	833	0.9
NeoGenomics (NEO)	9.10	16.48	-45%	1,420	689	2.1
Interpace Biosciences (IDXG)	0.98	2.70	-64%	7	46	0.2
Biodesix (BDSX)	7.32	30.60	-76%	110	77	1.4
Totals & Averages			22%	\$154,457	\$45,552	3.4

*Sonic Healthcare's figures are in Australian dollars

Source: Laboratory Economics from SeekingAlpha.com



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The Data is Presented in a User-Friendly Excel Spreadsheet and Includes:

- Hospital Name
- Complete Address
- Health System Affiliation
- Total Laboratory Outpatient Charges (2024)
- Hospital-Specific Annual Medicare Part B Clinical Laboratory Payments for Outreach (2024)
- Hospital-Specific Annual Medicare Part B Anatomic Pathology Payments for Outreach (2024)
- Overall Estimated Annual Clinical Lab & Anatomic Pathology Outreach Revenue by Hospital (2024)

Abbreviated Sample Data from Hospital Outreach Laboratory Database:

Hospital Name	System Affiliation	Laboratory Outpatient Charges 2024	Medicare CLFS Payments 2024	Medicare Pathology PFS Payments 2024
Northwestern Medicine Central DuPage Hospital	Northwestern Medicine	\$1,700,049,895	\$16,950,076	\$560,24
Northwestern Memorial Hospital	Northwestern Medicine	\$1,428,274,458	\$11,312,832	\$899,9
The University of Texas MD Anderson Cancer Center	University of Texas System	\$948,122,457	\$4,164,975	\$7,342,16
The Cleveland Clinic	Cleveland Clinic Health System	\$2,072,483,075	\$9,669,058	\$401,32
Tisch Hospital	NYU Langone Health	\$1,484,364,888	\$7,433,512	\$1,789,51
Eisenhower Medical Center	Independent	\$330,575,294	\$8,363,304	\$451,39
Atrium Health Carolinas Med Center	Advocate Health Care	\$2,337,167,925	\$8,063,865	\$707,63
Evanston Hospital	Endeavor Health	\$353,574,228	\$8,010,342	\$365,976
Stanford Hospital	Stanford Health Care	\$2,159,388,385	\$6,112,897	\$1,440,0
Hospital of the Univ. of Pennsylvania	Penn Medicine	\$1,398,973,589	\$4,723,464	\$2,807,77

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