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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

How to Keep Your Existing LDTs on the Market

Labs have some tough decisions to make now that the FDA has issued a final rule giving it authority to regulate LDTs. Labs offering LDTs prior to publication of the final rule on May 6 have three choices: 1) comply with the new FDA regs and keep their LDTs on inhouse test menus; 2) switch to an FDA-cleared test kit (if available); or 3) ignore the FDA regs and risk potential enforcement actions and fines. For expert advice on option 1 from regulatory attorney Christine Bump, *see pages 3-4*.

ACLA Lawsuit Says FDA Lacks Authority to Regulate LDTs

As widely expected, the American Clinical Laboratory Association (ACLA) and its member company HealthTrackRx (Denton, TX) are suing the FDA over its final rule to regulate LDTs. The lawsuit was filed on May 29 in the United States District Court for the Eastern District of Texas (Tyler, TX). The case has been assigned to Judge Sean D. Jordan, age 59, who was appointed to serve by former President Trump in 2019. "The Eastern District of Texas has generally been viewed as more hostile to federal government regulation, so it's not surprising that ACLA filed there," notes Nathan Brown, Partner at Akin Gump (Washington, DC). *Full analysis on page 5*.

Tempus AI Goes Public at $6.1 Billion Valuation

Tempus AI (Chicago, IL), which specializes in next-gen sequencing and PCR-based testing services, completed its initial public offering (IPO) on June 13. The company raised $411 million by selling 11.1 million shares at $37 per share, giving it a market value of $6.1 billion—an amount equal to 11.5x its revenue of $532 million for 2023.

Tempus AI plans to use the proceeds to pay taxes related to stock-based compensation and for general corporate purposes, including working capital and operating expenses. The lead banks that managed the IPO were Morgan Stanley, J.P. Morgan, and Allen & Company.

Shares of Tempus AI rose by 8% on their first day of trading on the Nasdaq on June 14, raising the company's market value to $6.6 billion. *Continued on page 2*.

Contents

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TEMPUS SEEKS TO RAISE UP TO $411M FROM IPO (*cont'd from page 1*)

Tempus AI operates CLIA-certified labs in Chicago, Atlanta and Raleigh, North Carolina, that specialize in cancer testing and pharmacogenomic profiling for neuropsychology. The company has a total of 2,300 employees, including 250 PhDs and MDs.

In April 2023, Tempus AI received its first FDA clearance for a companion diagnostic (named xT CDx) that profiles the underlying genetic makeup of solid tumors. xT CDx is a 648-gene test that helps identify the patients most likely to benefit from the two targeted therapies for colorectal cancer—Amgen's Vectibix (panitumumab), and Bristol Myers Squibb and Eli Lilly's Erbitux (cetuximab).

Tempus AI's competitors include Roche's Foundation Medicine, Caris Life Sciences, Guardant Health and NeoGenomics.

Tempus AI recorded a net loss of $266 million in 2023 versus a net loss of $334 million in 2022; revenue increased by 66% to $532 million. The company's average reimbursement for NGS tests in oncology was approximately $1,452 in 2023, up from $916 in 2022. Oncology NGS test volume increased by 48% to 218,700 in 2023.

Tempus AI has accumulated losses totaling $1.5 billion since being formed in August 2015.

Tempus AI, formerly named Tempus Labs, is also positioning itself as an AI company even though AI revenue accounted for only $5.5 million of revenue, or approximately 1% of total revenue in 2023.

Eric Lefkofsky, age 54, is Founder, Chairman and CEO of Tempus AI. He founded the company after his wife was diagnosed with breast cancer. Following her successful treatment and recovery, he became fixated with the idea of supplying physicians with more information so they could make data-driven cancer treatment decisions.

Eric Lefkofsky

Lefkofsky is best known as the co-founder of daily deals pioneer Groupon, which went public at a valuation of nearly $13 billion in 2011. He resigned as Groupon's CEO in 2015, when the company's value had fallen to $2.6 billion. Groupon has a current market value of about $600 million.

Lefkofsky owns 30% of Tempus AI's outstanding shares that have 65% of the voting power. Other debt and equity investors in Tempus AI include Ares Management, Baillie Gifford, Franklin Templeton, Softbank and Google.

Tempus AI Financial History ($000)

	2023	2022	2021	2020	2019	4-Year CAGR
Genomic testing revenue	$363,022	$197,984	$195,012	$151,911	$27,890	90%
Data and other revenue	168,800	122,684	62,841	36,093	34,167	49%
Total revenue	531,822	320,668	257,853	188,004	62,057	71%
Total costs & operating expenses	727,905	586,110	501,564	381,458	181,838	41%
Loss from operations	-$196,083	-$265,442	-$243,711	-$193,454	-$119,781	NA
Net loss to shareholders	-$265,964	-$333,928	-$297,736	-$253,905	-$148,144	NA
Oncology NGS tests delivered	218,700	148,000	97,000	64,300	40,600	52%

Source: Tempus AI (IPO registration statement)

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HOW TO KEEP YOUR EXISTING LDTS ON THE MARKET (*cont'd from page 1*)

Christine Bump, a regulatory attorney at Penn Avenue Law & Policy (Washington, DC), has been guiding laboratories and test manufacturers through the FDA's premarket clearance process and postmarket compliance requirements for 20 years. Below we summarize Bump's advice for keeping existing LDTs on the market.

Christine Bump

FDA Stage 1 requirements for currently marketed LDTs

Nearly all LDTs, including currently marketed LDTs (prior to May 6, 2024), "unmet need" LDTs performed by "integrated" health systems and NYS CLEP-approved tests, must meet Stage 1 requirements by May 6, 2025.

Stage 1 includes FDA Medical Device Reporting (MDR), which will require laboratories to report adverse events for any LDT that they perform. Under FDA's regulations, an adverse event is any event that reasonably suggests that a device has or may have caused or contributed to a death or serious injury, or would be likely to cause or contribute to a death or serious injury if the event happens again. An adverse event report would therefore be required for an incorrect test result that has, may, or could cause such consequences. The incorrect test result could be caused by instrument malfunctions as well as mislabeled or contaminated specimens.

An adverse event report must generally be reported to the FDA within 30 days after the lab became aware of the error. The regulations require specific information be included in the report, and labs will also need to file a report that describes what corrective action they took, or if they chose to remove that LDT from their test menu.

An adverse event report could prompt the FDA to ask follow-up questions or schedule an on-site inspection.

The FDA is especially sensitive to incorrect test results that delayed patient treatment or caused unnecessary treatment (or had the potential to do so).

Stage 1 also requires labs to maintain complaint files for each LDT they offer, including the date the complaint was received; the name, address, and phone number of the complainant; the nature and details of the complaint; any corrective action taken, etc. Specific records and reports must also be maintained and submitted regarding corrections and removals of tests, including for repairs, adjustments, relabeling, etc.

FDA Stage 2 requirements for currently marketed LDTs

Once again, Stage 2 requirements apply to nearly all LDTs and become effective May 6, 2026.

Stage 2 requires each laboratory to be registered with the FDA and list all of the LDTs they perform.

Stage 2 also requires labs to submit labeling for each LDT they offer. Labeling includes test performance information and a summary of supporting validation. As part of its review of labeling, the FDA plans to look closely at claims of superior performance and whether those claims are adequately substantiated. This includes any test claims made on a lab's website, brochures or by sales reps.

Labeling information is typically included as a package insert or affixed to test kit box for FDA-cleared or approved IVD tests. However, since LDTs are not distributed in boxed test kits, it is unclear exactly where the label for an LDT will need to be placed. Labels might be required on the LDT test requisition form, but this hasn't been confirmed yet. We're waiting for the FDA to issue more guidance on label requirements.

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FDA Stage 3 requirements for currently marketed LDTs

By May 6, 2027, currently marketed as well as "unmet need" LDTs developed and used within "integrated" health systems need to be in compliance with the records requirements of the quality system regulation. These records relate to the device master record, the device history record, and the quality system record. (Note: Complaint file record requirements are already covered under Stage 1.)

The device master records must include information about device specifications, production process specifications, quality assurance procedures and specifications, packaging and labeling specifications, and procedures and methods for installation, maintenance, and servicing.

The device history records must include information about the dates and quantity manufactured, the quantity released for distribution, acceptance records, information to identify each production unit and device identifiers.

Labs must have the required information compiled, documented, and in a records system that is accessible and readily available to FDA investigators during inspections.

FDA On-site Inspections

All registered lab facilities performing LDTs are subject to scheduled on-site inspections by the FDA every two years. FDA inspections are completely different than and are independent of CMS CLIA and CAP inspections. FDA inspectors will be focused on reviewing LDT test records and files. However, the reality is that the FDA already lacks the resources to perform regularly scheduled on-site inspections of existing test kit manufacturers. The agency may have difficulty keeping up with the thousands of new lab facilities that fall under its purview as a result of its final rule.

FDA LDT Regulation Matrix

Stage	Requirement (FDA Final Rule section link)	Effective Date	NYS CLEP Approved	Unmet Need	Currently Marketed (pre 5/6/24)	New LDT (post 5/6/24)	Currently Marketed - Modified*
1	MDR Correction, Removal (§ 803 and § 806)	May 6, 2025	Yes	Yes	Yes	Yes	Yes
1	Complaint Files (§ 820.198)	May 6, 2025	Yes	Yes	Yes	Yes	Yes
2	Registration (§ 807)	May 6, 2026	Yes	Yes	Yes	Yes	Yes
2	Listing (§ 807)	May 6, 2026	Yes	Yes	Yes	Yes	Yes
2	Labeling (§ 809.10)	May 6, 2026	Yes	Yes	Yes	Yes	Yes
2	Investigational Device (§ 812)	May 6, 2026	Yes	Yes	Yes	Yes	Yes
3	Design Controls (§ 820.30)	May 6, 2027	Yes	No	No	Yes	Yes
3	Purchasing Controls (§ 820.50)	May 6, 2027	Yes	No	No	Yes	Yes
3	Acceptance Activities (§ 820.80 and § 820.86)	May 6, 2027	Yes	No	No	Yes	Yes
3	CAPA (§ 820.100)	May 6, 2027	Yes	No	No	Yes	Yes
3	Records (part 820, subpart M)	May 6, 2027	Yes (store now)	Yes (store now)	Yes (store now)	Yes (store now)	Yes (store now)
4	Premarket Review (high-risk); PMA	Nov. 6, 2027	No	No	No	Yes	Yes
5	Premarket Review (mod/low risk); 510k and De Novo	May 6, 2028	No	No	No	Yes	Yes

*Significant modification to a currently marketed LDT (e.g., changes in specimen type, instrument changes, addition of artificial intelligence to test algorithm, and changing from targeted sequencing to whole genome sequencing)

Source: *Laboratory Economics* from ARUP Laboratories (J. Genzen)

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ACLA LAWSUIT SAYS FDA LACKS AUTHORITY TO REGULATE LDTs (*cont'd from page 1*)
ACLA and HealthTrackRx are being represented by King & Spalding (Austin, TX), while the FDA will be represented by lawyers from the U.S. Dept. of Justice.

HealthTrackRx, which has more than 300 employees, operates CLIA-certified labs in California, Georgia, Indiana and Texas that specialize in PCR-based testing for infectious disease. HealthTrackRx is also an ACLA member. Other ACLA members that have filed declarations in support of the lawsuit include ARUP Labs, Labcorp, Mayo Clinic Labs and Quest Diagnostics.

Brown notes that the plaintiffs did not seek a preliminary injunction that would freeze the status quo pending the outcome of the litigation. ACLA and HealthTrackRx still have the right to ask for a preliminary injunction at a future point. However, as of now, the case will proceed on a traditional schedule, and it can be expected that one or both parties will move for summary judgment later this year, according to Brown.

Brown adds that while this lawsuit was the first to challenge the new LDT regs, other plaintiffs may come forward with separate suits, either filed in the same court or a different court.

The ACLA and HealthTrackRx lawsuit alleges that the final rule violates the Administrative Procedure Act—the federal law governing challenges to agency action—in two ways:

- The plaintiffs argue that the final rule is not a permissible interpretation of the Federal Food, Drug and Cosmetic Act (FDCA). The rule amends the regulatory definition of "in vitro diagnostic products"—which are "devices" for purposes of the FDCA—to include LDTs. The complaint contends that the amended definition is unlawful because the term "devices" can only be interpreted to refer to physical products—such as a medical instrument or apparatus—and does not include intangible services, such as professional laboratory testing.
- Separately, the complaint challenges the adequacy of the FDA's decision-making process underlying its adoption of the final rule. The plaintiffs contend that the FDA did not adequately respond to the more than 6,000 comments it received during the comment period for the proposed rule, and failed to provide a sufficiently reasoned justification for the regulatory approach it selected.

ACLA has estimated that the cost to the lab industry for complying with the new LDT regs will be about $101 million in year 1, $113 million in year 2, $386 million in year 3, and more than $1.6 billion every following year.

"This expensive new regulation will negatively impact patient care….We simply had no choice but to file a lawsuit," ACLA President Susan Van Meter tells *Laboratory Economics*.

The plaintiffs have asked the court to vacate the final rule and enjoin its enforcement. The FDA has not yet filed its response to the lawsuit .

Which Tests are Exempt from FDA LDT Regulation?

The short answer is very few, according to Jonathan Genzen, MD, PhD, Chief Medical Officer and Senior Director of Government Affairs at ARUP Laboratories (Salt Lake City, UT). LDTs exempt from the FDA's final rule include 1976-type LDTs that use manual techniques (without automation) performed by lab personnel with specialized expertise. Examples of 1976-type LDTs include Gram stains, manual immunohistochemistry testing, Wright-Giemsa stains for peripheral blood, sweat chloride testing and manual FISH, according to Genzen.

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Labcorp Workers in Portland Vote to Unionize

Eighty-six percent of Labcorp workers at seven Legacy Health facilities in the Pacific Northwest voted "yes" in a union election held from May 1 to May 3.

The 434 Labcorp employees are now represented by the Oregon Federation of Nurses and Health Professionals (OFNHP), a local affiliate of the American Federation of Teachers (AFT). Nationally, AFT represents 1.7 million members who are teachers, public service employees and healthcare workers.

The Labcorp employees joining the union include medical technologists (MTs), histotechnologists, medical lab technicians (MLTs), phlebotomists and couriers.

Labcorp paid $108 million to acquire the outreach lab business of Legacy Health (Portland) in November 2023 (see *LE*, July 2023 & December 2023). As part of the arrangement, Labcorp hired the staff and signed a long-term deal to manage Legacy's inpatient labs.

Shane Burley, Communications Organizer at OFNHP, says that the Labcorp workers feel underpaid and understaffed. Negotiations with Labcorp for a new union contract are expected to begin within a few months. Burley says that wage rates for lab workers have not kept up with inflation. He notes that modest homes (e.g., 1,200 square feet) in Portland are currently selling for $700,000. A new union contract proposal is likely to focus on wage increases, cost-of-living adjustments and staffing levels/workloads, according to Burley.

Labcorp/Dynacare Workers Threaten to Strike

Separately, union workers at Dynacare Northwest (Seattle), a wholly owned subsidiary of Labcorp, are making plans for a potential strike if they fail to reach a new contract agreement with Labcorp. The Labcorp/Dynacare workers are long-time members of UFCW 3000, which represents a total of over 50,000 members working in grocery, retail, healthcare, meat packing, and other industries across Washington, northeast Oregon and northern Idaho.

The Labcorp/Dynacare workers include MTs, histotechnologists, MLTs, phlebotomists and couriers who work at Swedish Health Services, which is the largest nonprofit health system in the Seattle area. Labcorp has held a contract to provide laboratory services, both onsite and reference, to Swedish since Labcorp acquired Dynacare in 2002.

The current union contract expired May 31, 2023. UFCW 3000 and Labcorp/Dynacare have been trying to negotiate a new contract for the past year. UFCW claims that Labcorp/Dynacare has stalled and offered minimal concessions (see table below). For example, the union workers are seeking an 11-14% increase in base wages and Labcorp has offered 1-6%.

Labcorp is scheduled to make another offer at the next June 17-18 bargaining session. The union has scheduled a vote on June 25-26 giving its members the option to either accept Labcorp's latest offer or authorize a strike.

New Contract Sticking Points

Union Proposals	*Labcorp Counterproposals*
11% - 14% increases to base wages (over what members are currently making)	1% - 6.29% increases to base wages (over the wage rates listed in the 2021 contract)
5% COLA increases for 2024 and 2025	2% COLA increase for 2024 and 2025
Eliminating "ghost steps" & getting members to the top of the pay scale faster	Agreed
Lower monthly healthcare premium costs	Higher monthly premiums, higher out-of-pocket maximums, and higher co-pays

Source: UFCW 3000 Union

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California Delays New $25 Healthcare Minimum Wage Law

On May 31, California Governor Gavin Newsom signed Senate Bill (SB) 828, which delays the effective date of the state's new $25 healthcare minimum wage law by one month.

Last October, Governor Newsom enacted a multi-tiered statewide minimum wage law for healthcare workers effective June 1, 2024. However, in light of California's significant budget shortfall, the Governor delayed its effective date to July 1, 2024.

The law sets a minimum wage for workers at most healthcare facilities — such as general and surgical hospitals, psychiatric hospitals, dialysis clinics, physician groups (with 25 or more physicians), and home health agencies. The initial wage increases will now begin July 1, 2024, and reach the $25 minimum standard in 2026, 2027, or 2028 for roughly 450,000 healthcare workers in California.

"Independent labs are not specifically mentioned in SB 828, so we do not believe it applies to them," notes Kristi Foy, Executive Director of the California Clinical Lab Assn. (CCLA-Sacramento). However, the law does apply to hospital lab workers and large pathology groups (≥25 pathologists). There are also expected to be spillover effects to independent labs because all labs are competing for many of the same employees (e.g., medical coding and billing personnel, medical lab technicians, phlebotomists, etc.).

The new law was delayed by one month so that it aligns with California's fiscal year (July 1, 2024 – June 30, 2025). The delay also gives the state more time to amend the law again to make it less costly. The governor's office has estimated that the new law will cost the state $4 billion annually, including from higher pay to state-employed healthcare workers, increased Medi-Cal payments to affected hospitals and providers, and increased costs for higher CalPERS healthcare premiums.

California's current minimum wage for all types of workers is $16 per hour. Some cities and counties have higher minimum wages than the state's rate.

The following chart shows when SB 828 wage increases would go into effect for each category of covered healthcare employers:

Healthcare Sector	*July 1, 2024*	*July 1, 2025*	*July 1, 2026*	*July 1, 2027*	*July 1, 2028*
Independent laboratories	Exempt				
Physician practices/groups with 24 or fewer physicians	Exempt				
Physician groups with 25 or more physicians	$21		$23		$25
Large health systems with more than 10,000 workers and dialysis clinics	$23	$24	$25		
Community clinics, rural health clinics, urgent care clinics and other licensed clinics	$21		$22	$25	
Hospitals with high mix of Medi-Cal and Medicare patients and rural independent hospitals	$18	Increase 3.5% annually until it reaches $25 in 2033.			

Source: SB 828

Organizations that support the new law include the Alameda County Democratic Party, SEIU California and AFSCME Local 3299.

Those that oppose the new law include CCLA, California Nurses Association and the California Dialysis Council. Opponents argue that more than half of California hospitals are losing money, and that SB 828 will force healthcare providers to cut hours, positions and services.

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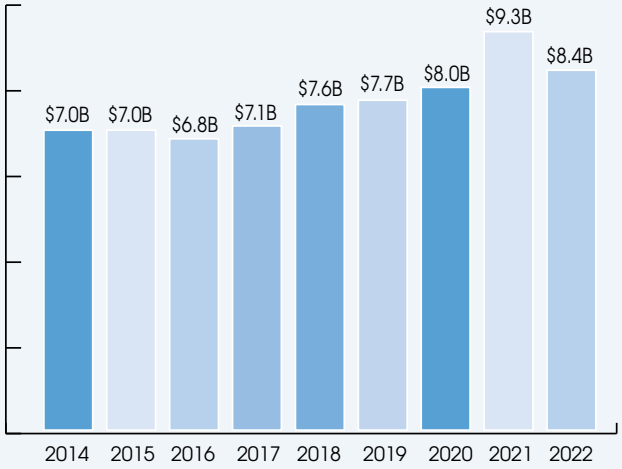
OIG Report Shows 10% Drop in CLFS Spending

The Medicare Part B spending on clinical lab fee schedule (CLFS) tests, including payments to independent labs, physician offices and hospitals, fell by 10% to $8.4 billion in 2022, according to the latest OIG review of Clinical Lab Fee Schedule (CLFS) payments. Total CLFS payments declined in 2022 primarily because of lower Covid-19 and genetic test volumes. Over the eight-year period from 2014 through 2022, overall Medicare Part B CLFS spending increased at an average annual rate of 2.3%.

Overall Medicare Part B Spending on CLFS Tests

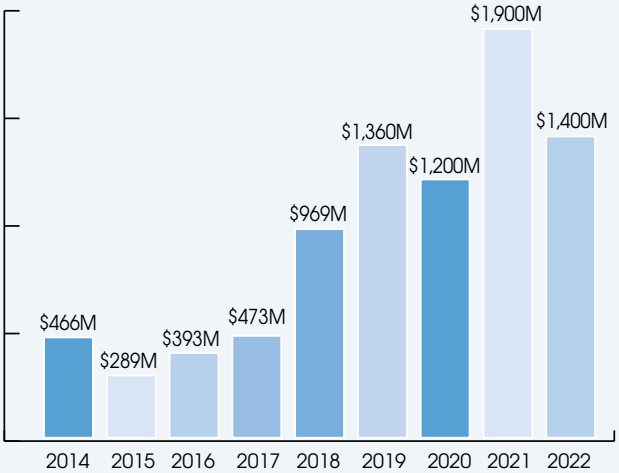


Source: OIG analysis of Medicare Part B Spending on Lab Tests (December 2023)

Genetic Testing

Medicare Part B spending on genetic tests decreased to $1.4 billion in 2022, down 26% from $1.9 billion in 2021. In particular, Medicare Part spending for CPT 81408 (Molecular pathology procedure, Level 9) tumbled by 99.9% to $371,000 in 2022 from $282.2 million in 2021 due to increased scrutiny for potential fraudulent billing activities. Genetic tests, as a group, comprise four categories of tests: molecular pathology tests, multianalyte algorithmic assays, genomic sequencing procedures, and proprietary lab analysis tests. Total spending on these genetic tests accounted for 17.5% of Medicare Part B spending for all CLFS tests in 2022. The average payment per genetic test was $824 in 2022. Over the eight-year period from 2014 through 2022, Medicare Part B spending on genetic tests increased at an annual rate of 15%.

Medicare Part B Spending on Genetic Tests



Source: OIG analysis of Medicare Part B Spending on Lab Tests (December 2023)

The Top 25 CLFS Tests

The OIG report highlighted the top 25 tests in 2022, which represented 57% of Medicare payments for all lab tests paid under the CLFS. Of the total $4.8 billion that Medicare spent on the top 25 tests in 2022, carrier payments to independent labs and POLs totaled $3.7 billion, or 77%, and payments to hospital labs totaled $1.1 billion, or 23%.

Medicare spending grew the fastest for CPT 81455 (Genomic sequence analysis panel for cancer; 51 or greater genes), which jumped 501% to $91.5 million.

Medicare spending also increased for PLA 0241U (Analysis of 55-74 genes associated with solid organ cancer), up 83% to $80.5 million; CPT 81528 ("Cologuard" DNA-based colorectal cancer screening), up 7% to $269.2 million; and CPT 87798 (Infectious agent detection by DNA or RNA; amplified probe technique, each organism), up 5% to $224.4 million.

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Top 25 Lab Tests Based on Medicare CLFS Payments in 2022 ($ millions)

CPT Code	Description	Medicare CLFS Payments to Independent Labs & Physicians for 2022	Medicare CLFS Payments to Hospital Labs for 2022	Total Medicare CLFS Spending for 2022	2021-2022 % Change
U0003	Covid-19, nucleic acid, high-thoughput	$493.7	$169.8	$663.5	-29%
80053	Comprehensive metabolic panel	277.9	132.4	410.3	-4%
80061	Lipid panel	227.6	111.0	338.6	-5%
84443	Thyroid stimulating hormone (TSH)	227.7	92.6	320.3	-4%
85025	Complete blood cell count	199.8	88.1	287.9	-4%
81528	DNA-based colorectal cancer screening	269.2	0.0	269.2	7%
82306	Vitamin D-3 level	183.7	73.8	257.5	-4%
U0005	Covid-19, $25 add-on payment for 2-day results	194.1	50.5	244.6	-20%
87798	Infectious agent detection by DNA or RNA	221.6	2.8	224.4	5%
U0004	Covid-19, any technique, high-throughput	153.7	32.6	186.3	-16%
83036	Hemoglobin A1C level	131.8	44.4	176.2	-3%
G0483	Drug test, definitive, 22+ classes	166.8	1.6	168.4	-17%
80307	Testing for presence of drug	133.6	8.5	142.1	-9%
G0482	Drug test, definitive, 15-21 classes	121.5	1.4	122.9	-6%
83970	Parathyroid hormone	70.2	33.1	103.3	2%
87635	Covid-19, Amplified probe technique	48.4	46.4	94.8	-10%
87426	Covid-19 antigen by immunoassay	66.7	27.1	93.8	-8%
81519	Breast cancer gene expression	93.3	0.0	93.3	1%
81455	Genomic sequence analysis panel for cancer (51 or greater genes)	73.6	17.9	91.5	501%
82607	Vitamin B-12	62.0	25.9	87.9	0%
80048	Basic metabolic panel	45.7	38.5	84.2	-7%
G0480	Drug test, definitive, 1-7 classes	73.7	8.1	81.8	-6%
0241U	Covid-19/influenza A&B/RSV test panel	17.9	63.3	81.2	141%
0242U	Analysis of 55-74 genes associated with solid organ cancer	80.5	0.0	80.5	83%
84153	Total PSA	57.3	19.3	76.6	0%
	Total for top 25 tests	**$3,692.0**	**$1,089.1**	**$4,781.1**	**-7%**

Source: *Laboratory Economics* from CMS and OIG analysis of Medicare Part B Spending on Lab Tests (December 2023)

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Versant Buys Associate Pathologists of Joliet

Versant Diagnostics (Grapevine, TX) has acquired Associate Pathologists of Joliet, a hospital-based pathology practice based at Ascension Saint Joseph Medical Center (Joliet, IL). James Urban, MD, PhD, age 69, is the President of the group, which has four pathologists. Urban will now become Versant's Regional Director for its five Chicago-area pathology groups.

Versant is a startup pathology company founded by Ven Aduana, MD, Jim Billington and Brian Carr in 2021 (see *LE*, November 2021). Versant, which currently manages 56 pathologists at seven practices, has $100 million in financing (both equity and debt) from Iron Path Capital (Nashville, TN).

Versant is acquiring pathology practices and then seeking to add volume through increased sales and marketing and the use of digital pathology.

Billington says that Versant's Chicago-area pathologists are now reading nearly 100% of their slides via digitized images on their computer monitors. Slide scanning is being performed by Alverno Clinical Labs (Hammond, IN), which is using Philips' scanners and image management system. Versant is also in the process of transitioning its pathology groups in Virginia and Maine to digital pathology. Versant has also begun placing scanners at specialty group clients with in-office labs, including a large gastroenterology group in the Chicago area.

Versant is expected to complete several more pathology group acquisitions by the end of the year, according to Billington.

Versant Diagnostics Acquisition History

Acquisition Date	Laboratory Name	# Pathologists
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*

Arbor Buys Avero's Women's Health Divison

Arbor - Women's Health Elevated (Dallas, TX) has acquired the women's health division of Avero Diagnostics (Irving, TX).

Avero, which employs 19 pathologists, is a pathologist-owned laboratory company (formerly known as Northwest Pathology). Avero owns CLIA-certified labs in Bellingham, WA, and Lubbock and Irving, TX. Ryan Fortna, MD, PhD, President of Avero, says the sale will allow Avero to focus its resources to better serve patients and providers in its more focused markets.

Arbor was founded by its President and Chief Medical Officer, Hampton Richards, MD, an Ob/Gyn physician, in 2016. Arbor's Medical Director is Sara Milchgrub, MD, who is board certified in anatomic pathology. Arbor operates a CAP-accredited lab in Dallas that specializes in women's health, including Pap and high-risk HPV testing, CT/GC/trichomonas, thyroid panels, etc.

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America's Fastest-Growing Labs

OptimaLab Inc. (Bolingbrook, IL) was the fastest-growing lab from 2019-2022, according to an *LE* analysis of newly released Medicare Part B payment data for 2022. OptimaLab's Medicare Part B allowed payments rocketed from $1.5 million in 2019 to $20.6 million in 2022 for a compound annual growth rate (CAGR) of 142%. OptimaLab's highest volume CPT codes in 2022 were U0003 (Covid-19), U0005 (Covid-19), P9603 (travel allowance) and G2024 (specimen collection for Covid-19).

Lifescan Labs (Skokie, IL) received $28.6 million in Medicare Part B allowed payments in 2022, an increase of 138% per year from $2.1 million in 2019. Lifescan's growth came largely from performing Covid-19 testing for nursing home clients.

Tempus AI (Chicago, IL) received $55.1 million in Medicare Part B allowed payments in 2022, an increase of 121% per year from $5.1 million in 2019. Tempus AI, which specializes in gene-based testing for cancer, recently announced plans for an IPO (see pages 1-2).

Overall, 3,472 independent labs saw their Medicare Part B allowed payments increase by 5% per year to $6.6 billion from 2019 to 2022.

Top 25 Fastest-Growing Labs by Medicare Part B Carrier Payments*

Laboratory Name	City & State	2022 Part B Allowed Payment	2019 Part B Allowed Payment	3-Year CAGR
OptimaLab Inc.	Bolingbrook, IL	$20,584,413	$1,455,345	142%
Lifescan Labs of Illinois	Skokie, IL	28,643,866	2,123,857	138%
Tempus AI	Chicago, IL	55,141,213	5,124,853	121%
Patients Choice Labs of Indiana	Indianapolis, IN	15,989,196	1,696,706	111%
QualiTox Laboratories	Pittsburgh, PA	9,730,254	1,229,324	99%
Veracyte Labs	San Diego, CA	55,759,812	7,109,661	99%
MedArbor Diagnostics	Bristol, PA	18,250,524	2,812,736	87%
GMI Laboratories	North Hollywood, CA	10,714,992	1,845,560	80%
Guardant Health	Redwood City, CA	129,991,480	23,648,968	76%
Industry Lab Diagnostic Partners	Nashville, TN	5,025,132	1,027,299	70%
Genetic Technological Innovations	Scottsdale, AZ	12,153,822	2,531,029	69%
Cirrus Dx	Rockville, MD	10,738,758	2,334,731	66%
Sherman Abrams Laboratory	Brooklyn, NY	7,631,749	1,714,149	65%
Adaptive Biotechnologies Corp.	Seattle, WA	14,839,327	3,528,108	61%
Simple Laboratories	Harwood Heights, IL	7,864,755	2,063,758	56%
Dx Solutions	Nicholasville, KY	7,894,309	2,177,841	54%
AIM Laboratories	Bridgeton, MO	5,647,931	1,619,418	52%
Wellness Health Group	Tulsa, OK	3,791,330	1,095,922	51%
Global Diagnostic Lab	Pasadena, CA	8,239,656	2,416,514	51%
University of Washington	Seattle, WA	4,841,785	1,421,857	50%
Quest Diagnostics	Schaumburg, IL	8,117,065	2,474,653	49%
IGeneX Inc.	Milpitas, CA	7,548,510	2,303,902	49%
Delaware Diagnostic Labs	Newark, DE	4,659,807	1,466,696	47%
Concord Life Sciences	Houston, TX	6,615,970	2,097,648	47%
Biological Laboratory Inc.	Pomona, CA	8,887,453	2,832,141	46%
Total for top 25 labs		**$469,303,109**	**$80,152,676**	**80%**
Grand Total (all 3,472 labs)		**$6,586,109,968**	**$5,664,331,237**	**5%**

*The top 25 were calculated from all independent clinical labs that had Medicare Part B Carrier payments of at least $1 million in 2019.
Source: *Laboratory Economics* from Medicare Part B Carrier utilization files, 2019 & 2022

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Lab Stocks Up 21% So Far In 2024

Twenty-four lab stocks have risen by an unweighted average of 21% year to date through June 14. In comparison, the S&P 500 Index is up 14% year to date. Only eight lab stocks have gained, while 16 have declined. The top-performing lab stock thus far in 2024 is GeneDx, up 947%. Quest Diagnostics is flat and Labcorp is down 12%.

Company (ticker)	Stock Price 6/14/24	Stock Price 12/29/23	2024 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
GeneDx (WGS)	28.78	2.75	947%	758	222	3.4
Natera (NTRA)	110.20	62.64	76%	13,160	1,209	10.9
Interpace Biosciences (IDXG)	1.40	1.08	30%	60	41	1.5
Myriad Genetics (MYGN)	23.20	19.14	21%	2,150	774	2.8
CareDx (CDNA)	14.19	12.00	18%	578	275	2.1
Guardant Health (GH)	30.21	27.05	12%	4,110	604	6.8
Castle Biosciences (CSTL)	22.92	21.58	6%	412	251	1.6
ProPhase Labs (PRPH)	4.59	4.52	2%	111	29	3.9
Quest Diagnostics (DGX)	137.85	137.88	0%	20,380	9,287	2.2
Exagen (XGN)	1.96	1.99	-2%	31	56	0.6
Labcorp (LH)	199.88	227.29	-12%	22,530	12,300	1.8
Opko Health (OPK)	1.25	1.51	-17%	1,240	800	1.6
Biodesix (BDSX)	1.52	1.84	-17%	280	55	5.1
NeoGenomics (NEO)	13.18	$16.18	-19%	1,940	611	3.2
Sonic Healthcare (SHL.AX)*	25.34	32.08	-21%	15,540	8,390	1.9
Veracyte (VCYT)	20.97	27.51	-24%	1,470	376	3.9
Psychemedics (PMD)	2.25	2.96	-24%	14	22	0.6
Fulgent Genetics (FLGT)	19.09	28.91	-34%	-256	288	-0.9
Exact Sciences (EXAS)	41.88	73.98	-43%	9,810	2,535	3.9
Aspira Women's Hlth (AWH)	2.04	4.08	-50%	24	9	2.6
23andMe (ME)	0.40	0.91	-56%	62	220	0.3
DermTech Inc. (DMTK)	0.32	1.75	-82%	26	16	1.6
Biocept (BIOCQ)	0.00	0.04	-100%	5	1	5.0
Invitae (NVTAQ)	0.00	0.63	-100%	1,250	482	2.6
Totals & Averages			**21%**	**$95,684**	**$38,848**	**2.5**

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

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