

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Breaking News: CLFS Rate Freeze Likely

The Medicare CLFS is likely headed for another one-year rate freeze and possibly a two-year freeze. *Details on page 11.*

Tennessee Pathologists Sue Cigna

Two Tennessee pathology groups, Anatomic and Clinical Laboratory Associates (Nashville, TN) and Cumberland Pathology Associates (Cumberland, TN), have filed a lawsuit against Cigna Corp. for alleged breach of contract. Both pathology groups provide clinical lab oversight services to hospital labs across Tennessee. The pathologists allege that Cigna breached its contracts when it stopped paying for the professional component of clinical pathology services (PC/CP) in late 2021. The plaintiffs are asking the court to block Cigna's new payment policies and award damages of at least \$75,000 each, plus legal fees. *Continued on page 9.*

Quest To Buy Outreach Lab In Maine

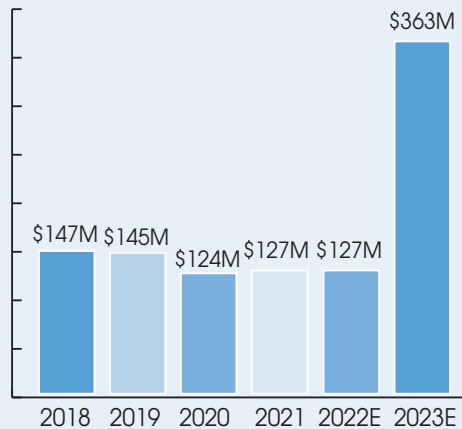
Quest Diagnostics has agreed to acquire certain outreach lab assets from Northern Light Health (Brewer, ME), an integrated healthcare system, in an all-cash transaction. In addition, Quest will manage nine of Northern Light Health's inpatient hospital labs, along with its cancer center lab at Northern Light Cancer Care in Brewer, Maine. *Full details on page 4.*

Big Specimen Collection Fee Hike for Labs

As part of its Medicare Physician Fee Schedule Final Rule for 2023, CMS nearly tripled its specimen collection fee for routine venipunctures (CPT 36415) to \$8.57 effective January 1, 2023. That's a hefty and long-overdue increase from the current Medicare rate of \$3, which had been unchanged since 1984. The hike will result in an estimated \$236 million of extra Medicare payments to independent labs and physician offices next year.

Full details on page 2.

Medicare Allowed Payments for Blood Draws*



*for CPT 36415
Source: CMS and Laboratory Economics' estimates for 2022 and 2023

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Big Specimen Collection Fee Hike (*cont'd from page 1*)

Medicare Part B carriers processed a total of 42.4 million allowed claims and \$127 million of allowed payments for CPT 36415 in 2021. Therefore, the \$5.57 fee hike for CPT 36415 should result in approximately \$236 million in additional reimbursement to labs and other providers in 2023 (42.4 million claims x \$5.57).

Inflation Updates

CMS explained that it set the new payment rate of \$8.57 by applying annual CPI inflation updates to the \$3 rate that had been in effect since 1984.

Furthermore, beginning January 1, 2024, CMS said it will update the specimen collection fee amount for each calendar year by the percent change in the CPI for the 12 months ending June 30 for the year preceding the update year.

“This is a rare bit of good news for labs. Over time, the specimen collection fee will likely be more than the reimbursement for many lab tests,” notes long-time industry consultant Dennis Weissman.

Rules for Payment

In announcing the new payment, CMS reiterated the eligibility requirements for billing for any specimen collection for clinical laboratory testing. The specimen must meet the following criteria:

- Used to perform a Medicare-covered laboratory test paid under the CLFS.
- Collected from a Medicare beneficiary who is either homebound or a non-hospital inpatient.
- One of the following types—a blood specimen collected through venipuncture or a urine sample collected by catheterization.
- Only one specimen collection fee is allowed for each single patient encounter.

Which Labs will Benefit the Most?

Quest Diagnostics will gain the most from the higher blood collection rate. Quest had 6.8 million Medicare allowed services and \$20.2 million allowed payments for CPT 36415 in 2020 (the latest year of available data). The rate hike should bring Quest an additional \$38 million of annual revenue (6.8 million services x \$5.57).

Labcorp had 6.3 million Medicare allowed services and \$18.7 million allowed payments for CPT 36415. The rate hike should bring Labcorp an additional \$35 million of annual revenue (6.3 million services x \$5.57).

Top 10 Labs by Medicare Specimen Collection Payments* for 2020

Lab Company	Location	Allowed Services	Total Allowed Payments
Quest Diagnostics	Nationwide	6,785,412	\$20,220,532
Labcorp	Nationwide	6,281,398	18,717,834
Sonic Healthcare USA	Nationwide	798,488	2,379,494
Sonora Quest Laboratories	Phoenix, AZ	614,154	1,830,179
Northwell Health Laboratories	Long Island, NY	285,694	851,368
PathGroup	Brentwood, TN	247,030	736,149
BioReference Laboratories	Nationwide	213,549	636,376
ACL Laboratories	West Allis, WI	211,525	624,104
HNL Lab Medicine	Allentown, PA	135,178	402,830
Diagnostic Laboratory Services	Aiea, HI	136,913	402,524
Total for Top 10 Labs		15,709,341	46,801,390
Grand Total (all providers)		41,382,192	\$124,137,338

*for CPT 36415

Source: *Laboratory Economics* from Medicare Part B Provider Utilization Data for 2020

Will Private Payers follow Medicare's Lead?

Most private payers either reimburse less than today's Medicare rate or nothing at all for blood draws. "Some private payers may make a proportional rate increase, while others may consider an incremental increase that is not proportional to Medicare. However, many payers have made the argument to follow the Blues in adopting a position that test fees are inclusive of the collection effort," according to Lâle White, Chief Executive of XIFIN Inc. (San Diego, CA).

White says that the cost of phlebotomy services is becoming more important as a result of the shift toward consumer-driven healthcare and physicians' continued efforts to lower their own office expenses. "During contract negotiations, all labs should be cognizant of making sure there is a meaningful specimen collection fee even if they do not collect specimens routinely," advises White.

Nursing Home Specimen Collection Fee Raised to \$10.57

The Medicare rate (HCPCS G0471) for labs providing phlebotomy services to a Medicare beneficiary in a nursing home or on behalf of a home health agency is also being raised next year. The Medicare rate for G0471 is being raised from \$5 to \$10.57 effective January 1, 2023. Thereafter, the rate for G0471 will be adjusted for inflation annually.

Medicare Part B carriers processed a total of 2.1 million allowed claims and \$10.6 million of allowed payments for G0471 in 2021. Therefore the \$5.57 fee hike for G0471 should result in approximately \$12 million in additional reimbursement to labs and other providers in 2023 (2.1 million claims x \$5.57).

Which Lab will Benefit the Most?

American Health Associates (AHA-Davie, FL) will gain the most from the higher blood collection rate for nursing home patients. AHA had 779,404 million Medicare allowed services and \$3.9 million allowed payments for G0471 in 2020 (the latest year of available data). The rate hike should bring AHA an additional \$4.3 million of annual revenue (779,404 services x \$5.57).

Trident Holdings (dba TridentCare), which emerged from bankruptcy in September 2019, should see additional annual revenue of \$2.2 million from the rate hike (403,848 services x \$5.57).

Top 10 Nursing Home Labs by Medicare Specimen Collection Payments* for 2020

Lab Company	Location	Allowed Services	Total Allowed Payments
American Health Associates	Florida and Ohio	779,404	\$3,865,836
TridentCare	CA, CO, MA, NV, TX, WA	403,848	2,002,891
Gamma Healthcare	Missouri and Texas	235,593	1,166,662
Aculabs Inc.	East Brunswick, NJ	170,836	842,221
Chicago Clinical Laboratories	Northbrook, IL	117,790	584,238
Centers Laboratory	New York and New Jersey	99,574	493,896
Clinical Laboratory Services	Winder, GA	97,173	481,978
Northwell Health Laboratories	Long Island, NY	68,296	338,875
Eccolab Group	Miami, FL	64,477	319,806
Lifescan Labs of Illinois	Skokie, IL	59,201	293,637
Total for Top 10 Labs		2,096,192	10,390,041
Grand Total (all providers)		2,608,421	\$13,034,988

*for G0471

Source: *Laboratory Economics* from Medicare Part B Provider Utilization Data for 2020

Quest To Buy Outreach Lab In Maine *(cont'd from page 1)*

Northern Light Health selected Quest following a competitive bid. The transaction is expected to be completed in the first quarter of 2023.

Northern Light Health's outreach lab services business does business as Northern Light Laboratory (formerly named Affiliated Laboratory Inc.). It has 225 employees and is based at a core laboratory in Bangor, Maine. It serves 250 physician practices throughout the region and provides reference testing services to more than two dozen hospitals.

Northern Light Laboratory is operated as a hospital-owned independent lab. It collected \$1.5 million of Medicare Part B Carrier allowed revenue from 135,489 allowed tests in 2020 (the latest year of available data). *Laboratory Economics* estimates that overall revenue for Northern Light Laboratory is between \$10 million and \$20 million per year.

Northern Light Health has a systemwide laboratory department budget of \$88 million, according to hospital cost reports for 2021. Its largest inpatient lab is at Northern Light Eastern Maine Medical Center (377 staffed beds), which has a lab department budget of \$35 million per year.

Non-urgent routine clinical lab testing and reference testing now performed by Northern Light Laboratory will be shifted to Quest's regional lab in Marlborough, Massachusetts (about 250 miles from Bangor). A Quest rapid response lab in the Bangor area and select Northern Light Health hospital labs will perform tests requiring rapid results.

Northern Light employees working in the labs will become Quest employees, and no one is being laid off, according to Northern Light spokesperson Suzanne Spruce.

In addition, Spruce says that the agreement with Quest will not affect anatomic pathology services that are now provided at Northern Light Health by Dahl-Chase Pathology Associates (Bangor, ME).

"This agreement will bring Quest scale in Maine. This market is largely a white space for Quest and the transaction makes strategic sense to both parties. It will create a low-cost consolidated lab in a state currently dominated by NorDx Laboratories," observes David Nichols, President of Nichols Management Group (York Harbor, ME).

Northern Light Health Hospitals to be Managed by Quest Diagnostics

<i>Hospital Name</i>	<i>Location</i>	<i>Staffed Beds</i>	<i>Annual Lab Dept. Budget</i>
Northern Light Eastern Maine Medical Center	Bangor	377	\$34,938,006
Northern Light Mercy Hospital	Portland	103	18,821,570
Northern Light AR Gould Hospital	Presque Isle	108	7,995,775
Northern Light Maine Coast Hospital	Ellsworth	45	7,180,680
Northern Light Inland Hospital	Waterville	33	5,207,718
Northern Light Mayo Hospital	Dover-Foxcroft	25	4,382,993
Northern Light Sebec Valley Hospital	Pittsfield	25	4,010,124
Northern Light Blue Hill Hospital	Blue Hill	25	3,260,944
Northern Light CA Dean Hospital	Greenville	25	1,759,153
Grand Totals		766	\$87,556,963

Source: *Laboratory Economics* from hospital cost reports for 2021

A Deep Dive Into Quest Diagnostics' Hospital Lab Service Agreements

Over the past 10 years, Quest Diagnostics has signed professional lab services (PLS) contracts with health systems representing more than 100 hospitals. These PLS contracts cover a range of services including lab instrument and reagent supply chain management, lab management, courier services, reference testing, etc. Michael Lukas, Vice President and General Manager for Health Systems, has led this effort at Quest since its launch in 2013. Below we summarize his insights into how Quest structures its PLS agreements.



Michael Lukas

How did Quest's PLS business get started?

Our recently retired CEO Steve Rusckowski, who is now Executive Chairman at Quest, started this new business line in 2013. Quest has always been active in making hospital lab outreach acquisitions and forming joint ventures (e.g., Diagnostic Laboratory of Oklahoma, Sonora Quest, UMass and UPMC). PLS agreements have allowed us to provide more services to hospitals outside of acquisitions and JVs. The PLS business now represents more than \$500 million of annual revenue for Quest.

Can you describe how the supply chain management component works?

Supply chain management allows hospital labs to participate in the purchasing power that Quest has with instrument and reagent vendors. Approximately 35% of the average hospital lab's budget is spent on instruments, maintenance, reagents and consumables.

Under a PLS agreement, Quest will buy out a hospital lab's analyzers and reagent inventory. Over time, we'll replace these equipment and supply contracts with the next generation of equipment taking advantage of the savings that Quest's size and scale provide. We share the savings with the hospital client. We are generally able to save hospitals an average of about 15% on a price-per-test basis. For a health system operating multiple labs, this can result in millions of dollars in annual savings. If our estimates don't work out, then it's a problem for me and Quest, not the hospital client.

Almost all of our PLS agreements include supply chain management.

Is reference testing usually part of each new PLS agreement?

Quest offers competitive pricing and already provides reference testing services to about half of all U.S. hospitals. Most hospitals use multiple reference labs. If a health system can help us capture more of their reference testing volume by consolidating its reference labs, then we can offer more savings. But a reference testing contract is not a requirement for our PLS agreements.

Can you give some examples of your PLS agreements?

Most recently, we reached an agreement to buy certain assets of Northern Light Health's outreach laboratory services business and provide management services for nine hospital labs (see page 1).

In addition, we recently announced a PLS contract with Lee Health in Southwest Florida. Quest will provide supply chain management for five hospitals owned by Lee Health and several outpatient centers. We will also continue to perform reference testing for Lee Health.

Our largest PLS contract to date is with Hackensack Meridian Health (HMH) in New Jersey—announced in late 2020. Quest is managing the lab operations and performing reference testing for 11 HMH hospitals. Approximately 30% of testing volume has been shifted to Quest's regional lab in Clifton, New Jersey, and 700 HMH lab employees are now employed by Quest. We're also standardizing the lab supply chain across the entire HMH network.

Does Quest share test result information with its hospital PLS clients?

Yes, Quest generally provides results back to the health system.

How are pathologists affected when their hospital enters a PLS contract?

Most pathology groups are either directly employed by or contract with a health system. More than 90% of the time Quest's PLS arrangements do not change the pathologist's relationship with the hospital. They continue to be the medical director and provide oversight to the lab. On rare occasions, a health system might be unhappy with their existing pathology relationship. Only then will Quest offer an alternate solution, but those instances are rare.

What about hospital lab employee layoffs?

Most of our PLS agreements result in only a limited number of layoffs. These often occur through natural attrition (e.g., voluntary retirements) as a contract is implemented over the course of one to two years. More pronounced layoffs can occur if a core outreach lab is being consolidated.

What are the biggest challenges for Quest when integrating an acquired hospital outreach lab?

Most hospital outreach labs don't maintain a separate profit and loss financial statement. Their focus is on lowering the overall average cost-per-test rather than profitability. We spend a lot of time developing accurate P&Ls for outreach labs to measure actual collections minus all costs, including customer service, IT, couriers, etc.

Does the redirection of volume to a Quest facility lengthen turnaround time?

If it's going to affect turnaround time and hurt patient care then the test stays on site. Generally, tests with results needed in four hours or less stay at the hospital lab. Less time-sensitive tests can be sent to one of our regional labs. Ultimately, it's the client's decision.

What's the biggest concern of hospital execs considering a PLS agreement with Quest?

Loss of control. However, we don't view our PLS agreements as outsourcing the hospital lab. We see them as a partnership and offer a lot of flexibility in the services we provide.

What's your outlook for Quest's PLS business?

The past three years have been the best so far for our PLS business as the Pandemic has put a lot of financial stress on health systems. Longer term, as U.S. healthcare shifts more toward population health management and risk-based contracting, hospitals will be focusing even more on having a low-cost structure.

Quest Diagnostics: Selected Professional Lab Services Agreements

Date	Health System	Brief Description
Dec-22	Northern Lights Health (Maine)	Lab outreach acquisition and management of 9 hospital labs
Sep-22	Lee Health (Southwest Florida)	Supply chain management and reference testing for 5 hospitals
Dec-20	Hackensack Meridian Health (New Jersey)	Manage 11 hospital labs and reference testing
Nov-20	Montefiore Nyack Hospital (Rockland County, NY)	Manage hospital labs, supply chain and reference testing
Nov-20	Goshen Hospital (Indiana)	Supply chain management and reference testing
Jan-20	Memorial Hermann Health System (Houston, TX)	Lab outreach acquisition and management of 21 hospital labs
Jan-20	West Tennessee Healthcare (Tennessee)	Supply chain management for 8 hospital labs
Jul-19	Catholic Health Services (Long Island, NY)	Supply chain management and reference testing for 6 hospitals and core lab
Mar-19	Regional Medical Center (South Carolina)	Manage hospital lab, supply chain and reference testing
Feb-19	Houston Healthcare (Georgia)	Manage 2 hospital labs, supply chain and reference testing
Sep-18	Regional Medical Center Health System (Alabama)	Supply chain management and reference testing
Feb-17	PeaceHealth (Vancouver, WA)	Lab outreach acquisition and management of 11 hospital labs
Jan-17	Montefiore Health System (NYC)	Outsource certain routine test volumes to Quest's NJ lab
May-16	HCA HealthONE (Denver, CO)	Manage inpatient labs at 6 Denver-area hospitals
Dec-15	Barnabas Health (New Jersey)	Manage inpatient labs at 7 hospitals in northern NJ

Source: *Laboratory Economics* from Quest Diagnostics

Haystack Oncology Raises \$56M To Launch Liquid Biopsy Test

Haystack Oncology (Baltimore, MD) has raised \$56 million from a Series A funding round led by New York-based investment firm Catalio Capital Management. The funds will be used to help commercialize Haystack's proprietary blood test for detecting trace amounts of circulating DNA from solid tumors. Here's a summary of *LE's* interview with Haystack CEO Dan Edelstein.



Dan Edelstein

Who founded Haystack Oncology?

Haystack was founded in early 2021 by three research professors at Johns Hopkins University, Bert Vogelstein, MD, Kenneth Kinzler, PhD and Nickolas Papadopoulos, PhD, along with CEO Dan Edelstein and CTO Frank Holtrup, PhD. The sixth founder is Josh Cohen, who is currently completing his MD and PhD from the Johns Hopkins University School of Medicine.

All four co-founders are focused on cancer genetics. Drs. Vogelstein and Kinzler were involved in the launch of Exact Sciences. The same pair, along with Dr. Papadopoulos, developed the CancerSEEK liquid biopsy screening test and founded Thrive Earlier Detection Corp. to commercialize this technology. Thrive was sold to Exact Sciences for \$2.2 billion in early 2021.

Finally, Josh Cohen, while working in the lab of Drs. Vogelstein and Kinzler, invented the chemistry behind Haystack's liquid biopsy test, called Haystack Duo.

How does Haystack's liquid biopsy work?

Our test detects minimum residual disease (MRD) in cancer patients after surgery. MRD is usually a small number of cancer cells left in the body after treatment which are often present below the detection resolution of standard imaging techniques such as CT scan. These cells have the potential to cause relapse in cancer patients.

Haystack Duo enables a two-step process that begins with tissue-based whole-exome sequencing to identify each patient's specific tumor mutations.

We use this information to create an individualized test specific for each patient's cancer that tracks up to 50 alterations, depending on how many targets are identified in each patient's tissue exome sequencing.

Detecting MRD has long been akin to looking for a needle in a haystack. We're searching for a small number of tumor-derived DNA molecules in a sea of normal molecules in a blood sample. If residual disease is detected, then additional treatment (e.g., chemotherapy) can be applied. Likewise, additional treatment can be avoided in patients whose tests show zero MRD.

How effective is your test?

A version of Haystack test was used in a study of 455 stage II colon cancer patients who had undergone surgery. The test was shown to significantly reduce the need of adjuvant chemotherapy without compromising recurrence-free survival. (see *New England Journal of Medicine*, June 16, 2022; 386:2261-2272).

What is the cost of Haystack's test?

We haven't finalized our pricing yet. However, Medicare through contractor Palmetto GBA's MolDX program is reimbursing similar tests at a bundled rate (tissue exome profile plus 4 MRD blood tests) of approximately \$5,900.

How is Haystack Duo different than competing tests?

The primary improvement is reduced background noise—with competing tests, as more mutations are tracked, analytical specificity suffers, which reduces the ability to detect ctDNA molecules at low levels typically observed in the MRD setting. Haystack Duo reduces noise by more than two orders of magnitude compared to other methods, providing the ability to detect as few as one ctDNA molecule in a million healthy DNA molecules. This increase in sensitivity and specificity means that treatment decisions can be made with more confidence and, if cancer does recur, it can be detected earlier when disease burden is low and more treatable.

Who are your investors?

In addition to Catalio Capital Management, others participating in our recent \$56 million round included Bruker Corp., Exact Sciences venture arm, Exact Ventures, and Alexandria Venture Investments.

What will you do with the funds?

Haystack and its 50 employees are currently based at Hopkins' FastForwardU campus of offices and labs for startup companies. We plan to move to a 20,000 square-foot lab and office in South Baltimore in the spring.

The money will also help with the commercial launch of our assay as a laboratory-developed test in mid-2023.

The initial target market will be colorectal cancer patients, supported by significant clinical data, but the testing technology can and will be applied to other solid tumors (breast, ovarian, head and neck, etc.) to assist patients' and clinicians' assessment of treatment success.

Pathnostics Opens New Lab In Florida

Pathnostics (Irvine, CA) has opened a new lab in Lake Mary, Florida (near Orlando). The Florida lab will initially focus on the firm's Guidance UTI test for the rapid identification and treatment of complicated, recurrent, and persistent urinary tract infections. The assay combines PCR and pooled antibiotic susceptibility testing. The new lab is 8,500 square feet and is in the process of hiring approximately 30 employees, including multiple laboratory assistant and medical technologist positions.

In addition to the new facility in Florida, Pathnostics is expanding its laboratory and headquarters in Irvine, California from 35,000 to approximately 55,000 square feet, with full relocation expected by the end of 2022.

Pathnostics also operates a third, CAP-accredited and CLIA-certified lab in Royal Oak, Michigan.

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Tennessee Pathologists Sue Cigna (*cont'd from page 1*)

The lawsuit (case 3:22-cv-00767) was originally filed on September 30, 2022, in the U.S. District Court for the Middle District of Tennessee in Nashville.

At the heart of the lawsuit is professional component payments made to hospital-based pathologists to compensate them for their oversight and management of clinical lab tests provided to hospital inpatients and outpatients.

Cumberland Pathology Associates, which has two members, provides anatomic and clinical pathology services to Tennova Healthcare (Clarksville, TN). Cumberland has provided services to Cigna members for more than ten years through an agreed-upon fee schedule, which includes PC/CP services, according to the lawsuit. Up until November 2021, Cigna had reimbursed Cumberland for all services provided to Cigna members pursuant to the fee schedule.

Anatomic and Clinical Laboratory Associates (ACLA) has 13 pathologists that provide anatomic and clinical pathology services to the nine hospitals of Saint Thomas Health as well as numerous outpatient clinics and ambulatory surgery centers in Middle Tennessee. ACLA is an in-network provider for MultiPlan Inc., which has a network agreement with Cigna. Its contract with MultiPlan required Cigna to reimburse providers, including ACLA, at rates specified in the providers' contracts.

The lawsuit alleges that Cigna stopped paying both group's pathology claims for PC/CP Services in November 2021. Cigna changed course in the spring of 2022, when it announced that, initially beginning on July 1, 2022, and then postponed until December 1, 2022, PC/CP services would be reimbursed at a flat rate of \$5 per test.

The pathologists say they received no formal notice of Cigna's policy changes. Cumberland and ACLA claim they have lost hundreds of thousands of dollars in reimbursement from Cigna. In addition, the pathologists say that the new flat rate of \$5 is below the rate that Cigna has paid for PC/CP services under long-standing contracts.

In response, Cigna argued that Cumberland has a contract with Cigna—and that contract obligates Cumberland to resolve its claims payment disputes with Cigna through arbitration, not a lawsuit. Cumberland has agreed to stay its claims pending arbitration.

Cigna says that it has no direct contract with ACLA. Therefore, ACLA's claims should be transferred to the Eastern District of Pennsylvania, which is the forum for its contract with MultiPlan. Alternatively, Cigna says the Middle District of Tennessee Court should dismiss the complaint with respect to ACLA.

PC/CP payments represent an average of between 10% and 30% of total compensation at most hospital-based pathology groups, notes Matt Zaborski, Vice President of Sales and Marketing at APS Medical Billing (Toledo, OH).

Zaborski says that Cigna has been trying to eliminate or lower these payments for years. He believes Cigna is selectively targeting enforcement of its new stingier PC/CP policies specifically at pathology groups with the higher-than-average billings for these services.

In addition, Cigna has begun to add contract language with hospitals that indicates the insurer is including payment for the pathologist's oversight of the clinical lab as part of the facility's payment. "It looks like Cigna may inevitably discontinue direct payment of PC/CP and expects pathologists to be reimbursed directly by their hospital," adds Zaborski.

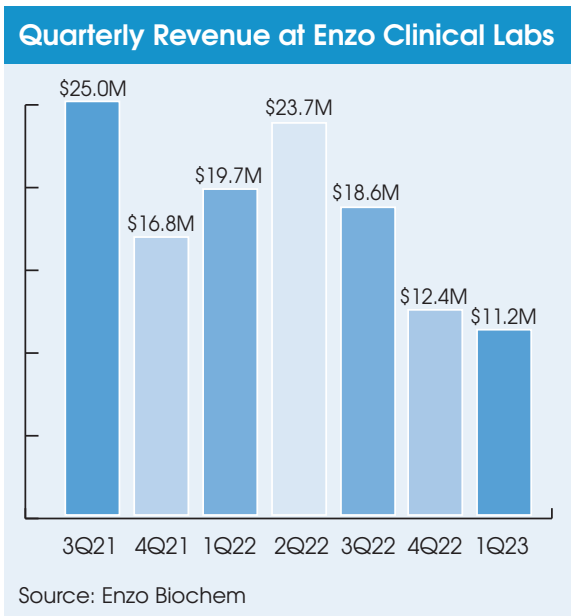
Enzo Biochem's Lab Revenue Drops; Potential Sale of Lab Division Under Review

Enzo Biochem (New York City) reported revenue for its Enzo Clinical Lab division of \$11.2 million for its fiscal first quarter ended October 31, 2022, a decrease of 43% compared to the \$19.7 million in the same quarter of last year. The decline in revenue was driven entirely by a steep drop off in Covid testing revenue, which fell to \$800,000 from \$9.2 million.

Companywide, Enzo Biochem reported a fiscal first-quarter net loss of \$10.6 million versus a net loss of \$2.3 million; overall revenue fell by 31% to \$18.3 million.

Enzo's long-time Chief Executive, Elazar Rabbani, PhD, and President, Barry Weiner, left the company in April 2022 under pressure from the activist investment firm Harbert Fund Advisors (see *LE*, April 2022).

Enzo hired the investment bank Jefferies LLC in June 2022 to help it evaluate strategic alternatives for the company, including its Enzo Clinical Lab and Enzo Life Sciences divisions. Enzo said its strategic review is progressing but offered no detailed update.



Enzo operates a full-service clinical laboratory in Long Island, a network of over 30 patient service centers throughout New York, New Jersey and Connecticut, and two free-standing STAT labs in New York City and Connecticut. Annual revenue is currently at a run rate of \$45 million.

The potential sale of Enzo's clinical lab business has likely attracted interest from all four major commercial labs doing business in the New York City area, including Quest Diagnostics, Labcorp, OPKO's BioReference Labs and Sonic Healthcare USA, which owns Sunrise Medical Labs (Long Island, NY).

Enzo Biochem has a current stock market valuation of \$68 million and an enterprise value of \$76 million.

Biodesix Raises \$71 Million From Stock and Debt Sales

Biodesix Inc. (Boulder, CO) raised gross proceeds of approximately \$70.7 million (\$65.8 million after deducting commissions, fees and expenses) from a new term loan and a secondary offering of its shares completed on November 21.

Biodesix obtained a term loan facility for \$30 million from Perceptive Advisors (New York City). The loan bears interest at an annual rate equal to the greater of the one-month SOFR (currently at 3.8%) or 3% per annum, plus a fixed 9%. The annual rate on the loan is currently 12.8%. The term loan is secured by a first lien on all Biodesix's assets. In addition, Biodesix raised gross proceeds of \$40.3 million from the sale of 35.1 million shares priced at \$1.15 per share. William Blair was the sole manager for the offering.

Biodesix will use the funds to pay down existing debt of \$24 million and the remainder will be used to help commercialize its blood-based tests for lung cancer.

CLFS Rate Freeze Likely *(continued from page 1)*

Lab lobbyists are scrambling to try to get the Saving Access to Laboratory Services Act (S. 449/H.R. 8188) inserted into a year-end omnibus spending package. The fate of SALSA will be determined by December 23.

SALSA would freeze Medicare CLFS rates next year and revamp the PAMA private-payer data analysis.

Almost 800 tests on the Medicare CLFS will receive rate cuts of up to 15% effective January 1, 2023, if SALSA is not included in the omnibus package.

The Congressional Budget Office has not officially scored the cost of SALSA, but preliminary CBO estimates peg it at \$6 billion over 10 years, according to Mark Birenbaum, PhD, Administrator of the National Independent Laboratory Association (St. Louis, MO). He notes that this added cost would have to be offset by spending cuts elsewhere.

Given its estimated cost, it is unlikely that the complete SALSA bill will be included in the year-end spending package.

“We have bipartisan and bicameral support for SALSA. The sticking point is cost,” notes Birenbaum.

Potential for a One- or Two-Year Delay

However, ACLA President Susan Van Meter thinks there is a very good chance that a one-year delay in the rate cuts and data reporting (now scheduled for January 1 – March 30, 2023) can get into the package. That’s because a one-year delay would actually save CMS an estimated \$730 million over 10 years, according to preliminary CBO estimates. Thus, a one-year delay would not require offsetting “pay fors.”

In fact, Van Meter believes the industry may even be able to get a two-year CLFS rate freeze.

CBO staff were expected to have made their final scoring estimates for either a one-year or a two-year delay over this past weekend. A final omnibus spending package will be decided by the end of this week.

Doomsday Scenario

In the unlikely scenario that the lab industry gets no delays, then a total of approximately 200 tests on the CLFS would get the maximum 15% Medicare rate cut in 2023; another 400 tests would receive cuts of between 10% and 15%; and nearly 200 tests would get cuts of between 0.1% and 10%. High-volume lab tests that would receive the maximum 15% Medicare rate cut in 2023, include lipid panel (CPT 80061), PSA free (CPT 84154) and strep A DNA test (CPT 87651).

In addition, labs would need to report their private-payer payment data from 2016 to CMS between January 1 – March 30, 2023. CMS would use this information to calculate the CLFS for 2024-2026.

Labcorp Buys AMS Reference Laboratory

Labcorp has purchased assets from Affiliated Medical Services Laboratories Inc., including the 17,000-square-foot AMS Reference Lab in Wichita, Kansas. This laboratory is now operated by Labcorp Kansas. AMS, which was owned by Ascension Via Christi Health, had been one of the largest independent labs in Kansas. Estimated annual revenue at AMS Reference Laboratory is roughly \$20-\$30 million. Labcorp’s purchase of AMS Reference Lab was related to a larger agreement the company signed with Ascension earlier this year (see *LE*, February & October 2022).

Lab Stocks Down 56% Year To Date

Twenty-four lab stocks have dropped by an unweighted average of 56% year to date through December 17. In comparison, the S&P 500 Index has fallen by 17% so far this year. The top-performing lab stocks thus far in 2022 have been ProPhase Labs, up 40%; Quest Diagnostics, down 14%; and Labcorp, down 28%. The worst performing lab stock has been Sema4, which is down 94%.

Company (ticker)	Stock Price 12/17/22	Stock Price 12/31/21	2022 Price Change	Enterprise Value (\$ millions)	Revenue for Trailing 12 mos. (\$ millions)	Enterprise Value/Revenue
ProPhase Labs (PRPH)	\$10.04	\$7.17	40%	\$150	\$146	1.0
Quest Diagnostics (DGX)	149.24	173.01	-14%	21,050	10,294	2.0
Labcorp (LH)	226.99	314.21	-28%	26,070	15,259	1.7
Psychemedics (PMD)	4.96	\$7.02	-29%	29	26	1.1
Exact Sciences (EXAS)	51.92	77.83	-33%	11,010	2,005	5.5
Veracyte (VCYT)	27.41	41.20	-33%	1,810	284	6.4
Sonic Healthcare (SHL.AX)*	30.38	46.63	-35%	16,990	9,340	1.8
Myriad Genetics (MYGN)	16.69	27.60	-40%	1,230	661	1.9
Castle Biosciences (CSTL)	24.07	42.87	-44%	382	124	3.1
Natera (NTRA)	43.32	93.39	-54%	4,620	776	6.0
Enzo Biochem (ENZ)	1.33	3.21	-59%	72	99	0.7
NeoGenomics (NEO)	11.02	34.12	-68%	1,560	497	3.1
Biodesix (BDSX)	1.70	5.29	-68%	138	36	3.9
Fulgent Genetics (FLGT)	31.21	100.59	-69%	70	803	0.1
Guardant Health (GH)	30.06	100.02	-70%	3,340	431	7.7
CareDx (CDNA)	12.42	45.48	-73%	411	319	1.3
Opko Health (OPK)	1.25	4.81	-74%	1,080	1,220	0.9
Exagen (XGN)	2.47	11.63	-79%	7	45	0.16
Aspira Women's Hlth (AWH)	0.32	1.77	-82%	22	8	2.8
Biocept (BIOC)	0.59	3.62	-84%	4	50	0.1
Invitae (NVTA)	2.11	15.27	-86%	1,680	520	3.2
Interpace Biosciences (IDXG)	1.00	7.47	-87%	55	41	1.4
DermTech Inc. (DMTK)	2.05	15.80	-87%	-63	15	NA
Sema4 Holdings (SMFR)	0.26	4.46	-94%	-12	231	NA
Unweighted Averages			-56%	\$91,705	\$43,230	2.1

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from YFinance and Seeking Alpha

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