

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

What The End of The PHE Means for Labs

President Biden has announced that his administration plans to end the Covid-19 Public Health Emergency (PHE) on May 11. Termination of the Covid-19 PHE will have a number of consequences for labs and pathologists. At the top of the list is reduced Medicare reimbursement for high-throughput Covid-19 testing (U0003 & U0004) effective at the end of the PHE. In addition, the Medicare add-on payment (U0005) of \$25 for two-day turnaround time of high-throughput Covid-19 test results will be eliminated.

Full details on page 4.

Pathologist Loses Suit Against Malpractice Insurer

Retired pathologist Joy Trueblood, MD, has lost her lawsuit against her former malpractice insurer MMIC Insurance (Minneapolis, MN). Trueblood had worked at the Iowa Clinic and had testified in a highly publicized medical malpractice case in 2019 that she was responsible for a mix-up in biopsy slides that resulted in a prostatectomy on the wrong patient. Trueblood alleged that MMIC officials pressured her to take the blame for the error, which she said the company knew was not her fault.

Full details on page 5.

MACs Target Toxicology Labs for Audits

As part of a new 2023 directive, CMS is asking Medicare Administrative Contractors (MACs) to focus payment audits and claim reviews on providers and labs performing definitive drug testing. While CMS targets labs that have high denial rates or unusual billing practices, they can conduct an audit on any lab performing services under the following toxicology codes: G0480, G0481, G0482 and G0483.

These audits are being conducted as part of the CMS Targeted Probe and Educate (TPE) program, which is intended to help providers identify common billing errors and correct them before implementing more substantial actions, such as prepayment reviews or takebacks, notes Ann Lambrix, Vice President, RCM Solutions at Lighthouse Lab Services (Charlotte, NC).

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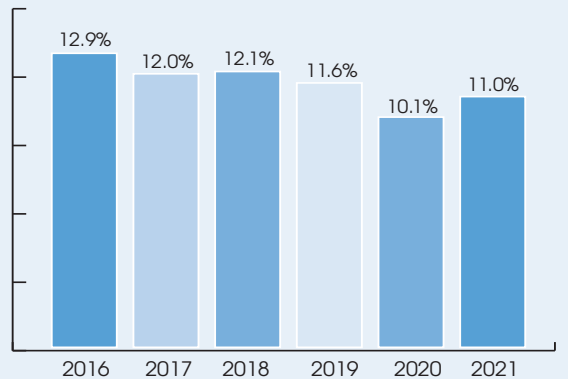
MACs Target Toxicology Labs for Audits *(cont'd from page 1)*

Lambrix says that MACs are asking toxicology labs to send them claims and supporting documentation for a sample of 20-40 claims. MACs are reviewing these claims for appropriate ICD-10 coding that supports the medical necessity of the billed tests. Overutilization of generic ICD-10 codes and missing physician signatures are red flags, notes Lambrix.

Lambrix says that past TPE audits have focused on ESRD clinics, rehabilitative therapy services, Mohs micrographic surgery, etc. She believes that clinical lab testing will be a focus area for the next 3-5 years.

A higher-than-average claims denial rate can be a trigger for a TPE audit. Medicare Part B carrier denial rates for the relevant toxicology codes (G0480-G0483) averaged 11% in 2021, according to data from CodeMap LLC (Chicago, IL). The most common reason for denials is that the documentation submitted does not support medical necessity for the testing.

Average Medicare Part B Claim Denial Rate for Toxicology Codes*



*For codes G0480-G0483 Source: www.CodeMap.com

Aegis Sciences Acquires HealthTrackRx's Toxicology Business

Aegis Sciences Corp. (Nashville, TN) has acquired the toxicology testing business of HealthTrackRx (Denton, TX) for an undisclosed amount. HealthTrackRx's 250 toxicology clients and approximately 100,000 in annual patient samples have been shifted to the Aegis laboratory in Nashville.

The HealthTrackRx toxicology testing business had operated under the name The American Institute of Toxicology (AIT Labs) and specialized in urine drug monitoring. HealthTrackRx says it will now focus on its bigger and faster-growing PCR-based infectious disease testing laboratory.

Aegis processed more than 1 million toxicology samples in 2022 (prior to the acquisition). This was a record for Aegis and well north of the company's pre-pandemic levels, according to CEO Frank Basile, MD.

Covid-19 PCR Testing Update

Separately, Basile says that Aegis has performed 14+ million Covid-19 PCR tests since the start of the pandemic. At its peak in the summer of 2021, Aegis was performing an average of up to 80,000 Covid-19 PCR tests per day. A smaller peak occurred in early 2022. Demand has since plummeted and Aegis is now performing roughly 2,000 Covid-19 PCR tests per day.

Expansion Into Infectious Disease Testing

Over the past year, Aegis has redirected its spare PCR testing capacity into infectious disease testing, including respiratory, gastrointestinal, sexually transmitted disease and urinary tract infection (UTI) testing, according to Mike Ziegler, Chief Commercial Officer at Aegis.

Ziegler says that Aegis is seeking to differentiate its services by offering targeted test panels with a limited number of tests. "Not very many labs are marketing infectious disease test panels comprised of tests based on medical necessity," according to Ziegler. For example, he says that Aegis's standard UTI profile does not include bacteria associated with hospital-acquired infections since most patients in a given practice may not have had a recent hospital stay.

Aegis Sciences Leads In Toxicology Testing

Aegis Sciences Corp. operates the nation's largest toxicology lab as measured by Medicare Part B carrier allowed payments for calendar year 2020 (the latest available data). Aegis received Medicare payments totaling \$32.4 million for 214,348 test services for five key toxicology codes (G0480-G0483 & 80307) in 2020. The acquisition of the HealthTrackRx toxicology line of business brings Aegis additional annual Medicare payments of \$2.6 million with total allowed test services of 17,716.

On a consolidated basis, Labcorp had total Medicare Part B allowed payments of \$45.3 million for 378,083 test services performed at 22 lab locations.

Quest Diagnostics had total Medicare Part B allowed payments of \$33.5 million for 328,888 test services performed at 28 lab locations.

Top 25 Toxicology Labs by Medicare Part B Carrier Allowed Payments for 2020

<i>Laboratory Name</i>	<i>Location</i>	<i>Medicare Part B Carrier Volume 2020*</i>	<i>Medicare Part B Carrier Allowed Payments 2020*</i>
Aegis Sciences Corp.	Nashville, TN	214,348	\$32,373,832
Labcorp	Burlington, NC	227,509	\$29,679,675
Millennium Health	San Diego, CA	147,202	\$24,306,334
Precision Toxicology	San Diego, CA	74,675	\$13,104,807
Labcorp	Research Triangle Park, NC	74,540	\$8,196,563
Beach Tox LLC	Torrance, CA	28,987	\$7,127,324
MD Spine Solutions (dba MD Labs Inc.)	Reno, NV	34,033	\$6,088,855
Dominion Diagnostics	North Kingstown, RI	59,487	\$5,638,370
Radeas LLC	Wake Forest, NC	29,599	\$5,390,406
Medscan Laboratory Inc.	Williston, ND	29,411	\$5,183,395
Ark Laboratory LLC	Waterford, MI	31,864	\$5,029,538
Ethos Holding Corp.	Newport, KY	34,246	\$5,010,661
Mako Medical Laboratories	Raleigh, NC	31,674	\$4,932,200
Regional Toxicology Services	Tacoma, WA	46,483	\$4,847,185
South Georgia Toxicology	Valdosta, GA	27,334	\$4,491,357
Quest Diagnostics	Wood Dale, IL	44,366	\$4,440,233
Paradigm Labs	St. Simons Island, GA	32,087	\$4,270,512
ACM/Drugscan Inc.	Horsham, PA	42,805	\$4,145,753
National Labs Inc.	Hayward, CA	31,437	\$4,090,937
Lifebrite Laboratories	Brookhaven, GA	23,544	\$3,947,368
Accu Reference Medical Lab	Linden, NJ	20,542	\$3,902,077
Compass Laboratory Services	Memphis, TN	24,819	\$3,756,847
Biotech Clinical Laboratories Inc.	Novi, MI	18,395	\$3,648,220
Quest Diagnostics	Tucker, GA	36,320	\$3,502,007
Genotox Laboratories	Austin, TX	19,844	\$3,286,417
Top 25 Total		1,385,551	\$200,390,873
Grand Total All Independent Labs		5,204,892	\$651,980,655

*Medicare Part B Carrier allowed volume and payments are for five toxicology codes (G0480-G0483 & 80307) for calendar year 2020

Source: CMS

What The End of The PHE Means for Labs *(cont'd from page 1)*

During the PHE, Medicare has paid labs \$75 for high-throughput Covid-19 testing (U0003 & U0004) plus \$25 for two-day turnaround of results (U0005) for a total of \$100. After May 11, Medicare reimbursement for high-throughput Covid-19 testing will be lowered to \$51 with no \$25 add-on payment. Furthermore, some private insurers are likely to discount their Covid-19 reimbursement rates below the new Medicare rates.

Out-of-Network Covid Testing

Private health insurance plans have been required to reimburse out-of-network labs for Covid-19 tests based on their listed cash charge. This requirement will end after May 11.

Prior Authorization

Private health insurance plans have been required to cover Covid-19 tests without cost sharing, prior authorization or other medical management requirements. These requirements will end after May 11.

At-Home Covid Tests

Beneficiaries with traditional Medicare will no longer receive free, at-home (or over-the-counter) Covid-19 tests. Those with private insurance and Medicare Advantage (private Medicare plans) will no longer be guaranteed free at-home tests, although some insurers might continue to voluntarily cover them. For those on Medicaid, at-home tests will be covered at no-cost through September 2024. After that date, home test coverage will vary by state.

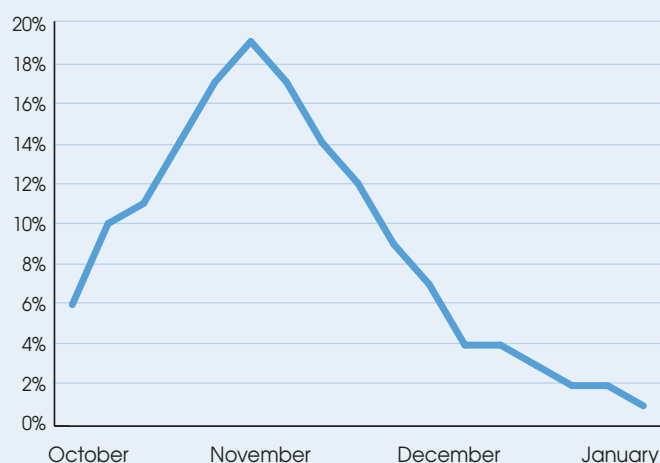
Specimen Collection from Homebound Patients

In order to facilitate Covid-19 testing of quarantined homebound patients, Medicare paid independent labs \$23.46 for specimen collection (G2023). Likewise, Medicare paid independent labs \$25.46 for specimen collection from nursing home patients (G2024). These payment amounts will end at the termination of the PHE.

RSV Has Sharp Early Peak

Respiratory Syncytial Virus's early peak in November 2022 proved to be just that—an early peak. Typically, respiratory viruses see their greatest infection and hospitalization rates in the first week of the new year. That's why RSV's 18.9% hospitalization rate in children in November

RSV Rate of Hospitalization in Children Ages 0-17



Source: U.S. Centers for Disease Control and Prevention

2022 was worth keeping an eye on (see *LE*, November 2022).

RSV is typically responsible for 100-300 deaths in children younger than 5 years old, according to the CDC. The multi-year high hospitalization rate in November led many to believe this winter would be especially deadly.

However, RSV has since tapered and mostly fizzled out as far as hospitalizations go. The RSV hospitalization rate fell to 1% by the end of January. This is likely due to immune systems getting back into shape after pandemic shutdowns.

Pathologist Loses Suit Against Malpractice Insurer *(cont'd from page 1)*

The patient who underwent unnecessary prostate surgery as a result of the error received a \$12.25 million jury award in April 2019, which was settled for \$9 million. The settlement amount was within Trueblood's malpractice insurance policy limits and was paid for by MMIC.

Nonetheless, Trueblood filed a lawsuit against MMIC in a Minnesota district court in April 2020. She sought punitive damages in the case, alleging bad faith, breach of fiduciary duty and intentional infliction of emotional distress on the part of MMIC.

Because Trueblood did not make any personal payment toward the settlement, MMIC did not breach its duty of good faith, and the Minnesota court dismissed the lawsuit with prejudice. The Minnesota Court of Appeals affirmed that ruling in February 2022.

In June 2022, Trueblood filed the same claims against MMIC, this time in Polk County District Court in Des Moines, Iowa. Trueblood argued the new lawsuit was permitted because the Minnesota case was not decided on the merits of her claim.

MMIC filed for judgment against Trueblood, arguing that the dismissal of the Minnesota case was binding and forbade her from bringing the same claims in any other jurisdiction. It also asked the Iowa court to sanction Trueblood's lawyer for filing what the company deemed a "frivolous" lawsuit.

Interestingly, Trueblood's lawyer is Nick Rowley from the law firm Jordan, Herington & Rowley. Rowley is the same medical malpractice attorney that had previously represented the patient who sued Trueblood.

In her Jan. 31 order, District Judge Samantha Gronewald agreed with MMIC that the case should be dismissed, citing the U.S. Constitution's dictate that each state give "full faith and credit" to the acts and court proceedings of other states.

"Dr. Trueblood's petition is barred as a matter of law in Iowa pursuant to the full faith and credit clause of the United States Constitution," Gronewald wrote.

Rowley says he plans to appeal.

FDA Lowers The Bar For AI Software Algorithms

On February 2, the Food and Drug Administration (FDA) published a final order that down-classifies AI software algorithms for digital pathology to class II from class III. The FDA's class II categorization will enable manufacturers of such devices to go through a less burdensome process of obtaining FDA clearance.

The FDA said that the change "will enhance patients' access to beneficial innovation."

AI software algorithms applied to digitized slides provide pathologists with information about the presence, location, and characteristics of areas of the image with clinical implications. That information assists pathologists with their diagnosis.

To date, the only AI software tool for digitized slides that has been cleared by the FDA is Paige Prostate, which was cleared in September 2021. The Paige Prostate software analyzes digitized biopsy slides and identifies areas that could be cancerous for the pathologist to review further (see *LE*, October 2021).

Spotlight Interview With IHD's Chris Howlett

An Inside Look at How One Lab is Approaching Acquisitions



Chris Howlett

Innovative Health Diagnostics (IHD-Irvine, CA) is a full-service independent lab with 170 employees that specializes in fertility and in vitro fertilization (IVF) testing and FDA donor testing for families completing surrogacies. Over the past three years, IHD also became one of the nation's higher-volume Covid-19 PCR testing labs. Last year, IHD hired Chris Howlett as a Senior Advisor to its Board to help execute its new acquisition strategy. Below we highlight his views on M&A trends in the lab industry.

Can you describe your experience in the lab industry?

I started with National Health Laboratories, which later became Labcorp, back in 1988 and ultimately became their Associate Regional Director in Nevada and Northern California. I also worked as Senior Vice President for Business Development at Unilab Corp. (now part of Quest Diagnostics). More recently I was CEO at the pharmacogenetic testing lab Genelex (Seattle, WA), which was acquired by Invitae in 2020. In addition, I helped found and serve on the board at Market Street Healthcare Partners (Houston, TX), a private equity firm focused on healthcare services.

What's the current situation at IHD?

IHD was among the first independent labs in California to offer Covid-19 PCR testing at the start of the pandemic. At its peak in early 2022, IHD was performing up to 15,000 Covid-19 PCR tests per day. They are currently averaging about 2,000 per day. IHD now plans to invest the capital it built up from Covid testing into lab acquisitions.

Who owns IHD?

Owners include Chairman Rajit Malhotra, President David White and myself, among others.

What's your process for finding potential acquisition candidates?

There is no formal process and we're fishing with different lures, including networking at conferences and using brokers. The huge volume of Covid-19 testing created a windfall for labs and has fast-forwarded the retirement plans for many independent lab owners in their 50s or 60s. We're expecting an above-average number of lab transactions to occur in the next 2-3 years and current activity supports this trend.

What's your ideal acquisition candidate?

A clinical lab on the west coast with annual revenue in the range of \$3 million to \$25 million with an EBITDA margin in the range of 20% to 40%.

Which types of labs are you avoiding?

Labs with questionable ethics, including those that rely on outside marketing firms instead of employed W-2 sales reps. In addition, we are also wary of one-trick pony labs that rely on a small number of test codes, or where the majority of the testing revenue is based on novel tests with unproven payer reimbursement. It just takes one change in reimbursement or coding to wreck their business models. We much prefer labs with a broad and diverse test mix.

What kinds of acquisition multiples are you currently seeing?

There is wide variation depending on each particular transaction, but the averages fall in the range of 3-7 times EBITDA and 0.8 to 2.0 times annual revenue. I would note that contingent consideration is generally part of most deals. It can range between 5% to 20% of the deal's value and is based on achievement of specific milestones such as EBITDA or revenue targets, client retention, or getting FDA clearance on a proprietary test.

What are IHD's goals for deal completions this year?

IHD closed on two deals in southern California late last year and I'm confident we'll close on at least another three acquisitions this year. Right now, we can self-fund, but eventually we may raise additional capital through a private placement debt offering.

An Expert's View on Today's Laboratory Acquisition Trends

Chris Jahnle co-founded, along with Kirk Rebane, the M&A consulting and business valuation firm Haverford Healthcare Advisors (Radnor, PA) in 1994. Over the past 29 years, Haverford has advised on more than 85 clinical lab and pathology practice transactions as well as approximately 2,000 healthcare services business valuations. Below we summarize Jahnle's thoughts on several key topics in today's laboratory M&A market.



Chris Jahnle

What are the latest M&A trends?

Number one, Quest Diagnostics and Labcorp are continuing to acquire hospital outreach labs at an accelerated pace. Hospitals are under financial pressure and their clinical lab outreach businesses are often only marginally profitable. The big labs are often paying within a range of 1.5x to 2.5x annual cash receipts. These transactions take a long time to complete but I expect several more hospital outreach lab transactions to close this year.

I also expect a pickup in pathology practice deals. Over the past few years, the most active big buyers have included Sonic Healthcare, PathGroup and Fulgent Genetics.

Additionally, private equity investors are getting more interested in pathology. They see the opportunity to bring capital into pathology labs that can be invested in digital pathology scanners and AI software tools. Examples of this include PathAI's purchase of Poplar Healthcare and Versant Diagnostics' recent acquisitions of several pathology groups.

What are you seeing in terms of routine clinical lab valuations?

I expect routine clinical labs focused on traditional physician office business to remain attractive acquisition targets for Quest and Labcorp. Larger independent labs showing consistent revenue growth can be valued as high as 2.0 to 2.5 times annual cash collections.

Generally, the national labs are not interested in acquiring nursing home labs and toxicology labs. Valuations for these types of labs is typically less than 1.0 times annual cash collections.

What about pathology practice valuations?

Pathology practices are valued based on their EBITDA, or pretax cash flow, after adjustments to normalize the cost of owner-pathologist compensation. Adjusted EBITDA multiples for pathology practice acquisitions often range from 6.0x to 10.0x. Higher valuations are paid for larger practices that are not reliant on just one or two hospital system clients. Ownership of a technical lab can also raise the value of a pathology group.

What's your advice on contingent consideration (aka earnouts)?

Earnouts typically represent between 10% to 33% of the purchase price paid to an owner(s) for their lab business.

In order to avoid confusion, an earnout arrangement should be very specific in defining the conditions that must be met in order to obtain an earnout payment. The seller should also insist on receiving regular interim financial reports from the buyer to minimize any surprises post transaction.

In addition, I often recommend earnout milestones tied to an event rather than financial results to avoid measurement discrepancies. Examples include earnouts tied to new client additions or hospital contract renewals.

If the buyer insists on earnouts tied to financial results than its better to use net revenue or cash collections goals as opposed to EBITDA which can vary depending on the accounting methods used. Simpler is always better.

How can a seller increase the value of their lab?

Button down any loose ends before going to market. Any key insurance or client contracts that expire within 12 months should be extended and any key open positions should be filled. A third-party billing audit should also be conducted. Any questionable historical billing practices should be addressed in advance. Buyers have zero tolerance for labs with material compliance issues uncovered during due diligence.

How can an owner minimize their capital gains taxes?

Most deals today are being structured as asset purchase transactions. Buyers prefer to purchase assets because it limits their exposure to potential liabilities as compared with stock purchase deals.

As a result, the best tax-advantage strategy from the seller's perspective is to structure their business legally as a "pass-through" entity such as an S-corporation, LLC or partnership. Under these structures, a seller of assets will generally pay federal taxes at the relatively low long-term capital gains tax rate of 20%.

In contrast, the owner of a lab company structured as a C-corporation would get taxed twice under an asset purchase transaction, at both the corporate and the personal level.

What's your best advice for a lab owner thinking about selling?

Hire an M&A advisor that can help to prepare your business for sale, orchestrate a formal competitive bidding process, and lead you through the due diligence process. Buyers have become increasingly intense in their scrutiny of the seller during due diligence and this process can extend for many months in complex cases.

Laboratory Acquisition Summary for 2022

Date	Buyer	Target & Location	Purchase Price (\$ millions)	Acquired Revenue (\$ millions)	Price/Revenue
Pending	Quest Diagnostics	Northern Light Health outreach lab (Bangor, ME)	NA	15E	NA
Feb-23	Avalon GloboCare	Laboratory Services LLC (Costa Mesa, CA)	41	20E	2.0
Jan-23	Aegis Sciences Corp.	HealthTrackRx toxicology lab (Denton, TX)	NA	20E	NA
Dec-22	Karrington Clinical Lab	Matrix Clinical Lab/Biocerna (Fulton, MD)	NA	NA	NA
Nov-22	Quest Diagnostics	Summa Health LabCare Plus (Akron, OH)	NA	NA	NA
Oct-22	Mana Capital	Cardio Diagnostics (Chicago, IL)	65	<1	NA
Oct-22	Labcorp	Ascension Health outreach labs (St Louis, MO)	400	150	2.7
Oct-22	Labcorp	Affiliated Medical Services Labs (Wichita, KS)	NA	25E	NA
Oct-22	Patients Choice Lab	Infinity Laboratories (Bridgeport, TX)	NA	NA	NA
Aug-22	MDxHealth	Exact Sciences Oncotype Prostate Test	100	33	3.0
May-22	Fulgent Genetics	Inform Diagnostics (Irving, TX)	170	125E	1.4
Oct-22	Labcorp	Accurate Diagnostics Labs (South Plainfield, NJ)	NA	75E	NA
Aug-22	Mako Medical Labs	ScientiaDx (Lyndhurst, NJ)	NA	NA	NA
Aug-22	Labcorp	RWJBarnabas Health outreach labs (New Jersey)	NA	NA	NA
Jun-22	Versant Diagnostics	Pathology Consultants of Chicago	NA	NA	NA
Jun-22	Versant Diagnostics	Elgin Laboratory Physicians (Elgin, IL)	NA	NA	NA
Jun-22	Labcorp	Prisma Health outreach labs (South Carolina)	NA	NA	NA
May-22	Innovative Gx Labs	Nationwide Laboratory Svcs. (insurance contracts only)	NA	NA	NA
May-22	LetsGetChecked	Veritas Genetics (Danvers, MA)	NA	NA	NA
May-22	EmeritusDX	Freedom Pathology Partners (Conshohocken, PA)	NA	NA	NA
May-22	GTCR and mgt.	PathGroup (Brentwood, TN)	NA	>500	NA
May-22	Labcorp	AtlantiCare outreach labs (southern NJ)	NA	NA	NA
Apr-22	Sema4	GeneDx (Gaithersburg, MD)	472	130	3.6
Apr-22	Castle Biosciences	AltheaDx (San Diego, CA)	140	3	46.7
Apr-22	Convergent Laboratories	First Path Laboratory (Pompano Beach, FL)	NA	NA	NA
Apr-22	MAWD Pathology	Boyce & Bynum Pathology Prof. Svcs. (Columbia, MO)	NA	NA	NA
Mar-22	Diversified Medical	Dynasty Medical Laboratory (Hurricane, UT)	NA	NA	NA
Feb-22	Labcorp	Personal Genome Diagnostics (Baltimore, MD)	545	40	13.6
Feb-22	Lucid Diagnostics	ResearchDx (Lake Forest, CA)	6	NA	NA
Jan-22	PathGroup	Pathology Consultants (Greenville, SC)	NA	NA	NA
Jan-22	Exact Sciences	PreventionGenetics (Marshfield, WI)	190	36	5.3

Source: *Laboratory Economics*

Quest Reports Full-Year 2022 Financial Results

Quest Diagnostics reported net income of \$946 million for full-year 2022, down from \$2 billion in 2021. Quest's overall revenue decreased by 8.4% to a \$9.9 billion, with acquisitions contributing roughly 1% to revenue growth. Quest's average revenue per requisition fell by 4.5% to an estimated \$46 per req. A summary of key topics discussed by CEO Jim Davis and CFO Sam Samad on a February 2 conference call follows.

Specimen Collection Fee Hike

The Medicare reimbursement rate for blood draws (CPT 36415) was nearly tripled to \$8.57 effective January 1, 2023 (see *LE*, December 2022). Davis said this will result in \$35-\$40 million of additional annual Medicare revenue for Quest. In addition, Davis noted that Quest currently gets reimbursed for about 25% of the blood draws it does for commercial payers. "We're gonna push hard not only to expand that 25%, but for those that do reimburse us, to take those rates up as well," said Davis.

Hospital Lab Outreach Acquisitions

Davis expects Quest to close on several deals in the first half of this year. "The funnel of opportunities with health systems, which are facing major margin pressures due to labor challenges and mix shift from inpatient to outpatient care, is as big as it's ever been."

Davis also said that following the Covid testing boom, some independent lab owners are "raising their hands and putting up the retirement flag to potentially sell out."

Direct-to-Consumer Testing

Last year, Quest recorded approximately \$96 million of revenue from its QuestDirect consumer testing business (mostly Covid-19 tests) versus \$70 million in 2021. Quest is ramping up marketing spending to consumers, including "Cyber Monday" online advertising and 15% off coupons.

Covid Testing

Quest performed an average of roughly 17,000 Covid-19 PCR tests in January, which represented less than 3% of its overall daily volumes. Quest is anticipating that it will perform an average of roughly 5,000 to 10,000 Covid-19 PCR tests per day for full-year 2023—

representing revenue of between \$175-\$275 million.

PAMA

A one-year delay in Medicare reimbursement cuts under PAMA that had been scheduled to take effect in 2023 has saved Quest \$80-85 million. Davis said that Quest continues to work with ACLA for a permanent legislative fix to PAMA.

Quest Diagnostics Financial Summary (\$ millions)

	2022	2021	% Chg
Total revenue	\$9,883	\$10,788	-8.4%
Base lab testing revenue	8,155	7,724	5.6%
Covid-19 testing revenue	1,454	2,770	-47.5%
Other revenue*	274	294	-6.8%
Operating cash flow	1,718	2,233	-23.1%
Capital expenditures	404	403	0.3%
Free cash flow	1,314	1,830	-28.2%
Pretax income	1,235	2,599	-52.5%
Net income	946	1,995	-52.6%
Diluted EPS	\$7.97	\$15.55	-48.7%
# Employees	50,000	50,000	0.0%
Avg. revenue per employee	\$197,660	\$215,760	-8.4%
Est'd number of requisitions (millions)	208	218	-4.5%
Est'd revenue per requisition	\$46.25	\$48.45	-4.5%

*Other revenue includes clinical trials testing, info tech services and testing for life insurance companies
Source: Quest Diagnostics and *LE*'s estimates for number of reqs and average revenue per req.

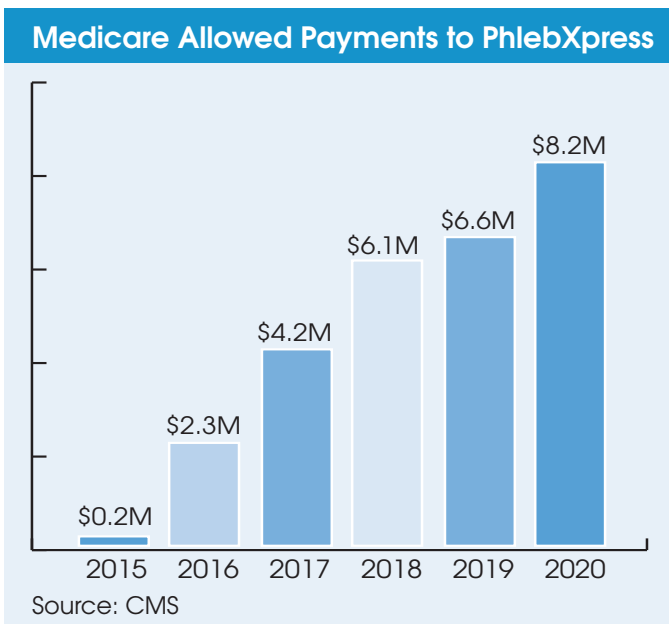
PhlebXpress Owners Plead Guilty To \$7.5 Million Medicare Fraud

Gabriella Santibanez, 58, and her sister Lisa Hazard, 54, have pleaded guilty to conspiring to commit over \$7.5 million in healthcare fraud, according to the U.S. Attorney's Office for the Eastern District of California.

Court documents show that Santibanez and Hazard ran a mobile phlebotomy company, PhlebXpress Inc. (Temecula, CA), from Dec. 1, 2015 through Dec. 1, 2020. The company provided collection services at patients' homes and long-term care facilities in Sacramento and elsewhere.

PhlebXpress billed Medicare for services that were not reimbursable and its bills overstated the mileage traveled by the company's phlebotomists. On average, PhlebXpress falsely billed Medicare for more than 140 miles of travel per patient and Medicare paid at least \$7.5 million based on false billings by the company, the U.S. Attorney's Office said.

CMS records show that the Medicare program paid PhlebXpress a total of \$28 million from 2015 to 2020.



In November 2020, Medicare ceased paying PhlebXpress due to "credible allegations of fraud."

According to court documents, Santibanez and Hazard circumvented the payment suspension by creating a new company named Phlebotomy Solutions in 2021. The new company used PhlebXpress's employees and offices, and billed Medicare for non-reimbursable services and overstated mileage, according to the U.S. Attorney's Office.

Santibanez and Hazard are scheduled to be sentenced on May 1. Each faces a maximum penalty of 10 years in prison and a \$250,000 fine.

Sema4 Changes Name To GeneDx; Raises \$150 Million

Sema4 (Stamford, CT) has changed its name to GeneDx in mid-January. Sema4 acquired GeneDx from Opko Health for \$472 million in April 2022 (see *LE*, February 2022). The company has announced two restructurings and three rounds of job cuts since the acquisition was completed. The newly named company is now focusing on GeneDx's exome and genome sequencing business.

Separately, GeneDx raised \$150 million in gross proceeds from the sale of 429 million shares of common stock priced at \$0.35 per share on January 31. The investment bank Jefferies Group acted as the sole manager for the offering. GeneDx intends to use the net proceeds from the offering primarily for general corporate purposes, including additions to working capital.

GeneDx reported a net loss of \$240 million in the nine months ended Sept. 30, 2022 versus a net loss of \$205 million in the same period a year earlier; revenue was \$173 million versus \$154 million. GeneDx is aiming to turn profitable in 2025.

Labcorp Names CRO Spin-Off: Fortrea

Labcorp says it will name its forthcoming contract research organization (CRO) spin-off Fortrea. The spin-off is on track to be completed in mid-2023.

Fortrea will operate as an independent, publicly traded global CRO that offers comprehensive drug development services to pharmaceutical and biotechnology organizations. The new company will have 19,000 employees and annual revenue of approximately \$3 billion.

Labcorp expects to complete the transaction through a distribution of a dividend of the CRO business' shares to Labcorp's shareholders. The transaction is intended to be structured as tax-free for U.S. federal income tax purposes. Post spin-off, Labcorp will continue to be publicly listed on the New York Stock Exchange, and Fortrea will be a newly listed public entity.

Tom Pike, the former CEO of Quintiles before it merged with another firm to become Iqvia, was recently hired to lead Labcorp's CRO business. Pike will be Chairman and CEO of Fortrea.

Adam Schechter will continue as Chairman and CEO of Labcorp.

PreciseDx Gets NYS Approval for an AI-Enabled Breast Cancer Test

PreciseDx (New York City) has received approval from the New York State Department of Health for its PDxBr lab developed test. PreciseDx can now begin commercially testing patient samples in the state of New York at its CLIA-certified lab located at Mount Sinai Morning-side in Manhattan.

The PDxBr test analyzes digitized breast cancer tissue images with artificial intelligence assessment of 12 histologic and immunohistochemical features. Results are reported as a recurrence score designed to predict the risk of early-stage recurrence. The test was given a Medicare proprietary laboratory analysis (PLA) code (0220U) at a rate of \$706 effective October 1, 2020.

PreciseDx also has a prostate cancer test in development.

The cancer risk stratification technology used by PreciseDx is based on intellectual property developed by Mount Sinai faculty.

PreciseDx was founded by four doctor-scientists in 2019, including two pathologists (Gerardo Fernandez, MD and Carlos Cordon-Cardo, MD, PhD) affiliated with the Icahn School of Medicine at the Mount Sinai Health System. In addition, Erik Lium, Chief Commercial Innovation Officer at Mount Sinai Health System, is on the board at PreciseDx.

PreciseDx raised \$10.75 million in Series A Preferred funding in late 2021. The round was led by the Merck Global Health Innovation Fund (Merck GHI) with additional investment from Mount Sinai Health System, Agilent Technologies, IBM Ventures and the Hobart Group.

Avalon GloboCare Buys Majority Stake in Laboratory Services LLC

Avalon GloboCare Corp. (Freehold, NJ) has completed its acquisition of a 40% stake in Laboratory Services LLC (Costa Mesa, CA) for \$21 million plus \$10 million in potential earnouts. The acquisition will mark Avalon's entry into the lab testing business. In addition, Avalon has the option to purchase an additional 20% of Laboratory Services for \$10 million. Laboratory Services specializes in drug and toxicology testing, immunology tests, STD/STIs, molecular UTI testing and Covid PCR testing (see *LE*, November 2022).

Lab Stocks Up 19% So Far In 2023

Twenty-four lab stocks have risen by an unweighted average of 19% year to date through February 10. In comparison, the S&P 500 Index is up 7% year to date. The top-performing lab stock thus far in 2023 is DermTech, up 212%. Shares of DermTech soared on news that two more private payers (in Hawaii and New York) will cover its DermTech Melanoma Test. The test is covered by Medicare under the proprietary laboratory analysis (PLA) code 0089U at \$760.

Company (ticker)	Stock Price 2/10/23	Stock Price 12/30/22	2023 Price Change	Enterprise Value (\$ millions)	Revenue for Trailing 12 mos. (\$ millions)	Enterprise Value/Revenue
DermTech Inc. (DMTK)	\$5.52	\$1.77	212%	\$41	15	2.8
Aspira Women's Hlth (AWH)	0.51	0.33	55%	46	8	5.9
GeneDx (formerly Sema4)	0.40	0.26	54%	216	231	0.9
NeoGenomics (NEO)	12.41	9.24	34%	1,740	497	3.5
CareDx (CDNA)	15.30	11.41	34%	565	319	1.8
Exact Sciences (EXAS)	64.05	49.51	29%	13,170	2,005	6.6
Myriad Genetics (MYGN)	18.65	14.51	29%	1,390	661	2.1
Psychemedics (PMD)	5.51	4.90	12%	32	26	1.2
Castle Biosciences (CSTL)	26.47	23.54	12%	445	124	3.6
Invitae (NVTA)	2.08	1.86	12%	1,670	520	3.2
Fulgent Genetics (FLGT)	32.95	29.78	11%	122	803	0.2
Natera (NTRA)	42.77	40.17	6%	4,560	776	5.9
Exagen (XGN)	2.54	2.40	6%	8	45	0.2
Labcorp (LH)	245.89	235.48	4%	27,750	15,259	1.8
Guardant Health (GH)	27.99	27.20	3%	3,130	431	7.3
Veracyte (VCYT)	24.35	23.73	3%	1,590	284	5.6
Opko Health (OPK)	1.25	1.25	0%	1,080	1,220	0.9
Interpace Biosciences (IDYG)	1.02	1.04	-2%	55	41	1.4
Sonic Healthcare (SHL.AX)*	28.78	29.97	-4%	16,280	9,340	1.7
Biocept (BIOC)	0.50	0.53	-6%	3	50	0.1
Quest Diagnostics (DGX)	144.80	156.44	-7%	20,490	9,883	2.1
Enzo Biochem (ENZ)	1.29	1.43	-10%	70	99	0.7
ProPhase Labs (PRPH)	8.23	9.63	-15%	127	146	0.9
Biodesix (BDSX)	1.80	2.30	-22%	146	36	4.1
Totals & Averages			19%	\$94,728	\$42,818	2.2

*Sonic Healthcare's figures are in Australian dollars

Source: Laboratory Economics from SeekingAlpha.com

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Top 25 Hospital Labs in Toxicology Testing

Santa Cruz Valley Regional Hospital (Green Valley, FL) is the largest hospital-based toxicology testing lab, according to Medicare OPPS data for calendar year 2021. SCVRH received total Medicare fee-for-service payments of \$931,856 for 5 toxicology codes (G0480-G0483 & 80307) in 2021. This was more than double the \$442,012 that second place Oroville Hospital (Oroville, FL) received for the same 5 codes in 2021.

Top 25 Hospital Labs in Toxicology Testing*

<i>Laboratory Name</i>	<i>Location</i>	<i>Total Medicare OPPS Test Services for 2021</i>	<i>Total Medicare FFS Allowed Amount for 2021</i>
Santa Cruz Valley Regional Hospital	Green Valley, FL	7,113	\$931,856
Oroville Hospital	Oroville, FL	5,740	\$442,012
Saint Elizabeth Edgewood	Edgewood, MO	2,359	\$296,102
Northeastern Health System	Tahlequah, TX	1,844	\$274,911
Baystate Medical Center	Springfield, NJ	4,339	\$249,635
Charlton Memorial Hospital	Fall River, NJ	6,616	\$236,206
Presbyterian Hospital	Albuquerque, OK	4,034	\$234,362
Pemiscot Memorial Main Hospital	Hayti, NC	1,985	\$229,416
OCH Regional Medical Center	Starkville, NC	1,805	\$188,404
Herrin Hospital	Herrin, ME	1,968	\$186,571
Rochester General Hospital	Rochester, PA	2,760	\$180,486
Northern Regional Hospital	Mount Airy, PA	2,594	\$171,044
UNC Health Southeastern	Lumberton, PA	2,880	\$164,217
UnityPoint Health - Methodist	Peoria, MI	2,526	\$148,056
Penn Highlands Connellsville	Connellsville, UT	1,773	\$147,229
OhioHealth Riverside Methodist Hospital	Columbus, SC	1,575	\$146,945
St. Joseph Mercy Ann Arbor	Ypsilanti, NY	2,566	\$145,291
UC Davis Medical Center	Sacramento, HI	4,400	\$145,046
White River Medical Center	Batesville, FL	1,777	\$144,321
Springfield Memorial Hospital	Springfield, MA	2,205	\$139,699
Alliance HealthCare System Hospital	Holly Springs, NC	1,185	\$135,136
Geisinger Medical Center	Danville, TX	2,471	\$133,132
Carolinas Medical Center	Charlotte, SC	2,515	\$128,926
San Juan Regional Medical Center	Farmington, OK	1,365	\$127,070
Providence Portland Medical Center	Portland, TX	1,919	\$124,131
Total for top 25 hospitals		72,314	\$5,450,204
Grand Total for all hospitals		942,128	\$17,788,695

*Total Medicare OPPS allowed volume and fee-for-service payments are for five toxicology codes (G0480-G0483 & 80307) for calendar year 2021

Source: CMS