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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Medicare Physician Rates Bumped Up 1.7%

Congress has approved a federal spending deal that provides partial relief to the Medicare Physician Fee Schedule (MPFS) cuts that became effective January 1, 2024. The $460 billion package signed into law by President Biden includes a 1.68% boost for the 2024 MPFS's conversion factor effective March 9 through December 31, 2024. The hike in the conversion factor will raise Medicare rates paid for anatomic pathology professional services and technical services.
More details on page 6.

New Vanderbilt Medical Laboratories Facility to Target Outreach Market in Southeast

Vanderbilt University Medical Center (VUMC—Nashville) opened a new freestanding core laboratory in early March. The new 110,000-square-foot lab is located approximately five miles north from VUMC's main Nashville campus. The new lab (dba Vanderbilt Medical Laboratories) will serve VUMC-affiliated hospitals and clinicians and will also market outreach and reference testing services to external clients.

VUMC's decision to invest in its laboratory operations follows years of deliberate planning. It stands in sharp contrast to other health systems that have chosen to exit their lab outreach businesses by selling to one of the national lab companies.
Full details on page 4.

FDA Final LDT Rule Could be Published Soon

On March 1, the FDA submitted its final rule for LDT regulation to the White House's Office of Information and Regulatory Affairs (OIRA). This is a perfunctory last step before the final rule is published in the Federal Register. This could occur as soon as April 1. This will be the most impactful new regulatory change for laboratories since PAMA completely overhauled the Medicare CLFS in 2018.
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FDA FINAL LDT RULE COULD BE PUBLISHED SOON (*cont'd from page 1*)
OIRA (pronounced "oh-eye-rah") is a statutory part of the Office of Management and Budget within the Executive Office of the President. OIRA is responsible for reviewing all federal regulations (i.e., the Executive Branch's administrative actions) to ensure they meet all statutory requirements. OIRA is currently headed by Richard Revesz, Administrator, who was appointed by President Biden and confirmed by the U.S. Senate in late 2022.

"OIRA reviewed the proposed rule in record time, so it is reasonable to expect that the review of the final rule will not be protracted. I would not be surprised if OIRA completes its review in 30 days and FDA publishes the final rule in the federal register in the first week of April," according to attorney Sheila Walcoff, Chief Executive at the IVD consulting firm Goldbug Strategies (Gaithersburg, MD).

Typically, a final rule will specify an effective date of 30 or 60 days after the publication date, adds Walcoff.

Once a final rule is published it will be difficult to overturn.

Last Chance to Sway OIRA Against Regulation
OIRA staff held nine teleconferences with organizations advocating both for and against FDA LDT regulation last year. OIRA is next scheduled to meet with The Association for Diagnostics and Laboratory Medicine (ADLM — formerly AACC) on March 18. ADLM, which represents approximately 8,000 members, including clinical labs and IVD manufacturers, has steadfastly opposed FDA regulation of LDTs. This could be the last chance that the lab industry has to sway OIRA against rubber-stamping the final rule.

Expected Legal Challenge
A final rule is almost guaranteed to trigger a lawsuit from lab trade groups, which will argue that the FDA does not have the authority to regulate LDTs.

The American Clinical Laboratory Assn. (ACLA — Washington, DC) seems to be gearing up for a lawsuit to the impending final rule. In a statement, ACLA President Susan Van Meter said:

> ACLA has significant concerns about the legality and impact of FDA unilaterally imposing an ill-fitting medical device scheme on laboratory-developed testing services, which are professional services and not medical products. Should the agency promulgate a final rule, ACLA will assess its options at that time; but we continue to urge the agency to withdraw the proposed rule and reengage on advancing appropriate legislation.

Could a New Trump Administration Put the Kibosh on LDT Regulation?
As a component of OMB, OIRA is part of the Executive Office of the President and helps ensure that covered agencies' rules reflect the President's policies and priorities.

The FDA is moving quickly because the national election in November could result in a new administration opposed to LDT regulation. A new President could, immediately upon taking office, prevent a proposed rule from being finalized, according to long-time lab regulation expert Dennis Weissman (Falls Church, VA).

However, Weissman says that changing or canceling a final rule is much more difficult. Once a federal rule has been finalized a new administration would be required to undergo the formal rulemaking process (i.e., opportunity for public comment on a proposal followed by final rule) to change or repeal all or part of a final rule.

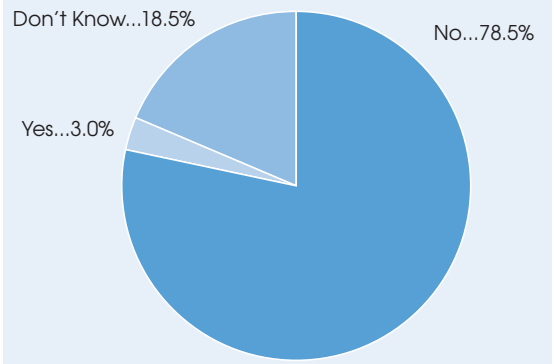
In addition to this administrative action, Congress could also take legislative action to overturn a final rule, notes Weissman.

Most Labs Don't Have the Money to Comply with LDT Regulation

Nearly 79% of respondents to an ARUP Laboratories survey said their labs do not have the financial resources to pay for user fees to get their LDTs cleared by the FDA.

FDA user fees for 2024 are $21,760 per "moderate risk" 510(k) submission and $483,560 per "high-risk" premarket authorization submission. Only 3% of respondents said they have the financial resources to comply and 18.5% responded "don't know."

Does your lab have the financial resources to pay for FDA user fees?



Source: ARUP Survey (February 2024: n=303)

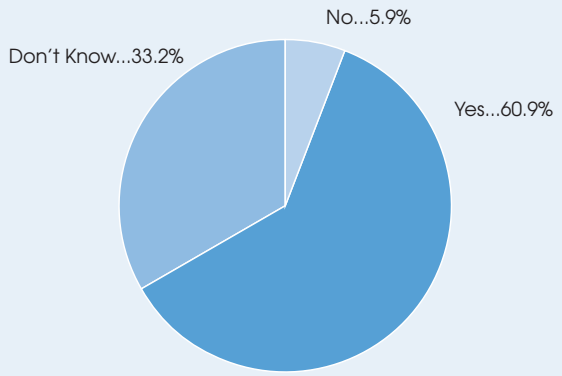
"If labs cannot afford to comply with the proposed regulations, they will have to discontinue essential tests, and that harms patients," noted Jonathan Genzen, MD, PhD, Chief Medical Officer and Senior Director of Governmental Affairs at ARUP.

The ARUP survey took place in February 2024 and received a total of 523 responses, including 303 responses from labs that perform LDTs. Most respondents identified as lab managers, lab supervisors, lab directors, medical directors or PhD scientists. The survey was emailed to 15,513 individuals at clinical lab clients of ARUP. Most of the respondents worked at community hospitals (55%), academic medical centers (20%) or independent labs (12%).

When asked how their laboratories would likely respond to the new regulatory requirements if the FDA adopts the proposed rule, nearly 61% of participants said they would likely remove tests from their laboratory menus. One-third of respondents were not sure what they would do. Only 6% said they would not remove any tests from their menu.

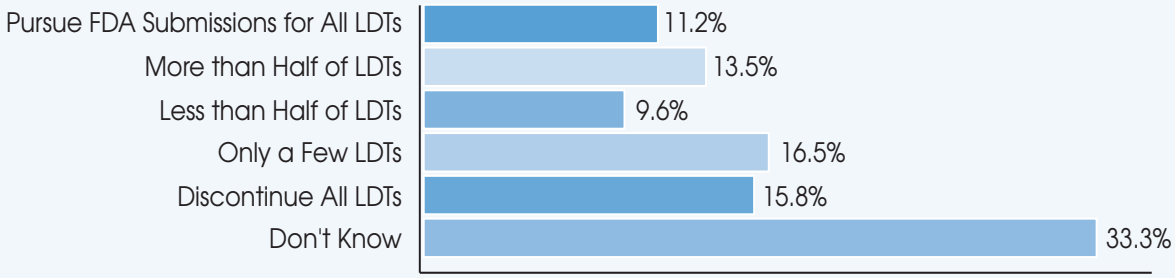
Nearly 16% of respondents said they would discontinue all existing LDTs if the FDA finalizes its proposed rule. Only 11% said they would pursue FDA submissions for all of their LDTs. One third of respondents chose "don't know" to this question, demonstrating they need to learn more about the proposed regulation and associated costs to formulate their laboratory's strategy.

Do you anticipate having to remove tests from your menu if the proposed rule is enacted?



Source: ARUP Survey (February 2024: n=303)

How will your lab respond to FDA regulation of LDTs?



Source: ARUP Survey (February 2024: n=303)

NEW VANDERBILT MEDICAL LABORATORIES FACILITY (*cont'd from page 1*)

Vanderbilt University Medical Center (VUMC) includes seven hospitals led by the flagship Vanderbilt University Hospital— 1,175 beds. The new lab is home to over 350 employees and includes most of VUMC's clinical and anatomic pathology operations. It also includes offices for lab administration and trainees. Here is a summary of *Laboratory Economics'* interview with VUMC's Adam Seegmiller, MD, PhD, Executive Medical Director of Pathology and Laboratory Medicine, and Victoria Laughman, Chief Business Development Officer for Laboratory Services.

Adam Seegmiller, MD, PhD

Victoria Laughman

What prompted the decision to build the new laboratory?
Vanderbilt's leadership recognizes that lab testing is a key part of patient care. The new laboratory will more than double the space of the prior laboratory and will allow for greater efficiencies to support future growth. The former lab was based at the VUMC main campus and is being downsized into a rapid testing lab (13,000 sq. ft./130+ test menu) to support inpatient care, surgeries and emergency departments.

How much did Vanderbilt invest in the new lab?
A significant amount that's part of a 10-year strategic plan for the laboratory with the necessary capital and resources to carry it out.

Can you describe the automation at the new lab?
We are using the Roche cobas connection sample conveyor system to connect to Roche instrumentation. We are the first lab in the country where a vertical lift component of the system has been installed. It takes specimens from the mainline up and over a walkway to a storage module. This allows us to keep a walking aisle open, so we do not create a barrier in the laboratory.

Can you describe your plans to expand outpatient/outreach testing?
We plan to provide more testing services to VUMC, which includes 3,000 physicians and more than 200 ambulatory locations. We also plan to market our lab services to other physician offices and nursing homes throughout Middle Tennessee.

Will Vanderbilt Medical Laboratories offer reference testing services to other hospitals?
Yes. We do this today and expect to grow this service offering throughout the Southeast region. Our current test menu consists of more than 550 tests, and we have plans to more than double this number through test insourcing.

What are some of your new test additions?
One significant addition will be human leukocyte antigen (HLA) testing, which determines if a potential organ donor and transplant recipient are a match. The Vanderbilt Transplant Center is the fifth-largest transplant center by volume in the nation. HLA testing is expected to be brought in-house by the first quarter of 2025.

Other areas of test menu expansion will include toxicology/drug monitoring and next-gen sequencing.

How are anatomic pathology services provided?
The new lab includes a full-service histology lab. Professional services are provided by Vanderbilt's 48 faculty pathologists, most of whom will be based at the new lab.

Any plans to begin digitizing your pathology slides?
Yes. We recently announced an agreement with Pramana Inc. (Cambridge, MA) and plan to begin digitizing slides for archiving, education, and research purposes this summer. This is a first step toward eventually using digital pathology for primary cancer diagnosis.

An Overview of the Nashville Lab Market

Total Population (2024): ..... 2.1 million

Annual population growth rate, 2019-2024: 1.9%

Total Medicare Part B allowed spending 2022 (independent labs): .....~$25 million

Total Medicare Part B allowed spending 2022 (hospital outreach labs): .....~$7 million

Estimated physician office lab services market size: .....$250 million

Greater Nashville, including Davidson, Murfreesboro and Franklin, currently has 2.1 million residents and is growing its population by an average of 1.9% per year. *Laboratory Economics* estimates the physician office lab services market in Nashville is $250 million. Below we summarize the largest lab players in the Nashville market.

PathGroup (Brentwood), the largest privately held lab company, has overall annual revenue of $575 million, including an estimated $60 million from the Nashville market.

Vanderbilt Medical Laboratories (Nashville), which is part of Vanderbilt University Medical Center, has an estimated $40 million outreach business in the Nashville area.

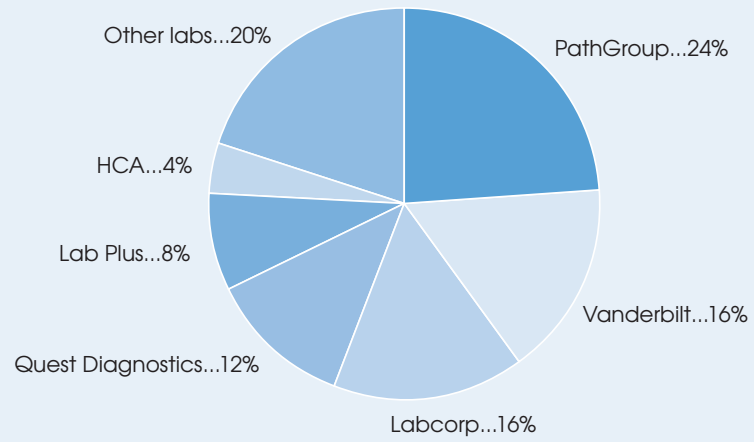
Labcorp has a total of 13 patient service centers (PSCs), including four at Walgreens stores, in the Nashville area. Estimated annual revenue from physician office clients in Nashville is $40 million.

Quest Diagnostics has a total of eight PSCs in the Nashville area. Estimated annual revenue from physician office clients in this region is $30 million.

Lab Plus LLC (Murfreesboro) is the brand name for the outreach lab business at Ascension Saint Thomas Health. Ascension sold most of its lab outreach business to Labcorp in 2023. As part of the agreement, Labcorp manages Ascension's hospital-based labs in Tennessee and nine other states. Estimated lab outreach revenue for Lab Plus is $20 million per year.

HCA Healthcare opened a new central lab (dba TriStar Central Laboratory) in Nashville in April 2023. The new lab serves 17 hospitals in HCA's TriStar Division spanning two states – Tennessee and Kentucky. Estimated lab outreach revenue is $10 million per year in the Nashville area.

Share of the Physician Lab Services Market in Nashville



Source: Estimated by *Laboratory Economics*

Specialty labs based in Nashville include **Aegis Sciences Corp.**, a national reference lab focused on toxicology testing, **Industry Lab Diagnostic Partners**, an independent lab focused on PCR-based testing, and **DCI Laboratory**, which is focused on dialysis patients.

MEDICARE PHYSICIAN RATES BUMPED UP 1.7% (*cont'd from page 1*)
This year Medicare reimbursement to physicians had declined, driven by a 3.4% reduction to the conversion factor (CF). The CF—the dollar multiplier used to convert adjusted relative value units into payment amounts for physician services—was dropped from 33.89 in 2023 to 32.74 for 2024, representing a 1.15 decrease (or -3.4%).

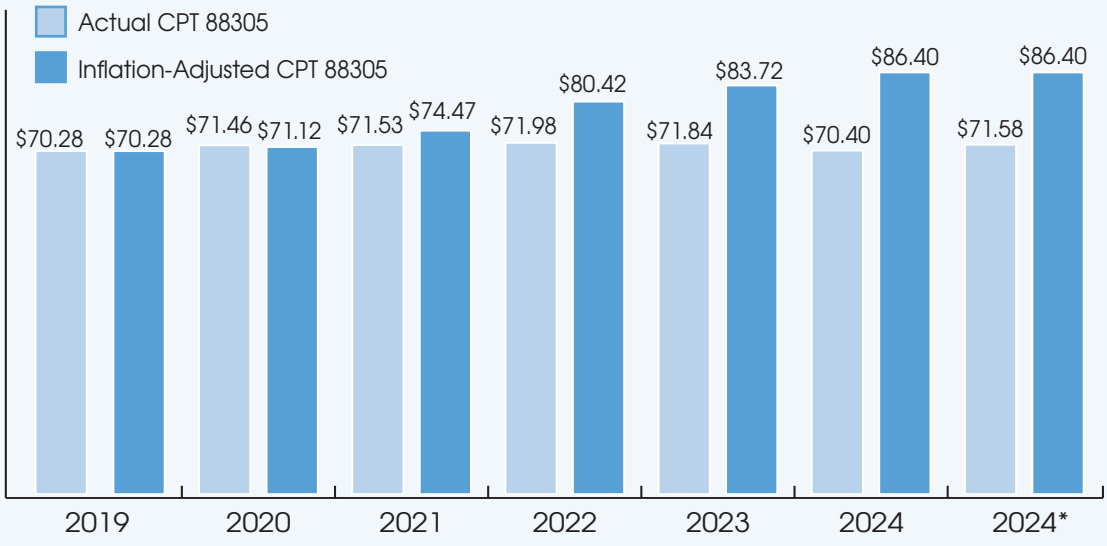
The new federal spending package has raised the CF by 1.7% to 33.29 effective March 9 through the end of the year. As a result, the national Medicare payment rate for CPT 88305 (Level IV – tissue exam by pathologist) has also increased by 1.7% to a global rate of $71.58, including $35.95 for the professional component and $35.63 for the technical component, according to preliminary estimates by *LE*.

This new relief equates to $19.1 million dollars for pathologists, according to the College of American Pathologists (CAP). Changes to Medicare payment rates are especially important because they influence reimbursement from other payers, including Medicaid and private insurers, notes *Laboratory Economics*.

Meanwhile, CAP and other physician groups continue to lobby for long-term Medicare payment reform. In particular, the American Medical Association (AMA) is seeking inflation-based updates to payment rates. AMA and other physician groups say that the 1.7% increase is insufficient, especially against the backdrop of rising inflation and operational costs.

Despite the small win for pathologists, Medicare reimbursement rates for pathology services have not kept up with inflation. The Medicare payment rate for CPT 88305 would currently be $86.40 if it had been annually adjusted for inflation (consumer price index—CPI) over the past five years.

Medicare Reimbursement Rate for CPT 88305



*After March 9, 2024
Source: *Laboratory Economics* and Bureau of Labor Statistics for Consumer Price Index (CPI)

New Avalon Network Targets 10+% Savings on Genetic Test Spending

Avalon Healthcare Solutions (Tampa, FL) is launching the AvalonSelect Genetic Network (ASGN), which will allow health plans to outsource the management of genetic test pricing, utilization and new test evaluation to Avalon. There are more than 175,000 genetic tests currently available and 10 new genetic tests are being introduced every day, notes Avalon's Mike Snyder, Executive Vice President, Network Solutions. The ASGN aims to provide health plans with 10+% savings on overall genetic test spending.

Snyder says that Avalon is in the process of adding genetic testing labs to ASGN. Requirements to join the network include having at least 20% of overall test volume coming from genetic tests, including Tier I & II molecular pathology procedures, genomic sequencing procedures, multianalyte assays with algorithmic analyses (MAAAs) and proprietary lab analysis (PLA) tests. In addition, Snyder says that labs joining the network must agree to a national fee schedule for genetic tests developed by Avalon.

The benefits for labs joining ASGN include greater certainty of payment, reduced prior authorization requests, and increased volume, according to Snyder.

Avalon has also begun marketing the ASGN product to health plans. Likely candidates include the 30 health plans, covering 39 million members, that already contract with Avalon for other services. Among Avalon's existing national and regional clients are BCBS plans from North Carolina and South Carolina, as well as HCSC- Health Care Service Corporation.

"Phase 1" of UnitedHealthcare Z-Code Requirement Starts April 1

Beginning April 1, UnitedHealthcare commercial plans will require DEX Z-Codes for certain molecular diagnostic test services on facility and professional claims for the claims to be considered for reimbursement.

Phase 1 of the Z-code requirement will affect 133 CPT codes as well as 104 proprietary lab analysis (PLA) codes. These codes cover:

- Adult molecular diagnostic tests relevant to Medicare age population, except inherited cancer testing
- Prenatal carrier screening tests
- Specific services billed under CPT 81479 (Unlisted molecular pathology procedure), including:
    - Genetic disease carrier status for procreative management
    - Pharmacogenomics testing (PGx), including single-gene and multi-gene panels

Furthermore, UnitedHealthcare has confirmed that it will be expanding its Z-code requirement to more tests later this year. "We're planning additional phases later in 2024 for other molecular pathology services. Once we have exact dates, we'll publish a Network News article so you can prepare accordingly," according to a February 1 announcement. Billing experts believe UnitedHealthcare is most likely to expand its Z-code requirement to PCR-based tests (see *LE*, January 2024).

UnitedHealthcare covers a grand total of 47.2 million members in the United States, including 27.3 million commercial members, 7.7 million Medicare Advantage, 4.4 million Medicare supplement and 7.8 million Medicaid.

Revenue at UnitedHealthcare totaled $281 billion in 2023, up 13% from $250 billion in 2023. Pretax earnings were $16.4 billion, up 14% from $14.4 billion. UnitedHealthcare is a business unit of UnitedHealth Group (Minnetonka, MN).

Capstone Settles False Claims Act Case for $14.3 Million

Capstone Diagnostics (aka ISPM Labs — Atlanta), and its owner CEO Drew Maloney, 57, have agreed to pay $14.3 million to settle allegations that they billed Medicare and Medicaid programs for medically unnecessary testing and violated the Anti-Kickback Statute.

According to the U.S. Department of Justice (DOJ), between August 2017 and December 2018, Capstone hired independent marketers to arrange for the ordering of toxicology testing on children participating in an after-school and youth mentoring program known as Do It 4 The Hood (D4H). Teenagers enrolled in the program were required to submit frequent urine specimens for drug testing without regard to medical need or the history of the participant. Capstone paid operators of D4H a percentage of Medicaid reimbursements for samples submitted by the program, in violation of federal law. Maloney and four others have pleaded guilty in connection with this fraud, according to DOJ.

In addition, DOJ charged Capstone and Maloney with taking advantage of the pandemic by billing the government for millions of dollars in unnecessary respiratory pathogen panels (RPPs). DOJ says that between April 2020 and December 2021, Capstone and Maloney paid independent contractor sales reps to recommend expensive RPPs to senior communities. To generate orders, Capstone's contracted sales reps completed test requisition forms for RPPs using forged signatures of physicians who had only ordered Covid tests. Capstone billed Medicare for these medically unnecessary tests and paid sales reps a commission for each test, according to DOJ.

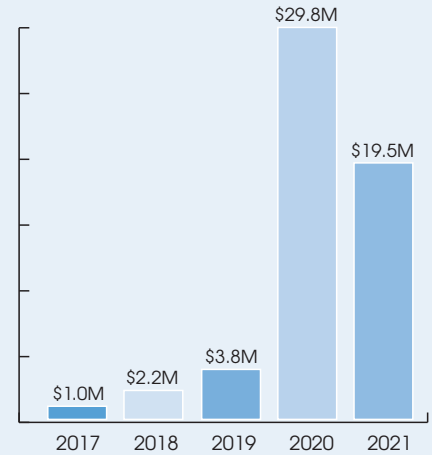
In addition to paying a $14.3 million settlement, Maloney could be sentenced to a prison term. Maloney's sentencing is scheduled for May 29 and will be decided by U.S. District Judge J.P. Boulee.

Whistleblower Gets $2.86 Million

Capstone's malfeasance was first brought to the government's attention by whistleblower Jesse Allen. Allen worked as Capstone's laboratory manager from April 2017 to January 2019. Allen says that he resigned after Capstone asked him to engage in illegal activities. He then hired the whistleblower law firm Bracker & Marcus (Atlanta).

Bracker & Marcus say that two days after Allen resigned, someone hacked into his personal email and deleted much of its contents, including evidence he had gathered about Capstone's alleged fraud. Then Capstone sued Allen on frivolous grounds, aiming to get him to settle away his ability to report their wrongdoing, according to Bracker & Marcus. This lawsuit was ultimately dismissed.

Medicare Part B Allowed Payments to Capstone Diagnostics



Source: *Laboratory Economics* from CMS

The U.S. government will pay Allen 20% ($2.86 million) of the $14.3 million settlement amount for his role as whistleblower. In addition, Maloney has agreed to pay $150,000 to Bracker & Marcus for attorneys' fees and costs.

Capstone Received Medicare Payments Totaling $49 Million

During the three-year period from 2018-2021, Capstone was one of the fastest-growing labs in the nation based on Medicare Part B allowed payments (see *LE*, June 2023). For example, in 2020 and 2021, Capstone received Medicare Part B allowed payments totaling more than $49 million. Over this two-year period, Capstone averaged more than 20 Medicare Part B allowed tests per year for each beneficiary served.

Quest Finalizes Acquisition of Lenco Labs for $111 Million

Quest Diagnostics has completed its purchase of Lenco Diagnostic Laboratories (Brooklyn, NY) for $111 million in cash. Lenco is an independent lab with 239 employees. Lenco's test volumes are expected to be shifted to Quest's regional lab in Clifton, New Jersey (see *LE*, February 2024). The law firm Dechert (Philadelphia, PA) advised Quest on the deal.

Labcorp Paid $108 Million for Legacy Outreach Lab

Labcorp's new 10-K annual report revealed that the company paid $107.7 million to acquire select assets of Legacy Health's outreach lab business in Portland, Oregon (see *LE*, December 2023).

Overall, Labcorp spent $671.5 million on lab acquisitions in 2023, while Quest Diagnostics spent a total of $611 million.

Summary of Biggest Lab Acquisitions in 2023 ($ millions)

Date	Buyer	Acquisition Target	Purchase Price
Feb-24	Quest Diagnostics	Lenco Diagnostic Labs (Brooklyn, NY)	$111.0
Dec-23	Sonic Healthcare	Pathology Watch (Salt Lake City, UT)	130.0
Nov-23	Labcorp	Legacy Health outreach lab (Portland, OR)	107.7
Sep-23	Labcorp	Tufts Medicine outreach lab (Boston, MA)	157.0
Aug-23	LabGenomics	QDx Pathology (Edison, NJ)	60.0
Jul-23	Labcorp	Enzo Biochem's Clinical Lab (Long Island, NY)	112.8
Jun-23	Labcorp	Providence Oregon outreach lab (Portland)	110.0
Jun-23	Quest Diagnostics	Haystack Oncology (Baltimore, MD)	392.0
May-23	Labcorp	Jefferson Health outreach labs (Philadelphia)	110.2
Apr-23	Quest Diagnostics	NewYork-Presbyterian outreach lab (NYC)	275.0
Mar-23	Quest Diagnostics	Northern Light Health outreach lab (Bangor, ME)	31.0
Feb-23	Avalon GloboCare	Laboratory Services LLC (Costa Mesa, CA)	41.0

Source: *Laboratory Economics*

Invitae Reports Cash Burn Rate of $365 Million

Genetic testing firm Invitae Corp. (San Francisco, CA) reported a cash burn rate of $365 million in full-year 2023; revenue was $487 million in 2023, down 6% from $516 million in 2022. As of December 31, 2023, Invitae had total debt of approximately $1.6 billion and $209 million in cash and marketable securities. The company filed for Chapter 11 bankruptcy protection on February 13. Invitae's largest creditor is the Japanese investment holding company Softbank (Tokyo), which is owed $1.15 billion (see *LE*, February 2024).

Invitae: Top 10 Unsecured Creditors

Creditors	Nature of the Claim	Unsecured Claim
U.S. Bank Trust Company (collateral agent for Softbank Group)	Unsecured Loan 2028	$1,150,000,000
U.S. Bank Trust Company (collateral agent for various investors)	Unsecured Loan 2024	27,058,000
Salesforce.com Inc.	Trade Debt	2,098,431
Illumina Inc.	Trade Debt	2,086,883
Amazon Web Services	Trade Debt	1,707,438
FedEx	Trade Debt	1,227,182
Agilent Technologies	Trade Debt	1,103,445
Workday Inc.	Trade Debt	986,668
Redox Inc.	Trade Debt	889,800
ACCO Engineered Systems	Trade Debt	811,193
Total owed to top 10 unsecured creditors		$1,187,969,040

Source: Invitae bankruptcy filing

Hologic Gets FDA clearance for AI-Reviewed Pap Test

Hologic (Marlborough, MA) has received FDA clearance for its Genius digital diagnostics system. The product creates digital images of Pap test slides and uses an AI algorithm to pinpoint cells that cytologists and pathologists should review. The system will enable staff to focus on cells that could be precancerous or cancerous and to view slides remotely and collaborate on cases.

Hologic says that its new technology demonstrated an overall improvement in sensitivity without a corresponding decrease in specificity. Notably, a study linked the technology to a 28% reduction in false negatives of high-grade squamous intraepithelial and more severe lesions compared to traditional microscopic review.

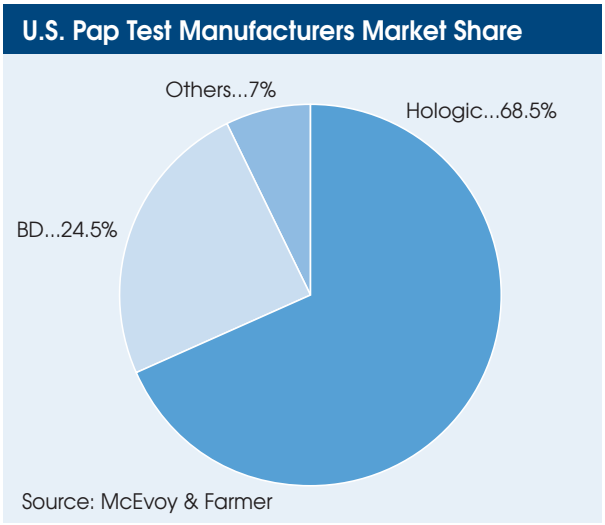
Hologic's Genius system is the first FDA-cleared digital cytology platform.

Meanwhile, Becton Dickinson recently signed an agreement with Techcyte (Orem, UT) to market an AI-assisted digital cervical cytology system for Pap testing. Techcyte is planning to pursue FDA clearance of the technology, after which it will be able to roll out the BD-partnered solution in the U.S.

The introduction of AI-assisted digital imaging systems may reinvigorate the moribund Pap testing market. Over the past 10 years, Pap test volumes have been declining by an estimated 5-10% per year because of extended testing intervals due to DNA-based HPV testing and new vaccines.

A total of 25-30 million Pap tests were performed last year in the United States. The highest volume Pap testing labs include Labcorp, Quest Diagnostics, Sonic Healthcare, BioReference Labs, PathGroup and Northwell Health Labs.

U.S. cervical cancer screening labs spent an estimated $380-400 million on Pap testing supplies in 2023, according to the IVD market research firm McEvoy & Farmer (New York City). Hologic (ThinPrep) has a 68.5% share of the Pap testing supply market and Becton Dickinson (SurePath) has a 24.5% share.



Comparing Productivity at Quest, Labcorp and BioReference for 2023

On a weighted basis, three publicly-traded lab companies collected average revenue of $46.22 per requisition in 2023. Average collected revenue per test was an estimated $15.41.

The three companies—Quest Diagnostics, Labcorp and OPKO's BioReference Labs—generated a weighted average of $202,988 in revenue per employee in 2023. The average number of requisitions and tests processed per employee per year were 4,392 and 13,175, respectively. These figures are based on the total number of FTEs at the three companies, including all administrative, couriers, sales and marketing, and lab technical staff.

Overall, the three companies received an average of 44% of their revenue from healthcare insurers, 33% from client payers (hospitals, physicians, etc.), 12% directly from patients, 9% from Medicare (CLFS & PFS) and 2% from Medicaid fee-for-service.

Productivity Stats at Quest Diagnostics, Labcorp and BioReference for 2023

2023 Financials	*Quest Diagnostics*	*Labcorp Diagnostics**	*BioReference Laboratories*	*Combined Total*
Total Lab Testing Revenue 2023	$9,252,000,000	$9,415,100,000	$515,275,000	$19,182,375,000
Operating Income 2023	$1,262,000,000	$1,591,300,000	-$155,596,000	$2,697,704,000
# Employees**	45,000	46,500	3,000	94,500
EMPLOYEE EFFICIENCY				
Avg. Annual Revenue per Employee	$205,600	$202,475	$171,758	$202,988
Avg. Annual Operating Income per Employee	$28,044	$34,222	-$51,865	$28,547
REQUISITION STATS				
Est'd Annual Requisitions 2023	206,000,000	200,000,000	9,000,000	415,000,000
Est'd Avg. Revenue per Requisition	$46.25	$47.08	$57.25	$46.22
Est'd Avg. Operating Income per Requisition	$6.13	$7.96	-$17.29	$6.50
Est'd Avg. Reqs Processed per Employee	4,578	4,301	3,000	4,392
TEST STATS***				
Est'd Annual Test Volume 2023	618,000,000	600,000,000	27,000,000	1,245,000,000
Est'd Avg. Revenue per Test	$15.42	$15.69	$19.08	$15.41
Est'd Avg. Operating Income per Test	$2.04	$2.65	-$5.76	$2.17
Est'd Avg. Tests Processed per Employee	13,733	12,903	9,000	13,175
BILLING STATS				
Accounts Receivable	$1,210,000,000	1,135,200,000	$111,041,100	$2,456,241,100
Est'd Bad-Debt % (pre-ASC 606)	4% - 5%	4% - 5%	5% - 10%	4.5%
Days in AR	48	44	79	47
REVENUE BY PAYER				
Private Patients	12.4%	11.6%	3.3%	11.7%
Medicare CLFS	8.1%	8.8%	11.0%	8.5%
Medicare PFS	1.1%	0.4%	2.5%	0.8%
Medicaid (fee-for-service)	2.1%	1.4%	2.5%	1.8%
Client Payers (physicians, hospitals, etc.)	35.1%	31.0%	19.4%	32.6%
Healthcare Insurers	41.3%	46.5%	61.2%	44.4%

*Data is for Labcorp's lab testing business only. **Full-time equivalents (part-time employees are counted as ½ FTE)

***Test volume stats assume an average of 3 tests per requisition.

Source: Company reports and *Laboratory Economics'* estimates

Lab Stocks Down 5% So Far in 2024; GeneDx Up 337%

Twenty-four lab stocks have declined by an unweighted average of 5% year to date through March 15. In comparison, the S&P 500 Index is up 7% year to date. The top-performing lab stock thus far in 2024 is GeneDx, up a whopping 337%. Shares of GeneDx have soared as the company is making progress with its turnaround plan. GeneDx reported that fourth-quarter 2023 revenue from continuing operations increased by 27% year-over-year to $58.1 million; net loss narrowed to $25.8 million, compared with a loss of $308.8 million in fourth-quarter 2022.

Company (ticker)	Stock Price 3/15/24	Stock Price 12/29/23	2024 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
GeneDx (WGS)	$12.01	$2.75	337%	$303	$203	1.5
Interpace Biosciences (IDXG)	1.62	1.08	50%	4	40	0.1
Natera (NTRA)	89.52	62.64	43%	10,370	1,083	9.6
ProPhase Labs (PRPH)	5.04	4.52	12%	108	63	1.7
Myriad Genetics (MYGN)	21.16	19.14	11%	1,910	753	2.5
Psychemedics (PMD)	2.96	2.96	0%	18	23	0.8
Quest Diagnostics (DGX)	128.28	137.88	-7%	19,120	9,252	2.1
Labcorp (LH)	209.21	227.29	-8%	23,030	12,162	1.9
NeoGenomics (NEO)	14.69	16.18	-9%	2,070	592	3.5
Aspira Women's Health (AWH)	3.60	4.08	-12%	39	9	4.3
Sonic Healthcare (SHL.AX)*	28.05	32.08	-13%	16,740	8,390	2.0
Castle Biosciences (CSTL)	18.85	21.58	-13%	290	220	1.3
CareDx (CDNA)	10.14	12.00	-16%	324	280	1.2
Exagen (XGN)	1.62	1.99	-19%	24	52	0.5
Biodesix (BDSX)	1.47	1.84	-20%	178	49	3.6
Exact Sciences (EXAS)	57.71	73.98	-22%	12,270	2,500	4.9
Veracyte (VCYT)	21.10	27.51	-23%	1,380	361	3.8
Fulgent Genetics (FLGT)	22.09	28.91	-24%	-179	289	NA
Guardant Health (GH)	17.74	27.05	-34%	2,340	564	4.1
Opko Health (OPK)	0.89	1.51	-41%	854	864	1.0
23andMe (ME)	0.44	0.91	-52%	51	248	0.2
DermTech Inc. (DMTK)	0.69	1.75	-61%	22	15	1.5
Invitae (NVTAQ)	0.02	0.63	-97%	1,260	487	2.6
Biocept (BIOCQ)	0.00	0.04	-100%	5.0	1.4	3.6
Totals & Averages			-5%	$92,531	$38,499	2.4

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor Harrison Klipp, Data Analyst

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About the Author

Jondavid Klipp is president and publisher of ***Laboratory Economics LLC***, an independent market research firm focused on the business of laboratory medicine. Prior to founding ***Laboratory Economics*** in April 2006, Mr. Klipp was managing editor at Washington G-2 Reports. During his seven-year employment with G-2, he was editor of Laboratory Industry Report and Diagnostic Testing & Technology Report. Mr. Klipp also authored several landmark research reports, including ***G-2's Lab Industry Strategic Outlook 2005, U.S. Laboratory Reference Testing: Profile and Pricing Trends*** and ***The Laboratory Market Leaders Report***. Prior to joining G-2, Mr. Klipp was an HMO analyst at Corporate Research Group in New Rochelle, New York, and a senior writer in the equity research department at Dean Witter in New York City.

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