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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

FDA Final Rule on LDT Regulation Expected by End of Month

"I don't have a crystal ball, but the expectation is that the FDA will publish its final rule on LDT regulation sometime in late April," according to Sheila Walcoff, Founder and CEO of Goldbug Strategies (Gaithersburg, MD).
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Google Releases AI Tool for Pathology

Google has released a free cloud-based tool ("Path Foundation") that transforms digitized slide images into numerical data that researchers can use to create AI tools for pathology. "This is a landmark for us," says David Steiner, MD, PhD, Clinical Research Scientist at Google. Based on feedback to Path Foundation, Google will make decisions toward developing commercial AI tools for pathologists.
Full details on pages 5-6.

Labcorp to Buy Select Assets of BioReference

Labcorp has agreed to acquire OPKO Health's BioReference laboratory testing businesses focused on clinical diagnostics and reproductive and women's health across the U.S. outside of New York and New Jersey. BioReference will continue to offer oncology and urology testing services nationwide, as well as maintain its full lab operations in New York and New Jersey. The assets that Labcorp is acquiring currently generate $100 million in annual revenue. The purchase price is $237.5 million in cash, which equates to a price-to-revenue multiple of 2.4x.
Full details on page 4.

Babson Diagnostics to Launch Unique Lab Service in Texas

Babson Diagnostics (Austin, TX) will launch its micro-sample blood testing service at H-E-B supermarkets in Austin and San Antonio this July, according to Babson Founder and Chief Operating Officer Eric Olson. The service (branded "BetterWay") will utilize BD's FDA-cleared MiniDraw fingerstick blood collection system at kiosks located at the pharmacy sections at H-E-B supermarkets. Patient samples will be couriered to Babson's CLIA-certified and CAP-accredited 21,000-square-foot laboratory in North Austin. Babson is aiming to have blood-collection sites set up at 100 supermarkets and independent pharmacies throughout Texas by the end of the year.
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BABSON DIAGNOSTICS TO LAUNCH UNIQUE LAB SERVICE IN TEXAS (*cont'd from page 1*)
San Antonio-based H-E-B operates more than 430 grocery stores across Texas and Mexico. Babson also has agreements to open BetterWay collection sites at two independent pharmacies in the Austin area, Peoples Rx and Lake Hills Pharmacy.


Eric Olson

Olson says that Babson's BetterWay sites will focus on traditional physician-ordered lab tests for patients with private insurance, Medicare and Medicaid. Self-paying patients will also be served. Olson says that Babson is working with several private health insurers in Texas and expects to have several in-network contracts in place by July.

Based on a study by the University of Chicago and West Health Institute, Olson says that up to 40% of patients fail to get ordered lab tests. He believes that Babson's convenient locations and fingerstick sample collection can improve patient compliance.

The initial test menu includes 55 routine blood tests, including CBC, lipid panel, comprehensive metabolic panel, A1c, Vitamin D, PSA, TSH, etc.

Babson Diagnostics at a Glance

Eric Olson	Founder, Chairman & COO
David Stein, PhD	Chief Executive & Director
# Employees	50
Laboratory & Headquarters	N. Austin (21,000 sq. ft.)
Total capital raised	$44+ million
Investors	Siemens Healthineers, Emerald Development, Prism Ventures, etc.

Source: Babson Diagnostics

Created at Siemens Healthineers
Prior to founding Babson, Olson spent 17 years at Siemens Healthineers — most recently as Vice President of Disruptive Technologies. Babson was incubated at Siemens in 2015 and then spun out as an independent company in early 2017.

How the BetterWay Process Works
Babson will supply its retail partners with supplies for fingerstick sample collection and transport. Babson is utilizing BD's Minidraw Capillary Blood Collection System, which was cleared by the FDA in December 2023. Trained pharmacy employees, rather than phlebotomists, will collect specimens. Here's a summary of the BetterWay process:

Step 1: The patient places their palm on BetterWay's warming device (slightly larger than a computer mouse) for one to five minutes. A pharmacy employee then slips a plastic finger sleeve over the patient's ring finger. A lancet is used to prick the finger. Wings on the finger sleeve are squeezed to produce blood drops.

Step 2: A tube attached to the finger sleeve collects 435 to 635 µL of whole blood (approximately 5-10 drops). The tube is then placed in a storage device for centrifugation and cold storage.

Step 3: A Babson courier picks up and delivers specimens to Babson's CLIA-certified lab in North Austin for testing on conventional analyzers.

Investors Backing Babson Diagnostics

Babson has raised a total of more than $44 million to date. Most recently, Babson raised $21 million from a Series B financing round in June 2021. Emerald Development Managers (New York City) was the lead Series B investor, and existing investors Siemens Healthineers, Prism Ventures and Lago Consulting also participated.

An Overview of the San Antonio Lab Market

Total Population (2024):	2.5 million
Annual population growth rate, 2019-2024:	1.9%
Total Medicare Part B allowed spending 2022 (independent labs):	~$20 million
Total Medicare Part B allowed spending 2022 (hospital outreach labs):	~$3 million
Estimated physician office lab services market size:	275 million

Greater San Antonio, including New Braunfels, currently has 2.5 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 San Antonio is $275 million. Below we summarize the largest lab players in the San Antonio market.

Quest Diagnostics has a total of 19 patient service centers (PSCs) and one small CLIA-certified lab in San Antonio. Estimated annual revenue from physician office clients in San Antonio is $67 million. Quest's largest labs in Texas are located in Irving (northwest of Dallas) and Houston.

Labcorp has a total of 14 PSCs and one small CLIA-certified lab in San Antonio. Estimated annual revenue from physician office clients in San Antonio is $52 million. Labcorp's biggest Texas labs are located in Dallas and Houston.

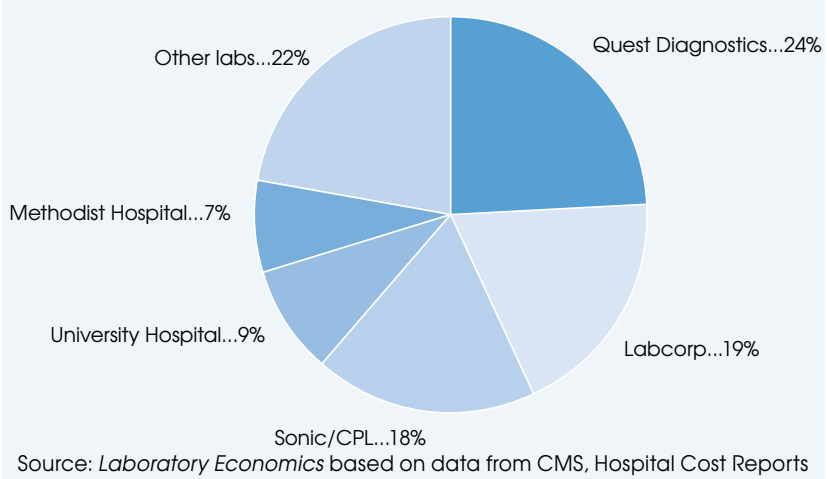
Sonic Healthcare (dba Clinical Pathology Laboratories) has a total of 13 PSCs in San Antonio. Its main lab is located in Austin. Estimated annual revenue from physician office clients in San Antonio is $50 million.

University Hospital (San Antonio), which has 669 beds and an annual lab department budget of $77 million, has an estimated $25 million outreach business in the San Antonio area.

Methodist Hospital (San Antonio) has 1,831 beds and an annual lab department budget of $95 million. Estimated lab outreach revenue for Methodist is $20 million per year in the San Antonio area.

Specialty labs based in San Antonio include **Qualtex Laboratories**, which screens blood and plasma donations, **Innovative Genomics**, an independent lab focused on pharmacogenomic and PCR-based testing, and **Pathology Reference Laboratory**, which is focused on anatomic pathology services.

Share of the Physician Lab Services Market in San Antonio



Source: *Laboratory Economics* based on data from CMS, Hospital Cost Reports and CLIA Database

LABCORP TO BUY SELECT ASSETS OF BIOREFERENCE (*cont'd from page 1*)
"Through this transaction we are able to significantly streamline our laboratory services business while retaining its core operations, positioning BioReference for sustained growth and profitability," OPKO Chairman & CEO Phillip Frost, age 88, said in a March 28 statement.

OPKO will keep BioReference's main laboratory in northern New Jersey as well as smaller CLIA-certified labs in Long Island and Manhattan. OPKO is also keeping BioReference's national cancer testing business and its proprietary 4KScore blood test for assessing the probability of aggressive prostate cancer. These testing businesses have combined annual revenue of roughly $415 million.

The sale to Labcorp includes patient service centers and certain customer contracts related to seven CLIA-certified labs that BioReference operates outside of New York and New Jersey. This includes four CLIA-certified labs in California, as well as labs in Melbourne, FL, Houston, TX, and Columbus, OH. These labs are likely to be closed with test volumes shifted to the nearest Labcorp facility.

The deal is expected to close in the second half of 2024.

Lazard is serving as Labcorp's financial advisor, and Hogan Lovells, Kilpatrick Townsend and Parker Poe are serving as legal counsel.

Piper Sandler & Co. is serving as OPKO's financial advisor, and Greenberg Traurig is serving as legal counsel.

OPKO originally acquired BioReference for $950 million worth of stock in August 2015.

OPKO sold BioReference's genetic testing business to Sema4 (now named GeneDx) for $472 million in April 2022.

BioReference Financial Results
OPKO reported that BioReference recorded an operating loss of $156 million in 2023, compared with an operating loss of $174 million in 2022; revenue fell by 32% to $515 million. BioReference processed 9 million patient requisitions in 2023, down 25% from 12 million requisitions in 2022.

OPKO's Pharmaceutical Business
OPKO also has a pharmaceutical business that features Rayaldee, an FDA-cleared treatment for secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease and vitamin D insufficiency. SHPT happens when the body produces too much parathyroid hormone (PTH). OPKO's pharmaceutical business recorded an operating profit of $41 million on revenue of $348 million in 2023.

BioReference Key Performance Indicators

	2023	2022	2021	2020	2019	2018	5-Year CAGR
Revenue ($000)	$515,275	$755,630	$1,607,106	$1,262,242	$716,434	$813,248	-8.7%
Operating Income ($000)	-155,596	-173,652	98,067	138,922	-123,359	-44,942	NA
Patient Requisition Volume (millions)	9	12	21	19	11	11	-3.9%
Avg. Revenue per Patient Req.	$57.25	$62.97	$76.53	$66.43	$65.13	$73.93	-5.0%
# Patient Service Centers	104	124	128	200	200	200	-12.3%
Employees	~3,000	3,300	5,000	4,500	4,500	5,000	-9.7%

Source: *Laboratory Economics* from OPKO Health 10K annual reports

GOOGLE RELEASES AI TOOL FOR PATHOLOGY (*cont'd from page 1*)

David Steiner, MD, PhD

For more than seven years, Google has employed a team of clinical research scientists based in Mountain View, California and London, England, tasked with developing AI software tools for radiology and pathology. Below is a summary of *LE*'s interview with Google's David Steiner, MD, PhD, Clinical Research Scientist.

How can labs and pathologists use Path Foundation?
Commercial labs and academic medical centers, for example, can use Path Foundation to convert patches of their digitized slide images into numerical vectors, known as embeddings. These embeddings capture important features and patterns contained in digitized slide images which are learned by Path Foundation during its training on millions of pathology images. After the embeddings for each image are collected, this data can be used to train and create custom algorithms for a range of tasks such as identifying tissue type, tumors, or performing quality assurance on digitized images.

What's the benefit of using a "Foundation" model to analyze content in images?
Leveraging the embeddings from Path Foundation requires less data and computational resources than traditional methods, giving researchers a big head start toward developing their own algorithms.

In contrast, traditional methods such as strongly supervised deep learning models require more resources because every task requires fresh training in its own unique deep learning model and many labeled images for each category of interest.

The foundation model is similar to that of seasoned guitar player quickly learning a new song by ear. Because the guitar player has already built up a foundation of skill and understanding, they can quickly pick up the patterns and groove of a new song.

Where did you get the digitized images to train Path Foundation on?
We used 20,000 whole-slide images, covering millions of image patches, from a variety of sources, including the National Cancer Institute's Cancer Genome Atlas, as well as academic medical centers and some private pathology labs.

What is the user roadmap to getting started with Path Foundation?
After filling out the access form, users can run a small demo notebook that walks them through how to train a tumor classifier. To use Path Foundation on their own task (i.e., identifying tissue type) they would need to collate a set of digital pathology images with accompanying labels. The user would then upload these images and labels into Google Cloud.

From there, the users can adapt the demo notebook to call the Path Foundation API on their uploaded images. Using the existing code in the demo notebook they would then train a model to classify their images based on the labels and evaluate its performance on a held-out part of the dataset not used to train the model. In the future we hope to make it even easier to use Path Foundation and the embeddings directly in your pathology slide viewer with no coding required.

We're offering Path Foundation free to users on github.com/Google-Health.

Do labs that use Path Foundation need to share their digitized images or the results of their research with Google?
They don't need to share the images or the results of their research with Google. They do need to have their images stored in Google Cloud (in their own private or institution account), but these are kept private to the user and not accessible by Google. In addition, when the images are sent to the Path Foundation model to compute the embeddings, they are not saved or stored by Google.

Any plans to develop commercial AI software tools like Ibex, Paige or PathAI?
Yes. Path Foundation represents a landmark toward that end.

What is the next step for your research team in terms of developing AI tools for pathologists?
We'll take feedback on users from Path Foundation to understand key-use cases and how to make the tool better and easier to use. We'll also explore how these embeddings might be used with large language and large multimodal models (LLMs & LMMs). And then we plan to develop useful approaches and models for working with whole slide images (WSIs), in addition to the "patch-based" models and applications that this current tool represents.

Has Google completed any studies related to AI-assisted diagnostic tools for cancer?
Yes. We have published several studies in peer-reviewed journals.

Most recently, we published a study that used AI to predict immunotherapy outcomes from digitized slide images in non-small cell lung cancer (*Cancer Research*, vol. 84, 2024).

In 2023, we published a paper that showed how AI can be used for clinical decision-making in colorectal cancer (*Nature Communications Medicine*, vol. 3, 2023). And, in 2022, we published a study that used AI for diagnosis and Gleason Grading of prostate cancer (*Nature Medicine*, vol. 28, 2022).

We have also published studies focusing on AI models for breast cancer.

Will AI algorithms eventually replace pathologists?
AI will make pathologists better rather than replace them. Initially, AI will be used to automate repetitive tasks such as locating the image patches that pathologists should focus their eyes on. Eventually, AI could be used to query images. Pathologists and researchers may someday be able to type in specific questions and get AI answers about an image.

Is there the potential to integrate pathology and radiology image data using AI?
I'm excited to explore this and do see the promise in bringing these two specialties together. I believe the combination will yield more than the sum of the parts. Google does have a team of research scientists working on AI tools for radiology. And we did introduce an AI tool for chest x-rays (CXR Foundation) in July 2022.

Incyte Diagnostics Shifting to Digital Pathology

Incyte Diagnostics (Spokane Valley, WA) has installed two Philips IntelliSite scanners at its main laboratory in Spokane Valley in eastern Washington. Each scanner can scan up to 30 barcoded slides at a time with each whole slide image taking about one minute to digitize at 40x magnification.

Mari Patel, MD, CEO of Incyte, says that digital pathology will help give its clients in outlying communities quicker access to Incyte's subspecialists in pulmonary pathology, neuropathology, pediatric pathology, etc. Philips IntelliSite's viewing software will also help Incyte's pathologists measure tumors and their distance from surgical margins. Digitization also enables multiple pathologists to conduct live consultations from their computer screens.

Incyte is a pathologist-owned full-service pathology lab that includes 45 pathologists and 350 other employees. Incyte serves 45 hospitals in the Pacific Northwest and processes roughly 600,000 slides per year.

Incyte operates two smaller histology labs in the Seattle area (Richmond and Tukwila) and plans to add scanners at these locations in the future.

Incyte is also considering adding AI applications to its digitized images.

QDx Pathology Moving Toward 100% Digital Pathology

QDx Pathology Services (Edison, NJ) recently installed a high-volume slide scanner and has begun digitizing its slides. QDx specializes in gastrointestinal and uropathology, cytology and PCR-based testing for respiratory viruses, gastrointestinal pathogens and urinary tract infections. QDx has eight staff pathologists and performs technical slide-prep services for another 14 pathologists. Overall, QDx processes approximately 500,000 slides per year at its CAP-accredited lab in central New Jersey. The company was acquired by South Korea-based LabGenomics last year (see *LE*, August 2023). *Laboratory Economics* recently spoke with Pierre Mouawad, Vice President of Laboratory Operations, about QDx's move into digital pathology.

Pierre Mouawad

Which slide scanner is QDx using?
We have installed one Hamamatsu NanoZoomer S360MD. We chose this system as it is FDA-cleared and it has high-volume reliability (up to 1,000 slides per day and more if run over several shifts). We plan to add a second scanner soon.

In addition, we're using Proscia's Concentriq AP software system to store and manage digitized slide images. In particular, Concentriq AP provides an intuitive user interface and the ability to view multiple slide images simultaneously. For example, pathologists can view H&E and IHC stain images side-by-side.

Where does your transition to digital pathology currently stand?
One QDx client pathologist in Georgia completed the CAP guidelines for validation earlier this year. For validation, he interpreted more than 60 GI cases using a traditional microscope. After a two-week washout period, he interpreted those same 60+ GI cases from digital images. His concordance of the two methods was above the 95% threshold recommended by CAP. He switched to digital pathology interpretations in February and QDx is now sending him an average of 200-300 digitized slide images per day.

How does QDx benefit from digital pathology?
We're able to transmit digitized slide images to our external pathologist clients quicker, as opposed to shipping glass slides to them. This allows our pathologist clients to shave 12-24 hours off their result reporting turnaround times. It also saves on shipping costs. In addition, our first pathologist to use digital pathology says that the vivid colors and cell details are helping him find more cases.

What's next in your transition to digital pathology?
We plan to validate and move all of our external pathologist clients to digital pathology by the end of this year. Our staff pathologists will follow next.

Can digital pathology help QDx win more slide-prep pathologist clients?
Yes, it can definitely help QDx in attracting additional clients, given the current industry trends leaning toward digitization.

Any plans to add AI programs?
Yes, we plan to incorporate FDA-cleared AI software programs over time — possibly in early 2025. AI stands to revolutionize both pathologist efficiency and accuracy.

What's your advice to other pathology labs considering digital pathology?
It's inevitable. Choose user-friendly tools that give your pathologists a clear advantage over the microscope. Digitizing slides does add another step in the laboratory, so allocate technician staff for loading and maintaining scanners. Finally, have a formal validation process based on CAP guidelines and other published literature, to reinforce the integrity of the results for each pathologist that switches to digital interpretations.

FDA FINAL RULE ON LDT REGULATION EXPECTED BY END OF MONTH (*cont'd from page 1*)
The FDA submitted its final rule to the White House's Office of Information and Regulatory Affairs (OIRA) on March 1 (see *LE*, March 2024). OIRA could clear the final rule with or without changes, return the rule to the FDA for reconsideration, or encourage the agency to withdraw it.

Walcoff notes that a final rule is unlikely to be published before Monday, April 22 since OIRA has scheduled meetings with stakeholders through Friday, April 19. She adds that once OIRA concludes its review, publication of a final rule can happen within a matter of days.

In the meantime, OIRA has held or will hold 18 publicly listed meetings (between March 18 and April 19) with lab, hospital and pathology trade groups seeking to convince OIRA to reject or modify the final rule. The last three meetings will be with Duke University Health System (April 19), College of American Pathologists (CAP-April 18) and the lobbying firm CRD Associates (April 15).

Separately, the House Energy and Commerce committee held a hearing on FDA regulation of LDTs on March 21. The hearing featured witnesses from the American Clinical Laboratory Association (ACLA), CAP and the Academic Coalition for Effective Laboratory Developed Tests—all opposed to FDA regulation. Witnesses from AdvaMedDx and Friends of Cancer Research spoke in favor of regulation.

The hearing also revealed which House members favor and oppose FDA LDT regulation.

Favor FDA LDT Regulation	*Oppose FDA LDT Regulation*
Frank Pallone (D-NJ)	Brett Guthrie (R-KY)
John Sarbanes (D-MD)	Cathy McMorris Rodgers (R-WA)
Tony Cardenas (D-CA)	Robert Latta (R-OH)
	Larry Bucshon, MD (R-IN)
	Michael Burgess, MD (R-TX)

Source: *Laboratory Economics*

AvertD Opioid Test Was Cleared by FDA Despite Pushback

SOLVD Health (Carlsbad, CA) received FDA clearance for its AvertD genotyping test in December 2023. AvertD analyzes a cheek swab for 15 genetic markers to assess whether an individual may have an elevated risk of developing opioid use disorder (OUD). The test is meant to be used as a screening test before prescribing opioids with the hope of preventing addiction.

The FDA cleared AvertD despite an FDA independent advisory committee voting 11-2 against the AvertD test. Furthermore, in an April 4 open letter to the FDA, a group of 31 doctors and scientists urged the FDA to rescind its clearance of AvertD. The letter cited independent analyses showing that the 15 variants tested by AvertD provide no more predictive power than chance. The group of experts is also imploring CMS to deny coverage of a test that they say doesn't work.

FDA's decision to approve the test may have been driven by its more activist approach in combating opioid addiction as part of its implementation of the FDA Overdose Prevention Framework—a plan designed to reduce drug overdoses and death.

SOLVD is preparing to commercially launch AvertD and says that it will conduct prospective postmarketing studies to further assess the test's performance in real-world settings. "Many of the individuals behind recently submitted letters opposing the approval have significant conflicts of interest with seeing AvertD come to market, including developing competitive technologies and/or research grants that could potentially lose funding due to AvertD's approval," according to a statement from SOLVD.

Publicly Traded Lab Revenue Fell 1.9% in 2023; Castle Up 60%

On a combined basis, 24 publicly traded labs reported a revenue decline of 1.9% to $28.4 billion in full-year 2023 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*. A continued sharp drop-off in Covid-19 PCR testing was responsible for lower revenue for most labs in 2023.

Revenue growth was fastest at **Castle Biosciences** (Friendswood, TX), up 60% to $220 million. Castle operates CLIA-certified labs in Phoenix and Pittsburgh. Revenue growth was driven by Castle's TissueCypher Barrett's Esophagus test, which increased volume by 328% to 9,100 tests in 2023. TissueCypher is a laboratory-developed test designed to predict future development of high-grade dysplasia and/or esophageal cancer in patients with Barrett's esophagus. TissueCypher is reimbursed by Medicare (CPT 0108U) at $4,950.

In addition, Castle reported that volume for its DecisionDx-SCC test increased by 92% to 11,442 tests in 2023. DecisionDx-SCC is a genomic test for patients with cutaneous squamous cell carcinoma (SCC), the second most common form of skin cancer. The Medicare rate for DecisionDx-SCC (CPT 0315U) is set at $8,500.

Revenue Growth at 24 Publicly-Traded Lab Companies ($000)

Company	*Full-Year 2023*	*Full-Year 2022*	*Reported Change*	*Pro Forma Change**
Labcorp (lab testing only)	$9,415,100	$9,203,500	2.3%	0.0%
Quest Diagnostics	9,252,000	9,883,000	-6.4%	-6.9%
Sonic Healthcare USA[1]	1,295,270	1,432,660	-9.6%	-13.0%
Opko/BioReference Labs	515,275	755,630	-31.8%	-25.0%
Enzo Clinical Labs (lab testing only)[2]	30,087	74,428	-59.6%	-59.6%
Total, 5 National/Clinical Labs	$20,507,732	$21,349,218	-3.9%	-5.2%
Exact Sciences	$2,499,766	$2,084,279	19.9%	19.9%
Natera	1,082,571	820,222	32.0%	32.0%
Myriad Genetics	753,200	678,400	11.0%	11.0%
NeoGenomics	591,643	509,728	16.1%	16.1%
Guardant Health	563,948	449,538	25.5%	25.5%
Invitae Corp.	486,976	516,303	-5.7%	-5.7%
Veracyte	361,051	296,536	21.8%	21.8%
23andMe[3]	299,489	271,893	10.1%	10.1%
Fulgent Genetics	289,213	618,968	-53.3%	-60.0%
CareDx	280,324	321,793	-12.9%	-12.9%
Castle Biosciences	219,788	137,039	60.4%	60.4%
GeneDx (formerly Sema4)	202,566	234,694	-13.7%	-34.0%
Exagen Inc.	52,548	45,563	15.3%	15.3%
Biodesix	49,087	38,212	28.5%	28.5%
ProPhase Labs	44,384	122,647	-63.8%	-63.8%
Interpace Biosciences	40,214	31,838	26.3%	26.3%
Psychemedics	22,098	25,240	-12.4%	-12.4%
Dermtech	15,296	14,518	5.4%	5.4%
Aspira Women's Health	9,154	8,184	11.9%	11.9%
Total, 19 Specialty/Genetic Labs	$7,863,316	$7,225,595	8.8%	7.6%
Grand Total, All 24 Lab Companies	$28,371,048	$28,574,813	-0.7%	-1.9%

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.

[1]Sonic Healthcare USA revenue is for the 12 months ended June 30, 2023, at constant exchange rate of 1 Australian Dollar equal to 0.66 U.S. Dollar. [2]Enzo's revenue is for lab services only for 12 months revenue ended July 31, 2023; [3]23andMe revenue is for the 12 months ended March 31, 2023.

Source: *Laboratory Economics* from company reports

UnitedHealthcare Pushes Back Z-Code Requirement to June 1

Once again, UnitedHealthcare (UHC) has delayed its requirement of Z-codes for certain molecular test claims submitted to its commercial health plans to June 1. This gives labs another two months from the previously scheduled effective date of April 1. UHC says that the latest delay was made "in order to allow additional time for providers to integrate DEX Z-Codes into their claims processes."

This marks the third time that UHC has delayed the effective date of its Z-code requirement for commercial claims. Initially the requirement was scheduled to start August 1, 2023. It was then delayed to October 1, 2023, and delayed again to April 1, 2024.

The latest delay was announced in a UHC bulletin issued on April 1. Effective June 1, UHC will deny payment for 133 CPT codes and 104 proprietary lab analysis codes unless the test has received a Z-code and successfully passed a technical assessment from Palmetto GBA's MolDX program. High-volume codes that will be affected by the requirement include CPT 81479 (unlisted molecular pathology procedure), CPT 81279 (JAK2 gene targeted sequence analysis) and CPT 81455 (targeted genomic sequence analysis panel).

In spite of the delays, UHC has given no indication that they are going to abandon their Z code requirement, notes William Baus, President of the billing management firm Lab Revenue Navigator (Carrollton, TX). He says that UHC has "Smart Edits" in place that can be turned on at any time, so UHC is all set to implement its Z-code requirement for commercial claims. Baus adds that UHC's Z-code requirement for its Medicare Advantage claims has been in effect since October 1, 2021.

Gamma to Pay $13.6M for Unnecessary PCR Tests

The U.S. Department of Justice has finalized a settlement with Gamma Healthcare Inc. (Poplar Bluff, MO) and three of its owners—Chairman & CEO Jerry W. Murphy, President Jerrod Murphy and Chief Information Officer Joel Murphy. Under the settlement, the defendants will pay $13.6 million to resolve allegations of billing Medicare for lab tests that were not ordered by healthcare providers and were not medically necessary.

In particular, the DOJ alleged that during 2020, Gamma submitted claims to Medicare for medically unnecessary PCR-based urinary tract infection (UTI) panel tests that were not ordered by treating physicians. The DOJ contended that when a physician ordered a simple urinalysis with culture and Sensitivity (C&S) from Gamma, Gamma automatically performed and submitted Medicare claims for more expensive PCR testing using CPT codes 87798, 87500, 87641, 87651 and 87481. For example, Medicare reimbursement for urinalysis with C&S is typically $11, but a PCR-based UTI panel is reimbursed an additional $573.

The DOJ further contended that Gamma's order form was structured in such a way that physicians could not opt out of the (more expensive) PCR testing.

The claims leading to this settlement were initially brought by whistleblower Bradley Bibb, MD, a family doctor who served patients for whom Gamma had provided lab services. Under the terms of the agreement, Bibb will receive 17% ($2.3 million) of the settlement proceeds. Bibb was represented by the law firm Mitchell Blackstock Snedden (Little Rock, AR).

Gamma and its owners were represented by former Assistant U.S. Attorney Ellen Persons at Polsinelli PC (Atlanta).

Gamma had provided lab and radiology services to more than 2,000 nursing homes in the Midwest. After 39 years in business, Gamma was closed in November 2020.

Eurofins Buys Ascend Clinical

Eurofins Scientific has acquired Ascend Clinical LLC (Sunnyvale, CA), the largest independent laboratory for end-stage-renal-disease (ESRD) testing in the United States. Founded in 2000, Ascend operates a 93,000-square-foot CAP-accredited laboratory and headquarters in the San Francisco area. Ascend has 170 employees and estimated annual revenue of $25-50 million. The purchase price was not disclosed.

Ascend's laboratory is expected to remain in operation as part of the Eurofins clinical diagnostics business line in the United States. Patti Hunsader, the current COO of Ascend, will assume the role of President of Ascend. Current President Paul Beyer is expected to retire.

The largest ESRD testing labs include Spectra Laboratories (Rockleigh, NJ and Southhaven, MS), owned by Fresenius, and DaVita Labs (Deland, FL), owned by DaVita Inc.

US BioTek Acquires RealTime Labs

US BioTek Laboratories (Shoreline, WA) has acquired RealTime Laboratories (Carrollton, TX) for an undisclosed sum.

Founded in 2005, RealTime is a CLIA-certified and CAP-accredited clinical and environmental diagnostic laboratory that specializes in testing for hazardous toxins from mold (mycotoxins) in humans, houses and animals. RealTime also offers PCR-based test panel for urinary tract infections (UTIs) that includes 17 bacterial targets.

"By joining forces, we can provide our clients with a more comprehensive suite of diagnostic testing services," Jack Frausing, CEO of US BioTek, said in a statement. US BioTek is a CLIA-certified and CAP-accredited lab based in the Seattle area. US BioTek specializes in food sensitivity and allergy testing.

The two laboratories will continue operations at their respective locations in Seattle and Carrollton.

Sonic Healthcare USA Picks Roberts as CEO

Cory Roberts, MD, age 56, has been named Chief Executive of Sonic Healthcare USA (Austin, TX). Roberts was previously President of Sonic Healthcare USA's Anatomic Pathology Division. Prior to that, Roberts was Chairman and CEO at ProPath (Dallas, TX), which Sonic acquired in December 2021. Roberts has filled the position left by Jerry Hussong, MD, 62, who recently retired from Sonic Healthcare USA after five years as CEO.

California Raises Healthcare Minimum Wage to $25

California recently enacted Senate Bill 525, which will increase the minimum wage for healthcare workers to $25 per hour in the coming years. The law sets a minimum wage for workers at most healthcare facilities—such as general and surgical hospitals, psychiatric hospitals, outpatient clinics, offices of physicians, and home health agencies. Wage increases will begin June 1, 2024, and reach the $25 minimum standard in 2026, 2027, or 2028 for the vast majority of California healthcare workers. More details in next issue of *Laboratory Economics*.

Lab Stocks Down 9% So Far In 2024

Twenty-four lab stocks have declined by an unweighted average of 9% year to date through April 12. In comparison, the S&P 500 Index is up 8% year to date. Only five lab stocks have gained, while 19 have declined. The top-performing lab stock thus far in 2024 is GeneDx, up 245%. Quest Diagnostics is down 7% and Labcorp is down 10%.

Company (ticker)	Stock Price 4/12/24	Stock Price 12/29/23	2024 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
GeneDx (WGS)	$9.62	$2.75	245%	$281	$203	1.4
Natera (NTRA)	94.47	62.64	50%	11,240	1,083	10.4
ProPhase Labs (PRPH)	6.52	4.52	40%	132	44	3.0
Interpace Biosciences (IDXG)	1.40	1.08	29%	60	40	1.5
Myriad Genetics (MYGN)	19.55	19.14	2%	1,850	753	2.5
Exact Sciences (EXAS)	71.34	73.98	-4%	15,030	2,500	6.0
Psychemedics (PMD)	2.76	2.96	-5%	17	22	0.8
Quest Diagnostics (DGX)	128.53	137.88	-7%	19,360	9,252	2.1
Castle Biosciences (CSTL)	20.06	21.58	-8%	346	220	1.6
Labcorp (LH)	205.73	227.29	-10%	22,800	12,162	1.9
NeoGenomics (NEO)	14.09	16.18	-14%	2,050	592	3.5
Sonic Healthcare (SHL.AX)*	27.07	32.08	-16%	16,370	8,390	2.0
Aspira Women's Hlth (AWH)	3.45	4.08	-18%	43	9	4.7
Opko Health (OPK)	1.23	1.51	-19%	1,090	864	1.3
Exagen (XGN)	1.48	1.99	-26%	13	53	0.3
Veracyte (VCYT)	20.23	27.51	-27%	1,310	361	3.6
Fulgent Genetics (FLGT)	20.78	28.91	-28%	-207	289	NM
CareDx (CDNA)	8.53	12.00	-29%	241	280	0.9
Biodesix (BDSX)	1.23	1.84	-33%	175	49	3.6
Guardant Health (GH)	18.26	27.05	-33%	2,410	564	4.3
23andMe (ME)	0.44	0.91	-52%	50	248	0.2
DermTech Inc. (DMTK)	0.62	1.75	-64%	20	15	1.3
Invitae (NVTAQ)	0.01	0.63	-98%	1,260	487	2.6
Biocept (BIOCQ)	0.00	0.04	-100%	5	1	3.6
Totals & Averages			-9%	$95,945	$38,481	2.8

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

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