Jondavid Klipp, Editor, jklipp@laboratoryeconomics.com Volume 19, No. 10 October 2024

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Mount Sinai Converts to 100% Digital Pathology

All 50 pathologists on the faculty at Mount Sinai Health System (New York City) are now interpreting all of their pathology case volumes by digital images on their computer monitors. The conversion took place over a two-year period and was completed on April 15, making Mount Sinai the largest academic digital pathology department in the United States. "I haven't touched a piece of glass in more than 14 months," says Gregory Henderson, MD, PhD, Executive Vice Chairman of Anatomic and Digital Pathology at Mount Sinai. *Full details on page 3.*

Medicare CLFS Rate Cuts Postponed Again

On September 26, President Biden signed into law a short-term spending package that includes a one-year freeze in Medicare CLFS rates for 2025. Medicare rates for nearly 800 tests on the CLFS had been scheduled to be reduced by up to 15% effective Jan. 1, 2025. The latest freeze will mark the fifth straight year (2021-2025) that CLFS rates have been unchanged. However, reimbursement rate freezes are small consolation to labs that are struggling with rising employee wages and supply costs. *Continued on page 4.*

Yuma Regional Doubles Lab Size, Eyes Outreach Market

Yuma Regional Medical Center (Yuma, AZ) is moving into a newly renovated lab space that is double in both size and test volume capacity. The new lab is 20,000 square feet and is capable of conducting up to two million tests annually, according to YRMC's Laboratory Medical Director Brent Bedke, MD. He says the expanded lab will allow YRMC to begin providing outreach testing services to physician offices in southwest Arizona.
Full details on page 5.

Northwell Health Core Lab Workers Unionize

Employees at Northwell Health Laboratories' main laboratory in Long Island, NY have voted 502-113 to join 1199SEIU United Healthcare Workers East. The National Labor Relations Board, a federal agency that protects private sector employees' right to organize, counted the mail-in ballots and released the results on September 25. Unionization will affect 867 full-time and part-time medical technologists, technicians, phlebotomists and customer service reps at Northwell. "Now lab staff will have a real voice in our workplace. I'm excited to begin negotiating our first contract," said Nardia Skyers, a phlebotomist at Northwell. *Continued on page 2.*

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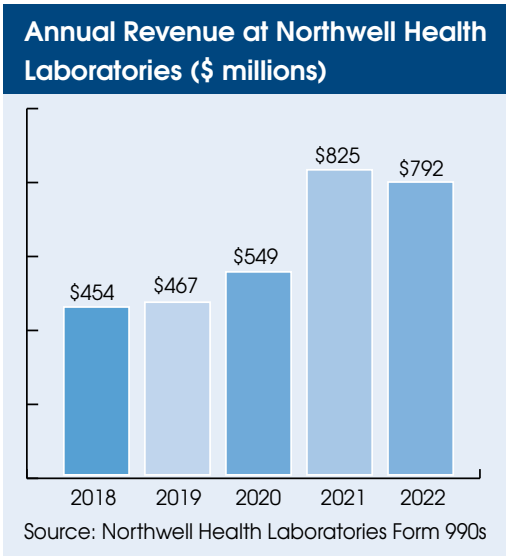
NORTHWELL HEALTH CORE LAB WORKERS UNIONIZE (*cont'd from page 1*)
Northwell Health Laboratories is a not-for-profit independent lab company that is owned by Northwell Health, which is New York State's largest healthcare system, with more than 81,000 employees at 21 hospitals and 900 ambulatory facilities.

This is the second group of lab workers at Northwell that have voted to unionize in the past year. More than 100 employees at Northwell's specialized lab in Little Neck voted to join 1199SEIU in December.

A spokesperson for 1199SEIU says the newly unionized lab workers will seek no-cost family health insurance, guaranteed pensions, education funds, childcare benefits and higher wages.

Union member dues for 1199SEIU are 2% of base wages (not including overtime or differentials) and capped at $125 per month. Members do not start paying dues until after a first contract with better wages and benefits has been negotiated.



"We appreciate the continued relationship we have with our laboratory team members. We are grateful for their continued commitment to our patients, our team and the community that we are privileged to serve. We look forward to continuing our important work caring for patients, together, as we have always done," according to a statement from Barbara Osborn, Vice President of Public Relations at Northwell Health.

Originally formed in 1997, Northwell Health Laboratories has grown to become one of the largest labs in the country. The company recorded net income of $96 million on revenue of $792 million for the 12 months ended December 31, 2022, according to its latest available Form 990 tax return. The core lab performs more than 23 million tests per year.

The national shortage of lab employees combined with union efforts targeting large regional labs has resulted in pro-union votes at five locations across the country in the past 12 months. Most recently, Labcorp workers based at seven Legacy Health facilities in the Portland area voted (311-43) to join the Oregon Federation of Nurses and Health Professionals (see *LE*, June 2024).

Recent Labs Voting to Unionize

Vote Tally Issued Date	*Laboratory Name & Location*	*No. of Eligible Voters*	*Votes for Labor Union*	*Votes Against*
9/25/2024	Northwell Health Laboratories (Lake Success, NY)	867	502	113
5/3/2024	Labcorp (Portland, OR)	435	311	43
3/6/2024	Tempus AI (Chicago, IL)	353	243	38
12/20/2023	Northwell Health Laboratories (Little Neck, NY)	146	100	31
10/11/2023	Quest Diagnostics (Tucker, GA)	52	29	17

Source: National Labor Relations Board

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MOUNT SINAI CONVERTS TO 100% DIGITAL PATHOLOGY (*cont'd from page 1*)

The Mount Sinai Health System includes eight hospitals and more than 400 ambulatory sites in the greater New York City area, including the flagship Mount Sinai Hospital (1,148 beds) in Manhattan. Mount Sinai's Department of Pathology employs a staff of 50 pathologists who interpret 235,000 anatomic pathology cases and 28,000 cytopathology cases—processing a total of more than 1.1 million glass slides—per year. Below we summarize a presentation that Dr. Henderson gave at the recent American Pathology Foundation National Meeting in New Jersey, Sept. 20-21.

Gregory Henderson, MD, PhD

How did you convince health system administration to invest in digital pathology?
It was a hard sell because the costs are significant. But Mount Sinai is cognizant of the role AI will play in cancer diagnostics and you can't utilize AI on glass slides. In addition, we projected an improvement in turnaround time (TAT) which has been realized. Our TAT for pathology cases has been reduced to an average of 2.2 hours versus 24 hours previously with traditional microscope-based reads.

How many slide scanners are used by Mount Sinai?
We've got a total of 14 Philips Intellisite scanners (300 slide capacity per scanner) all located in a newly renovated space at Mount Sinai's Annenberg Building in Manhattan. We employ a total of eight digital pathology technicians. The DP center is staffed by three techs 24/7.

What about image management and viewing monitors?
We're using the Intellisite Image Management System as well as Philips monitors (~$6,000 per monitor).

How did you get all of your pathologists to convert to digital sign-out for clinical diagnosis?
It is now a requirement in our department of pathology with zero tolerance for glass-slide reads.

What are some lessons learned in Mount Sinai's transition to digital pathology?
Among the many is the need for uniform high-quality slide prep. As part of the transition, we consolidated all histology services into two hospitals (Mount Sinai Hospital and Mount Sinai Morningside) and reworked our slide prep processes. The scanners require good slides, with no artifacts or bubbles, in order to create high-quality images. We also learned that plastic cover slips don't work well with scanners.

What is your cost for digital pathology?
All in, including DP techs, scanners, image management and storage, it's roughly $5-$7 per slide.

What are some of the unexpected benefits of digital pathology?
Our completely digitized practice now allows us to offer a variety of work models that range from 100% remote work to any combination of remote/onsite that works for both the department and the pathologist. Many pathologists that we have recruited have declined other offers with higher salaries because of the appeal of a flexible remote/onsite work model. I estimate that working remote may be equal to $25,000 worth of annual salary to pathologists. Furthermore, there have been several highly coveted members of our department who have dismissed efforts to recruit them away from Mount Sinai because they don't want to go back to looking at glass slides.

Is Mount Sinai applying AI to its digitized slide images?
Yes. Our Center for Computational and Systems Pathology has developed AI tools for Gleason Grading of prostate cancer, breast cancer grading and diagnosing Parkinson Disease from IHC-stained biopsy tissue.

Your advice to other pathology labs considering digital pathology?
Bite the bullet or be left behind.

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MEDICARE CLFS CUTS POSTPONED AGAIN (*cont'd from page 1*)
The new law—The Continuing Appropriations and Extensions Act of 2025—also includes a one-year delay in the next PAMA reporting period for laboratories. The next reporting period for private-payer payment data will now be January 1, 2026, through March 31, 2026.

Meanwhile, the American Clinical Laboratory Assn. continues to lobby for the Saving Access to Laboratory Services Act (SALSA). SALSA would require CMS to take a representative sample of private-payer rates from independent labs, hospital labs and physician office labs to determine future CLFS rates. SALSA would ensure that the higher rates paid to hospitals are accurately included in CLFS rate calculations.

But the Congressional Budget Office (CBO) has projected that passing SALSA into law would cost the federal government $6 billion over 10 years. A separate study by ACLA showed that SALSA would cost $2.8 billion. Either way these projected cost increases would need to be offset by other federal government spending cuts. As a result, the passage of SALSA is unlikely.

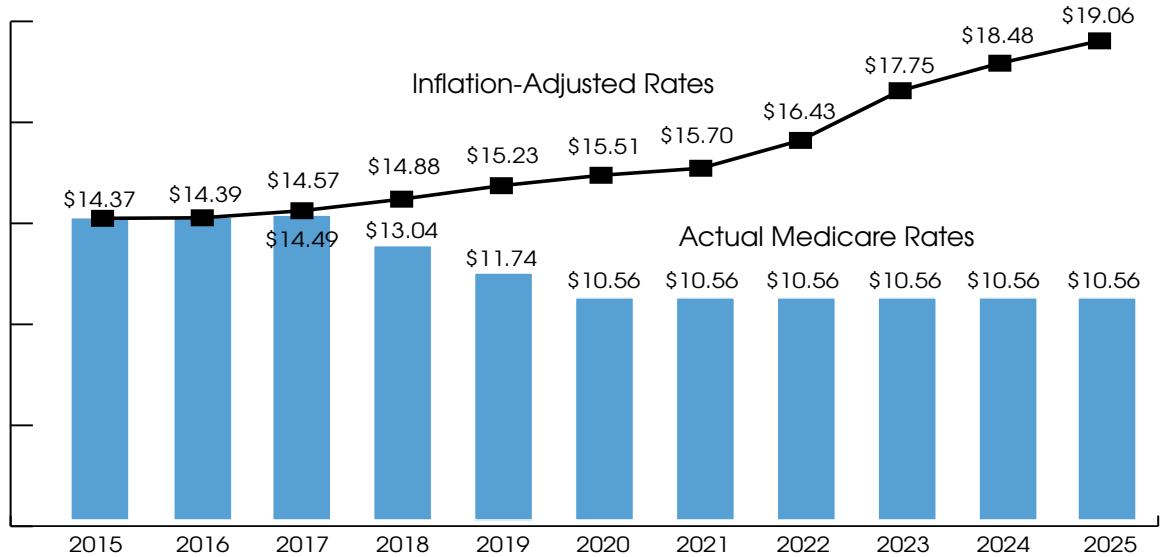
ACLA is now working on alternative long-term reforms to PAMA, according to Mary Lee Watts, Vice President of Government Affairs and Policy at ACLA. "It all boils down to cost," she said at the recent New York State Clinical Laboratory Assn. Annual Meeting, Sept. 18-19.

Medicare CLFS Rates vs. Inflation
Five straight years of Medicare CLFS rate freezes may seem like a victory given the 10% per year PAMA rate cuts that took place in 2018-2020. But lab operating costs have risen substantially over the past few years, leading to lower profit margins for most labs.

For example, the comprehensive metabolic panel (CPT 80053) is the most frequently billed clinical lab test. Medicare reimbursement for CPT 80053 had been stable until PAMA rate reductions of 10% per year kicked in from 2018-2020. Since then, the Medicare rate for CPT 80053 has been unchanged.

However, if the Medicare rate for CPT 80053 had simply been given an inflation adjustment every year from 2015-2025, it would now be set at $19.07. That's nearly double the current actual rate of $10.56.

Medicare Rate History for Comprehensive Metabolic Panel (CPT 80053)



Source: Medicare CLFS 2010-2025 and Bureau of Labor Statistics for Consumer Price Index

YUMA REGIONAL DOUBLES LAB SIZE, EYES OUTREACH MARKET (*cont'd from p. 1*)

Yuma Regional Medical Center (Yuma, AZ) is an independent 430-bed hospital based in the southwest corner of Arizona. Yuma has a current population of 102,000 that has grown by 4.5% per year since 2020, according to U.S. Census Bureau estimates. The YRMC lab has 140 employees and currently performs one million tests per year with annual growth of about 5%. Below we summarize our interview with Dr. Bedke.

Brent Bedke, MD

Can you describe the new laboratory?
With the help of our primary reference lab, Mayo Clinic Laboratories, we began planning about four years ago. We had outgrown our current lab space located at YRMC and the infrastructure (ventilation, electrical, etc.) was not up to date.

The new lab is located at YRMC's old emergency room—just down the hall from the old lab. We moved our pathology and microbiology departments in mid-October. The next phase will be sections of chemistry and blood bank. We hope to be completely moved into the new space by January.

Can you describe the automation at the new lab?
We're using the Siemens Aptio Automation Line with pre- and post-analytical modules to connect with Siemens Atellica immunoassay & clinical chemistry analyzers and Sysmex hematology analyzers.

Are you expanding your in-house test menu?
Yes. We've added new BioFire and Cepheid analyzers to expand our PCR-based test menu to include respiratory panels (flu/RSV/Covid), meningitis/encephalitis, and gastrointestinal (GI) panels.

How about digital pathology?
We've had a Ventana DP 200 slide scanner in place for several years that was initially used for tumor boards. We're now applying digital pathology to breast cancer IHC analysis, including ER, PR, HER2, and Ki67. We're also looking at using digital pathology for PDL1 testing, HER2 for metastatic solid tumors, and mismatch repair (MMR) proteins.

How are pathology services provided at YRMC?
Professional services and lab directorship are provided through a contract with Monolith Diagnostics (Kingman, AZ), which includes myself and five other pathologists.

What about your plans to expand outreach testing services?
The YRMC lab is currently primarily focused on hospital inpatient and outpatient testing. However, after we complete the move to the new lab, we do plan to develop outreach testing services for physician offices in southwest Arizona. We now have the capacity and outreach testing has the potential to become a big focus for us over the next few years.

The biggest competing commercial labs in Arizona include Sonora Quest Labs (Phoenix), a joint venture between BannerHealth and Quest Diagnostics, as well as Labcorp, which has a regional lab in Phoenix.

What's your advice to other lab directors planning a major renovation or expansion?
Get input and opinion from as many sources as possible, including hospital administration, lab leadership, outside consultants, architects, etc., on the design, equipment and lab workflow. The same goes for planning and scheduling the move into your new lab. However, final decision-making should be made by a single quarterback, or small group of people.

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Quest Diagnostics Wins Sentara Health Contract

Beginning January 1, 2025, Quest Diagnostics will be the exclusive national lab provider of clinical laboratory and anatomic pathology services for Sentara Health Plans (Virginia Beach, VA), including its commercial and government programs.

Sentara Health Plans and Quest will also collaborate on expanding Quest's patient service center (PSC) network in some geographic areas. Quest currently operates three PSCs in the Virginia Beach-Norfolk area.

Sentara Health Plans covers a total of 1.1 million members, including 934,000 Sentara Health Plans members in Virginia and 140,000 AvMed members in Florida.

Sentara Health Plans is the health plan division of Sentara Health, an integrated health system with 12 hospitals in Virginia and Northeastern North Carolina.

Labcorp currently provides lab services and will continue to do so until the contract with Quest begins on January 1.

Labcorp Buys Lab Works in Alabama

Labcorp acquired the independent lab company Lab Works (Birmingham) on October 12. Lab Works was founded in 2017 and was owned by three individuals: Adam Earl, Head of Operations; Todd Cook, Head of Sales; and David Dyer, Head of Client Development.

Lab Works operates a CLIA-certified and COLA-accredited laboratory in Homewood (just outside of Birmingham) that specializes in PCR-based testing and toxicology. Lab Works has recently been expanding its test menu into more routine blood testing. Estimated annual revenue is $10-$20 million.

Lab Works was advised by Advanced Strategic Partners (Sunny Isles Beach, FL) on the deal.

The transaction follows Labcorp's recently announced exclusive national lab contract with BlueCross BlueShield of Alabama (see *LE*, September 2024).

Labcorp Buys 15% Stake in SYNLAB

Labcorp has agreed to acquire a 15% stake in SYNLAB (Munich, Germany) for €140 million (USD $154 million) from the European private equity investor Cinven (London, United Kingdom). Cinven will retain a majority ownership in SYNLAB. Completion of the transaction is expected in the first quarter of 2025.

The purchase price gives SYNLAB a valuation of USD $1 billion, or 0.35x its annual revenue of USD $2.9 billion.

SYNLAB operates in over 30 countries, primarily in Europe (France and Germany). SYNLAB, which has 27,000 employees, performed approximately 600 million lab tests and recorded net income of €92.3 million (USD $101 million) on revenue of €2.64 billion (USD $2.9 billion) in 2023. Average revenue per test at SYNLAB is approximately USD $4.83, while average revenue per employee is $107,000 per year.

"Our investment in SYNLAB as a minority shareholder provides Labcorp with a role on the co-investors' holding company board and the commitment to explore possible opportunities in the future to bring Labcorp's innovative specialty tests to markets in Europe, consider possible procurement collaborations, evaluate opportunities to support advances in clinical trials and enrollment and improve personalized care," according to Labcorp CFO Glenn Eisenberg.

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UnitedHealthcare's "Gold Card" Program Offers Little Help for Labs

Effective October 1, 2024, UnitedHealthcare (Minnetonka, MN) launched a gold card program aimed at reducing prior authorization (PA) requirements for in-network providers. Providers, including labs, that obtain gold card status can avoid PA requirements for approximately 500 procedure codes, including 62 lab CPT codes.

"We're introducing our first-of-its-kind national gold card program, recognizing provider groups who consistently adhere to evidence-based guidelines. The UnitedHealthcare gold card program is the next step in our continual efforts to modernize the prior authorization process and simplify the healthcare experience for consumers and providers," according to a UHC spokesperson.

However, the 62 lab CPT codes in the gold card program are comprised almost entirely (58 out 62 tests) of extremely low-volume drug testing codes. The highest-volume drug testing (G0480-G0483 and 80305-80307) are not included. The remaining four lab test codes in the gold card program include pregnancy tests (81025 and 84702-84703) and a vitamin test (84591).

There are no genetic or molecular PCR tests included in UHC's gold card program.

"The gold card is a small step in the right direction, but it covers a limited set of tests with low utilization," notes Thomas Cronin, Senior Vice President at Quadax Inc. (Middleburg Heights, OH). Cronin says that labs are often burdened with the task of meeting PA requirements on behalf of ordering providers. PA requires submitting medical necessity documentation to the insurer and can delay patient care by an average of 3-7 days, adds Cronin.

UHC says that it will continue to evaluate and evolve its gold card program, including the potential to add more lab test procedures.

Providers will not have to apply for UHC's gold card but must meet certain requirements:

- Be in-network for at least one UnitedHealthcare commercial, individual exchange, Medicare Advantage or community (Medicaid) plan.
- Meet a minimum annual volume of at least 10 prior authorizations each year for two consecutive years across gold-card-eligible codes.
- Have a prior authorization approval rate of 92% or more across all gold-card-eligible codes for each of the review years.

UHC says that providers that earn gold card status are required to complete advance notification for services to confirm eligibility and network status, but no clinical information will be requested.

UHC is the largest private health insurer in the United States. A total of 45 million UHC members will be affected by the gold card program, including 29.6 million commercial, 7.8 million Medicare Advantage and 7.4 million Medicaid members.

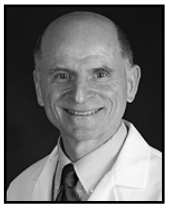
UnitedHealthcare Expands Z-Code Requirement

UnitedHealthcare is adding 96 more genetic test codes to its Z-code requirement effective November 1, 2024. UHC now requires a total of 264 lab tests to be registered with the Palmetto MolDx program and included on claims for UHC Medicare Advantage and commercial members (see *LE*, January 2024). UHC has indicated plans to add even more test codes to its Z-code requirement in the near future.

Separately, Humana (Louisville, KY) began requiring Z-codes for certain genetic tests for its Medicare Advantage plans effective September 18, 2024. Humana covers a total of 6.2 million Medicare Advantage members nationwide.

CAP Files Brief Supporting LDT Lawsuits

The FDA's final rule to regulate LDTs "imposes draconian new restrictions—and crushing compliance costs—on the development and use of LDTs," according to an amicus brief filed by the College of American Pathologists (CAP) in support of consolidated lawsuits filed by the American Clinical Laboratory Assn. and Assn. for Molecular Pathology (AMP) versus the FDA.



Donald Karcher, MD

CAP's amicus brief was filed on October 7 to offer additional arguments for the U.S. District Court for the Eastern District of Texas to consider before making its ruling.

In addition to affecting clinical lab LDTs (e.g., genetic, PCR-based and pediatric LDTs), CAP President Donald Karcher, MD, notes that the final rule also affects most immunohistochemical stains and flow cytometry tests used by pathologists to diagnose and classify cancer. "Pathologists and their laboratories are now having conversations about which LDTs will no longer be available to patients in their communities," says Karcher. CAP is urging the court to vacate the final rule as arbitrary and capricious.

CAP's amicus brief was prepared with the help of the law firm Sidley Austin (Chicago).

Meanwhile, Karcher says that CAP continues to work with members of Congress on revising and re-introducing a version of the VALID Act. "FDA regulation of LDTs should focus on high-risk tests, while giving more flexibility to all other LDTs," says Karcher.

ASCP Urges Court to Overturn FDA Final Rule on LDTs

Separately, the American Society for Clinical Pathology (ASCP) and four other groups have filed an amicus brief supporting the ACLA-AMP lawsuits. ASCP argues that the FDA's final rule has already had "serious detrimental effects on the clinical labs that perform these tests, and, ultimately, on the provision of medical care to patients."

Besides ASCP, the American Association of Bioanalysts, the American Society for Microbiology, the Association for Diagnostics & Laboratory Medicine, and the Infectious Disease Society of America signed the brief.

Representing ASCP in developing the amicus brief was Jane Pine Wood of McDonald Hopkins (Cleveland).

Consolidated Briefing Schedule

On September 19, the ACLA and AMP lawsuits were consolidated for briefing purposes and will be decided by Judge Sean D. Jordan in the U.S. District Court for the Eastern District of Texas Sherman Division (Plano, TX).

The timeline for the consolidated cases is as follows:

- Amicus briefs supporting ACLA-AMP were due by October 7, 2024.
- The FDA's opening brief is due by October 25, 2024.
- Amicus briefs supporting the FDA are due by November 4, 2024.
- ACLA's and AMP's closing briefs are due by November 25, 2024.
- The FDA's closing brief is due by December 23, 2024.

A decision from Judge Jordan is not expected until sometime next year. Judge Jordan, who was appointed by former President Trump in 2019, may be receptive to ACLA-AMP arguments opposing LDT regulation. The FDA has already indicated it plans to appeal any ruling against it.

Don't Wait to Generate Labeling for Your Lab's LDTs; Early Efforts Can Help Improve Tests, Assist with Later Marketing Submissions

Clinical laboratories with lab-developed tests (LDTs) should begin working on labels for these tests now even though the compliance deadline for labeling is still a year and half away, advises Kelly Gordon, PhD, Founder of Boudicca Dx LLC, a consulting company based in Brentwood, TN. The work that goes into developing labeling now can be helpful in identifying where there may be gaps in information needed for the lab to submit a marketing submission later, says Gordon.


Kelly Gordon, PhD

"My advice is to start doing labeling now, don't wait," says Gordon. "You might find you don't have enough data for a submission, and this would give you time to generate more data. If there are a lot of gaps in your data, you might want to send a pre-submission to the FDA."

A pre-submission lays out for the FDA all the information that would support a marketing submission, allowing the lab to receive feedback from the agency before a formal marketing submission is made, explains Gordon.

Gordon also notes that beginning work on labeling now can help facilitate compliance with Stage 1 (medical device reporting, complaint files and correction and removal reporting). The compliance date for Stage 1 is May 6, 2025.

Under the final rule on Food and Drug Administration (FDA) oversight of LDTs, issued May 6, 2024, clinical laboratories must comply with labeling requirements for most in-vitro diagnostic tests by May 6, 2026. The FDA held a webinar Sept. 24, 2024, to provide information on how to comply with labeling requirements for IVDs, including LDTs.

According to the FDA, labeling provides users, healthcare providers and patients with information on the test, including its intended use, limitations and performance. Labeling must prominently display all required information and be truthful and non-misleading. An LDT without such labeling would be misbranded, says the agency.

Gordon notes that developing the type of labeling that the FDA requires is more difficult than developing labeling typically used in a CLIA laboratory. In a CLIA lab, testing information and data is more aggregated, while FDA labeling is more detailed and focused on individual test components, she explains.

"I think the biggest challenge for labs will be in making sure there are no gaps in the analytical validity and clinical validity data," she says. "CLIA tests weren't required to have clinical validity data. They were only required to have analytical validity data. So, for some labs, this will be new."

Components of a Label

Labeling accompanying an IVD, including an LDT, may include one or more of the following: package insert, test protocol, reagent and instrument specification documents, test menu and test report template. According to the FDA, each label should contain the following elements:

1. Name of product. This includes the proprietary name and common name, if any.

2. Intended use, including the type of procedure (e.g., qualitative or quantitative).

3. Summary and explanation of test. This should include a short history of the methodology, with pertinent references and a balanced statement of the special merits and limitations of the product. If the product labeling refers to any other procedures, appropriate literature citations should be included and the labeling should explain the nature of any differences from the original and their effect on the results.

4. Principles of procedure, such as chemical, physical or biological principles of the procedure. Explain concisely, with chemical reactions and techniques involved, if applicable.

5. Reagents, including a declaration of the established name, quantity, proportion of concentration of each reactive ingredient; a statement of warnings or precautions; adequate instructions for reconstituting, mixing, dilution; appropriate storage instructions; a statement of any purification of treatment required for use; physical, biological or chemical indications of instability or deterioration.

6. Instruments, including use or function; installation procedures and special requirements; principles of operation; performance characteristics and specifications; operating instructions; calibration procedures, including materials and/or equipment to be used; operational precautions and limitation; hazards; and service and maintenance information.

7. Specimen collection/preparation, including special precautions and special preparations of the patient; additives, preservatives, etc., necessary to maintain the integrity of the specimen; known interfering substances; recommended storage, handling or shipping instructions for the protection and maintenance of stability of the specimen.

8. Procedure. A step-by-step outline of recommended procedures from reception of the specimen to obtaining results. List any points that may be useful in improving precision and accuracy. This would include a list of all materials provided, materials required but not provided, a description of the amounts of reagents necessary, a statement describing the stability of the final reaction material to be measured and the time within which it shall be measured, details of calibration, and details of kinds of quality control procedures and materials required.

9. Results. Explain the procedure for calculating the value of the unknown, explain each component of the formula used for the calculation of the unknown, include a sample calculation, explaining the answer. If the test provides other than quantitative results, provide an adequate description of expected results.

10. Limitations, including known extrinsic factors or interfering substances affecting results. If further testing, either more specific or more sensitive, is indicated in all cases where certain results are obtained, the need for the additional test shall be stated.

11. Expected values. State the range of expected values as obtained with the product from studies of various populations. Indicate how the range was established and identify the population on which it was established.

12. Specific performance characteristics. Include, as appropriate, information describing such things as accuracy, precision, specificity and sensitivity. These shall be related to a generally accepted method using biological specimens from normal and abnormal populations. Include a statement summarizing the data upon which the specific performance characteristics are based.

13. Bibliography.

14. Name and place of business.

15. Date of issuance of labeling.

Don't Wait to See What Happens

Gordon advises labs not to wait to see how the courts will rule on pending challenges to the LDT final rule before beginning to develop labeling for their tests.

"If the rule is repealed or stayed, all the work you've done will only improve your LDTs," she says. "A pragmatic approach is important just in case it's repealed."

Gordon adds that an advantage of filing a pre-submission request with the FDA for a novel test is that you then set the rules for that kind of test. "When you are the first test, you become a predicate for your competitors' tests," she notes.

23andMe Board Resigns as Plans to Go Private Stall

All seven independent board members of the direct-to-consumer testing company 23andMe (South San Francisco, CA) resigned on September 17. The mass resignations leave Chair and CEO Anne Wojcicki as the company's sole remaining board member. 23andMe says that it is searching for new independent directors to join its board.

Wojcicki, who owns 49% of the voting power at 23andMe, had announced plans to take the company private back in April (see *LE*, May 2024). Wojcicki had voiced her desire to maintain control over 23andMe and that no alternatives would be considered. In late July, she proposed paying $0.40 per share. That amount valued the company at $136 million, which is less than the $170 million in cash that 23andMe holds on its balance sheet (as of June 30, 2024). The board rejected this offer because it offered no share-price premium and lacked committed financing.

In a letter announcing their resignations, the seven board members said, "After months of work, we have yet to receive from you [Wojcicki] a fully financed, fully diligenced, actionable proposal that is in the best interests of the non-affiliated shareholders."

23andMe markets direct-to-consumer DNA testing for genetic ancestry and consumer health. 23andMe contracts its actual lab testing to third-party labs (primarily Labcorp).

The company reported a net loss of $69.4 million for the three months ended June 30, 2024, as compared with a net loss of $105 million in the same period a year ago. Revenue was down 34% to $40.4 million. 23andMe has accumulated total losses of $2.2 billion since being formed in 2006.

Precision Diagnostics to Pay $27M; Whistleblower Gets $2.7M

Precision Diagnostics (San Diego) has agreed to pay $27 million to settle allegations by the U.S. Department of Justice and multiple states that it billed federal healthcare programs for unnecessary urine drug tests. Precision has also entered into a five-year Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.

The DOJ alleged that from 2013 to 2022, Precision encouraged physicians to order excessive urine drug tests through "custom profiles" that bypassed individualized patient assessments, resulting in medically unnecessary tests. In addition, Precision allegedly violated the Anti-Kickback Statute by providing free test cups to physicians, as long as the physicians used the cups to send samples back to Precision for further testing.

The DOJ's case against Precision was first prompted by a lawsuit brought before the District Court of Maryland by whistleblower Bryce Hudak on May 25, 2018. Hudak is receiving $2.74 million of the settlement amount.

Precision, which has more than 400 employees, operates CLIA-certified labs in San Diego and Dartmouth, Massachusetts. Between 2013 and 2022, Precision received $97 million in Medicare Part B payments.

Lab Stocks Up 79% So Far In 2024

Twenty-five lab stocks have risen by an unweighted average of 79% year to date through October 11. In comparison, the S&P 500 Index is up 22% year to date. Ten lab stocks have gained, while 15 have declined. The top-performing lab stock thus far in 2024 is GeneDx, up a whopping 2,082%. Quest Diagnostics is up 8% and Labcorp is down 5%.

Company (ticker)	Stock Price 10/11/24	Stock Price 12/29/23	2024 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
GeneDx (WGS)	$60.00	$2.75	2082%	$1,630	$244	6.7
CareDx (CDNA)	30.62	12.00	155%	1,420	297	4.8
Natera (NTRA)	130.06	62.64	108%	15,640	1,361	11.5
Interpace Biosciences (IDXG)	2.01	1.08	86%	62	42	1.5
Castle Biosciences (CSTL)	31.31	21.58	45%	634	288	2.2
Exagen (XGN)	2.65	1.99	33%	46	57	0.8
Tempus AI (TEM)	48.82	37.00	32%	7,520	596	12.6
Myriad Genetics (MYGN)	24.08	19.14	26%	2,230	802	2.8
Veracyte (VCYT)	34.02	27.51	24%	2,400	400	6.0
Quest Diagnostics (DGX)	148.67	137.88	8%	21,480	9,346	2.3
Opko Health (OPK)	1.46	1.51	-3%	1,250	716	1.7
Exact Sciences (EXAS)	70.96	73.98	-4%	14,950	2,612	5.7
Labcorp (LH)	216.39	227.29	-5%	23,970	12,488	1.9
Biodesix (BDSX)	1.69	1.84	-8%	266	61	4.4
Sonic Healthcare (SHL.AX)*	27.18	32.08	-15%	16,930	8,970	1.9
NeoGenomics (NEO)	13.53	16.18	-16%	1,950	628	3.1
Guardant Health (GH)	21.40	27.05	-21%	2,990	644	4.6
Psychemedics (PMD)	2.32	2.96	-22%	14	21	0.7
Fulgent Genetics (FLGT)	19.84	28.91	-31%	-227	291	NA
ProPhase Labs (PRPH)	2.41	4.52	-47%	71	18	3.9
23andMe (ME)	0.29	0.91	-68%	52	199	0.3
Aspira Women's Hlth (AWH)	0.76	4.08	-81%	14	9	1.5
DermTech Inc. (DMTKQ)	0.02	1.75	-99%	15	16	1.0
Invitae (NVTAQ)	0.00	0.63	-100%	1,250	482	2.6
Biocept (BIOCQ)	0.00	0.04	-100%	5	NA	NA
Totals & Averages			**79%**	**$116,561**	**$41,108**	**2.8**

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

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U.S. Laboratory Reference Testing:
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- Which tests your peers aim to bring in-house over the next 12 months
- How national reference labs are rated by service, turnaround time, price and overall best value
- An analysis of the new FDA LDT regulations and how they will affect the reference testing market

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Our Research Methodology

The U.S. Laboratory Reference Testing: Market Profile & Trends 2024-2027 includes data gathered the old-fashioned way—through primary research. The estimates and market analysis in this report have been built from the ground up. Our proprietary reference testing survey combined with extensive interviews with commercial lab executives, hospital lab directors, and respected consultants form the basis of this report. And no stone has been left unturned in our examination of Medicare test volume and expenditure data, hospital cost reports, Securities & Exchange Commission filings and non-profit company tax reports.

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. 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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