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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Will President-Elect Trump Put the Kibosh on LDT Regulation?

No President can rescind a regulation or final rule by executive order, according to Christine Bump, regulatory attorney at Penn Avenue Law (Washington, DC). All existing laws and regulations, including FDA regulation of LDTs, will remain in effect when Trump takes office on January 20. However, Bump notes that there are other pathways that the new Trump administration might use to end the FDA's final rule to regulate of LDTs. *See page 5 for Bump's analysis.*

Iowa Pathology vs. Goldfinch Legal Battle Gets Uglier

The legal fight between Iowa Pathology Associates (IPA-Des Moines) and four dermatopathologists who left to start their own competing group, Goldfinch Laboratory (Urbandale, IA), is heating up. The Goldfinch dermatopathologists—Drs. Tiffani Milless, Caitlin Halverson, Renee Ellerbroek and Jared Abbott—now allege that IPA is potentially harming patient care by refusing to share biopsy slides with the new group. Furthermore, Goldfinch alleges that IPA took advantage of its "monopoly power" and charged "above-market fees for their services" to small Iowa hospitals. These are just the latest in a series of accusations between IPA and Goldfinch, which was created by the former IPA doctors in early 2023. *Full details on page 6.*

23andMe to Lay Off 200 Employees

Direct-to-consumer genetic testing firm 23andMe (South San Francisco, CA) has announced plans to lay off 40% of its staff, or 200 of its total 500 employees, and discontinue its drug development program as part of a restructuring program to conserve cash. *Continued on page 9.*

Tempus AI to Buy Ambry Genetics for $600M

Tempus AI (Chicago, IL) has agreed to acquire Ambry Genetics (Aliso Viejo, CA) for $375 million in cash plus $225 million in stock. The deal is expected to close in the first quarter of 2025. The purchase price of $600 million works out to be 1.9x Ambry's current annual revenue of $315 million and 15x its EBITDA of $40+ million. Ambry, which has approximately 800 employees, owns a CAP-accredited lab located in Aliso Viejo (just south of Los Angeles). *Continued on page 2.*

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TEMPUS AI TO BUY AMBRY GENETICS FOR $600M (*cont'd from page 1*)
Ambry specializes in next-gen sequencing (NGS) tests for hereditary cancer. Some of its proprietary tests include BRCAplus for hereditary breast cancer (PLA 0129U—CLFS rate: $1,304) and ColoNext for hereditary colon cancer (PLA 0101U—CLFS rate: $1,744).

In a letter to customers, Ambry CEO Tom Schoenherr said Ambry will operate as a wholly-owned subsidiary of Tempus, retain employees and continue its full test menu.

Ambry was originally founded by Charles Dunlop in 1999, who raised approximately $500,000 from friends and family and opened a small office above a Harley-Davidson motorcycle shop in 1999. The company was sold to the Japanese firm Konica Minolta in 2017 for $1 billion, including $800 million of cash plus up to $200 million based on financial performance. Konica had hoped that the acquisition of Ambry would help it diversify away from its slumping office equipment business. However, Ambry required ongoing investment and recorded consistent losses. In the fiscal year ended March 31, 2024, Konica reported that Ambry posted an operating loss of $8 million versus an operating loss of $47 million in the same period a year earlier; revenue was up 14% to $240 million.

Ambry Genetics Financials (FY ends March 31; $ millions)

	FY 2024	FY 2023	FY 2022
Revenue	$240	$211	$189
Operating Profit	-8	-47	-86
Net income	-19	-51	-105
Total assets	160	157	183

Source: Konica Minolta

Meanwhile, on a November 4 conference call, Tempus CEO Eric Lefkofsky said that Ambry has turned the corner and is now growing its revenue by 25% per year. Ambry's calendar-year 2024 revenue is expected to reach $315 million with EBITDA (earnings before interest, taxes, depreciation and amortization expenses) of more than $40 million.

Separately, Tempus reported a net loss of $733 million for the nine months ended Sept. 30, 2024, versus a net loss of $199 million for the same period a year earlier; revenue increased by 28% to $493 million. Tempus has accumulated losses totaling $2.1 billion since being founded in 2015. Tempus, which raised $411 million from an IPO in June 2024, specializes in NGS testing to guide cancer treatment (see *LE*, June 2024, pp. 1-2).

Sonic Healthcare USA Acquires Genetics Associates

Sonic Healthcare USA has acquired Genetics Associates Inc. (GAI-Nashville, TN). GAI has 40 employees and operates a CAP-accredited lab that specializes in cytogenetic and molecular testing. GAI was founded by Jesse Gore and Vaithilingam G. Dev, PhD, in 1990. Sonic plans to keep the GAI lab in operation under the leadership of David Murray, Vice President and Regional Director at Sonic.

InterPath Buys Pathology Services P.C.

InterPath Laboratory (Pendleton, OR) has acquired Pathology Services P.C. (PSPC- North Platte, NE). PSPC, which has 60 employees, operates a full-service clinical and anatomic pathology lab serving central and western Nebraska and portions of Kansas and Colorado.

PSPC was founded in 1967 by two University of Nebraska pathology professors. Pathologist Byron Barksdale, MD, was the most recent owner. InterPath, which is owned by healthcare entrepreneurs Tom and Judy Kennedy, is one of the largest independent labs in the northwestern United States

Haverford Healthcare Advisors (Radnor, PA) acted as sellside advisor for PSPC.

NYU Langone Making Rapid Conversion to 100% Digital Pathology

NYU Langone Health (New York City) went live with whole-slide-scanning on September 18 and plans to reach 100% conversion to digital interpretations within the next 12 months. The launch follows an eight-year $115 million agreement with Philips announced in late 2023 that covers scanners and image management software as well as certain diagnostic imaging technologies (e.g., handheld ultrasound devices). NYU Langone includes six inpatient hospitals, two medical school campuses, and over 300 outpatient locations in New York and Florida. Here's a summary of our interview with NYU Langone's Joan Cangiarella, MD, Vice Chair of Clinical Operations, and Syed Hoda, MD, Director of Digital Pathology.

Joan Cangiarella, MD

Syed Hoda, MD

Can you describe NYU Langone's Department of Pathology?
We're a faculty practice that employs 80 anatomic pathologists at multiple locations. Our largest AP labs are based at Tisch Hospital (1,775 beds) in Manhattan and NYU Langone Hospital (511 beds) in Mineola, Long Island. Overall, we process 225,000 pathology cases, involving 450,000-500,000 specimens and 1.5 million glass slides per year.

How many scanners is NYU Langone installing and where are they located?
We went live with nine Philips SG300 scanners (60 slides per hour) at Tisch Hospital on September 18. The scanners are located in a room directly across the hall from the histology lab. In addition, we plan to have four more Philips SG300 scanners up and running at NYU Langone Hospital in January.

We're also using Philips for digital image management.

Finally, our pathologists are using a few different medical-grade monitors for image viewing, including Barco MMPC-4227F1 (PP27QHD) Monitors (26-inch screen).

How many of your pathologists have converted to digital pathology?
As of this week, 25 pathologists have moved over to digital pathology sign-out. We have at least 25 more pathologists that will be phased in over the coming weeks/months.

Digital pathology sign-outs have been made a requirement and all NYU Langone pathologists are expected to make the switch. We're not buying any more microscopes and plan to stop delivering glass slides to pathologists within the next 12 months.

The Chief Executive of NYU Langone, Robert Grossman, MD, is a radiologist and he's made it clear that we're going "all-in" on digital pathology. A big selling point for pathologists has been the potential to sign-out cases from home. The ability to work from home is also allowing us to recruit pathologists who don't live in New York City.

How are you handling intra-operative frozen sections?
These slides will be digitized also. We have installed one Glissando desktop scanner for frozen section duty at five different locations, including Tisch Hospital, NYU Brooklyn, NYU Long Island-Mineola, Long Island Community Hospital and NYU Long Island Ambulatory Center.

How are you assisting pathologists in the switch to digital interpretations?
We're in the process of hiring 24 digital pathology coordinators (DPCs). This is a new posi-

tion whose responsibilities will include training pathologists to use digital pathology for primary diagnosis, tumor boards and educational purposes. Our DPCs will also be in charge of loading slides into the scanners, uploading slide images and managing quality control.

How are you validating pathologist use of digital pathology?
We used CAP guidelines in accordance with our own best practices to validate digital pathology on a system-wide basis. Furthermore, each pathologist switching to digital sign-outs will initially perform traditional microscope interpretations plus digital reads on each case until they are comfortable with the new technology. Some pathologists are switching to 100% digital almost immediately.

Where and for how long will you store slide images?
We're currently using on-premises storage, but plan to soon switch to storage on Amazon Web Services (AWS) within the next 90 days. Although digital storage is a big component of cost, we plan to keep slide images forever. We're actually hoping to get rid of glass slide storage—once the standards have been set.

What are some of the initial benefits you're seeing from digital pathology?
A pathologist can log in to their computer and find their cases immediately. Switching through slide images is also more efficient than changing glass slides under a microscope. And the ergonomic benefits for pathologists are fantastic as compared with being hunched over a microscope. Other benefits include the ability to easily assign cases to subspecialists throughout our system and real-time sharing of cases for second opinions. As a result, overall turnaround times are decreasing with digital pathology.

What about the longer-term benefits?
Sometime next year we expect to begin applying our own AI algorithms to digitized images to help pathologists interpret cases. This effort is being led by Sean Hacking MD, Director of Digital Pathology Research, and our in-house team of computational scientists. We're currently developing AI applications that can, for example, analyze Ki-67 (a protein that indicates how quickly cancer cells are dividing) from digitized immunohistochemistry images.

The key is to develop AI applications that can easily be integrated into pathologist workflows and our LIS.

Longer term, digital pathology also provides the potential to integrate pathology and radiology data into a single enhanced patient case report that correlates the two specialties.

What is your outlook on digital pathology?
It's going to be a "must have" for pathologists because eventually there will be so many supplemental tools, including AI, available that improve pathologist efficiency and accuracy. It's inevitable.

What is your advice to other labs planning to convert to digital pathology?
Implementing digital pathology requires an in-depth and consistent collaboration between pathology teams, IT staff, and administrative components as well as new digital pathology roles and staffing being added. Start the conversation as soon as you can and design a realistic and attainable series of goals in order to start moving towards the final goal of full implementation. Talk to other labs and pathology departments that have successfully moved to digital pathology and gain as much insight into their obstacles, successes, and thoughts about it, so that you can develop strategies for your own institution.

Will President-Elect Trump Put the Kibosh on LDT Regulation? (*cont'd from p. 1*)
Bump says that President Trump's FDA could go through the notice-and-comment rulemaking process to propose a new rule that rescinds the LDT final rule. However, LDT regulation is not expected to be a high priority for the Trump administration. A Trump FDA is more likely to focus on food safety and prescription drug issues, according to Bump.


Christine Bump, Esq.

It's unlikely that the Trump administration will take action on LDTs before a ruling in ACLA and AMP's lawsuits against the FDA, notes Bump. A potential scenario involves Judge Jordan, who was appointed by Trump in his first term, issuing a summary judgment in the ACLA/AMP suits in early 2025. If Judge Jordan sides with ACLA/AMP and stops the FDA final rule from being implemented, then a Trump FDA is not likely to appeal that ruling. In contrast, President Biden's FDA had indicated plans to appeal such a decision.

Meanwhile, in Congress, Bump says that it now seems likely that new legislation for regulating LDTs will be introduced and passed. The Republicans now have a majority in the Senate and very likely in the House too. An early champion of the VALID Act, Rep. Diana DeGette (D-CO), retained her House seat, and Senator Bill Cassidy (R-LA), who has questioned the FDA's authority to regulate LDTs, holds his seat through at least 2026.

In summary, Bump believes that Judge Jordan could issue a summary judgment siding with ACLA/AMP early next year—probably February after Trump takes office. New "lab-friendly" legislation from Congress to regulate LDTs could also be introduced and possibly passed next year.

Nonetheless, Bump says that labs cannot assume that the ACLA/AMP lawsuits will prevail. She notes that the LDT final rule is still now in effect and that the stage 1 compliance deadline remains May 6, 2025.

CAP Joins New Coalition Calling for LDT Reform Legislation

With litigation pending over LDT regulation, the College of American Pathologists (CAP) has joined a new coalition that is urging Congress to pass comprehensive LDT legislation. In addition to CAP, other members of the Coalition for Effective Diagnostics are Alexion, Friends of Cancer Research, Mayo Clinic, Roche and Thermo Fisher.

In a November 12 letter to congressional leaders, the coalition said it supports passage of comprehensive diagnostics legislation that includes an abbreviated premarket pathway for LDTs with regulatory exemptions for tests for rare and pediatric diseases.

The coalition said that the FDA final rule to regulate LDTs requires significant investment by labs and the FDA's discretion to change its policy at any time creates significant regulatory uncertainty.

Members of the Coalition for Effective Diagnostics

Alexion	The group within AstraZeneca focused on rare diseases; created following AstraZeneca's 2021 acquisition of Alexion Pharmaceuticals.
College of American Pathologists	Represents approximately 18,000 board-certified pathologists.
Friends of Cancer Research	A non-profit cancer research and advocacy organization funded primarily by oncology drug makers (AstraZeneca, Bristol-Myers, Merck, Novartis, etc.)
Mayo Clinic	An academic medical center that includes Mayo Clinic Labs.
Roche	A global healthcare company that specializes in diagnostics and pharmaceuticals.
Thermo Fisher	One of the world's largest laboratory equipment and reagent manufacturers.

Source: The Coalition for Effective Diagnostics

IOWA PATHOLOGY-GOLDFINCH LEGAL BATTLE GETS UGLIER (*cont'd from page 1*)
The four dermatopathologists claim that prior to the formation of Goldfinch, IPA was the only independent pathology practice in central Iowa that was not exclusively tied to one source of referrals. They say that IPA was also the only independent pathology practice in central Iowa that offered dermatopathology services.

IPA sued the four dermatopathologists, alleging breach of contract (*LE*, January 2023, p. 4), in December 2023. IPA claims that the four dermatopathologists began conspiring to form Goldfinch, which is located less than 12 miles from IPA's office, sometime in 2021.

In May 2024, Goldfinch sued IPA, alleging that IPA's noncompete clause (which the pathologists say they refused to sign) was not tied to a legitimate business interest but was simply an attempt to prevent competition.

In addition, Milless and Halverson have sued IPA, alleging that the practice discriminated against them on the basis of sex, age and pregnancy (a trial in this case is scheduled for August 2025).

Motion to Dismiss
IPA has denied any wrongdoing and filed a motion to have Goldfinch's noncompete case dismissed. According to the Iowa Capital Dispatch, in a recent response to that motion, Goldfinch rejected what it calls the defendants' "self-righteous assertion that any injuries suffered by Goldfinch are its own fault."

Goldfinch argues that IPA took advantage of its "monopoly power" and charged "above-market fees for their services" to small Iowa hospitals. Specifically, Goldfinch claims that IPA charged rural hospitals in Iowa "at least 400% of the actual Medicare fee amount for the technical component of pathology services."

Goldfinch also says that IPA's refusal to share biopsy slides with Goldfinch's dermatopathologists "could well have caused harm to patients."

Goldfinch is seeking damages for an estimated $3.3 million in losses and is also seeking an injunction barring IPA from engaging in the "unlawful acts" alleged in the lawsuit. A judge has yet to rule on IPA's motion to dismiss the case.

Noncompete Backdrop
The IPA/Goldfinch fight is set against a backdrop of challenges as to whether noncompete agreements are even legal. National Labor Relations Board General Counsel Jennifer Abruzzo on Oct. 7, 2024, issued a memo (Memo GC 25-01) signaling that employers could be prosecuted for violating the National Labor Relations Act (NLRA) and face significant monetary liability for using noncompete and so-called "stay-or-pay" provisions in agreements with their employees.

According to Michael Ferrell, a labor attorney with Epstein Becker Green (Chicago), the new prosecutorial theory advanced by General Counsel Abruzzo applies where an employer uses such agreements with non-supervisory employees and thereby, in Abruzzo's view, violates the NLRA by restricting or discouraging employees from moving (or threatening to move) to better paying jobs.

"The party that controls the White House determines whether Abruzzo is permitted to finish or possibly extend her term as General Counsel of the NLRB and pursue her aggressive agenda to attack noncompete and stay or pay provisions in agreements with non-supervisory employees," says Ferrell. "The other possibility is that Abruzzo will be summarily fired on January 20, 2025, and replaced by a more employer-friendly General Counsel who likely will have no interest in trying to expand the NLRA to attack such agreements with employees."

Michael Ferrell: Noncompete Agreements and "Stay or Play"

The National Labor Relations Board (NLRB) General Counsel Jennifer Abruzzo issued a memo Oct. 7, 2024, signaling that employers could face civil prosecution and significant monetary remedies for using noncompete agreements and so-called "stay-or-pay" provisions in agreements with their employees. The Federal Trade Commission (FTC) on April 23, 2024, issued a rule banning noncompete agreements, but that ban was overturned Aug. 20. 2024, by the U.S. District Court for the Northern District of Texas. To gain a better understanding of how these developments could affect laboratories, *Laboratory Economics* spoke with Michael Ferrell, a labor attorney with Epstein Becker Green (Chicago).

Michael Ferrell, Esq.

Given that a federal judge blocked the Federal Trade Commission's ban on noncompetes, what does this NLRB memo mean for lab businesses?
What it means changed entirely with the results of the election. With Trump's win, the day he takes office on Jan. 20, 2025, I expect Jennifer Abruzzo will be fired. Traditionally, a new administration allows a general counsel to finish their four-year term, but Biden broke with that tradition when he fired the Republican General Counsel Peter Robb on the first day and the expectation is that Trump will do the same.

If Trump doesn't fire Abruzzo, then her term of office would otherwise continue until July of 2025. If she continued in office throughout the remainder of her term, then Abruzzo's office could bring noncompete cases and prosecute them against employers. Unlike the Federal Trade Commission's now blocked rule banning noncompete agreements, the National Labor Relations Act (NLRA), which the NLRB enforces, only pertains to non-supervisory employees. It does not apply to statutory supervisors. So, the position Abruzzo outlines in her memo would apply, for example, to laboratory technicians and employee physicians but not to their managers or supervisors. It's narrower than the scope of the ban attempted by the FTC.

The FTC deals with civil enforcement of antitrust issues. The NLRB deals with the workplace rights of only nonsupervisory employees. Abruzzo's theory is that noncompete agreements infringe on the rights of employees to improve their pay and benefits by restricting their freedom to leave for another job or at least leverage the possibility they may leave for a better paying job. The FTC's proposed rule banning noncompete agreements and Abruzzo's memo are two separate things.

Is it fair to say that both the FTC and the NLRB have indicated their opposition to noncompete agreements?
The FTC and the general counsel's office of the NLRB have, but the members of the National Labor Relations Board have not.

The October 7 memo also takes aim at "stay or pay" provisions. Can you explain how it does this and in what cases such a provision would be acceptable?
That was a new one. Abruzzo's declaration of war on noncompetes started with her memo of May 20, 2023. That memo did not address "stay or pay" provisions. The October 7 memo is the first time she mentions these types of provisions. That's why Abruzzo stated she is giving employers 60 days to get into compliance before her office would start prosecuting. "Stay or play" provisions are those that might require someone to pay back the cost of graduate school or a sign on bonus, etc., if they leave within a certain period after the employer has incurred the expense. Similar to her view on noncompetes, Abruzzo says this unlawfully inhibits a nonsupervisory employee's ability to move to other jobs that offer better pay or benefits or other more favorable terms of employment.

She said there could be some circumstances where those provisions are lawful, such as when the employer gives the employee options. For example, an employer offering an employee the choice between receiving a sign-on bonus now and if you leave before a certain date you'll have to pay it back, or you can choose to receive the sign-on bonus once you have already stayed for a certain period. She also said a retention incentive bonus is legal. So that one presents a pretty easy work-around for employers to amend their agreements with employees, avoid litigation risk and still likely achieve the same benefit. All they have to do is give employees a choice.

That said, again, with Trump's win, Abruzzo is on the way out. It is highly unlikely that any new Trump-appointed General Counsel would share Abruzzo's position on stay or pay provisions in agreements with employees, so I think this initiative is also dead.

What steps should clinical and anatomic pathology laboratories be taking right now? Abruzzo states that she will give employers a 60-day window, until Dec. 6, 2024, to review and "cure" existing agreements to ensure compliance before her office will issue complaints based on unfair labor practice charges.

The 60-day window only applies to stay or play provisions. The noncompete theory is essentially in effect as of the date of when the memo was issued – October 7. In terms of what employers should do now, for "stay or play," I would consider modifying their agreements where you are able to give employees an option, which really removes this potential issue entirely.

However, in light of Trump's election win, an employer could reasonably decide to simply ignore Abruzzo's memo and run out the clock on her remaining tenure at the NLRB.

Common Coding Problem: Non-Specific Diagnosis

A common reason that laboratory claims get denied is because they are not specific enough, according to Sarah Stewart, Vice President, Revenue Cycle Services at TELCOR (Lincoln, NE). Many ordering providers struggle to keep current with ever-changing payer rules and coverage policies. If claims are sent with diagnosis codes that are not supported, payers will deny the claim, leading to lost or delayed reimbursement, medical record requests and additional burdens on the lab to identify the incorrect diagnosis code and provide updated coding.

For example, a common issue is diagnosis code Z00.00 – encounter for general adult medical examination without abnormal findings. This is a diagnosis code that is commonly used by physicians for appointments with patients, but it will not cover most lab testing if it is the only diagnosis on the claim, says Stewart.

"For Medicare specifically, most lab testing claims will be denied if no other diagnosis codes are sent to further indicate that testing was needed," she explains. "This includes testing like Vitamin D, toxicology, lipid panels and more." In this case, the laboratory would need to contact the ordering physician for a more specific diagnosis code.

Disappointing Preliminary Rates for New Alzheimer's Blood Tests

CMS issued new CPT and PLA codes and preliminary Medicare reimbursement rates for more than 100 tests in early October. Final rate determinations for these tests will be announced by CMS in late November and take effect January 1, 2025.

Among the notable new codes are five biomarkers for Alzheimer's disease. IVD manufacturers and laboratories had pushed to crosswalk rates for these five codes (CPT 82233, 82234, 83884, 84393 & 84394) to PLA 0358U x 0.5 for a rate of $130.25. Most new Alzheimer's tests include two neurobiomarkers, so Medicare reimbursement would have been $260.50 per panel.

However, the American Medical Assn., which creates and maintains CPT codes, and the Procedure Coding Caucus refused to allow specimen type (e.g., blood or cerebrospinal fluid (CSF)) or methodology into the CPT code descriptions. Consequently, CMS stated in its preliminary determination rationale that this lack of detail caused them to recommend cross-walking to CPT 83520 with a low rate of $17.27 (or $34.54 for a two-biomarker test panel).

IVD manufacturers and laboratories say that reagent costs alone to perform the new neurobiomarker analytes are approximately 5 times more than the CLFS rate of $17.27. Furthermore, they argue that blood-based biomarkers improve patient access, expedite the pathway to treatment, and require fewer ancillary resources than do PET scans or CSF testing. Inadequate payment may deter labs from offering these tests, thereby limiting their availability to Medicare beneficiaries (See *Laboratory Economics*, July 2024).

New Alzheimer's CPT Codes and Preliminary Medicare Rates

Final CPT Code	Code Descriptor	CMS Preliminary Recommendation	Preliminary Rate Recommendation
82233	Beta-amyloid; 1-40 (Abeta 40)	Crosswalk to 83520	$17.27
82234	Beta-amyloid; 1-42 (Abeta 42)	Crosswalk to 83520	$17.27
83884	Neurofilament light chain (NfL)	Crosswalk to 83520	$17.27
84393	Tau, phosphorylated (e.g., pTau 181, pTau 217), each	Crosswalk to 83520	$17.27
84394	Tau, total (tTau)	Crosswalk to 83520	$17.27

Source: CMS and www.CodeMap.com

XiFin Wins Big Sonic Healthcare USA Contract

XiFin Inc. (San Diego, CA) has won a contract to provide billing management services to Sonic Healthcare USA (Austin, TX). Sonic had previously managed its billing in-house. Sonic's biggest lab division, Clinical Pathology Laboratories, transitioned to XiFin's billing software in October and other Sonic divisions may follow. Sonic has annual U.S. revenue of $1.5 billion making it the third biggest lab—after Labcorp and Quest Diagnostics—in the country.

23ANDME TO LAY OFF 200 EMPLOYEES (*cont'd from page 1*)

23andMe expects annualized cost savings of more than $35 million from the restructuring. CEO Anne Wojcicki, who has been trying to take the company private since April, is facing a tough challenge after all seven independent directors of 23andMe resigned in September (see *LE*, October 2024, p. 11). In the six-month period ended Sept. 30, 2024, 23andMe reported a net loss of $129 million versus a net loss of $179 million in the same period a year ago; revenue was down 24% to $84 million. 23andMe has accumulated total losses of $2.3 billion since being formed in 2006.

Quest Diagnostics Signs Expanded Contract with Elevance Health

Quest Diagnostics has renewed and expanded a national health plan agreement with Elevance Health (formerly Anthem Inc.) that will give it in-network coverage to an additional four million members. The expanded agreement takes effect January 1, 2025, and gives Quest new access to Anthem BCBS plans in Colorado (1.5 million members) and Nevada (700,000 members). In addition, Quest now has expanded in-network coverage to Anthem BCBS plans in Georgia and Virginia.

UnitedHealthcare Eliminates Coverage of Pharmacogenomic Testing

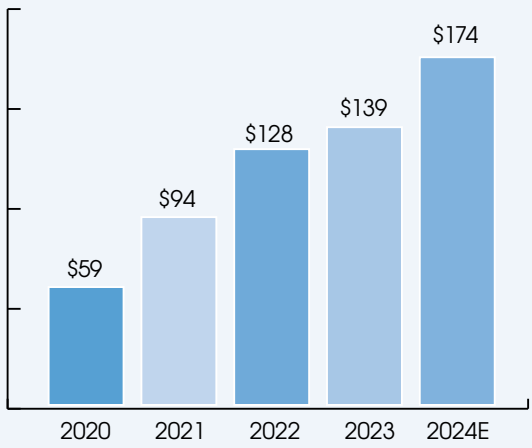
On November 1, UnitedHealthcare (UHC) issued a new policy bulletin to eliminate coverage of multi-gene panel (five or more genes) pharmacogenetic tests for its commercial and individual exchange plans effective January 1, 2025. The new UHC non-coverage decision (policy number 2024T0587T) will be especially damaging to labs performing pharmacogenetic test panels for guiding therapy decisions for antidepressant and antipsychotic medications.

The new policy will affect approximately 30 million UHC commercial and individual exchange members, but does not affect UHC's Medicare Advantage (7.8 million members) and managed Medicaid (7.5 million members) plans.

"The use of pharmacogenetic multi-gene panels (five or more genes) for the evaluation of drug-metabolizer status is unproven and not medically necessary for any indication due to insufficient evidence of efficacy," according to UHC. The policy bulletin cited a systematic review (Saadullah Khani et al; 2024) of 13 studies assessing the influence of PGx testing on individuals undergoing antipsychotic treatment. The study authors determined that existing evidence shows either no difference or positive clinical outcomes with pharmacogenetic-guided prescribing.

UHC says that its non-coverage decision will apply to 21 proprietary lab analysis (PLA) and two CPT test codes (81418 & 81479). Among the PLA tests affected by the change is Myriad Genetics' GeneSight Psychotropic Test (PLA 0345U). GeneSight uses cheek-swab samples to analyze 15 genes associated with 60 drugs prescribed for depression, anxiety, ADHD, and other psychiatric conditions. GeneSight is a laboratory-developed test performed at Myriad's CLIA-certified lab in Mason, Ohio. GeneSight has a Medicare rate of $1,336, although the test is offered to self-paying patients at a price of $330.

Myriad's Annual Revenue from GeneSight ($ million)



Source: Myriad Genetics

Myriad is expected to generate a total of approximately $174 million of revenue from GeneSight in 2024, including $40 million from UHC commercial and individual plan members. Myriad has warned that it will lose this UHC revenue in 2025.

Myriad says that it strongly disagrees with UNC's decision and its rationale that there is insufficient evidence of efficacy to support coverage of GeneSight. Myriad is asking UHC to suspend this policy decision for one year, so that additional clinical evidence can be reviewed.

Other labs offering pharmacogenomic testing include Genomind (King of Prussia, PA), Castle Biosciences (Friendswood, TX), OneOme (Minneapolis, MN), Tempus Labs (Chicago, IL) and Mayo Clinic Labs (Rochester, MN).

Baptist Medical Center Leads in Lab Outreach Growth

The laboratory at Baptist Medical Center (Jacksonville, FL) grew its Medicare fee-for-service payments for clinical and anatomic pathology services provided to outreach patients by 37% to reach $3.7 million in 2023. Other fast-growing hospital-based outreach labs included AdventHealth (Orlando, FL), up 35% to $6.3 million, and The Miriam Hospital (Providence, RI), up 30% to $4.8 million. Overall, total Medicare fee-for-service payments to hospital outreach labs fell by 5% to $1.56 billion in 2023.

Top 25 Fastest-Growing Hospital Outreach Labs*

Hospital Name & Location	System Affiliation	Grand Total Medicare Part B CLFS & PFS Payments 2023	Grand Total Medicare Part B CLFS & PFS Payments 2022	1-Year Growth
Baptist Medical Center (Jacksonville, FL)	Baptist Health	$3,705,168	$2,710,302	37%
AdventHealth Orlando (Orlando, FL)	AdventHealth	6,282,339	4,668,040	35%
The Miriam Hospital (Providence, RI)	Brown University Health	4,776,601	3,679,904	30%
Kennestone Regional Medical Center (Marietta, GA)	WellStar Health System	3,678,577	2,961,816	24%
Ochsner Medical Center-New Orleans (New Orleans, LA)	Ochsner Health	2,636,466	2,174,687	21%
Englewood Health (Englewood, NJ)	Independent	3,593,883	2,998,863	20%
Morristown Medical Center (Morristown, NJ)	Atlantic Health System	5,689,214	4,803,558	18%
Beverly Hospital (Beverly, MA)	Beth Israel Lahey Health	2,410,656	2,049,977	18%
White Plains Hospital (White Plains, NY)	Montefiore Health System	4,304,432	3,662,589	18%
City of Hope Comprehensive Cancer Center (Duarte, CA)	City of Hope	3,332,140	2,836,800	17%
Renown Regional Medical Center (Reno, NV)	Renown Health	3,012,435	2,577,754	17%
University of Minnesota Medical Center (Minneapolis, MN)	Fairview Health Services	2,464,174	2,112,163	17%
UPMC Harrisburg (Harrisburg, PA)	UPMC	3,444,724	2,955,756	17%
Eisenhower Medical Center (Rancho Mirage, CA)	Independent	8,362,652	7,176,704	17%
Geisinger Community Medical Center (Scranton, PA)	Geisinger	2,485,348	2,153,126	15%
Sarasota Memorial Health Care Center (Sarasota, FL)	Sarasota Memorial	6,675,226	5,811,778	15%
Winchester Hospital (Winchester, MA)	Beth Israel Lahey Health	2,781,249	2,449,112	14%
Morton Plant Hospital (Clearwater, FL)	BayCare Health System	4,737,138	4,179,933	13%
Saint Luke's Hospital of Kansas City (Kansas City, MO)	BJC HealthCare	4,907,351	4,333,464	13%
Atrium Health Wake Forest Baptist Med Ctr. (Winston-Salem, NC)	Advocate Health Care	3,298,968	2,923,088	13%
Tisch Hospital (New York, NY)	NYU Langone Health	6,532,934	5,810,275	12%
Emory University Hospital (Atlanta, GA)	Emory Healthcare	4,475,890	3,981,311	12%
OSF Saint Francis Medical Center (Peoria, IL)	OSF Healthcare System	2,638,166	2,360,228	12%
Marian Regional Medical Center (Santa Maria, CA)	CommonSpirit Health	2,433,048	2,189,739	11%
UCI Medical Center (Orange, CA)	UCI Health	2,981,425	2,687,790	11%
Total for Top 25 Hospitals		$101,640,204	$86,248,757	18%
Total for All Hospitals		$1,560,466,757	$1,650,935,965	-5%

*Includes all hospitals with at least $2 million in Medicare fee-for-service lab & pathology payments in 2022 & 2023.
Source: *Laboratory Economics* from Medicare Clinical Lab Fee Schedule and Physician Fee Schedule (pathology only) fee-for-service payments for 2022-2023. Source: *Laboratory Economics* Hospital Outreach Lab Database

Lab Stocks Up 106% So Far In 2024

Twenty-five lab stocks have risen by an unweighted average of 106% year to date through November 12. In comparison, the S&P 500 Index is up 25% year to date. Thirteen lab stocks have risen this year while 12 have declined. GeneDx continues its 2024 success, now up 2,697% YTD. Quest Diagnostics is up 17% and Labcorp is up 7%.

Company (ticker)	Stock Price 11/12/24	Stock Price 12/29/23	2024 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
GeneDx (WGS)	$76.92	$2.75	2,697%	$2,110	$263	8.0
Interpace Biosciences (IDXG)	2.99	1.08	177%	11	45	0.2
Natera (NTRA)	135.12	62.64	116%	16,260	1,532	10.6
CareDx (CDNA)	23.32	12.00	94%	1,040	313	3.3
Tempus AI (TEM)	68.04	37.00	84%	10,720	640	16.7
Castle Biosciences (CSTL)	32.78	21.58	52%	666	312	2.1
Exagen (XGN)	2.79	1.99	40%	48	57	0.8
Veracyte (VCYT)	38.24	27.51	39%	2,710	425	6.4
Quest Diagnostics (DGX)	161.70	137.88	17%	24,370	9,539	2.6
Guardant Health (GH)	29.73	27.05	10%	3,980	692	5.8
Labcorp (LH)	244.26	227.29	7%	26,700	12,713	2.1
Opko Health (OPK)	1.61	1.51	7%	1,210	711	1.7
NeoGenomics (NEO)	16.33	16.18	1%	2,310	644	3.6
Myriad Genetics (MYGN)	16.17	19.14	-16%	1,520	824	1.8
Sonic Healthcare (SHL.AX)*	26.68	32.08	-17%	16,684	8,970	1.9
Psychemedics (PMD)	2.34	2.96	-21%	14	21	0.7
Biodesix (BDSX)	1.40	1.84	-24%	235	66	3.6
Exact Sciences (EXAS)	50.16	73.98	-32%	11,040	2,692	4.1
Fulgent Genetics (FLGT)	19.16	28.91	-34%	-223	278	NA
23andMe (ME)**	4.71	18.27	-74%	67	193	0.3
Aspira Women's Hlth (AWH)	0.84	4.08	-79%	15	9	1.7
ProPhase Labs (PRPH)	0.74	4.52	-84%	39	18	2.2
Invitae (NVTAQ)	0.00	0.63	-100%	1,250	465	2.7
Biocept (BIOCQ)	0.00	0.04	-100%	5	NA	NA
DermTech Inc. (DMTKQ)	0.00	1.75	-100%	15	16	0.9
Totals & Averages			106%	$122,796	$41,438	3.0

*Sonic Healthcare's figures are in Australian dollars **23andMe had a 1-for-20 reverse stock split on Oct. 16, 2024

Source: *Laboratory Economics* from SeekingAlpha.com

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

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- Hospital-Specific Annual Medicare Part B Clinical Laboratory Payments for Outreach (2023)
- Hospital-Specific Annual Medicare Part B Anatomic Pathology Payments for Outreach (2023)
- Overall Estimated Annual Clinical Lab & Anatomic Pathology Outreach Revenue by Hospital (2023)

Abbreviated Sample Data from Hospital Outreach Laboratory Database:

Hospital Name	*System Affiliation*	*Laboratory Outpatient Charges 2023*	*Medicare CLFS Payments 2023*	*Medicare Pathology PFS Payments 2023*	*Grand Total Medica Part B Paym for Clinical L Pathology 2*
Reading Hospital	Tower Health	$337,428,206	$3,830,751	$156,255	$3,987
The Christ Hospital	Independent	$236,757,913	$3,929,562	$49,820	$3,979,
Nebraska Medical Center	Nebraska Medicine	$192,667,469	$2,776,164	$1,081,040	$3,857,
St. Elizabeth Edgewood Hospital	Saint Elizabeth Healthcare	$193,866,470	$3,723,460	$61,560	$3,785,
Saint Joseph's Hospital	BayCare Health System	$304,540,468	$3,568,088	$160,713	$3,728
Baptist Medical Center Jacksonville	Baptist Health	$385,958,167	$3,705,168	$0	$3,705,
Baylor Scott & White Medical Center	Baylor Scott & White Health	$512,405,444	$3,447,096	$234,480	$3,681,
Wellstar Kennestone Regional Med. Ctr.	WellStar Health System	$180,651,311	$3,591,210	$87,367	$3,678
Duke University Hospital	Duke Health	$725,908,214	$2,957,280	$716,590	$3,673,
The Valley Hospital	Valley Health System	$172,354,867	$3,320,100	$349,962	$3,670

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