Jondavid Klipp, Editor, jklipp@laboratoryeconomics.com VOLUME 18, NO. 10 OCTOBER 2023

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

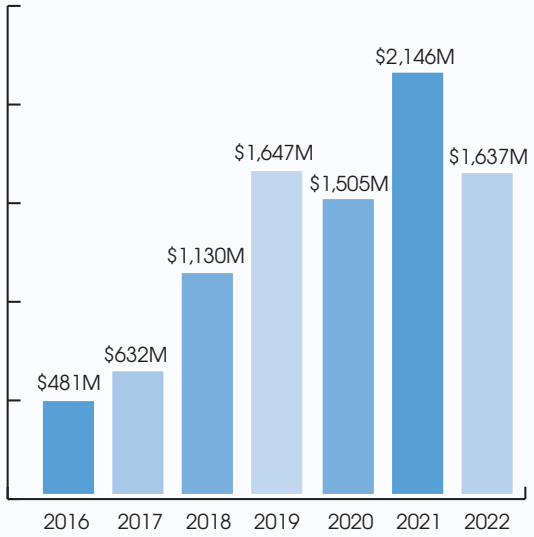
Proposed LDT Regulation Would Hit 1,000+ Labs

There are more than 1,000 labs, including 592 hospitals and 280 independent labs, that perform laboratory-developed tests (LDTs) in the United States, according to the market research firm IVD Logix (Dallas, TX). These labs will need to make major adjustments if the FDA's new proposed rule to regulate nearly all LDTs is finalized.
In-depth analysis on pages 4-5.

Genetic Test Spending Plunged 24% In 2022

National Medicare Part B carrier allowed payments for genetic test codes dropped by 24% to $1.6 billion in 2022, according to an *LE* analysis of newly released data from CMS. The decline appears to be largely the result of efforts by the Department of Health and Human Services Office of Inspector General (OIG) to target genetic testing fraud schemes nationwide. These efforts have shut down at least a half dozen genetic testing lab companies that had been billing the Medicare program hundreds of millions of dollars per year for dubious tests.
Full details on page 3.

Medicare Part B Carrier Spending on Genetic Tests*



*Total Medicare Part B Carrier allowed payments for all Molecular Pathology Tests, Multianalyte Algorithmic Assays, Genomic Sequencing Procedures and certain Proprietary Lab Analyses codes

Source: Medicare Part B National Summary Data, 2016-2022

Labcorp to Buy Baystate Outreach Lab Assets

Baystate Health (Springfield, MA) has agreed to sell its outreach laboratory assets to Labcorp for an undisclosed amount. The transaction is expected to close in early 2024. Labcorp is already the primary reference testing lab for Baystate, an integrated healthcare system with four hospitals in western Massachusetts. *Continued on page 2.*

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LABCORP TO BUY BAYSTATE OUTREACH LAB ASSETS (*cont'd from page 1*)
Baystate Health's outreach lab does business under the name Baystate Reference Laboratory and is based at the 780-bed flagship Baystate Medical Center (BMC-Springfield, MA). Hospital cost report data show that BMC had a total laboratory department cost of $152 million (including hospital overhead costs) in the fiscal year ended Sept. 30, 2022. BMC's outpatient laboratory charges totaled $295 million. Medicare CLFS payments to BMC totaled $5.7 million and Medicare pathology service payments totaled $290,326 in fiscal year 2022.

Baystate Health Laboratory Metrics for FY 2022

Hospitals	*Total Beds*	*Laboratory Department Costs*	*Total Laboratory Outpatient Charges*	*Medicare CLFS Payments*	*Medicare PFS Payments*	*Total Medicare Part B Payments 2022*
Baystate Medical Center	767	$151,936,562	$294,637,103	$5,742,448	$290,326	$6,032,774
Baystate Franklin Med. Ctr.	89	8,105,992	14,133,297	160,900	0	160,900
Baystate Wing Hospital	68	5,276,690	13,887,048	270,665	620	271,285
Baystate Noble Hospital	85	5,529,052	11,938,113	140,555	0	140,555
Totals	**1,009**	**$170,848,296**	**$334,595,561**	**$6,314,568**	**$290,946**	**$6,605,514**

Source: Baystate Health Hospital Cost Reports for fiscal year ending 9/30/22

Laboratory Economics estimates that Baystate Reference Laboratory has outreach revenue in the range of $30 million to $50 million per year. Key clients include Baystate Medical Practices (a multi-specialty academic group practice with over 1,000 employed providers).

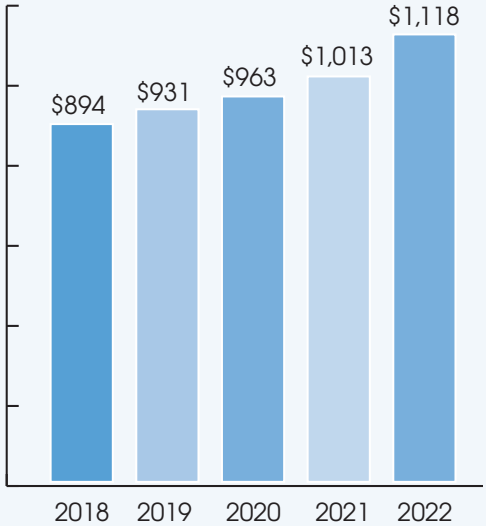
Under the agreement, Labcorp will build a regional laboratory located within Baystate's facility in Holyoke (8 miles north of Springfield). In addition to performing clinical lab testing, Labcorp will also perform anatomic pathology technical services. Baystate and its pathologists will continue to provide anatomic pathology professional services and perform select specialty testing. The deal will not affect the inpatient hospital labs at Baystate.

Labcorp expects to offer jobs to the majority of Baystate lab employees working in impacted areas.

Salary & Wage Pressure at Baystate Health
"Baystate Health's overall finances in fiscal year 2022 were the most challenging in the organization's long history," noted Chief Financial Officer Raymond McCarthy in a letter accompanying the health system's financial report. Baystate reported an operating loss of $178 million in fiscal year 2022 which represented a negative margin of 6.2% compared to the prior year's positive operating income of $27 million or 1%.

The primary drivers that caused Baystate's negative performance were the resurgence of Covid in early 2022 as well as sustained labor shortages and skyrocketing contract/temporary staffing costs that haunted all healthcare organizations throughout 2022, according to McCarthy. Baystate's salary and wage expense increased by 10% to $1.1 billion in fiscal year 2022.

Baystate Health's Wage & Salary Expenses ($ millions)



Source: Baystate Health

GENETIC TEST SPENDING FELL 24% IN 2022 (*cont'd from page 1*)

The data analyzed covers Medicare CLFS payments made to labs and physicians, but not payments made to hospitals through fiscal intermediaries. Academic medical centers and hospital labs represent a tiny portion (<2%) of all Medicare fee-for-service claims for genetic testing. (See page 13 for the top hospitals performing genetic testing.)

The OIG's enforcement initiative, dubbed "Operation Double Helix," put many fraudulent genetic testing labs out of business and has led Medicare Administrative Contractors to scrutinize genetic test claims more carefully for medical necessity.

Among the big genetic testing labs that have gone out of business within the past three years are Acadian Diagnostic Labs (Baton Rouge, LA), Artemis DNA (Houston, TX), CLIO Laboratories (Lawrenceville, GA), Crestar Labs (Spring Hill, TN), LabSolutions (Atlanta, GA), Performance Laboratories (Oklahoma City) and US Genomix (Houston, TX).

The genetic test codes that saw the most precipitous declines were Tier 2 Molecular Pathology Procedures (CPT 81400-81408). In particular, Medicare Part B allowed payments for CPT 81408 (Molecular pathology procedure, Level 9) dropped from $283 million in 2021 to just $312,824 in 2022. CPT 81408 is supposed to be billed by labs that test for multiple genes associated with rare childhood diseases. The OIG has highlighted CPT 81408 as a code that should be infrequently used for the Medicare population. An OIG report estimated that as much as $888 million in improper Medicare payments were made to labs between 2018 and 2021 (see *LE*, July 2023).

Meanwhile, Medicare Part B carrier allowed payments were highest for CPT 81479 (Unlisted molecular pathology procedure) at $477 million in 2022, up 16% from $409 million in 2021. The average Medicare denial rate for CPT 81479 was 37% in 2022. The average allowed payment was $2,363 per test.

Top 10 Genetic Test Codes by Medicare Part B Carrier Allowed Payments for 2022

CPT CODE	Short Description	2022 Allowed Charges	2021 Allowed Charges	% Chg
81479	Unlisted molecular pathology procedure	$476,549,936	$409,228,421	16%
81528	Exact Sciences: Oncology (colorectal) screening	272,957,395	253,299,916	8%
81519	Oncology breast mRNA, gene expression	94,900,119	92,986,857	2%
0242U	Guardant Health: Targeted genomic seq analysis panel, 55-74 genes	81,500,000	44,618,420	83%
81162	BRCA 1&2 full seq analysis & full dup/deletion analysis	75,464,285	92,935,697	-19%
81455	Targeted genomic seq analysis panel, 51+ genes	74,405,764	12,189,300	510%
0037U	Foundation Medicine: Targeted genomic seq analysis, 324 genes	61,936,000	74,238,500	-17%
81542	Oncology (prostate), mRNA, microarray gene expression, 22 genes	53,331,280	37,406,800	43%
81595	Cardiology (heart transplant), mRNA, gene expression profiling	31,457,160	27,488,160	14%
81541	Oncology (prostate), mRNA gene expression, 46 genes	31,342,364	28,979,834	8%
	Total for Top 10 Genetic Tests	1,253,844,303	1,073,371,906	17%
	Total for all Genetic Tests*	**$1,637,184,639**	**$2,146,437,158**	**-24%**

*Total Medicare Part B Carrier allowed payments for all Molecular Pathology Tests, Multianalyte Algorithmic Assays, Genomic Sequencing Procedures and certain Proprietary Lab Analyses codes

Source: Medicare Part B National Summary Data, 2021-2022

PROPOSED LDT REGULATION WOULD HIT 1,000+ LABS (*cont'd from page 1*)
Laboratory-developed tests (LDTs) are those designed, manufactured and performed within a single high-complexity CLIA-certified lab. Historically, the FDA has not formally required labs offering LDTs to comply with its regulatory requirements for medical devices.

The FDA issued its proposed rule on September 29 and is accepting comments for 60 days through December 4. Assuming it is finalized, regulation of LDTs will be phased in over a four-year period from the date FDA publishes a final rule.

Timeline for Proposed FDA Regulation of LDTs

- **Phase 1** (effective one year post-finalization): Labs must comply with medical device (adverse event) reporting and correction/removal reporting requirements.
- **Phase 2** (effective two years post-finalization): Labs must comply with all other device requirements (e.g., registration/listing, labeling, investigational use), except for quality systems and premarket review.
- **Phase 3** (effective three years post-finalization): Labs must comply with quality systems requirements.
- **Phase 4** (effective three and a half years post-finalization, but not before October 1, 2027): Labs must comply with premarket review requirements for high-risk tests (i.e., tests subject to premarket approval (PMA) requirement).
- **Phase 5** (effective four years post-finalization, but not before April 1, 2028): Labs must comply with premarket review requirements for moderate- and low-risk tests (i.e., tests subject to de novo or 510(k) requirement).

Source: McDermott Will & Emery

Which labs and types of tests will be affected by LDT regulation?
More than half of the 1,002 sites that perform LDTs are hospital labs, including academic medical centers, teaching hospitals and community hospitals, notes Larry Worden, President of IVD Logix. Independent labs comprise 28%. More than half of all the LDT labs perform flow cytometry LDTs. Other common LDT test categories include molecular genetics, molecular infectious disease and immunochemistry.

Types of Labs Performing LDTs by Test Category

	# Sites[1]	Hospitals[2]	Independent Labs	Clinic/POL	Other Labs[3]
Total # Labs Performing LDTs	1,002	592	280	50	80
- Flow Cytometry LDTs	525	343	124	28	30
- Molecular Genetics LDTs	494	284	173	13	24
- Molecular Infectious Disease LDTs	449	303	106	8	32
- Immunochemistry LDTs	329	224	90	8	7
- Microbiology LDTS	227	157	38	3	29
- Autoimmune Disease LDTs	92	74	14	3	1
- Chemistry LDTs	68	45	21	1	1
- Infectious Immunology LDTs	11	8	3	0	0
- Hematology LDTs	9	6	0	0	3
- Coagulation LDTs	3	0	3	0	0

1) IVD Logix defines a "site" as a physically distinct location that performs clinical laboratory testing under one or more CLIA licenses.
2) Includes academic medical centers, community hospitals and teaching hospitals.
3) Includes public health labs, blood banks and other labs.
Source: IVD Logix

Will existing LDTs be grandfathered from new FDA regulatory requirements?

There would be no grandfathering for existing LDTs currently on the market, including tests performed at academic medical centers (AMCs), notes Katherine Tynan, PhD, President of the consulting firm Tynan Consulting (San Francisco, CA). Grandfathering had been included in prior proposals, including the Valid Act, which failed to get passed into law last year.

Katherine Tynan, PhD

However, Tynan says that the proposed rule invites comments on the potential to exempt academic medical centers (AMCs) from LDT regulation. There are approximately 150 AMCs in the United States. A key question is: Could teaching hospitals also be exempted?

The FDA has requested that any comments supporting grandfathering include both an explanation of the public health rationale for grandfathering (including supporting data) and an outline of steps to help support a grandfathering approach.

Which labs will be hurt the most and least from LDT regulation?

The biggest commercial labs with a track record of navigating the FDA regulatory process may be in a relatively better position than smaller labs, according to Tynan. The cost and time associated with obtaining FDA clearance may also force smaller labs to switch from performing their own LDTs to purchasing more expensive FDA-cleared test kits from IVD vendors.

Will FDA regulation stifle innovation?

Mark Roth

FDA regulation will likely slow innovation of new tests, according to Mark Roth, Chief Executive of Lighthouse Laboratory Services (Charlotte, NC). LDTs have been a way for smaller labs to bring new tests to market. The time and expense associated with getting FDA clearance will force test developers to prioritize their time and money toward commercializing a smaller number of new tests, says Roth.

CAP is seeking an extended 120-Day Comment Period.

Due to the complexity of the rule and implications for laboratory testing, the CAP is calling on the FDA to extend the comment period to at least 120 days to give stakeholders more time to review the proposal and respond, CAP President Emily Volk, MD, tells *Laboratory Economics*. She says that CAP requires additional time to evaluate the proposed rule, including the FDA arguments regarding oversight jurisdiction.

What can labs do to prepare for potential LDT regulation?

Tynan says that labs should assume that greater oversight of LDTs is coming. "Get ready to meet FDA level quality systems requirements and start developing intended use statements and design studies to support your LDTs claims," advises Tynan.

What's the potential for a lawsuit blocking FDA regulation of LDTs?

Jeffrey Shapiro

A viable lawsuit could be made against the final rule, and it would be based on a legal position that the final rule is arbitrary and capricious and/or not in accordance with law, says Jeffrey Shapiro, an attorney who specializes in medical device law at King & Spalding (Washington, DC). An argument could be made that the Federal Food, Drug, and Cosmetic Act (FDCA) does not grant FDA authority to regulate LDTs and that the Clinical Laboratory Improvement Amendments (CLIA) is a more specific statute authorizing CMS to regulate laboratories that offer these tests, precluding FDA from doing so, according to Shapiro.

Spotlight on Cleveland Clinic Laboratories

Ziad Peerwani, MD

Dajan Ninic, MHA

Cleveland Clinic, which includes 12 hospitals in Ohio, has 2,200 lab employees that perform a total (inpatient/outpatient/outreach) of 23 million tests per year. Its outreach division, Cleveland Clinic Laboratories, based at the Cleveland Clinic Main Campus (1,326 beds), provides reference laboratory services to local, national, and international healthcare providers. *Laboratory Economics* recently spoke with Ziad Peerwani, MD, Medical Director, and Dajan Ninic, MHA, Director of Cleveland Clinic Laboratories (CCL) on a range of topics.

Can you describe the clinical laboratory outreach business at CCL?
Our clinical lab outreach currently performs a total of 1.8 million tests per year and has been growing at an average annual rate of 20% since 2021. This is entirely non-Cleveland Clinic work with a focus on independent physician offices and nursing homes in northeast Ohio, although we're beginning to expand to other parts of the state as well. CCL also provides reference testing services to hospitals nationwide.

Are you experiencing any lab staff shortages?
CCL has more than 65 access points for phlebotomy in Ohio and our biggest staffing challenge has been finding phlebotomists. Cleveland Clinic recently developed its own School of Phlebotomy with free tuition, and we're hoping to hire graduates. The most recent class graduated six students in June of 2023.

And how about anatomic pathology services?
Cleveland Clinic has a staff model with 100 employed pathologists covering 18 subspecialties--all based at the Cleveland Clinic Main Campus. Although our pathologists are quite active in research and engaged academically, our pathology department is clinically oriented and all pathologists, including our Chairman, sign out cases.

We'll process a total of 235,000 surgical cases and 95,000 cytopathology cases this year.

Outreach is focused on providing expert consultations. We expect to perform 27,000 consults this year, up 20% year over year. Roughly 5-10% of our consults are for international clients, primarily from the Middle East, South America and Central America.

Are you having trouble hiring pathologists?
No. We hired an additional five pathologists over the past year. They are attracted to the Cleveland Clinic reputation and the fact that we are a clinically oriented subspecialized practice with 18 subspecialties. Our pathologists have the opportunity to interpret unusual and complex cases while also having robust opportunities for research and education.

Are you utilizing digital pathology?
Some of our international clients are sending us digitized slide images, which can cut down turnaround time by two days. We're also exploring digital pathology for use in the United States. It's fine for routine work like dermatopathology. However, for larger more complex cases (e.g., 10-20 slides) our pathologists find it easier and quicker to use the traditional microscope.

What are your thoughts on the FDA's proposed regulation of laboratory-developed tests (LDTs)?
I understand the desire to regulate LDTs. However, Cleveland Clinic has a long history of using LDTs and they represent a substantial subset of our testing that is integrated into our practice of laboratory medicine and patient care. The suggested regulation risks being too functionally prohibitive, preventing its utility and implementation within academic medical centers without sufficient commercial alternatives. The potential care gap negatively impacting patients is of concern.

bioAffinity Buys Lab Assets of Precision Pathology for $3.5 Million

bioAffinity Technologies (San Antonio, TX) has acquired the laboratory assets of Village Oaks Pathology Services (dba Precision Pathology Services) effective September 18. The purchase price was $3.5 million, including $2.5 million in cash and $1 million worth of bioAffinity common stock.

In connection with the asset purchase agreement, bioAffinity entered into a 20-year management services agreement with Precision Pathology Services (PPS). Under the MSO, bioAffinity will provide comprehensive management and administrative services to PPS in connection with its professional cytopathology, histopathology, clinical and anatomic pathology interpretation services. bioAffinity will get a management fee of 70% of the net professional service revenues received by PPS.

Roby Joyce, MD

PPS was founded by its principal Roby Joyce, MD, age 75, in 2007. Dr. Joyce is board-certified in anatomic and clinical pathology by the College of American Pathologists (CAP). He is also board-certified in neurology by the American Academy of Neurology. In connection with the transaction, Dr. Joyce signed a three-year agreement to serve as the Medical Director and Laboratory Director at bioAffinity at a base salary of $333,333 per year. He has also joined bioAffinity's Board of Directors.

The CAP-accredited lab at PPS has 54 employees and specializes in PCR testing for Covid-19, influenza and STDs, as well as skin biopsies for dermatologists, and morphological stains (particularly for research organizations). The lab serves 155 client locations, including seven hospitals in central Texas.

PPS reported a net loss of $461,632 in calendar year 2022 versus net income of $406,497 in calendar year 2021; revenue increased by 11% to $6.9 million from $6.2 million. Revenue increased by 12.5% in the six months ended June 30, 2023.

Precision Pathology Services at a Glance

Founder & Medical Director	Roby Joyce, MD
Employed pathologists	9
Total employees	54
Annual Revenue	$7 million
Total # client locations	148 offices/7 hospitals
Total # physician clients	600

Source: PPS and bioAffinity

Over the past five years, bioAffinity and PPS have been working together to develop and commercialize a noninvasive lung cancer test under the brand name CyPath Lung. The test utilizes flow cytometry to detect and analyze cells in a patient's sputum, or phlegm, to determine likelihood of lung cancer. CyPath Lung is currently being marketed as a lab-developed test and billed using CPT 88185 (x8), 88184 (x1) and 88188 (x1) for total Medicare reimbursement of $329. The target market is smokers, or former smokers, at high risk for lung cancer.

bioAffinity received a Proprietary Laboratory Analyses code for CyPath Lung in June 2023 (PLA code 0406U). CMS is expected to issue a final decision on a reimbursement rate for the new code in November for an effective date of January 1, 2024.

bioAffinity plans to begin a two-year 1,800-patient clinical trial study for CyPath Lung in early 2024. Study results will be used to support an eventual FDA application for the test.

bioAffinity, which now has 74 employees, raised net proceeds of $6.2 million from an IPO late last year (see *LE*, September 2022). bioAffinity reported a net loss of $3.3 million in the six months ended June 30, 2023, compared with a net loss of $1.6 million in the same period a year earlier; revenue was $20,659 versus $1,306.

Spotlight Interview with AdventHealth Lab's Judith White

AdventHealth (Altamonte Springs, FL), which includes 51 hospitals in nine states, operates one of the nation's largest laboratory outreach programs. *Laboratory Economics* recently spoke with Judith White, FACHE, Executive Director of Laboratory Outreach at AdventHealth.

Judith White

Can you describe the laboratory outreach business at AdventHealth?
Our outreach program does business as AdventHealth Lab and is based at AdventHealth Orlando, which has 2,840 beds and is the largest hospital within the AdventHealth System. The central laboratory at AdventHealth Orlando has 530 employees and performs a total (inpatient/outpatient/outreach) of more than 6.4 million tests per year. Additionally, we have 165 staff dedicated to outreach operations and sales.

Outreach testing volume is on track to reach approximately 2.4 million tests this year, or about 38% of overall volume at AdventHealth Orlando. Outreach test volume growth at AdventHealth Lab has averaged more than 9% annually since 2018.

What geography does AdventHealth Lab cover?
Our outreach test services cover physician offices, extended care facilities and hospitals in the Orlando and Tampa regions. In the coming year, we are expanding north into the Daytona region.

Is your outreach testing focused on AdventHealth Medical Group practices?
About 50% of our physician office testing comes from AdventHealth Medical Group. Additionally, we have a sales and marketing team of 9 employees that calls on non-AdventHealth physician offices, extended care facilities, hospitals and surgery centers.

Does AdventHealth Lab provide reference testing services to hospitals?
Yes, we have a test menu of over 1,000 tests and receive send-outs tests from all 20 AdventHealth hospitals in Florida. Due to our extensive test menu, we also receive reference tests from non-AdventHealth hospitals. AdventHealth Lab is able to perform 99% of test volume in-house. ARUP Laboratories is our primary reference lab for the remaining 1%.

Right now, our reference testing services are focused on Florida, but we have plans to expand this service to 30+ AdventHealth hospitals in other states starting in 2025. AdventHealth's biggest presence outside of Florida includes Colorado, Georgia, Illinois and Kansas.

Which tests do you plan to bring in-house?
We're planning to add 10 new tests next year, including Legionella PCR, antibiotic synergy susceptibilities, pancancer TSO500 NGS tumor panel, organism identification by NGS and Calprotectin. Our outreach volume helps bring more tests in-house.

What's your average turnaround time for outreach testing?
The majority of our test results are delivered in under 24 hours. Our quick TAT is helped by a dedicated specimen processing team that sorts out manual reqs from non-affiliated clients, enters them into our system, and gets them fully labeled and rack-ready before entering the lab.

Are lab staffing shortages an issue?
We've been able to keep our vacancies and turnover low as a result of 1) wage increases; 2) a new bachelor's degree program in Medical Laboratory Science at AdventHealth University launched in fall 2022; and 3) international recruitment, especially from the Philippines.

How do you handle billing for outreach testing?
The main hospital billing department has a specialized team dedicated to lab outreach billing.

What is the biggest challenge to growing your outreach testing?
Gaining access to national managed care contracts as our reference testing services expand into new states.

What separates a successful outreach lab from a not-so-successful outreach lab?
Some health systems view lab outreach as "nice-to-have" as opposed to "must-have." AdventHealth has strategic plans to grow its ambulatory services. Laboratory services are a critical component of our clinical integration.

UnitedHealthcare Delays Z-Code Start Date Again

Once again, UnitedHealthcare (UHC) has delayed its requirement of "Z-codes" for certain molecular test claims submitted to its commercial health plans. UHC first announced its Z-code requirement on May 1, 2023, with plans to enforce the policy effective August 1. It then delayed enforcement until October 1 (see *LE*, July 2023). Now UHC has lifted the October 1 start and has not announced a new date. The change was made "to ensure that those providers who have not yet taken steps to register applicable tests or have not yet completed the registration process have additional time to do so and to receive Z-codes for use in submitting claims," according to a UHC spokesperson. Labs who have questions or need assistance can email united_genetics@uhc.com.

Everlywell Lawsuit Dismissed; Referred to Arbitration

The Massachusetts District Court (Boston) has dismissed a proposed class action lawsuit filed against Everly Health Inc. (dba Everlywell) and referred it to arbitration pending an appeal. The lawsuit was filed by Massachusetts resident Joyce Toth who alleges that the Everlywell Food Sensitivity Test does not identify food sensitivities as advertised (see *LE*, September 2023).

Quest Diagnostics Couriers in Georgia Join Teamsters

Fifty-two couriers employed by Quest Diagnostics in Tucker, Georgia have voted to join Teamsters Local 728. The vote was held on October 10 & 11 at Quest's facility in Tucker (just north of Atlanta).

"These workers overcame an aggressive anti-union campaign at Quest and successfully voted to organize their facility," said Matt Higdon, President of Local 728 in Atlanta, in an October 13 press statement. Teamsters hope to negotiate better healthcare benefits, wage increases and an end to "at will" employment for the Quest couriers. Average pay for Quest couriers in Tucker is currently $16-17 per hour.

Separately, Teamsters Local 542 is attempting to unionize 44 couriers at Quest facilities in San Diego and El Centro, CA, according to information from the National Labor Relations Board.

Quest has approximately 49,000 employees, of whom approximately 40,000 are full-time. Fewer than 1% of its employees are represented by a union.

Pathologist Job Openings Remain Near Record-High

The biggest online job board for pathologists, PathologyOutlines.com, currently has 705 pathologist jobs listed (see page 11). That's near the site's all-time record of 706 pathologist job ads reached in February 2022. Prior to 2020, the average number of job openings was between 300 and 400.

Rich Cornell, President and Founder of the life sciences recruiting firm Santé Consulting (St. Louis, MO), says it's important for labs to understand that the shortage is not going away soon. Cornell says, "Labs must establish an internal sense of urgency in the hiring process in order to hire effectively in this market. The total actual number of U.S. pathologist openings is currently closer to 1,000 when including jobs that are not advertised on PathologyOutlines.com. The biggest competition exists for jobs in the subspecialties in highest demand: cytopathology, hematopathology and gastrointestinal.

According to Cornell, only about 600 pathologist residents and fellows graduate each year. A large percentage of those graduates will require visa sponsorship, but only about 1/3 of visa requests will likely get accepted. In other words, the market is out of balance and will continue this way for the next several years, says Cornell.

So what should labs do in this tight job market? Cornell says it boils down to these two things:

1. The interview-to-hire ratio has changed. Pathology practices should expect to interview an average of five candidates in order to successfully hire one pathologist. That's the new average.

2. Young millennial pathologists (age 27-42 years) are seeking low stress working environments and a quick interview timeframe. They expect offers within 48 hours after an interview. The timing and pace of your offer are crucial once the interview takes place.

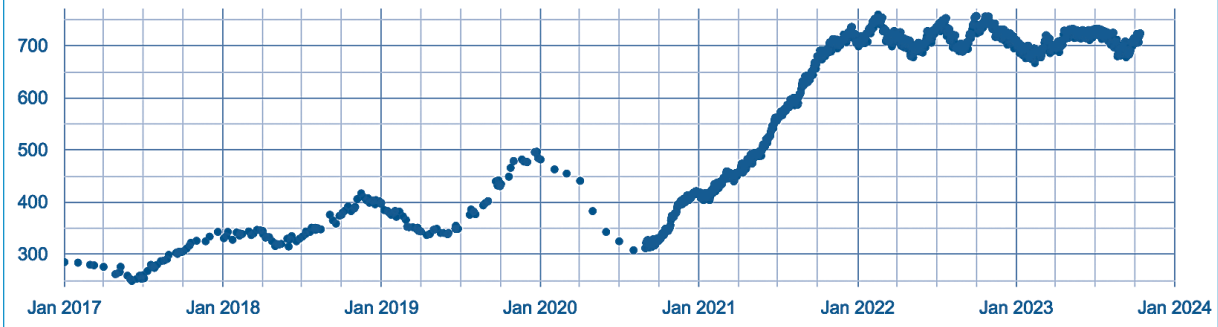
How are other labs advertising for pathologist openings in light of this severe shortage? Here are some recent examples from PathologyOutlines.com:

$100K Sign-On Bonus
A large independent pathology practice in Connecticut is offering $100,000 sign-on bonuses in an effort to hire one or more full-time surgical pathologists with subspecialty training in gastrointestinal pathology, breast or hematopathology. The annual salary range is highly competitive with four weeks vacation. Current fellows, pathologists straight out of fellowships and experienced pathologists are encouraged to apply.

22 Pathologists Needed at HCA Healthcare
HCA Healthcare has ads for 22 pathologist job openings—mostly for its hospitals in Florida, Georgia and Texas. HCA Healthcare is offering sign-on bonuses of up to $30,000. Other organizations with a large number of job ads include Sonic Healthcare (21 pathologist openings), Rutgers New Jersey Medical School (11 openings) and Northwell Health in New York (10 openings).

Cornell says that many groups are struggling because of their hiring process, or lack thereof. "We recently worked with a large healthcare system with more than 20 pathologists. They needed four additional pathologists to handle their workload volume increases. However, their internal process prevented them from being successful. They would take 4 weeks to make an offer once the interview had occurred. Candidates would lose interest because they were left waiting for too long after they were interviewed. Younger candidates expect feedback from employers immediately following the interview."

Pathologist Job Ads Posted on PathologyOutlines.com



Source: PathologyOutlines.com

Average Pathologist Compensation Edges Up 1.5% to $339K

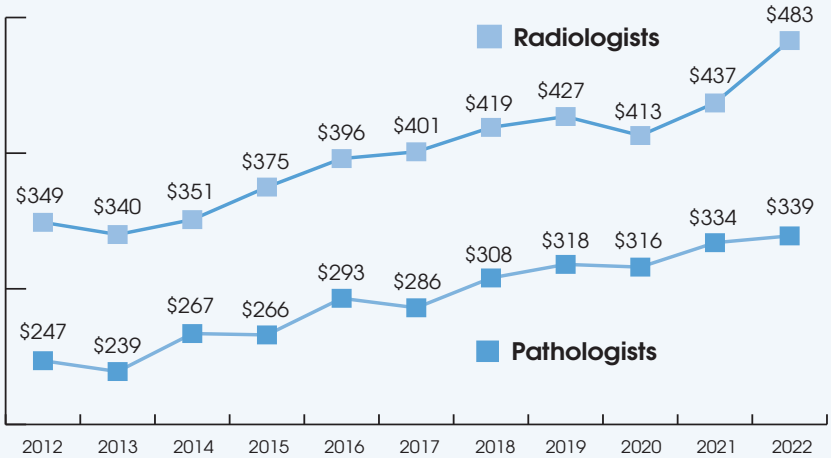
Pathologists average compensation was $339,000 in 2022, up 1.5% from $334,000 in 2022, according to the latest Medscape Physician Compensation Report. Over the 10-year period (2012-2022), pathologist compensation grew by an average of 3.2% per year.

Fifty-one percent of pathologists felt they were fairly paid. Eighty-one percent said they would choose the same specialty again if they had the chance. The job challenges that pathologists most often picked were: 1) too many rules and regulations (26%); 2) having to work long hours (18%); and 3) difficulties getting fair reimbursement from or dealing with Medicare and/or other insurers (16%).

In comparison, average compensation for radiologists increased by 10.5% to $483,000 in 2022, according to Medscape. Over the 10-year period (2012-2022), radiologist compensation grew by an average of 3.3% per year.

As in prior years, plastic surgery ($619,000), orthopedics ($573,000), and cardiology ($507,000) remained the highest-paid specialties in 2022. These specialties have consistently topped this list for over 10 years. Other top-earning specialties include urology ($506,000), gastroenterology ($501,000), and radiology ($483,000).

Pathologist vs. Radiologist Compensation ($000)



Source: Medscape Physician Compensation Reports

The latest Medscape survey was based on 10,011 physicians in more than 29 specialties. Survey responses were collected from October 7, 2022 through January 17, 2023. For employed physicians, compensation figures include salary, bonus and profit-sharing contributions. For self-employed physicians, they include pretax income. Only full-time physicians were included in the Medscape survey.

Lab Stocks Down 20% Year-to-Date In 2023

Twenty-four lab stocks have dropped by an unweighted average of 20% year to date through October 13. In comparison, the S&P 500 Index is up 13% year to date. The top-performing lab stocks thus far in 2023 are NeoGenomics, up 35%; Exact Sciences, up 32%; and Opko Health, up 8%. Labcorp shares are flat (after adjusting for spinoff of Fortrea) and Quest Diagnostics is down 22%.

Company (ticker)	Stock Price 10/13/23	Stock Price 12/30/22	2023 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
NeoGenomics (NEO)	$12.50	$9.24	35%	$1,790	$552	3.2
Exact Sciences (EXAS)	65.27	49.51	32%	13,590	2,301	5.9
Opko Health (OPK)	1.35	1.25	8%	1,230	868	1.4
Aspira Women's Hlth (AWH)	5.14	4.95	4%	50	9	5.6
Natera (NTRA)	41.54	40.17	3%	4,630	931	5.0
Sonic Healthcare (SHL.AX)*	30.14	29.97	1%	16,600	8,170	2.0
Myriad Genetics (MYGN)	14.54	14.51	0%	1,270	699	1.8
Enzo Biochem (ENZ)	1.43	1.43	0%	90	71	1.3
Labcorp (LH)	201.56	202.30	0%	22,260	14,881	1.5
Guardant Health (GH)	27.03	27.20	-1%	3,320	510	6.5
Veracyte (VCYT)	21.28	23.73	-10%	1,370	329	4.2
Interpace Biosciences (IDXG)	0.91	1.04	-13%	60	37	1.6
Fulgent Genetics (FLGT)	24.90	29.78	-16%	-78	307	-0.3
Exagen (XGN)	1.88	2.40	-22%	26	53	0.5
Quest Diagnostics (DGX)	122.50	156.44	-22%	18,700	9,488	2.0
DermTech Inc. (DMTK)	1.22	1.77	-31%	10	14	0.7
Biodesix (BDSX)	1.54	2.30	-33%	148	42	3.6
Psychemedics (PMD)	2.67	4.90	-46%	16	24	0.7
Castle Biosciences (CSTL)	12.38	23.54	-47%	121	168	0.7
CareDx (CDNA)	5.65	11.41	-50%	60	309	0.2
ProPhase Labs (PRPH)	4.37	9.63	-55%	80	80	1.0
GeneDx (WGS)	3.23	8.71	-63%	2	236	0.0
Invitae (NVTA)	0.61	1.86	-67%	1,420	494	2.9
Biocept (BIOC)	1.02	15.90	-94%	8	1	5.4
Totals & Averages			-20%	$86,773	$40,573	2.1

1) Aspira had a 1-for-15 reverse stock split on May 11. 2) GeneDx had a 1-for-33 reverse stock split on May 4. 3) Biocept had a 1-for-30 reverse stock split on May 16. *Sonic Healthcare's figures are in Australian dollars Source: *Laboratory Economics* from SeekingAlpha.com

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor Kimberly Scott, Associate Editor