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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

AMA Announces New Add-On Digital Pathology Codes

The American Medical Association (AMA) CPT Editorial Panel has announced 13 new digital pathology add-on codes effective on January 1, 2023. The new digital pathology Category III CPT codes will be used to report additional clinical staff work and service requirements associated with digitizing glass slides for primary diagnosis.

Introduction of the codes will allow CMS to monitor the usage of digital pathology. However, no relative value units (RVUs) or national payment rates have been assigned to the new codes.

"It's an important first step, but widespread use in clinical practice will need to be demonstrated before the new codes are moved to Category I and assigned RVUs," notes Jonathan Myles, MD, Chair of the Council on Government and Professional Affairs at the College of American Pathologists (CAP).
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New Bill Would Delay & Reduce Medicare CLFS Cuts

New legislation would, if passed, make major modifications to the PAMA law for determining lab test rates on the Medicare Clinical Laboratory Fee Schedule (CLFS). The bill is titled *Saving Access to Laboratory Services Act (SALSA)*. It has been introduced in both the Senate and House by Sens. Sherrod Brown (D-OH) and Richard Burr (R-NC), along with Reps. Bill Pascrell (D-NJ), Scott Peters (D-CA), Richard Hudson (R-NC), Gus Bilirakis (R-FL) and Kurt Schrader (D-OR). Without congressional intervention, more than 800 tests on the CLFS will receive up to 15% rate cuts effective January 1, 2023.
Full details on page 4.

Genomic Testing Labs: Strong Revenue Growth With Rivers of Red Ink

Twelve publicly traded genomic testing lab companies recorded annualized revenue growth of 25% for the five years ended December 31, 2021. However, over the same period, these 12 companies accumulated total losses of a staggering $6.7 billion. Furthermore, only one of the 12 companies, Myriad Genetics, is expected to turn a profit this year.
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Genomic Testing Labs: Strong Revenue Growth And Red Ink (*cont'd from page 1*)

The expected 2022 profit at Myriad Genetics follows a painful restructuring that saw the company's headcount fall to 2,400 from a year-ago peak of 2,700 employees. Myriad Genetics sold its Vectra autoimmune testing business to Labcorp in February 2022 and its myPath Melanoma laboratory to Castle Biosciences in May 2021.

Meanwhile, the 12 publicly traded labs have accumulated total losses of $9 billion since each of the companies was formed. The "Genomic Revolution" and next gen-sequencing have captured the imagination of investors who have been willing to fund these companies in anticipation of a big future payday. But there are structural challenges that are being overlooked.

- **High Claims Denial Rates.** Medicare Part B claims denial rates for genetic tests ranged between an average of 23% and 55% from 2013 through 2020 (see *LE*, December 2021). Denial rates at private insurers are even higher. It's hard for a genomic testing lab to make a profit when as much as 50% of their claims are being rejected for payment.
- **High Marketing Costs.** Unlike a lipid panel or Pap test, new and proprietary genomic tests require a huge investment in marketing and direct sales reps to educate physicians and establish brand awareness.
- **Technical Expertise of Employees.** The laboratory staff at genomic testing labs requires more MDs, PhDs and molecular genetics technologists than at routine clinical labs. For example, the median employee salary levels at Exact Sciences and Guardant Health were $129,000 and $260,000, respectively in 2021. This compares with $58,000 at Labcorp and $67,000 at Quest Diagnostics (see *LE*, May 2022).
- **Increasing Competition.** Growing understanding of the importance of biomarkers linked with cancer detection and therapy selection has led to a wave of lab companies being formed to commercialize new genomic testing technologies. In addition, Quest Diagnostics and Labcorp are making targeted acquisitions of startup genomic testing labs with promising technologies.

Rising interest rates and falling stock prices will make it more difficult for genomic testing labs to raise capital to fund operating losses. As a result, *Laboratory Economics* is anticipating a shakeout (i.e., consolidation and restructuring) to occur among genomic testing labs over the next 24 months.

Annual Losses at Genomic Testing Lab Companies

Company	2021	2020	2019	2018	2017	Accumulated Losses Since Inception
Exact Sciences	-$595,625,000	-$823,605,000	-$213,090,000	-$175,149,000	-$114,397,000	-$2,641,520,000
Natera	-471,716,000	-229,743,000	-124,827,000	-128,154,000	-137,628,000	-1,394,836,000
Guardant Health	-405,670,000	-253,783,000	-75,651,000	-85,063,000	-83,221,000	-1,007,825,000
Invitae Corp.	-379,006,000	-602,170,000	-241,965,000	-129,355,000	-123,380,000	-1,722,848,000
Sema4 Holdings	-245,390,000	-241,340,000	-29,704,000	NA	NA	-575,441,000
DermTech	-78,335,000	-36,477,000	-20,130,000	-10,004,000	NA	-206,364,000
Veracyte	-75,563,000	-34,909,000	-12,599,000	-22,999,000	-31,003,000	-357,157,000
Biodesix	-43,159,000	-31,350,000	-30,726,000	NA	NA	-301,973,000
Castle Biosciences	-31,292,000	-10,284,000	2,991,000	-10,162,875	-15,307,427	-93,767,000
Myriad Genetics	-27,200,000	-199,500,000	4,600,000	133,300,000	17,400,000	-254,200,000
Interpace Biosciences	-14,943,000	-29,484,000	-27,169,000	-12,189,000	-12,216,000	-227,059,000
Biocept Inc.	-2,824,000	-17,810,000	-25,259,611	-25,207,971	-21,613,737	-263,527,000
Total for 12 cos.	-$2,370,723,000	-$2,510,455,000	-$793,529,611	-$464,983,846	-$521,366,164	-$9,046,517,000

Source: *Laboratory Economics* from Securities & Exchange 10K filings

AMA Announces New Add-On Digital Pathology Codes (*cont'd from page 1*)

The new digital pathology add-on codes are linked with 13 of the most commonly billed pathology procedures, including CPT 88305 (Level IV-Tissue Exam). CAP's Myles says that the new add-on codes should only be reported when used for clinical diagnosis and not for things like archiving slides, training or validation of AI algorithms, or tumor board conferences. "It's clear that digital pathology will be a part of the practice of pathology and lab medicine, but it has to be proven to be in widespread clinical use to gain Medicare reimbursement," says Myles.

Assuming that digital pathology volumes prove to be significant, the very earliest that CMS could assign RVUs and establish national payment rates for the new add-on codes would be for an effective date of January 1, 2024, notes *Laboratory Economics*. However, the process is more likely to take at least a few years. In the meantime, each individual Medicare Administrative Contractor (MAC), as well as private insurers, could establish their own payment rates, but are not required to do so.

Many pathology labs in the United States are experimenting, but very few have gone fully digital, according to Michael Rivers, Vice President and Lifecycle Leader for Digital Pathology, Roche Tissue Diagnostics (Santa Clara, CA). "Digitization is a means to an end. It will allow the application of innovative AI solutions to pathology images and ultimately integrated multi-modal analysis of patient cases combining anatomic pathology, clinical lab and gene-sequencing data," says Rivers.

"My prediction is that if the Category III codes are converted to Category I code status, in the future Medicare could potentially reimburse the new add-on codes at roughly 3% to 5% of the global rates for related existing codes," says Erick Lin, MD, PhD, Senior Director, Medical Affairs, PathAI (Boston, MA). Thus, the add-on code for digitizing one unit of CPT 88305 (current global rate of $72) could be reimbursed at between $2 and $4. The key is for all pathology labs to be aware of the new add-on codes, prepare systems to report, and then begin reporting the new codes effective January 1, 2023. If all clinical utilization is appropriately reported on claims, it can help facilitate Medicare's establishment of national reimbursement rates, explains Lin.

"Although digital pathology, including usage of AI algorithms, could improve pathologist efficiency, this should not be the sole focus of reimbursement calculations. Digital pathology helps labs and pathologists expand their network of brainpower through greater access to information, second opinions and subspecialist expertise. This ultimately could lead to optimized diagnostic decision-making and inherently leads to better patient management," according to Esther Abels, Chief Clinical and Regulatory Officer, Visiopharm Corp. (Westminster, CO) and President of the Digital Pathology Association (Carmel, IN).

New Category III CPT Codes for Digital Pathology

Category III CPT Code	Short Description	Use in conjunction with Category I CPT Code
0751T	Digitization of glass slides for level II, surgical pathology	88302
0752T	Digitization of glass slides for level III, surgical pathology	88304
0753T	Digitization of glass slides for level IV, surgical pathology	88305
0754T	Digitization of glass slides for level V, surgical pathology	88307
0755T	Digitization of glass slide for level VI, surgical pathology	88309
0756T	Digitization of glass slides for special stain, group I	88312
0757T	Digitization of glass slides for special stain, group II	88313
0758T	Digitization of glass slides for special stain, frozen tissue block	88314
0759T	Digitization of glass slides for special stain, enzyme constituents	88319
0760T	Digitization of microscope slides for immunohistochemistry, initial stain	88342
0761T	Digitization of glass slides for immunohistochemistry, each additional stain	88341
0762T	Digitization of glass slides for immunohistochemistry, each multiplex stain	88344
0763T	Digitization of glass slides for morphometric analysis, tumor IHC	88360

Source: American Medical Association

New Bill Would Delay & Reduce Medicare CLFS Cuts (*cont'd from page 1*)

Washington insiders tell *Laboratory Economics* that there is precious little time for the lab industry to lobby for SALSA. Members of Congress will be on "summer recess" from Aug. 8 until Sept. 6, after which all attention will be on the midterm elections. All 435 House seats are up for election on Nov. 8, as well as 34 of the Senate's 100 seats. The hope is that SALSA can get passed as part of a larger end-of-year Medicare spending package. Lobbying efforts are being directed at members of the Senate Finance Committee and House Ways and Means Committee.

Key provisions of the SALSA Act:

- **Freezes Medicare CLFS rates in 2023.** Reimbursement rates would be held steady for the third year in a row in 2023. CLFS rates for most lab tests were cut by 10% per year in 2018-2020.
- **Lowers the cap on annual rate cuts.** CLFS rate cuts for each lab test would be capped at 2.5% for 2024, and then 5% for 2025 and each subsequent year. The current cap on rate cuts is 15% per year.
- **Postpones the next private-payer data reporting period.** The next PAMA reporting period would be pushed back to Jan. 1, 2026 to March 31, 2026. Labs would be required to report private-payer payment data collected from Jan. 1, 2025 through June 30, 2025. This data would be used to set CLFS rates starting in 2027. This compares with the current reporting schedule of Jan. 1, 2023 to March 31, 2023, based on data collected from the first six months of 2019, and used to set CLFS rates for 2024.
- **Use of statistical sampling.** CMS would be required to use a statistically representative sample of private-payer payment rates from independent labs, hospitals and POLs when setting CLFS lab test rates. The initial PAMA survey was dominated by the lower rates offered by the national labs, resulting in higher-than-expected rate reductions.
- **Extends the reporting cycle.** The PAMA reporting cycle would be extended to every four years versus the current three-year cycle.

PAMA Lawsuit Update

On July 15, the U.S. Court Of Appeals, DC Circuit issued a decision in favor of the American Clinical Laboratory Assn. (ACLA) for its long-running PAMA lawsuit, originally filed in December 2017, against the Department of Health and Human Services (HHS). The DC Circuit Court said that HHS was wrong to exclude private-payer payment data from nearly all hospital outreach labs in the initial PAMA survey that led to drastic cuts to Medicare CLFS rates in 2018-2020.

The DC Circuit Court's decision sends the case back to the District Court with instructions to enter a declaratory judgment in ACLA's favor. However, the decision does not require HHS to recalculate past Medicare CLFS rates, in light of PAMA's provision stripping jurisdiction to review Medicare payment amounts. Furthermore, because HHS has already replaced the 2016 PAMA Rule with the 2018 PAMA Rule—which provides an updated methodology to collect hospital outreach lab data—the DC Circuit Court denied ACLA's request to vacate the 2016 PAMA Rule.

"As has long been the case, we think comprehensive legislation to set Medicare reimbursement for clinical laboratories on a sustainable pathway forward is essential. We fully support and urge Congress to pass *The Saving Access to Laboratory Services Act*," according to a statement from ACLA.

"Getting legislation passed to fix the flawed PAMA lab reporting process remains far and away our top priority," says Susan Van Meter, who became ACLA President effective April 25.

Spotlight Interview: Pathnostics' CEO Dave Pauluzzi

Pathnostics, with a main lab in Irvine, California, and a satellite lab in Royal Oak, Michigan, specializes in advanced molecular testing for infectious disease (70% of volume), cancer diagnostics (20%) and Covid-19 PCR testing (10%). A second satellite lab in Orlando is set to open later this year. Pathnostics has a total of 300 employees, including three employed pathologists and six contracted pathologists. *Laboratory Economics* recently spoke with Chief Executive and Co-Founder Dave Pauluzzi.

Dave Pauluzzi

When and why did you start Pathnostics?
I co-founded Pathnostics, along with David Baunoch, PhD, in 2011. The goal was to create a research-driven laboratory that would bring new precision diagnostics to the clinical market.

For example, we currently have 25 employees devoted to R&D and clinical studies. Over the past 5 years we've invested more than $10 million on clinical research related to our proprietary Guidance UTI test. This research has so far resulted in four completed studies and articles published in six peer-reviewed journals.

Can you describe the development of your Guidance UTI test?
Soon after starting Pathnostics, we identified current testing methods for urinary tract infections (UTIs) as needing improvement. Standard urine culture testing takes multiple days to process and yields a substantial number of false-negative results (30-50%) because of colonization and lack of sensitivity.

Furthermore, while traditional PCR testing for UTIs may be more sensitive than urine culture, it doesn't provide phenotypic susceptibility and thus lacks clinically actionable results.

Our proprietary Guidance UTI represents the next generation in UTI testing. It includes PCR testing for 27 individual organisms, and 3 bacterial groups, combined with genotyping for 32 antibiotic resistance genes and our patented Pooled Antibiotic Susceptibility Testing (P-AST) for phenotypic sensitivity. P-AST is important since bacterial interactions can impact antibiotic susceptibility allowing more informed treatment decisions

There are a total of 38 million UTI patient cases each year in the United States. The target market for Guidance UTI is the subset of 13 million complicated or recurrent cases. These patients are difficult to treat and often cycle through different antibiotic treatments.

How are Guidance UTI test results used?
Guidance UTI helps doctors select the best treatment, out of 19 commonly prescribed antibiotics, for each individual patient. Getting the right prescription, the first time helps reduce UTI-related emergency room visits and hospitalizations.

There are more than 40 antibiotic drugs FDA approved for use in UTIs, including some older antibiotics for which resistance is now significant. We continually monitor guidelines and current practice for the most relevant antibiotics in use, and periodically update the antibiotics used in Guidance UTI. Priority is given to oral and intramuscular antibiotics which are readily available and easily administered in an outpatient setting.

What are your volumes for Guidance UTI?
Since launching Guidance UTI in 2016, Pathnostics has performed 200,000 patient tests on behalf of more than 1,000 Urologists.

What is the list price or range of pricing for Guidance UTI?
We keep our pricing information confidential for competitive reasons.

Has Pathnostics raised money from outside investors?
The company was initially funded entirely by myself and Dr. Baunoch. In early 2019, Water Street Healthcare Partners acquired a 70% stake. I had previously collaborated with Water Street when I was President and CEO of PLUS Diagnostics, which was sold to Miraca Life Sciences in 2013.

How did Pathnostics fare through the worst peaks of the Pandemic?
We had the PCR testing capacity in place, so we were able to ramp up Covid-19 testing early in the Pandemic. At our peak in late 2020, we were performing 100,000 Covid-19 tests per month, including overflow for some of the nation's largest commercial labs.

Pathnostics is currently performing 10,000 to 30,000 Covid-19 tests per month. Our Covid customer base overlaps with our Guidance UTI customer base as we have focused on skilled nursing and long-term care facilities, urgent cares and at-home healthcare organizations.

Have Pathnostics' non-Covid testing volumes bounced back to pre-pandemic levels?
Our volume in infectious disease and cancer diagnostics testing has grown past its pre-Pandemic levels.

Update on ClaraPath's New Automated Microtomy System

ClaraPath Inc. (Hawthorne, NY) has received UL certification for its SectionStar automated microtomy system from Underwriter Laboratories (Northbrook, IL), a third-party product safety testing company. UL certification indicates that SectionStar meets electrical safety and performance standards.

Eric Feinstein, CEO of ClaraPath, says that the company plans to submit an FDA application, gain clearance and begin marketing SectionStar by the end of the year.

The desktop SectionStar is capable of autonomously processing 72 tissue blocks into 150-250 glass slides every three hours (see *LE*, December 2021).

Over the past six months, ClaraPath has been building its manufacturing capabilities at its headquarters in Westchester, New York. The company now has 40 employees and occupies 30,000 square feet of office, assembly and manufacturing space. "Right now, we're stocking up on parts and have the potential to assemble up to 20 SectionStars per month," says Feinstein.

Feinstein anticipates that the fully-automated version of SectionStar will sell for $400,000 plus variable costs of $15,000 to $20,000 per year depending on volume. The target market is medium to large size histology labs. Feinstein expects demand to be strong given the severe histotech shortage.

Versant Diagnostics Buys Two More Pathology Groups In Chicago Area

Versant Diagnostics (Oak Brook, IL) has acquired Pathology Consultants of Chicago as well as the ongoing assets and operations of Elgin Laboratory Physicians (Elgin, IL). These two deals follow Versant's acquisitions of Alliance Pathology Consultants and Addison Central Pathology late last year (see *LE*, November 2021). In addition, Versant is currently under letter of intent, non-disclosure agreements, and/or in discussions with approximately 12 pathology groups across the U.S. ranging from 3 to 30 pathologists, according to Rob Albert, Chief Development Officer at Versant.

Proposed Medicare Rate Cuts For Most Pathology Services In 2023

Medicare professional component (PC) and technical component (TC) rates for most pathology services will be cut by a few percent next year, according to the newly released Proposed Medicare Physician Fee Schedule (MPFS) for 2023.

The reductions are the result of a 4.4% decrease in the proposed conversion factor for 2023. CMS says that the conversion factor is slated to be lower next year mostly due to the expiration of the 3% increase in Physician Fee Schedule reimbursements in 2022 as required by the Protecting Medicare and American Farmers From Sequester Cuts Act. Congress temporarily boosted physician reimbursement last year to mitigate the impact of Covid-19 Pandemic-related expenses.

The College of American Pathologists and other physician advocacy organizations are lobbying CMS and Congress to extend specific Pandemic-era relief measures, such as the boost in physician reimbursement. Comments on the proposed rule are due to CMS by September 7. The Final MPFS for 2023 is expected to be released in November.

Surgical Pathology-CPT 88305

The national Medicare rate (unadjusted for geographic location) for the PC of CPT 88305 is proposed to be cut by 4% to $36.05, while the TC will increase by 0.3% to $34.73. Overall, the proposed global rate for CPT 88305 will decline by 2% to $70.79.

Prostate Biopsies

The global rate for G0416 (Surgical pathology for prostate biopsy) is proposed to decrease by 1% to $355.91; professional interpretation down 5% to $169.36; technical component up 3% to $186.56.

Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) is proposed to decrease by 3% to $99.23; professional interpretation down 3% to $33.41; technical component down 3% to $65.82.

The global rate for CPT 88341 (IHC, additional slide) is proposed to decline by 5% to $85.01; professional interpretation down 4% to $26.79; technical component down 5% to $58.55.

Proposed Medicare Rate Changes for Key Pathology Codes for 2023

CPT/HCPCS	Short Description	Proposed 2023[1]	Actual 2022[2]	Proposed Rate % Change
88305-Global	Tissue exam by pathologist	$70.79	$71.98	-2%
88305-26	Tissue exam by pathologist	36.05	37.37	-4%
88305-TC	Tissue exam by pathologist	34.73	34.61	0%
88307-Global	Level V, tissue exam by pathologist	286.78	290.69	-1%
88307-26	Level V, tissue exam by pathologist	78.39	82.36	-5%
88307-TC	Level V, tissue exam by pathologist	208.39	208.33	0%
88341-Global	Immunohistochemistry (Add'l stain)	85.01	89.63	-5%
88341-26	Immunohistochemistry (Add'l stain)	26.79	28.03	-4%
88341-TC	Immunohistochemistry (Add'l stain)	58.55	61.60	-5%
88342-Global	Immunohistochemistry (1st stain)	99.23	102.43	-3%
88342-26	Immunohistochemistry (1st stain)	33.41	34.61	-3%
88342-TC	Immunohistochemistry (1st stain)	65.82	67.83	-3%
G0416-Global	Prostate biopsy, any method	355.91	358.52	-1%
G0416-26	Prostate biopsy, any method	169.36	177.53	-5%
G0416-TC	Prostate biopsy, any method	186.56	180.99	3%

Note: Rates presented in table are national rates (unadjusted for geographic location)

[1]Payments based on proposed 2023 conversion factor of 33.0775; [2]Payments based on the 2022 conversion factor of 34.6062
Source: *Laboratory Economics* from CMS

Lab Lobby Spending Hits Record High

Twelve of the lab industry's largest trade organizations and companies spent a record total of $11.7 million on lobbying efforts in 2021, according to data from the nonprofit OpenSecrets.org (Washington, DC), which tracks lobbying and political contributions. Over the past five years, lobby spending by the 12 lab organizations has risen by an average of 15% per year.

Individually, ACLA had the biggest lobbying budget last year at a record $3.2 million. Quest Diagnostics ($1.8 million) and LabCorp ($1.6 million) also spent large amounts. Lobbying efforts were mostly directed at the Centers for Disease Control & Prevention (CDC), the Dept. of Health & Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), the Food & Drug Administration (FDA) and the Executive Office of the President.

At the top of the lab industry's lobbying agenda last year were payment rates and coverage of Covid-19 testing, including federal policy and programs related to K-12 school testing for Covid-19. Revising PAMA regulations for setting Medicare CLFS rates was also high on the list. Other issues included potential FDA regulation of laboratory-developed tests under the VALID Act and surprise medical billing, according to lobbying disclosure reports.

Several genomic testing lab companies also spent heavily on lobbying last year.

Exact Sciences spent a record $1.3 million. It focused its lobbying efforts on legislation that would provide Medicare coverage of multi-cancer early detection screening tests (HR 1946, S. 1873) and provide coverage and payment for blood-based colorectal cancer screening tests (S. 2149).

Guardant Health also spent a record $800,000. It focused on the VALID Act and issues related to Medicare coverage and reimbursement for lab developed tests.

Myriad Genetics spent $770,000. It focused on the VALID Act as well as issues related to the regulation of pharmacogenomic tests.

Lab Industry Lobby Spending

Organization	*2021*	*2020*	*2019*	*2018*	*2017*
American Clinical Laboratory Assn.	$3,164,921	$1,766,906	$1,251,843	$1,168,193	$789,227
Quest Diagnostics	1,840,000	880,000	890,000	1,850,000	1,100,000
Labcorp	1,630,000	1,750,000	1,650,000	1,390,000	640,000
Exact Sciences	1,290,000	426,000	270,000	340,000	320,000
Guardant Health	800,000	667,500	260,000	240,000	240,000
Myriad Genetics	770,000	716,000	910,000	640,000	770,000
Foundation Medicine	590,000	610,000	320,000	320,000	270,000
Coalition for 21st Century Medicine	552,500	498,500	520,000	620,000	640,000
College of American Pathologists	477,040	784,063	1,190,890	1,300,049	1,287,467
Association for Molecular Pathology	248,000	230,000	250,000	240,000	240,000
Opko/BioReference Labs	200,000	210,000	175,000	165,000	180,000
American Society for Clinical Pathology	125,500	138,500	168,625	208,675	202,175
Total, 12 organizations	**$11,687,961**	**$8,677,469**	**$7,856,358**	**$8,481,917**	**$6,678,869**

Source: www.opensecrets.org

Spotlight Interview:
Jefferson Health Enterprise VP of Labs Christopher Tomlinson


Christopher Tomlinson

Jefferson Health (Philadelphia) is an integrated health system that has grown considerably through mergers with four additional health systems over the past seven years. Jefferson Health now employs over 40,000 people and serves primarily southeastern Pennsylvania and southern New Jersey. *Laboratory Economics* recently spoke with Christopher Tomlinson, Enterprise Vice President of the Clinical Lab/Pathology and Radiology/Imaging.

Tell us more about Jefferson Health.
The Jefferson Health System is one of the fastest growing health systems in the U.S. Revenue has increased from $2 billion to almost $10 billion in seven years. There have been a number of mergers during that time, including a recent merger with Einstein Healthcare Network (Philadelphia) in 2021. We now own 18 hospitals, including some specialty hospitals, as well as the health insurer Health Partners Plans which covers about 300,000 members in the greater Philadelphia area.

We have centralized some of the laboratories at the high end of the technology spectrum, such as molecular/genomics, cytogenetics, flow cytometry and histocompatibility, so that boutique technologies and instrumentation are not duplicated and each division—New Jersey, Center City, Northeast, Abington and Einstein – has its own "right-sized" clinical laboratory directed by a clinical service chief.

The academic medical center, Thomas Jefferson University Hospital, is where the esoteric laboratories have been consolidated in addition to a full menu of "routine laboratory sections" that have high-throughput automation.

How many people are employed by laboratory services?
We have 930 employees, including 46 pathologists.

What were your overall test volumes in 2021?
We do about 13 million tests a year.

How is your Covid testing trending?
We were the largest provider of Covid testing among health centers in this region. In addition to our employees, patients, and students, we performed testing at the Philadelphia International Airport.

Our Covid testing fluctuates as different variants appear. Right now, we're in a bit of climb. We are performing about 1,500 Covid-19 PCR tests a day. At the height of the pandemic, we performed about 2,300 a day.

Excluding Covid testing, we are still growing, especially in the laboratories performing specialized testing that support clinical areas that are showing increased market share. For example, a full menu of testing for precision diagnostics in oncology and full-service testing for our growing transplantation programs are performed in-house. We're still on a good trajectory.

Who is your reference laboratory?
Quest is our main one.

Who are your main competitors?
We compete against very capable health systems in each of our markets. We also compete with Quest Diagnostics and Labcorp for outpatient/outreach business. In the old days, Quest and Labcorp were

so much cheaper, but with our automation, we are becoming more competitive in terms of pricing. That's really something hospital labs have to address – how to operate in the outpatient market, getting their pricing in line as they prepare for risk-based contracts and population health strategies.

Our Health Partners Plans is more of a Medicare and Medicaid managed care payer, so pricing is important for us. We have a lot of fixed costs in the hospitals to support the emergency department and inpatient areas. We like to allocate those fixed costs over a larger volume of lab tests, including additional outpatient and reference business.

What sets Jefferson's laboratory services apart from your competitors?
We are actively pursuing standardization of testing and quality across our 18-hospital system. I think the testing at the high end of the spectrum is where a big health system like ours that has a big university hospital and a medical school really shines. We are able to really push the barriers on esoteric testing due to our expertise in the MD/PhD space.

Do you use digital pathology or artificial intelligence in the labs?
Yes. Radiology has been in the digital and AI space for a while, but we are just starting to use it in pathology.

Have you had difficulty finding qualified staff for your laboratory?
Absolutely, everybody is. We have one advantage, though. Our university has a medical technologist program, so we are trying to leverage that. We have tuition benefits. We try to create some stickiness with our schools. Many labs are getting more automated, so we can redeploy some of our people to higher-end tasks as more automation comes online. We can also consolidate some labs, which allows us to focus our resources. I can't stress enough how important our medical technologists are to the success of the labs.

CDC Selects Five Labs To Expand Monkeypox Testing

The Department of Health and Human Services (HHS), through the Centers for Disease Control and Prevention (CDC), has begun shipping orthopoxvirus test kits to five commercial labs in an effort to quickly increase monkeypox testing capacity. The labs include Aegis Sciences Corp. (Nashville, TN), Labcorp, Mayo Clinic Labs, Quest Diagnostics and Sonic Healthcare.

Labcorp was the first to announce it had begun monkeypox testing (July 6). All of the CDC-selected commercial labs are expected to begin testing by the end of July.

Previously, the CDC's monkeypox tests were only available through 78 public health labs across the U.S. The public health labs have a combined capacity to perform 10,000 tests per week. The five commercial labs are each expected to perform 10,000 tests per week. Thus, total capacity will soon reach 60,000 tests per week.

There was a total of 1,814 confirmed monkeypox/orthopoxvirus cases in the U.S. as of July 15, 2022. Cases have been detected in 41 states as well as in the District of Columbia and Puerto Rico. The greatest number of cases are in New York (489), California (266), Illinois (174), Florida (154) and District of Columbia (108). The country's first confirmed case was reported in Massachusetts on May 18.

The fatality rate for monkeypox is currently estimated to be between 3% to 6%, according to the World Health Organization.

OIG Looks Unfavorably on Specimen-Collection Payment Arrangements


Greg Root, Esq.

In case there was any question, the Health and Human Services Office of Inspector General (OIG) has made clear that clinical labs may not pay hospitals to collect, process and handle specimens sent to the labs for testing. Doing so would violate the anti-kickback statute, the OIG said in recent advisory opinion (AO 22-09).

This opinion, combined with a 2014 special fraud alert on payment arrangements between clinical labs and physician offices, is a clear indication that the OIG looks unfavorably on any arrangement in which labs pay an entity that could refer Medicare or Medicaid business for specimen collection, notes Greg Root, Chief Operating Officer and General Counsel at CodeMap, a compliance consulting company based in Chicago.

"Any lab that does not pay particularly close attention to advisory opinions directed toward labs would be foolish," says Root. "It's an indication of how the OIG feels about payment practices and how they might implicate the anti-kickback statute. It's clear that between this and the 2014 fraud alert that the OIG just does not like these kinds of arrangements."

Under the arrangement proposed, the requestor, which operates a network of clinical labs, would enter into contracts with hospitals throughout the country pursuant to which the requestor would pay the contract hospitals on a per-patient-encounter basis to collect, process and handle specimens that are then sent to the requestor's clinical laboratories for testing. The requestor would bill any applicable third-party payer, including federal health care programs, for the testing.

In its analysis, the OIG says the proposed arrangement would implicate the federal anti-kickback statute because it would involve remuneration from a laboratory to a party that is in a position to make referrals to the laboratory for services that may be paid for in whole or part by a federal health care program.

"Specifically, where an individual—who may be a federal health care program beneficiary—presents to a contract hospital without a laboratory specified on the order for laboratory services, the contract hospital could refer specimens from that individual to requestor for reimbursable testing," the OIG wrote. "Indeed, because of the per-patient-encounter fees paid by requestor for the services (which contract hospitals agree to receive in lieu of any reimbursement for the services from a third-party payer), contract hospitals have a financial incentive to direct any such specimens to requestor for the furnishing of laboratory services."

The only way a laboratory could pay another entity, such as a physician office or hospital, for specimen collection is if the compensated entity had no ability to refer patients covered by federally funded health care programs to the lab that is paying for the service, notes Root.

Root says it is likely the advisory opinion was requested by a clinical lab seeking a negative opinion. "There's an uneven playing field out there," he says. "Sometimes someone asks for an opinion to make sure their competitors can't do something they themselves are unwilling to do."

Optum Marketing New Laboratory Benefit Management Program

Optum (Eden Prairie, MN), which is owned by UnitedHealth Group, has launched a new laboratory benefit management program aimed at lowering genetic test spending. Optum says that its new LBM program can potentially save health plans between $12-36 per member per year. Optum says its LBM is largely automated and involves: 1) properly identifying genetic tests; 2) mapping billing codes to these tests; and 3) probing for appropriate billing behaviors.
More details in the next issue of Laboratory Economics.

Lab Stocks Down 41% Year To Date

Twenty-four lab stocks have dropped by an unweighted average of 41% year to date through July 14. In comparison, the S&P 500 Index has fallen by 19% so far this year. The top-performing lab stocks thus far in 2022 have been ProPhase Labs, up 92%; Psychemedics, down 13%; and Quest Diagnostics, down 23%. Labcorp is down 24% and Sonic Healthcare is off 28%.

Company (ticker)	Stock Price 7/14/22	Stock Price 12/31/21	2022 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
ProPhase Labs (PRPH)	$13.74	$7.17	92%	$211	$111	1.9
Psychemedics (PMD)	6.14	$7.02	-13%	37	26	1.4
Quest Diagnostics (DGX)	133.23	173.01	-23%	19,690	10,680	1.8
Labcorp (LH)	240.37	314.21	-24%	27,390	15,859	1.7
Myriad Genetics (MYGN)	20.72	27.60	-25%	1,430	682	2.1
Enzo Biochem (ENZ)	2.39	3.21	-26%	105	112	0.9
Sonic Healthcare (SHL.AX)*	33.46	46.63	-28%	18,640	9,080	2.1
Exagen (XGN)	7.34	11.63	-37%	65	48	1.3
Veracyte (VCYT)	25.58	41.20	-38%	1,680	251	6.7
Exact Sciences (EXAS)	46.02	77.83	-41%	9,680	1,852	5.2
Fulgent Genetics (FLGT)	58.31	100.59	-42%	725	953	0.8
Castle Biosciences (CSTL)	24.52	42.87	-43%	344	98	3.5
Opko Health (OPK)	2.70	4.81	-44%	2,010	1,560	1.3
CareDx (CDNA)	23.27	45.48	-49%	940	308	3.0
Aspira Women's Hlth (AWH)	0.89	1.77	-50%	77	7	10.7
Guardant Health (GH)	48.06	100.02	-52%	4,730	391	12.1
Natera (NTRA)	43.57	93.39	-53%	3,850	667	5.8
DermTech Inc. (DMTK)	6.36	15.80	-60%	15	13	1.1
Interpace Biosciences (IDXG)	2.70	$7.47	-64%	69	42	1.7
Biodesix (BDSX)	1.88	5.29	-64%	71	32	2.2
Sema4 Holdings (SMFR)	1.53	4.46	-66%	337	195	1.7
Biocept (BIOC)	0.99	3.62	-73%	1	63	0.0
NeoGenomics (NEO)	8.33	34.12	-76%	1,220	486	2.4
Invitae (NVTA)	2.82	15.27	-82%	1,500	464	3.2
Unweighted Averages			**-41%**	**$94,816**	**$43,981**	**3.1**

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from YFinance

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