Jondavid Klipp, Editor, jklipp@laboratoryeconomics.com Volume 19, No. 8 August 2024

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Why Does Big Pharma Support LDT Regulation?

Friends of Cancer Research (FOCR-Washington, DC) has been a steadfast advocate for FDA regulation of LDTs (both the VALID Act and the FDA's final rule). FOCR contends that FDA regulation will reduce variability in diagnostic tests used to identify cancer patients who are most likely to benefit from cancer therapy.

The nonprofit FOCR has a mission "to accelerate policy change, support groundbreaking science, and deliver new therapies to patients quickly and safely." A *Laboratory Economics'* analysis of FOCR's Form 990 tax statements shows that it gets most of its funding from major pharmaceutical companies.

So why does big pharma support LDT regulation?
Full details on page 2.

Intermountain Doubles Lab Size to Accommodate 10+% Volume Growth

Following a two-year construction process, Intermountain Health (Salt Lake City, UT) has opened an expanded central lab with 85,728 square feet (up from 40,542 sq. ft.). The central lab, which has 600 employees, processed 15 million tests and 200,000 tissue specimens last year and is on track to increase volume by more than 10% in 2024, according to Sterling Bennett, MD, Medical Director of Intermountain Central Laboratory (ICL-Murray, UT). The expanded space will allow ICL to add new specialty testing lines and handle increased outreach testing volume, which now accounts for 40-45% of overall volume.

Sterling Bennett, MD

Full details on page 6.

Clarapath Raises $36 Million; Begins Sales of Automated Microtomy System

Clarapath (Hawthorne, NY) has raised $36 million from a Series B-1 funding round led by Northwell Ventures, a for-profit investment arm of Northwell Health (Long Island, NY). The funds will be used for commercial launch of Clarapath's SectionStar, a benchtop robotic system that automates tissue block cutting and transfer to glass slides. See page 8 for our interview with Clarapath CEO Eric Feinstein.

Contents

WHY DOES BIG PHARMA SUPPORT LDT REGULATION? (*cont'd from page 1*)
Twelve pharmaceutical companies and their trade organization, the Pharmaceutical Research & Manufacturing Assn. (PhRMA), contributed a total of $2.9 million to FOCR in 2021, according to FOCR's latest publicly available Form 990 tax statement. This accounted for 58% of the total contributions and grants received by FOCR in 2021.

Over the three-year period (2019-2021), the biggest contributors to FOCR have included Bristol-Myers ($1.2 million), Merck ($986,500) and Astra Zeneca ($850,075). PhRMA also contributed $430,000.

The pharmaceutical companies supporting FOCR are developing expensive oncology drugs targeted at cancer patients with specific genetic mutations. For example, in November 2023, the FDA approved Bristol-Myers' Augtyro to treat adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer. The wholesale price for Augtyro is $29,000 per month/$348,000 per year. There is no FDA-cleared test to detect ROS1 rearrangements for selecting patients for treatment with Augtyro. LDT test panels for ROS1 include LungOI (PLA 0414U; Medicare rate: $706) performed by the Imagene Lab (Phoenix, AZ).

Laboratory Economics thinks that big pharma may be concerned that some LDTs have erroneously high cut-off values—the benchmarks that determine a positive or negative test result—that can limit patient access to cancer drugs.

FOCR President Jeff Allen, PhD, gave testimony on LDTs before the U.S. House of Representatives' Committee on Energy and Commerce, Subcommittee on Health on March 21, 2024. Allen said that FDA regulation of LDTs was necessary to "Establish uniform performance standards, regulatory processes, and transparency for all diagnostic tests to ensure accuracy of results." [See page 3.]

Major Contributors to Friends of Cancer Research

Company	2021	2020	2019
Bristol-Myers	$500,000	$400,000	$300,000
Merck & Co.	$385,000	$325,000	$276,500
Astra Zeneca	$300,000	$350,075	$200,000
Novartis	$255,000	$140,000	$190,000
Takeda Oncology	$200,000	$175,000	$125,000
Pfizer	$175,000	$175,000	$165,000
Daiichi Sankyo	$175,000	$0	$0
Pharmaceutical Research & Manufacturing Assn. (PhRMA)	$175,000	$137,000	$118,000
Johnson & Johnson	$150,100	$100,000	$112,500
Amgen	$150,000	$250,000	$280,000
Sanofi	$150,000	$170,500	$0
Kite Pharma	$150,000	$0	$0
Pharmacyclics	$125,000	$0	$0
Bayer Healthcare Pharmaceuticals	$0	$130,000	$289,375
Eli Lilly	$0	$0	$110,000
Genentech	$0	$400,000	$150,000
Roche's Foundation Medicine	$0	$0	$150,000
Contributions from drug companies	$2,890,100	$2,752,575	$2,466,375
Total contributions and grants	$5,017,309	$4,633,439	$5,067,259

Source: Friends of Cancer Research Form 990s for 2019-2021

Spotlight Interview with FOCR President Jeff Allen

Jeff Allen, PhD, who has a PhD in cellular and molecular biology from Georgetown University School of Medicine, has been President and CEO of Friends of Cancer Research since 2006. FOCR has been advocating for LDT regulation for over 10 years and was involved in the discussion of legislative proposals that were the precursors to the VALID Act. Below is a summary of our interview with Dr. Allen.

Jeff Allen, PhD

In addition to pharmaceutical companies who else contributes to FOCR?
Other supporters include data development and clinical trial management companies, not-for-profit foundations [e.g., The Berlin Family Foundation, Reagan-Udall Foundation, etc.] as well as individual philanthropic donors.

Did FOCR support the VALID Act?
Yes, and we were disappointed when it failed to get passed into law. At the same time, we support the FDA final rule to regulate LDTs. Something needed to be done to reduce the variability of test results among LDTs with the same intended use. There is certainly still the opportunity for Congress to revisit the VALID Act or to create a more tailored regulatory approach for LDTs. However, this is a topic that has been considered for many years and has never made it across the finish line.

Can you summarize FOCR's Tumor Mutational Burden (TMB) Harmonization Project?
TMB is the number of mutations in a tumor's genome. If the tumor shows a large number of mutations, it's more likely the patient will benefit from targeted treatment with immune checkpoint inhibitors (ICIs). Our TMB Harmonization Project focused on the variability in how TMB is defined, analyzed, and used in clinical practice, and the need for establishing industry standards. Several leading labs and test developers evaluated a common set of samples (in silico, cell lines, tissue) and compared their outputs to TMB values determined by whole exome sequencing. We found variations in test results that could affect treatment decisions unless there is sufficient understanding about how different tests relate to predetermined TMB thresholds. Study results can be found at: https://www.annalsofoncology.org/article/S0923-7534(21)04495-1/fulltext.

Who should decide the cutoff points for lab tests that determine if an oncology drug is prescribed?
The cutoff point for a biomarker would initially be established by the drug developer and how they incorporate the test for patient selection in their clinical trials. In some cases, this may be relatively straightforward, such a binary decision based on whether the marker is present or not.

But it's not always that clear. For example, with continuous biomarkers that have more of a range of detection, a specific cutoff point may be used in a clinical trial to demonstrate safety and efficacy of the drug, but in clinical practice a determination of the best treatment may occur with the clinician and patient based on a variety of factors, including biomarker levels alongside details of the patient's clinical situation.

Do LDTs disincentivize IVD manufacturers from submitting new tests to the FDA?
I don't think LDTs disincentivize IVDs from going through FDA processes, because IVDs are already required to submit applications to FDA. However, historic enforcement discretion by FDA has allowed, in some cases, for LDT developers to opt not to go through FDA processes, while others chose to submit to FDA. With limited incentives and the option to not go through FDA processes [until recently], it's understandable why many labs chose not.

In the future, do you think pharmaceutical companies will develop their own companion tests?
The companion diagnostics and drug development industries have quite different models and market dynamics. So, in most cases, I don't think that we will see a shift toward pharmaceutical companies adding large-scale diagnostic development to their portfolios.

Top 25 Labs for Next-Gen Sequencing

Roche Foundation Medicine (Cambridge, MA) had the highest amount of Medicare allowed payments for NGS testing in 2022. Foundation Medicine collected $85 million for 24,527 NGS tests.

Guardant Health (Redwood City, CA) collected $80 million from Medicare for 16,304 NGS tests in 2022.

Tempus Labs (Chicago, IL) collected $51 million for 17,883 NGS tests.

Two hospitals were among the top 25 NGS testing labs: **The University of Texas M.D. Anderson Cancer Center** (Dallas, TX) and **Moffitt Cancer Center on Magnolia** (Tampa, FL).

Top 25 Labs by Medicare Allowed Payments for NGS Testing

Laboratory	*Location*	*Total Medicare Allowed Services 2022*	*Total Medicare Allowed Payments 2022*	*Avg. Allowed Payment per Test*
Roche Foundation Medicine	Cambridge, MA	24,527	$84,604,746	$3,449
Guardant Health	Redwood City, CA	16,304	80,474,424	4,936
Tempus Labs	Chicago, IL	17,883	50,827,781	2,842
Invitae Corp.	San Francisco, CA	25,253	39,931,793	1,581
Veracyte	So. San Fran, CA	8,417	29,750,223	3,535
Myriad Genetics	Salt Lake City, UT	12,894	24,421,530	1,894
The University of Texas M.D. Anderson Cancer Center	Dallas, TX	4,488	7,107,731	1,584
Cliffside Labs	Monmouth, NJ	8,286	6,104,554	737
BioReference Health	Elmwood Park, NJ	5,895	4,376,581	742
Circulogene Theranostics	Homewood, AL	1,536	4,367,305	2,843
NeoGenomics (31 Columbia)	Aliso Viejo, CA	5,589	3,994,101	715
E-Lab of Florida Inc.	Hollywood, FL	4,363	3,895,233	893
Exact Sciences/Genomic Health	Redwood City, CA	1,114	3,849,438	3,456
NeoGenomics (9490 NeoGenomics Way)	Fort Myers, FL	1,808	3,653,733	2,021
Siparadigm	Pine Brook, NJ	1,511	3,520,481	2,330
Ambry Genetics	Aliso Viejo, CA	1,930	3,450,269	1,788
Brookside Clinical Laboratory	Aston, PA	4,639	3,205,874	691
NeoGenomics (12701 Commonwealth Dr)	Fort Myers, FL	1,495	3,099,186	2,073
Hematopathology Associates	St. Petersburg, FL	4,790	2,994,255	625
American Oncology Network	Fort Myers, FL	948	2,726,818	2,876
Spartan Laboratories	Boca Raton, FL	3,535	2,353,016	666
Cairo Diagnostics	Woodcliff Lake, NJ	620	1,773,705	2,861
Florida Family Laboratory	Miami, FL	2,651	1,684,783	636
Moffitt Cancer Center on Magnolia (USF)	Tampa, FL	1,181	1,585,635	1,343
Dynix Diagnostix	Fort Pierce, FL	2,407	1,583,115	658
Total for Top 25 NGS Labs		**164,064**	**$375,336,310**	**$2,288**

Source: *Laboratory Economics* NGS Database; Medicare Part B carrier and hospital OPPS data for 2022 (for 31 NGS test codes, including CPT 81162, 81163, 81201, 81212, 81272, etc.)

The Outlook for Medicare Rates in 2025

CMS recently issued proposed rules for 2025 for the Medicare Physician Fee Schedule (MPFS) and Hospital Outpatient Prospective Payment System (OPPS). In addition, the final rule for the Hospital Inpatient Prospective Payment System for 2025 was released on August 1. Here's a summary of what they each mean for labs and pathologists next year.

Proposed Medicare Physician Fee Schedule

The proposed 2025 Medicare Physician Fee Schedule (MPFS) would result in an average rate cut of 2.8% for both pathology professional rates and technical lab services. The reductions are entirely the result of a 2.8% decrease in the proposed conversion factor (CF) to 32.36 for 2025. The CF is the multiplier that Medicare applies to relative value units (RVUs) to calculate reimbursement for all physician services and procedures under Medicare's fee-for-service system.

Under the proposed rule, for example, the national Medicare rate (unadjusted for geography) for the professional component of CPT 88305 will be cut by 3% to $34.94, while the technical component would also be cut by 3% to $34.62. Overall, the proposed global rate for CPT 88305 will decline by 3% to $69.57 in 2025.

The College of American Pathologists and other physician groups are lobbying CMS and Congress to mitigate the proposed cuts to the CF. The likeliest scenario is that Congress passes last-minute legislation at the end of the year that freezes the CF or reduces the cut.

Medicare CLFS

Under the Protecting Access to Medicare Act (PAMA), approximately 800 tests on the Medicare CLFS are scheduled to receive rate cuts of up to 15% effective January 1, 2025. However, it's more likely that year-end legislation will include freezing Medicare CLFS rates for the fifth straight year.

The House Ways and Means and Energy and Commerce Committees each marked up healthcare legislation earlier this summer. Each committee included a provision for a one-year delay in PAMA cuts and data reporting. The committees have relayed that CBO has estimated the 10-year impact of the one-year delay as providing savings of $3.28 billion.

Projected savings of $3.28 billion will be too hard for Congress to pass up when it scrambles to fund other spending at the end of the year.

Proposed Hospital Outpatient Rates

On July 10, CMS proposed Medicare payment rates that would affect approximately 3,500 hospitals and approximately 6,100 ASCs. OPPS payment rates for hospitals will increase by a proposed 2.6% in 2025. CMS has also proposed a 2.6% hike in ASC rates for 2025. Nearly all hospital outpatient lab tests and pathology technical services have been covered by Medicare under a bundled payment system for outpatient visits since 2014.

Final Rule for Hospital Inpatient Rates

The final rule will increase Medicare hospital inpatient rates by a net 2.9% effective October 1, 2024. The American Hospital Assn. (AHA) is unhappy with this payment update, arguing that it is insufficient. "CMS' payment updates for hospitals will exacerbate the already unsustainable negative or break-even margins many hospitals are already operating under as they care for their patients," according to Molly Smith, AHA Group Vice President for Public Policy. Hospital inpatient lab tests and pathology technical services are covered by Medicare Part A under a bundled payment for inpatient stays.

INTERMOUNTAIN DOUBLES LAB SIZE (*cont'd from page 1*)

The Intermountain Central Laboratory (ICL) is a freestanding building on the south end of the Intermountain Medical Center campus in Murray, Utah (just south of Salt Lake City). ICL currently serves 24 hospitals. It is in the process of adding eight more referring hospitals as a result of Intermountain's acquisition of SCL Health (Broomfield, CO) in 2022. In addition, ICL provides outreach testing services to hundreds of physician offices and nursing homes in Arizona, Colorado, Idaho, Nevada, Montana, Utah and Wyoming. Below we summarize key points discussed with Intermountain's Dr. Bennett and Karen Brownell, Vice President of Laboratory Services.

Karen Brownell

Specimen Tube Transport

Among the features in the expanded central lab is a new specimen tube system (Sarstedt's Tempus600 Vita) that transports vials from the emergency department directly to analyzers for testing in the lab. The system eliminates the need for a lab technician to load received vials into lab instruments. "While saving a few minutes may not seem like a lot, when testing for a heart attack that time can save a life," notes Bennett.

Expanded Specialty Testing

ICL has added organ donation histocompatibility testing to its menu. The lab is also expanding its hormone, allergy and molecular test menus, according to Brownell.

FDA Regulation of LDTs

Brownell says that new FDA regulation of LDTs is causing ICL to raise the volume thresholds required before it will add a new LDT to its test menu. ICL as well as all of Intermountain's hospital-based labs perform at least some LDTs. Brownell says she's particularly concerned about FDA regulation of modified IVD tests, including modifications made for pediatric patients and specimen type. ICL is in the process of analyzing its LDTs and putting teams together to meet the FDA's initial reporting requirements.

Digital Pathology

Intermountain contracts with eight different pathology groups to oversee its labs and provide professional interpretations. Its biggest contracted pathology group—Utah Pathology Services—is in the early stages of transitioning to digital pathology interpretations. A smaller contracted pathology group—Colorado Pathology Consultants—moved to digital reads about five years ago with Quest's AmeriPath in Denver doing the slide scanning.

Lab Employee Shortages

Brownell says that ICL has internship programs with all the universities and colleges offering medical laboratory science degrees in the mountain states, including University of Utah, Brigham Young, Utah Tech and Idaho State. This is where ICL gets most of its new MT hires. Recruiting for histotechnology and cytotechnology positions is more difficult because of the dearth of new graduates, according to Brownell.

Intermountain Commitment to Laboratory Services

Bennett says that health systems that have sold their labs have been willing to trade short-term financial gain for long-term pain (decreased service levels and lengthened turnaround times). ICL's rapid Covid testing was vital to the health system during the pandemic and allowed it to keep other hospital services open. Bennett says that the laboratory also provides critical medical expertise (pathologist medical directors and associate directors) that impact patient care models.

An Overview of the Salt Lake City Lab Market

Total Population (July 2023)	1.268 million
Persons aged 65 and over	11%
Annual population growth rate, 2018-2023	0.8%
Total Medicare Part B allowed spending 2022 (independent labs)	$75 million
Total Medicare Part B allowed spending 2022 (hospital outreach labs)	$9 million
Estimated physician lab services market	$175 million
Top 3 large-group health insurers	IHC Inc. Group (44%), Cambia/BCBS (30%), UnitedHealth (13%)

Source: U.S. Census Bureau and CMS

Salt Lake City currently has about 1.3 million residents and is growing its population by an average of 0.8% per year. *Laboratory Economics* estimates the physician office lab services market in Salt Lake City is $175 million (or about $138 per person per year). Intermountain Health dominates the Salt Lake City lab market, followed by Labcorp and Quest Diagnostics.

Intermountain Central Laboratory is based on the campus of Intermountain Medical Center (Murray, UT). Intermountain Health also operates a major hospital-based outreach lab at Intermountain St. George Regional Hospital in southwestern Utah. Overall estimated annual revenue for physician office outreach services is $75 million per year.

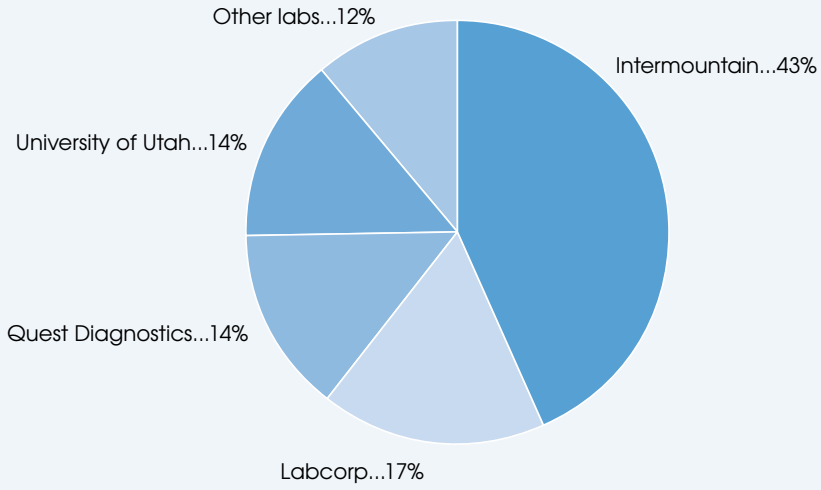
LabCorp operates a small laboratory and four PSCs in the Salt Lake City area plus another PSC in Saint George, Utah. Estimated annual physician office revenue is $30 million.

Quest Diagnostics has three PSCs in the Salt Lake City area. Quest also operates a small laboratory in West Valley City (a suburb of Salt Lake City). Estimated annual revenue is $25 million.

University of Utah Health Care, with 784 beds and a hospital lab budget of $71 million per year, operates the largest hospital in Utah. Estimated annual lab outreach revenue is $25 million. University of Utah also owns Associated Regional and University Pathologists, Inc. (ARUP Laboratories). ARUP is a national full-service reference lab with annual revenue of $850+ million.

Salt Lake City is also home to **Myriad Genetics,** which specializes in genetic predisposition testing, including its flagship BRAC-Analysis test for breast and ovarian cancer.

Share of the Physician Lab Services Market in Salt Lake City



Source: *Laboratory Economics*

CLARAPATH RAISES $36 MILLION (*cont'd from page 1*)

Clarapath was founded in 2014 as a spin-off to commercialize research conducted by Partha Mitra, PhD, at Cold Spring Harbor Laboratory (Long Island, NY). Dr. Mitra's prototype for an automated microtomy system was further developed and beta-tested at Northwell Health. Eric Feinstein, former Investment Director at Northwell Ventures, became President and CEO of Clarapath in 2018. Clarapath occupies 30,000-square-feet of office and manufacturing space in Hawthorne, NY (just above New York City). Below is a summary of our recent interview with Mr. Feinstein.

Eric Feinstein

How much space does SectionStar take up and what's its throughput?
SectionStar is about the same size as a mini-college-size fridge and can fit on a desktop.

SectionStar automates microtomy, water bath and transference to slides. Each SectionStar is capable of processing 72 tissue blocks into 150-250 glass slides every three hours. Cassettes of naïve unfaced tissue blocks are loaded into SectionStar and the output is glass slides ready for the next phase of staining.

It only takes about 30 minutes of training to learn how to operate and one technician can run up to four SectionStars at a time.

How is quality control maintained/improved?
In addition to increased productivity, SectionStar uses a dry tape transfer process to affix sliced tissue samples to slides. This process eliminates many of the chronic problems with water bath histology, namely tears, folds and the potential for floaters (a piece of tissue that does not belong to a patient case). In addition, SectionStar eliminates the variability in slide preparation that occurs from histotech to histotech, and laboratory to laboratory.

Where was beta-testing conducted?
At our own CLIA laboratory, Northwell Health and several pharmaceutical company labs.

Has SectionStar received FDA clearance?
SectionStar has been registered with the FDA as a Class I device and it's manufactured at our ISO 13485-certified facility in Hawthorne, NY.

How much does SectionStar cost?
Each SectionStar will sell for in the range of a few hundred thousand dollars plus variable consumable costs depending on volume. Labs should earn their return on investment within 12 months. It will free up the time that histotechs currently spend sectioning tissue so they have more time to do other things, including grossing, IHC staining, etc.

Can you describe your new agreement with Mayo Clinic?
Earlier this year Clarapath entered into a strategic collaboration with Mayo Clinic to explore additional ways to automate and consolidate the slide preparation process for optimization prior to whole-slide imaging/digital pathology. As part of the deal, Joaquin Garcia, MD, Chair of the Division of Anatomic Pathology at Mayo, has joined Clarapath's Board of Directors. Garcia also leads Mayo's digital pathology program.

How much has Clarapath raised from investors to date?
We've now raised a total of $75 million primarily from strategic investors. In addition to Northwell Ventures, other investors include CU Healthcare Innovation Fund (University of Colorado Anschutz Medical Campus), Mayo Clinic, Ochsner Ventures (Ochsner Health System) and East Post Road Ventures (White Plains Hospital).

Quest Diagnostics Mid-Year 2024 Review

Quest Diagnostics (Secaucus, NJ) reported net income of $423 million for the six months ended June 30, 2024, down 3.2% from $437 million in the same period for 2023. Overall, Quest's reported half-year revenue increased by 2% to $4.763 billion. Quest's first-half requisition volume was up 1.4% to an estimated 105.3 million reqs. Revenue per requisition increased by 0.9% to an estimated $43.98 per req. Here's a summary of some key topics discussed during the company's July 23 conference call with analysts:

Requisition Volume
Quest CEO Jim Davis said that Quest is now averaging more than 4 tests per requisition. Areas of volume growth include allergy panels, tick-borne diseases, cardiometabolic and neurology testing.

Digital Pathology
Quest completed its acquisition of the PathAI laboratory (Memphis, TN) for $100 million in cash on June 10. Quest plans to use the Memphis lab as a hub for histology and digitization. Quest currently operates more than 20 histology labs around the country and plans to consolidate them over time. Davis also said that Quest will offer a TC-only service to hospitals and health systems. Under this model, Quest will provide slide prep and scanning services and send digitized images to hospital-based pathologists for professional interpretations.

FDA Regulation of LDTs
Davis expects a court decision on ACLA's lawsuit challenging FDA regulation of LDTs in the November to January timeframe. In the meantime, Quest is preparing to comply with the first phase of requirements that become effective in May 2025.

Employee Drug Screening
Davis said that its employee drug screening business was experiencing weakness because some employers were dropping drug testing altogether, while others were switching to rapid onsite oral testing. Quest recently disclosed that it is shutting down its drug testing lab in Norristown, PA, and consolidating drug testing at its Lenexa, KS, facility.

Employee Turnover
Quest CEO Jim Davis said that high employee turnover in frontline jobs (phlebotomists, couriers, specimen processors, etc.) is improving, but still remains above the pre-pandemic average of 14%. Annual turnover in these jobs at Quest currently averages roughly 18% versus 20-25% last year.

PAMA & SALSA
Davis said that getting SALSA passed into law will be difficult in an election year. The most likely outcome for the Medicare CLFS for 2025 is another one-year freeze. He noted that the Congressional Budget Office (CBO) recently scored a one-year freeze in CLFS rates as providing more than $3 billion in savings to the Medicare program over 10 years.

Quest Diagnostics Mid-Year Financial Summary ($ millions)

Six months ended:	6/30/2024	6/30/2023	% Chg
Total revenue	$4,763	$4,669	2.0%
Laboratory testing revenue	4,631	4,527	2.3%
Other revenue	132	142	-7.0%
Operating cash flow	514	538	-4.5%
Capital expenditures	196	231	-15.2%
Free cash flow	318	307	3.6%
Net income	423	437	-3.2%
Diluted EPS	$3.75	$3.83	-2.1%
Est'd number of requisitions	105.3	103.8	1.4%
Est'd revenue per requisition	$43.98	$43.60	0.9%

*Other revenue includes life insurance testing and health information technology services (e.g., electronic health records, practice management and revenue cycle management)
Source: Quest Diagnostics and *Laboratory Economics*' estimates

Labcorp Mid-Year 2024 Review

Labcorp (Burlington, NC) reported net income of $433 million for the six months ended June 30, 2024, up 7.8% from $402 million in the same period for 2023. Overall, Labcorp's reported half-year revenue grew by 5.4% to $6.398 billion.

Looking specifically at Labcorp's lab testing business, revenue increased by 5.9% to $5.005 billion, including approximately 2.7% gained from acquisitions. On August 1, the company held a conference call with analysts and investors to discuss its mid-year results. Here's a summary of some key topics discussed:

Hospital Lab Management

Labcorp announced an agreement with Naples Comprehensive Healthcare (NCH) in Southwest Florida to manage the daily operations of NCH's inpatient lab operations. NCH operates two hospitals (NCH Baker Downtown and NCH North Hospital with a combined 713 beds). Labcorp will also serve as the primary lab for NCH's physician network. NCH Medical Group is the largest physician group in Collier County with 250 physicians, nurse practitioners and physician assistants at more than 40 locations.

FDA Regulation of LDTs

CEO Adam Schechter said that Labcorp supports ACLA's lawsuit challenging the FDA's final rule to regulate laboratory developed tests (LDTs). In the meantime, Labcorp has a team working on meeting the first-year LDT monitoring and reporting requirements of the final rule (effective May 2025).

Schechter said that most, if not all, of the LDTs offered by Labcorp are approved by the NYS Department of Health Clinical Laboratory Evaluation Program [and therefore do not need to go through the FDA premarket application process].

Schechter does not expect the final rule to have a significant impact on Labcorp's revenue or expenses. "I think the bigger impact is going to be to patients. These LDTs are typically for patients with rare diseases and for smaller patient populations. So, the question is will the FDA even have the ability to approve these quick enough so that all patients have access to these important tests."

Acquisitions

Labcorp disclosed that it paid $116.6 million in cash for the clinical lab outreach business of Baystate Medical Center (Springfield, MA). It paid $54.9 million in cash for the clinical lab outreach business of Providence Medical Foundation in California. In addition, Labcorp paid $97.7 million in cash to acquire Westpac Labs (Santa Fe Springs, CA) from Sonic Healthcare (see *LE*, May 2024).

Employee Turnover

CFO Glenn Eisenberg said that Labcorp's employee turnover is improving, but is still higher than pre-pandemic levels. He anticipates that Labcorp will experience roughly 3% labor cost inflation for 2024.

Labcorp Mid-Year Financial Summary ($ millions)

Six months ended:	6/30/2024	6/30/2023	% Chg
Total revenue	$6,397.5	$6,071.5	5.4%
LabCorp Diagnostics	5,004.6	4,723.6	5.9%
Biopharma Lab Services	1,417.9	1,360.3	4.2%
Operating cash flow	531.3	472.6	12.4%
Capital expenditures	262.0	181.5	44.4%
Free cash flow	269.3	291.1	-7.5%
Net income	433.3	401.8	7.8%
Diluted EPS	$5.13	$4.51	13.7%
Est'd number of requisitions	93.0	88.9	4.6%
Est'd revenue per requisition	$56.63	$55.85	1.4%

Source: Labcorp and *Laboratory Economics*' estimates

Tempus Lab Workers Join Union; Prepare for First Contract Negotiations

An overwhelming majority of 400 lab workers at Tempus AI (Chicago, IL) voted to join the IAM Union on March 7. The workers are employed at Tempus's CLIA-certified lab in Chicago. Tempus has a total of 2,300 employees nationwide.

Negotiations between Tempus workers and management are slated to begin at the end of summer. "We look forward to negotiating a first contract that includes rigorous safety protocols, pay and benefits that align with the rest of our industry, a voice on the job, and better the outcomes for patients that Tempus serves," according to the IAM Tempus Worker Organizing Committee.

The International Association of Machinists and Aerospace Workers (IAM) is among the largest industrial trade unions in North America and represents nearly 600,000 active and retired members in the manufacturing, aerospace, defense, airlines, transportation, shipbuilding, woodworking and healthcare industries.

Tempus became a publicly traded company through an IPO in June (see *LE*, June 2024). The company recently reported a net loss of $657 million for the six months ended June 30, 2024, versus a net loss of $133 million in the same period a year earlier; revenue was up by 26% to $312 million. Tempus has accumulated total losses of $2.1 billion since being formed in 2015.

DOJ to Offer Whistleblower Rewards for Private Insurance Fraud

The U.S. Department of Justice has started a pilot program to reward whistleblowers who expose healthcare fraud schemes involving private insurance plans. Effective August 1, whistleblowers can submit original information to DOJ's Criminal Division about certain types of corporate crime at www.justice.gov/CorporateWhistleblower. If DOJ's prosecution results in asset forfeiture, the whistleblower may be eligible for a portion of that forfeiture, including up to 30% of the first $100 million in net proceeds. Whistleblower rewards for those who report fraud against Medicare and Medicaid are already available under the False Claims Act.

Shield Blood Test Cleared by FDA for Colorectal Cancer Screening

Guardant Health (Palo Alto, CA) has received FDA clearance for its Shield blood test for colorectal cancer (CRC) screening in adults age 45 and older who are at average risk for the disease. It is the first blood test to be approved by the FDA as a primary screening option for CRC.

The Shield test has been on the market as an LDT since May 2022 at an out-of-pocket list price of $895. The test is performed at Guardant's CAP-accredited lab in Redwood City, California. A Medicare reimbursement rate has not yet been established.

Results from a 20,000-patient study, published in The New England Journal of Medicine (March 14, 2024), showed that Shield demonstrated 83% sensitivity for the detection of CRC, with 90% specificity for advanced neoplasia. The study found that Shield only detected 13% of earlier-stage precancerous polyps.

This is the second FDA-cleared blood test to screen for CRC. Epigenomics' Epi proColon was approved in 2016 (CPT 81327: $192). This test is intended for persons age 50 and older who are unwilling to be screened by colonoscopy or stool-based fecal immunochemical tests (FIT). But it's rarely used because of concerns about its accuracy and lack of insurance coverage.

Lab Stocks Up 38% So Far In 2024

Twenty-five lab stocks have risen by an unweighted average of 38% year to date through August 12. In comparison, the S&P 500 Index is up 12% year to date. Eleven lab stocks have gained, while 14 have declined. The top-performing lab stock thus far in 2024 is GeneDx, up an astonishing 1,117%. Quest Diagnostics is up 9% and Labcorp is down 2%.

Company (ticker)	Stock Price 8/12/24	Stock Price 12/29/23	2024 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
GeneDx (WGS)	$33.48	$2.75	1,117%	$912	$244	3.7
CareDx (CDNA)	26.90	12.00	124%	1,220	297	4.1
Natera (NTRA)	115.25	62.64	84%	13,800	1,361	10.1
Exagen (XGN)	3.36	1.99	69%	58	57	1.0
Myriad Genetics (MYGN)	27.95	19.14	46%	2,580	802	3.2
Castle Biosciences (CSTL)	26.75	21.58	24%	507	288	1.8
Interpace Biosciences (IDXG)	1.33	1.08	23%	59	42	1.4
Guardant Health (GH)	30.47	27.05	13%	4,160	644	6.5
Quest Diagnostics (DGX)	150.42	137.88	9%	21,680	9,346	2.3
Veracyte (VCYT)	29.96	27.51	9%	2,030	400	5.1
Tempus AI (TEM)	38.68	37.00	5%	5,950	596	10.0
Opko Health (OPK)	1.50	1.51	-1%	1,270	716	1.8
NeoGenomics (NEO)	15.93	16.18	-2%	2,260	628	3.6
Labcorp (LH)	223.34	227.29	-2%	24,560	12,488	2.0
Biodesix (BDSX)	1.61	1.84	-13%	251	61	4.1
Sonic Healthcare (SHL.AX)*	27.45	32.08	-14%	16,560	8,390	2.0
Fulgent Genetics (FLGT)	23.84	28.91	-18%	-106	291	NA
Exact Sciences (EXAS)	57.51	73.98	-22%	12,460	2,612	4.8
Psychemedics (PMD)	1.83	2.96	-38%	11	22	0.5
ProPhase Labs (PRPH)	2.65	4.52	-41%	70	29	2.5
23andMe (ME)	0.36	0.91	-60%	87	199	0.4
Aspira Women's Hlth (AWH)	1.13	4.08	-72%	18	9	2.0
DermTech Inc. (DMTKQ)	0.04	1.75	-98%	16	16	1.0
Biocept (BIOCQ)	0.00	0.04	-100%	5	1.4	3.5
Invitae (NVTAQ)	0.00	0.63	-100%	1,250	482	2.6
Totals & Averages			**38%**	**$111,669**	**$40,018**	**2.8**

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

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