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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

UPMC Ramping Up Transition to Digital Pathology & AI

University of Pittsburgh Medical Center (UPMC) has been a pioneer in digital pathology. UPMC's Liron Pantanowitz, MD, PhD, MHA, provides an update on UPMC's plans to move to 100% digital interpretations with AI assistance on *pages 5-6*.

Labcorp Wins BCBS of Alabama Contract

BlueCross BlueShield of Alabama (Birmingham) has designated Labcorp as its exclusive national laboratory and the only Preferred Medical Laboratory Plus (PMLP) provider in its network effective December 1, 2024. BCBS of AL's lab network will still include locally based hospitals and independent labs. However, national labs like Quest Diagnostics, Sonic Healthcare and PathGroup will no longer be in-network. BCBS of AL covers more than 3 million members, including 2.1 million Alabamians.
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ACLA Seeks Summary Judgment Against FDA

The American Clinical Laboratory Association (ACLA) has filed a motion for summary judgment asking the U.S. District Court for the Eastern District of Texas to strike down FDA's final rule to regulate LDTs. ACLA's lawsuit was filed on May 29. In its motion for summary judgment, filed on September 3, ACLA argued that the FDA doesn't have the power to regulate lab-developed tests. Summary judgment is a pretrial motion that can promptly resolve a lawsuit. However, a decision from Judge Sean D. Jordan is not likely at least until after FDA files its response.
More details on page 7.

Quest To Buy University Hospitals' Outreach Lab

Quest Diagnostics has agreed to acquire select assets of Cleveland-based University Hospitals' clinical laboratory outreach business for an undisclosed amount. Anatomic pathology is not part of the transaction. The transaction is expected to close by year's end. Assuming completion, the acquired test volumes will transition to Quest's full-service lab in Pittsburgh, with support from a rapid-response lab in Twinsburg, OH.
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QUEST TO BUY UNIVERSITY HOSPITALS' OUTREACH LAB (*cont'd from page 1*)
University Hospitals manages more than 20 hospitals (including five joint ventures). The system's flagship academic medical center, UH Cleveland Medical Center (725 staffed beds), is affiliated with Case Western Reserve University School of Medicine.

University Hospitals also has more than 5,000 physicians at 50 health centers and 200 physician offices in 16 counties throughout northern Ohio.

Quest CEO Jim Davis notes that the Cleveland lab market is dominated by two health systems, Cleveland Clinic and University Hospitals. The acquisition of University Hospitals' lab outreach business will give Quest new access to thousands of physicians employed by UH Medical Practices and UH Medical Group.

University Hospitals outpatient laboratory charges totaled $802 million in 2022, while its Medicare CLFS payments totaled $3.3 million. Total nonpatient clinical lab outreach testing revenue is estimated at roughly $50 million per year.

The agreement with University Hospitals follows Quest's recent deal to acquire the clinical lab outreach business of OhioHealth (Columbus)—see *LE*, July 2024.

Rising Costs at University Hospitals
University Hospitals posted operating losses of $256 million in 2023 and $302 million in 2022. Total revenue was $5.9 billion, an 8.4% increase over 2022. Total expenses were $6.1 billion, a 7.1% increase over 2022. Employee salaries and benefits increased by 7.1% to $3.4 billion, while patient care supply expenses were up 10.7% to $1.4 billion.

University Hospitals' cost reduction efforts have included closing its Bedford and Richmond hospitals in 2022. In addition, the health system recently announced that it cut more than 300 management and support service jobs effective August 1.

University Hospitals Outreach Laboratory Stats

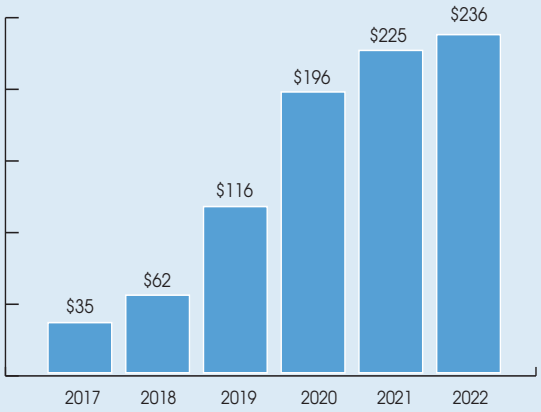
Hospital Name	Location	Total Staffed Beds	Total Outpatient Charges for Laboratory for 2022	Total Medicare CLFS Payments for 2022	Total Estimated Nonpatient Clinical Laboratory Outreach Testing Revenue
UH Cleveland Medical Center	Cleveland, OH	725	$309,545,721	$320,912	$12,716,115
University Hospitals TriPoint Medical Center	Concord, OH	329	175,053,614	1,262,223	12,486,823
UH Rainbow Babies & Children's Hospital	Cleveland, OH	231	NA	1,424	5,000,000
UH Portage Medical Center	Ravenna, OH	180	66,446,816	521,172	4,945,828
UH Saint John Medical Center	Westlake, OH	126	44,326,637	342,696	3,274,969
UH Parma Medical Center	Parma, OH	224	41,929,271	331,128	3,131,981
UH Elyria Medical Center	Elyria, OH	197	45,547,025	244,836	2,839,389
UH Ahuja Medical Center	Beachwood, OH	153	32,496,609	121,992	1,767,639
UH Geauga Medical Center	Chardon, OH	124	31,821,621	17,856	1,233,073
UH Geneva Medical Center	Geneva, OH	25	27,442,460	0	987,929
UH Samaritan Medical Center	Ashland, OH	39	9,110,274	92,595	781,685
UH Conneaut Medical Center	Conneaut, OH	25	11,823,709	0	425,654
University Hospitals Beachwood	Beachwood, OH	24	6,643,923	39,466	432,565
Grand Totals		**2,402**	**$802,187,680**	**$3,296,300**	**$50,023,649**

Source: LE Hospital Outreach Laboratory Database

LABCORP WINS BCBS OF ALABAMA CONTRACT (*cont'd from page 1*)

BCBS of AL has been trying to rein in lab expenses for several years. In particular, PCR-based test volume growth for the not-otherwise-specified/generic codes (e.g., CPT 87797, 87798 and 87799) has been a problem. For example, National Medicare Part B carrier spending for these three codes grew by an annual rate of 46% to $236 million in the five-year period 2017-2022.

National Medicare Spending on PCR NoS Testing ($ millions)*



*Includes test codes CPT 87797-87799
Source: *Laboratory Economics* from CMS

BCBS of AL sent out an RFP for an exclusive national lab contract about two years ago. Those vying for the contract included Labcorp, PathGroup, Quest Diagnostics and Sonic Healthcare. The formal announcement that Labcorp had submitted the winning proposal was made in late August. There were likely two big factors that led to Labcorp's win: 1) its major regional laboratory in Birmingham; and 2) competitive pricing.

"Considering that BCBS of AL is the largest commercial insurer in the state, excluded national labs like Quest, Sonic and PathGroup, will have less incentive to provide lab services in Alabama. Lab testing access in Alabama's rural and minority communities will likely be hurt," notes Chris Jahnle, Managing Director at Haverford Healthcare Advisors (Radnor, PA).

Meanwhile, some local labs are already benefitting from the network change. Steve Boyd, President of Southeast Clinical Labs (Birmingham), says that his lab added 29 new physician office clients in the week after BCBS of AL announced the change—mostly from Quest and Sonic clients that need to find a new lab.

Other independent labs based in Alabama that could benefit include Synergy Laboratories (Mobile), Core Diagnostic Laboratories (Birmingham), Proteus Molecular and Clinical Lab (Homewood) and Lab Works (Homewood).

The network change could also disrupt hospital-based pathology contracts held by Quest, Sonic and PathGroup in Alabama.

The BCBS of AL network change affects all of its health plans, including Blue Advantage, traditional PPO and Blue High Performance Network (BlueHPN). Out-of-network labs effective December 1, 2024, include:

- American Esoteric Labs (Sonic)
- AmeriPath (Quest)
- CBLPath (Sonic)
- Cleveland Heartlab (Quest)
- Cunningham Pathology (Sonic)
- Gulf Coast Pathology
- Interpace Diagnostics
- Kissimmee Pathology Lab
- Ocmulgee Medical Pathology Associates (Quest)
- PathGroup
- PhenoPath Laboratories (Quest)
- Quest Diagnostics
- ReproSource (Quest)
- Sonic Healthcare

Source: BCBS of Alabama

An Overview of the Birmingham Market

Total Population (July 2023)	1.184 million
Persons aged 65 and over	17.8%
Annual population growth rate, 2018-2023	1.7%
Total Medicare Part B allowed spending 2022 (independent labs)	$92 million
Total Medicare Part B allowed spending 2022 (hospital outreach labs)	$5 million
Total Medicare Part B allowed spending 2022 (physician office labs)	0.4 million
Estimated physician lab services market	$190 million
Top 3 large-group insurers	BCBS of AL (60%), UnitedHealth (25%), Viva Health Inc. (15%)

Source: U.S. Census Bureau and CMS

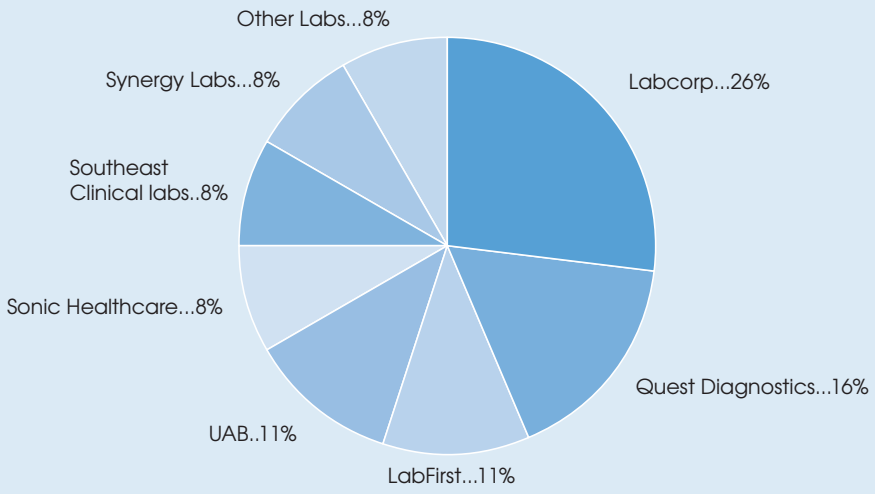
Birmingham currently has about 1.2 million residents and is growing its population 1.7% per year making it one of the fastest-growing cities in the United States. *Laboratory Economics* estimates the physician office lab services market in Birmingham is $190 million (or about $160 per person per year). Labcorp dominates the Birmingham Market, followed by Quest Diagnostics, LabFirst and UAB.

Labcorp operates a regional lab in Birmingham and eight patient service centers (PSCs), including two PSCs at Walgreens. Labcorp has estimated annual revenue of $50 million from physician office clients in Birmingham.

Quest Diagnostics has seven PSCs in Birmingham and serves this market from its regional lab in Tucker, Georgia (just north of Atlanta). Quest has estimated annual revenue of $30 million from physician office clients in Birmingham.

The largest hospital outreach labs in the Birmingham area include **LabFirst**, located on the Grandview Medical Center campus, and **UAB Hospital**.

Share of the Physician Lab Services Market in Birmingham



Source: *Laboratory Economics*

Sonic Healthcare serves the Birmingham market from its American Esoteric Laboratory in Memphis. Estimated annual revenue from Birmingham is $15 million.

Southeast Clinical Labs (Birmingham) and **Synergy Laboratories** (Mobile) are the largest independent full-service labs in Birmingham. Estimated annual revenue for each is $15 million.

UPMC Ramping Up Transition to Digital Pathology & AI

University of Pittsburgh Medical Center (UPMC) includes 40 hospitals and 800 clinical locations, including outpatient sites and doctors' offices. UPMC has been involved with digital pathology for almost 20 years, including through a 2008 joint venture with GE Healthcare named Omnyx (now defunct). UPMC is now in the midst of a long-term shift toward using digital pathology and AI for clinical interpretations for nearly all of its surgical pathology cases and Pap tests. Liron Pantanowitz, MD, PhD, MHA, Chair of the Department of Pathology at UPMC, is leading this project. Here's a summary of our interview:

Liron Pantanowitz, MD, PhD, MHA

Can you describe UPMC's Department of Pathology?
UPMC employs approximately 186 pathologists. UPMC operates a freestanding central laboratory building (CLB) with a full-service histology lab on its UPMC Presbyterian campus in Pittsburgh. In total, UPMC's central lab and hospital-based labs perform 24 million lab tests per year, including roughly 400,000 surgical pathology cases and 100,000 cytopathology tests, that generate 2.5 million glass slides.

How is UPMC currently using digital pathology?
Systemwide, UPMC has about 25 slide scanners in place for clinical diagnostics and non-clinical use, including 12 Leica/Aperio LV1 compact scanners, nine AT2 Dx scanners and four high-throughput GT 450 scanners.

Our five academic hospitals and central lab are currently using digital pathology prospectively on about 5% of their pathology cases. They are also retrospectively scanning 40% to 50% of their cases for archiving, quality control, tumor boards, education and research. In addition, our community hospitals are prospectively scanning about 1% of their pathology cases and 5-10% are being retrospectively scanned for archiving.

In all, UPMC has a digital archive of a few million pathology cases.

What are your goals for digital pathology utilization?
Over the next five years, we'll be adding more scanners with the goal of digitizing 100% of our surgical pathology and cytology cases. We're currently in the process of choosing more slide scanners and a new image management system. The transition will occur first at our academic medical centers and central lab and next at our community hospitals. Ultimately, we want all our pathologists connected to a single cloud-based system that is integrated into our LIS.

What is the cost of digital pathology?
It varies widely depending on volume, but roughly speaking it's between $12 and $15 per slide. The components of cost include 1) slide-scanning hardware (25%); 2) image management software (25%); 3) techs for loading scanners and digital pathology management (25%); and 4) image storage (25%).

Will digital pathology allow UPMC pathologists to work from home?
We currently have one perinatal pathologist doing digital interpretations from home. This pathologist, Robert Bendon, MD, recently retired and moved to Florida. His expertise in placental and perinatal pathology cases is hard to replace. His home office has accordingly been CLIA-certified, and his digital interpretations have been validated using CAP guidelines. Dr. Bendon is now signing cases out from home in Florida.

Other UPMC pathologists are eager to use digital pathology so they too can work from home a few days per week. We are working on setting them up to do so. But it's kind of a Pandora's Box. Who will stay behind at the hospital for on-site frozen sections and other acute care needs?

Will frozen sections ever be digitized?
UPMC has actually been doing remote frozen section reads for over two decades. We're currently using hybrid WSI-robotic scanners mostly for neuropathology intraoperative consultations. We even perform interinstitutional teleneuropathology for a hospital located 370 miles away in another state. Over the years, our neuropathologists have become much more facile with these digital reads as evidenced by declining deferral and concordance rates. It's much easier to move an image than it is to move a doctor or patient.

Are you applying AI algorithms to digitized slide images?
Yes. We have internally developed an AI algorithm to screen AFB-stained slides for mycobacteria.

In addition, three of our genitourinary pathologists based at UPMC Shadyside have been using the Ibex Galen Prostate algorithm on their prostate core needle biopsy cases for the past four years. It's being used as an initial screen to triage slide images and flag regions of interest for pathologist review.

We're also deploying digital cytology coupled with AI to screen our ThinPrep Pap test slides using the Hologic Genius Digital Diagnostics System at our UPMC Magee-Womens Hospital.

Finally, UPMC pathologists and data scientists in our Computational Pathology division are developing generative AI algorithms ("Pitt GPT") that can be applied to text and tabular data to automatically create pathology reports, and to generate synthetic images. This will initially be used by UPMC pathologists to help write hematopathology and then breast cancer reports, ideally in under one minute.

How much improvement in accuracy and time savings can AI-assistance provide?
If you use the right algorithm, deployed correctly in an integrated workflow (e.g. interfaced with the LIS), with the appropriate IT infrastructure (e.g. HPC for processing, workstation designed for digital pathology), then AI used in pathology practice can significantly improve both accuracy and time savings.

AI can prioritize urgent cases, handle time-consuming tasks (e.g. counting cells or mitoses) which speeds up workflow, reach certain diagnoses faster (e.g. detect perineural invasion), and can generate preliminary reports (like a "digital fellow").

AI algorithms can not only accurately detect cancer, but can help reduce human variability such as standardized reporting of various features (e.g. tumor grade).

What is your advice to other labs considering digital pathology?
Firstly, going digital is a continuous journey—not an endpoint. There are a continuous number of new applications being found for digitized slide images, including AI algorithms. The technology itself keeps improving, so it is imperative to keep up with these advances and even upgrade.

Second, is the importance of having the support of both health system leadership and pathologists in the move to digital pathology. In my experience, both a top down and bottom-up approach works best for successful digital pathology implementation.

I'd also stress the need for a single case management and viewing system for accessing images that is easily integrated into pathologist workflows. A key component here is saving all slide images in a common file format. I wish we had a standard to follow when we first started our digital pathology journey. However, looking forward we want to try use the DICOM image format.

Is digital pathology and AI inevitable?
Yes. That train has already left the station. I believe that there are several factors driving this inevitability. The cost is going down, standard practice guidelines have been published, and there is even regulatory support now. Once reimbursement follows for using these tools, I think it will be very hard to resist going digital.

ACLA SEEKS SUMMARY JUDGMENT AGAINST FDA (*cont'd from page 1*)
ACLA and its co-plaintiff HealthTrackRx (Denton, TX) contend that "the new rule is a classic example of the kind of agency overreach that judicial review under the Administrative Procedure Act (APA) is designed to prevent."

"FDA cannot meet its heavy burden to justify the new rule because Congress has never granted FDA authority to regulate professional laboratory services as manufactured medical devices—let alone done so with a clear statement," according to ACLA's motion for summary judgment.

FDA has not filed a response yet.

AMP Sues FDA Over LDT Regulation
Separately, the Association for Molecular Pathology (AMP) and pathologist Michael Laposata, MD, PhD, have also filed a lawsuit challenging FDA's authority to regulate LDTs as medical devices. The AMP has 3,000 members, including medical doctors, scientists and technologists. Laposata is a world-renowned pathologist who currently serves as Chairman of the Department of Pathology at the University of Texas Medical Branch (Galveston).

The lawsuit was filed on August 19 in the U.S. District Court for the Southern District of Texas (Galveston). The case was initially assigned to Judge Jeffrey V. Brown, who was appointed to serve by former President Trump in 2019. Judge Brown has transferred the case to the U.S. Magistrate Judge Andrew M. Edison.

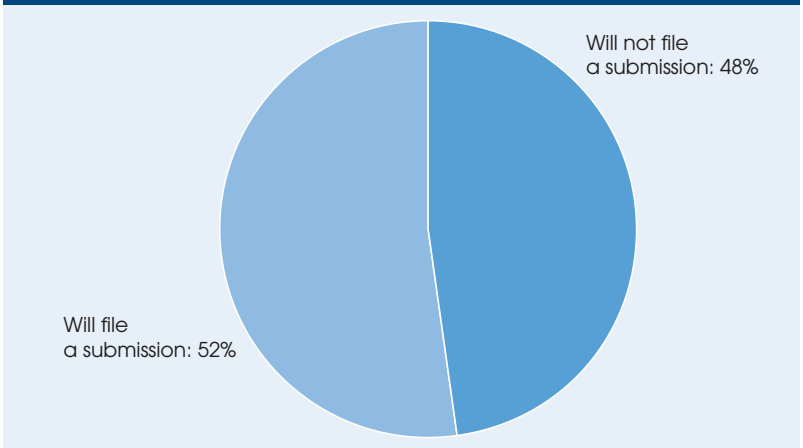
AMP and Laposata contend that the FDA's final rule to regulate LDTs represents "a historically unprecedented power grab that will jeopardize the health of hundreds of millions of Americans and, by Defendant FDA's own admission, impose tens of billions of dollars in new regulatory mandates on thousands of laboratories."

An initial pretrial and scheduling conference before Judge Edison has been set for December 4, 2024.

AMP and Lapostata are being represented by Mills Shirley LLP (Galveston) and Hyman Phelps & McNamara (Washington, DC). FDA has not filed a response yet.

FDA Regulation Will Force Labs to Discontinue Offering LDTs
A recent survey conducted by the Association for Diagnostics & Laboratory Medicine (ADLM—formerly AACC) shows that nearly half (48%) of all labs will discontinue performing LDTs that require a 510(k), de novo, or pre-market application. The survey results were sent in a September 5 letter to politicians, including Sen. Bernie Sanders, Chair, Senate Committee on Health, and Rep. Cathy McMorris Rodgers, Chair, Energy and Commerce Committee. ADLM is urging lawmakers to rescind the FDA rule and encouraging Congress to discuss separate remedies to streamline the FDA review process and review and update CMS standards pertaining to LDTs.

If your laboratory does not qualify for an exception under the FDA final rule, will you submit a 510(k), de novo, or pre-market application, or will you discontinue performing LDTs?



Source: ADLM Survey, August 2024 (n=121 respondents)

An Update on Quest Diagnostics' Hospital Lab Management Business

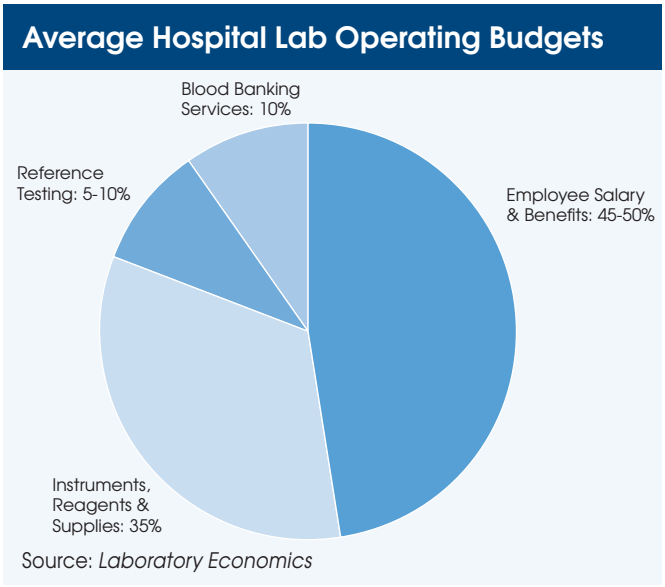
Over the past 12 years, Quest Diagnostics has signed professional lab services (PLS) contracts with 37 health systems and independent hospitals representing more than 100 hospitals.


Michael Lukas

These PLS contracts cover a range of services including lab management outsourcing, supply chain management, reference testing, etc. In 2023, Quest's PLS agreements generated approximately $780 million in revenues and management fees. Michael Lukas, Vice President and General Manager for Health Systems, has led Quest's PLS division since its launch in 2013. Below we provide more details on Quest's PLS business since our last interview with Mr. Lukas (see *LE*, December 2022).

Can you provide more details on how your supply chain management works?
If you look at the average hospital lab operating budget (excluding overhead allocations), then the biggest expense is employee salaries and benefits at roughly 45%. The next largest expense is supplies (instruments, maintenance, reagents, test tubes, etc.) at 35%.

In order to access our lower-cost contracts, we have to manage the hospital lab and own their equipment and reagent inventory. When we enter into a PLS contract, we buy out the hospital's existing instrument/reagent contracts and replace them with our lower-cost contracts when they expire. We are generally able to save hospitals an average of about 10-15% on a price-per-test basis from reduced staffing, capital equipment and reagents.



Almost all of our PLS contracts include supply chain management.

What is the average length of your PLS contracts?
It's typically 7 years. This matches the average contract cycle for most lab equipment.

How will the new FDA regulations for LDTs affect reference testing?
Hospitals that offer laboratory-developed tests will need to invest heavily to meet FDA regulations and keep those tests on their in-house menus. Some will choose to send their LDTs to a reference lab instead. There's an opportunity for reference labs like Quest. But we'll need to invest in our LDT infrastructure too. So, it's a double-edged sword.

What types of hospital lab tests are sent to the nearest Quest regional lab under a PLS?
That answer varies depending on what each health system wants to do, but generally tests that require turnaround time of 8 hours or less, including emergency department testing, stay onsite at the hospital lab. Tests that can be sent to a Quest lab include microbiology, toxicology, molecular diagnostics, histology, flow cytometry and cytogenetics. On average, we think that 40-45% of the typical hospital lab menu can be sent out to a Quest lab.

Do PLS agreements lead to significant hospital lab employee layoffs?
There is generally not a drastic upfront change. Overtime and the use of temporary employees is reduced. And Quest will usually offer jobs to affected hospital lab employees who live within 50 miles of a Quest regional lab. The hospital lab administrative director will typically become a

Quest employee. There is also some attrition from older hospital lab employees (age 55-65) who choose retirement.

How long do PLS agreements take to negotiate and what are the roadblocks?
These agreements involve all aspects of health system management, including the CEO, CFO, COO and human resources department, and usually take about 1 year to complete.

Pathologists are generally not the biggest fans of these arrangements because they fear a loss of autonomy/control. We're hoping our new digital pathology capabilities can help overcome those resistances [see below].

Setting up a new PLS also requires a lot of IT resources and that can be a bottleneck.

Can you describe the new digital pathology service being offered by Quest?
The digital component is very expensive. The broadband requirements for rendering, evaluating and storing whole-slide images are massive. Quest is definitely investing in this capability and our investment will be leverageable. We'll be able to provide technical services (slide prep and digitization) to hospitals and transmit images back to hospital-based pathologists for interpretations. Eventually, we'll also apply AI algorithms to digitized slide images as a "pre-read" tool. We think there's a big opportunity for histology lab outsourcing.

Over time, do you expect more hospital lab testing services to transition to Quest and other big commercial labs?
We currently see no shortage of opportunities and I think the trend is going to continue. The post-pandemic period has been characterized by higher employee and supply costs. Everything is more expensive, and reimbursement is flat.

Furthermore, it's become very competitive to hold and retain lab employees, especially phlebotomists, MTs and specimen processors. Labs are spending a lot of time and expense on retaining and luring new employees.

There's also a lot of emerging technology—like digital pathology and automated microbiology—that's very expensive to set up.

Quest Diagnostics: Selected Professional Lab Services Agreements

Date	Health System	Short Description
Mar-23	Tower Health (Pennsylvania)	Supply chain management for 3 hospital labs
Mar-23	Northern Lights (Maine)	Lab outreach acquisition and management of 9 hospital labs
Sep-22	Lee Health (Southwest Florida)	Supply chain management and reference testing for 5 hospitals
Dec-20	Hackensack Meridian Health (New Jersey)	Manage 11 hospital labs and reference testing
Nov-20	Montefiore Nyack Hospital (Rockland County, NY)	Manage hospital labs, supply chain and reference testing
Nov-20	Goshen Hospital (Indiana)	Supply chain management and reference testing
Jan-20	Memorial Hermann Health System (Houston, TX)	Lab outreach acquisition and management of 21 hospital labs
Jan-20	West Tennessee Healthcare (Tennessee)	Supply chain management for 8 hospital labs
Jul-19	Catholic Health Services (Long Island, NY)	Supply chain and reference testing for 6 hospitals and core lab
Mar-19	Regional Medical Center (South Carolina)	Manage hospital lab, supply chain and reference testing
Feb-19	Houston Healthcare (Georgia)	Manage 2 hospital labs, supply chain and reference testing
Sep-18	Regional Medical Center Health System (Alabama)	Supply chain management and reference testing
Feb-17	PeaceHealth (Vancouver, WA)	Lab outreach acquisition and management of 11 hospital labs
Jan-17	Montefiore Health System (NYC)	Outsource certain routine test volumes to Quest's New Jersey lab
May-16	HCA HealthONE (Denver, CO)	Manage inpatient labs at 6 Denver-area hospitals
Dec-15	Barnabas Health (New Jersey)	Manage inpatient labs at 7 hospitals in northern New Jersey
Mar-14	Carilion Health (Roanoke, VA)	Lab acquisition (Solstas Lab) and management of 7 hospital labs

Source: *Laboratory Economics*

Quest Finalizes Purchase of LifeLabs

Quest Diagnostics completed its acquisition of LifeLabs (Toronto, Canada) in late August. Quest paid CAN $1.35 billion (approximately USD $1 billion), including net debt (see *LE*, July 2024).

LifeLabs has 6,500 employees and operates 16 labs and 382 PSCs in the provinces of Ontario (population of ~15 million) and British Columbia (population of ~5 million). Lifelabs represents the first labs owned by Quest in Canada, according to Quest CEO Jim Davis. He notes that Quest has provided reference testing services to LifeLabs and other Canadian labs and hospitals for years.

Jim Davis

Charles Brown

Quest will keep LifeLabs' operations and management intact, including its President and CEO Charles Brown. Davis says that there are several opportunities to accelerate growth at LifeLabs. He notes that Canada's population is older (average age of 41) and growing faster (1% per year) than in the United States (average age 38 with growth of 0.5% per year).

Overall healthcare spending in Canada is about one half the level in the United States on a per capita basis. Lab services in Ontario are paid by the provincial government on a capitated-style basis with adjustments based on each lab's market share and test volume, according to Davis. British Columbia pays labs on cost-plus model.

Most Canadian physicians issue a paper requisition to patients who then choose which lab to use. The competition in Canada includes Labcorp's Dynacare as well as hospital-based labs.

Davis says that wage rates for lab employees (phlebotomists, MTs, specimen processors, etc.) are slightly higher in Canada versus the United States.

Over time, LifeLabs will take advantage of Quest's lower-cost contracts for supplies and reagents.

Opportunities for growth at LifeLabs include, for example, adding new testing programs for advanced lipid testing, Alzheimer's disease and cancer (e.g. MRD testing). In addition, Davis says that there are opportunities to expand Quest's direct-to-consumer platform (QuestHealth.com) in Canada. He notes that LifeLabs has the capacity to add volume.

Davis expects LifeLabs to generate about USD $710 million in annual revenue and add to earnings (excluding amortization of intangible assets) in the first 12 months as part of Quest.

Labcorp To Acquire Ballad Health Outreach Lab

Labcorp has agreed to acquire the clinical lab outreach business of Ballad Health (Johnson City, TN). Ballad (formerly Wellmont Health Systems/Mountain States Health Alliance) will continue to operate its inpatient and emergency department lab, as well as its anatomic pathology services to hospital-based practices. Ballad has 20 hospitals and a large multi-specialty physician practice that covers Northeast Tennessee, Southwest Virginia, Northwest North Carolina and Southeast Kentucky. The deal is expected to be finalized by year's end.

Versant Buys Cutaneous Pathology

Versant Diagnostics (Grapevine, TX) has acquired Cutaneous Pathology (Winston-Salem, PA), a dermatopathology practice with two dermatopathologists (Omar Sangueza, MD and Michael Hitchcock, MD). Versant has now acquired eight pathology practices with a combined 58 pathologists.

Publicly Traded Lab Revenue Up 5% In First-Half 2024

On a combined basis, 21 publicly traded labs reported revenue growth of 5% to reach $15 billion during the first six months of 2024 (after adjusting for acquisitions), according to financial reports collected by Laboratory Economics.

Among four national clinical labs (Quest Diagnostics, Labcorp, Sonic Healthcare USA and Bio-Reference), combined revenue grew by 2.6% (after adjusting for acquisitions).

Meanwhile, among 17 specialty and genetic testing labs, combined pro-forma revenue increased by 21%.

Revenue growth was fastest at **Castle Biosciences** (Friendswood, TX), up 74% to $160 million. Castle's lead product is its DecisionDx-Melanoma test for cutaneous melanoma (CPT 81529 at a Medicare rate of $7,193). Reported test results for DecisionDx-Melanoma increased by 11% to 17,969 tests in the six months ended June 30, 2024. Castle's fastest-growing test was its TissueCypher Barrett's Esophagus test (CPT 0108U at a Medicare rate of $4,950). Reported test result volume for TissueCypher was up 190% to 8,211 tests.

Revenue Growth at 21 Publicly Traded Lab Companies ($000)

Company	*First-Half 2024*	*First-Half 2023*	*Reported Change*	*Pro Forma Change**
Labcorp (lab testing only)	5,004,600	4,723,600	5.9%	3.3%
Quest Diagnostics (lab testing only)	$4,631,000	$4,527,000	2.3%	1.5%
Sonic Healthcare USA**	737,000	693,450	6.3%	6.3%
Opko/BioReference Labs	256,286	259,420	-1.2%	-1.2%
Total, 4 National/Clinical Labs	**10,628,886**	**10,203,470**	**4.2%**	**2.6%**
Exact Sciences	1,336,788	1,224,543	9.2%	9.2%
Natera	781,092	503,160	55.2%	55.2%
Myriad Genetics	413,700	364,700	13.4%	13.4%
Guardant Health	345,726	265,864	30.0%	30.0%
NeoGenomics	320,742	284,137	12.9%	12.9%
Tempus AI	311,789	248,041	25.7%	25.7%
Veracyte	211,272	172,744	22.3%	22.3%
CareDx	164,323	147,563	11.4%	11.4%
Castle Biosciences	159,976	92,175	73.6%	73.6%
Fulgent Genetics	135,513	134,021	1.1%	1.1%
GeneDx	132,936	91,845	44.7%	44.7%
Biodesix	32,743	20,928	56.5%	56.5%
Exagen	29,479	25,367	16.2%	16.2%
Interpace Biosciences	22,314	20,853	7.0%	7.0%
Psychemedics	10,085	11,396	-11.5%	-11.5%
ProPhase Labs	6,108	32,520	-81.2%	-81.2%
Aspira Women's Health	4,576	4,807	-4.8%	-4.8%
Total, 17 Specialty/Genetic Labs	**4,419,162**	**3,644,664**	**21.3%**	**21.3%**
Grand Total, All 21 Lab Companies	**$15,048,048**	**$13,848,134**	**8.7%**	**5.3%**

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions. **Sonic Healthcare USA revenue is for the six months ended June 30, 2024, at constant exchange rate of 1 Australian Dollar equal to 0.67 U.S. Dollar
Source: *Laboratory Economics* from company reports

Lab Stocks Up 48% So Far In 2024

Twenty-five lab stocks have risen by an unweighted average of 48% year to date through September 13. In comparison, the S&P 500 Index is up 18% year to date. Twelve lab stocks have gained, while 13 have declined. The top-performing lab stock thus far in 2024 is GeneDx, up 1,277%. Quest Diagnostics is up 12% and Labcorp is down 3%.

Company (ticker)	Stock Price 9/13/24	Stock Price 12/29/23	2024 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
GeneDx (WGS)	$37.87	$2.75	1,277%	$1,030	$244	4.2
CareDx (CDNA)	28.87	12.00	141%	1,330	297	4.5
Natera (NTRA)	126.51	62.64	102%	15,200	1,361	11.2
Exagen (XGN)	2.96	1.99	49%	51	57	0.9
Castle Biosciences (CSTL)	31.18	21.58	44%	630	288	2.2
Myriad Genetics (MYGN)	27.59	19.14	44%	2,550	802	3.2
Interpace Biosciences (IDXG)	1.48	1.08	37%	59	42	1.4
Tempus AI (TEM)	49.38	37.00	33%	7,610	596	12.8
Veracyte (VCYT)	32.92	27.51	20%	2,310	400	5.8
Quest Diagnostics (DGX)	154.38	137.88	12%	22,120	9,346	2.4
Opko Health (OPK)	1.57	1.51	4%	1,320	716	1.8
NeoGenomics (NEO)	16.40	16.18	1%	2,320	$628	3.7
Guardant Health (GH)	26.79	27.05	-1%	3,650	644	5.7
Labcorp (LH)	221.13	227.29	-3%	24,370	12,488	2.0
Biodesix (BDSX)	1.77	1.84	-4%	277	61	4.5
Exact Sciences (EXAS)	65.54	73.98	-11%	13,950	2,612	5.3
Sonic Healthcare (SHL.AX)*	27.02	32.08	-16%	16,850	8,963	1.9
Psychemedics (PMD)	2.33	2.96	-21%	14	21	0.7
Fulgent Genetics (FLGT)	22.35	28.91	-23%	-151	291	NA
ProPhase Labs (PRPH)	2.45	4.52	-46%	72	18	4.0
23andMe (ME)	0.34	0.91	-63%	76	199	0.4
Aspira Women's Hlth (AWH)	0.85	4.08	-79%	15	9	1.7
DermTech Inc. (DMTKQ)	0.03	1.75	-98%	16	16	1.0
Biocept (BIOCQ)	0.00	0.04	-100%	5	1	3.5
Invitae (NVTAQ)	0.00	0.63	-100%	1,250	482	2.6
Totals & Averages			**48%**	**$116,924**	**$40,579**	**2.9**

*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

New from Laboratory Economics

U.S. Laboratory Reference Testing:
Market Profile & Trends • 2024-2027

Featuring:

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Most hospital and independent lab directors and managers are acutely aware of the volume and cost trends for referred tests at their own facilities, but have scant access to reliable and comprehensive information on what's happening in the broader marketplace.

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- Which tests your peers aim to bring in-house over the next 12 months
- How national reference labs are rated by service, turnaround time, price and overall best value
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But that equilibrium is now being upset by new FDA regulations for laboratory-developed tests (LDTs). Complying with these regulations will raise the cost of performing existing LDTs. In addition, the introduction of new LDTs by hospitals and independent labs is being curtailed due to the lengthy and costly requirements of premarket review. As a result, send-out test volumes are increasing.

The U.S. Laboratory Reference Testing: Market Profile & Trends 2024-2027 has been written to help laboratories make more informed decisions regarding the tests they refer out, the prices they pay and how changes in referral and contracting processes might cut costs.

Our Research Methodology

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

About the Author

Jondavid Klipp is president and publisher of ***Laboratory Economics LLC***, an independent market research firm focused on the business of laboratory medicine. Prior to founding ***Laboratory Economics*** in April 2006, Mr. Klipp was managing editor at Washington G-2 Reports. During his seven-year employment with G-2, he was editor of Laboratory Industry Report and Diagnostic Testing & Technology Report. Prior to joining G-2, Mr. Klipp was an HMO analyst at Corporate Research Group in New Rochelle, New York, and a senior writer in the equity research department at Dean Witter in New York City.

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