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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

UnitedHealthcare Cutting Back on Prior Authorizations

UnitedHealthcare has announced that it will drop prior authorization requirements for 154 CPT codes for genetic tests and 65 proprietary lab analysis (PLA) codes. These codes account for tens of thousands of prior authorization requests a year from commercial and Medicaid members, according to UHC. Removal of prior authorization requirements for these codes will become effective September 1 for commercial and Medicare Advantage plans and November 1 for Medicaid plans. For more on UHC, including an update on its Z-code initiative, *see page 8*.

HNL Lab Medicine to Go 100% Digital

HNL Lab Medicine (Allentown, PA) plans to be scanning 100% of its surgical pathology slides into digital images within the next two years, according to Medical Director Jordan Olson, MD. "We've learned from the early-adopter pioneers…Digital pathology has matured to the point that it's ready to be used in day-to-day operations," says Olson. *Continued on pages 4-5.*

Exact Sciences to Settle "Gift Card" Lawsuit for $13.8M

Exact Sciences (Madison, WI) and Nils Rosen, MD, have reached a settlement in principle to settle a whistleblower lawsuit. Under the agreement in principle, Exact would pay $13.8 million to Rosen plus legal fees to settle his claims that Exact's $75 gift card program violated the Federal Anti-Kickback Statute and False Claims Act. *Continued on page 11.*

Labcorp to Buy Tufts Outreach Lab Assets

Tufts Medicine (Boston, MA) is selling its clinical lab outreach business to Labcorp for an undisclosed amount. The transaction, which does not involve anatomic pathology services, is expected to formally close in October. Tufts says the sale is the first step towards a broader partnership with Labcorp. The announcement comes as Tufts endures prolonged financial difficulties that led Fitch Ratings to downgrade its debt rating from BBB+ to BBB earlier this year. *Continued on page 2.*

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LABCORP TO BUY TUFTS OUTREACH LAB ASSETS (*cont'd from p. 1*)

Tufts Medicine (TM) includes three hospitals in the Boston area, including Tufts Medical Center (405 beds), Lowell General Hospital (390 beds) and Lawrence Memorial Hospital of Medford (216 beds). It also includes Tufts Medicine Integrated Network, which has more than 1,800 affiliated community and academic physicians.

The annual lab department budget at TM's three hospitals is a combined $122 million, according to Medicare Hospital Cost Reports. *Laboratory Economics* estimates that TM's clinical lab outreach business has annual revenue of roughly $30 million. Labcorp is expected to make job offers to nearly all 574 TM lab employees affected by the sale.

TM lost $399 million on operations in the fiscal year ended Sept. 30, 2022. TM management estimates that approximately $129 million of the losses were related to one-time items, including the stoppage of elective surgeries due to the pandemic (a $58 million loss of revenue) and installation of the electronic medical records system Epic ($71 million). The largest component of the rest of the operating loss was $217 million for increased staffing costs. The amount TM paid for contract labor increased an incredible 1,423%, to $155 million in the 12 months that ended Sept. 30, 2022, compared to pre-pandemic in 2019.

In addition, TM is facing stiff competition for hospital patients from Massachusetts General Hospital (Boston), which is aggressively competing for managed care contracts.

Sizing Up the Boston Lab Market

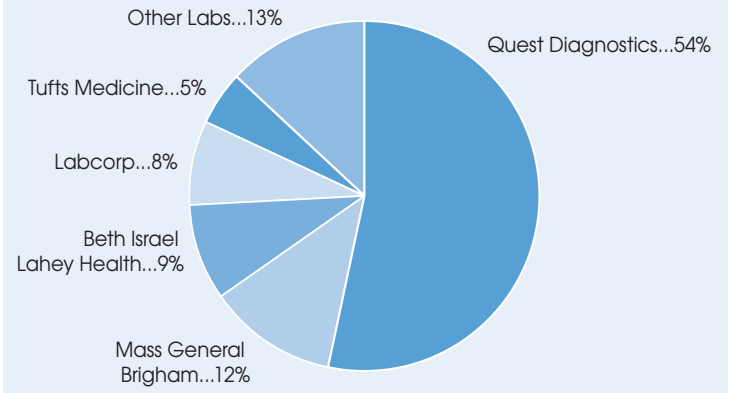
The Boston-Cambridge-Newton metropolitan area has a population of 4.9 million with an estimated physician lab services market of $650 million per year.

Quest Diagnostics has by far the largest market share in the Boston area. Quest purchased the Worcester-based clinical lab outreach business of UMass Memorial Medical Center in 2013. Quest then consolidated testing at a new 200,000-square-foot lab in Marlborough (30 miles west of Boston). Quest has a total of more than 100 patient service centers in the Boston area. It generates an estimated $350 million in revenue from physician office clients in the Boston area.

Labcorp has 15 PSCs in the Boston area and estimated physician client revenue of $50 million… per year (excluding Tufts Medicine deal). Labcorp's nearest major regional lab is located in Raritan, New Jersey (~5-hour drive).

Mass General Brigham provides lab outreach testing at several hospitals in the Boston area, including Massachusetts General Hospital (1,019 beds), Brigham and Women's Hospital (812 beds) and Newton-Wellesley Hospital (273 beds). Total estimated annual lab outreach revenue from the physician office market is $75 million.

Share of the Physician Lab Services Market in Boston



Source: *Laboratory Economics'* estimates based on Medicare Part B fee-for-service payments (2021) and CLIA data (March 31, 2023)

Beth Israel Lahey Health operates its biggest hospital-based outreach labs at Lahey Hospital and Medical Center Burlington (345 beds), Beth Israel Deaconess Medical Center (743 beds) and Winchester Hospital (194 beds). Total estimated annual lab outreach revenue from the physician office market is $60 million.

Labcorp Completes Purchase of Enzo Clinical Labs

Enzo Biochem (Farmingdale, NY) has completed its previously announced transaction to sell substantially all of the assets used in the operation of Enzo Clinical Labs to Labcorp for $113.25 million in cash. In accordance with the sale, Enzo Biochem has ceased its clinical lab operations. Jefferies (New York City) served as exclusive financial advisor and McDermott Will & Emery (Chicago) served as legal advisor to Enzo. Evercore (New York City) and Hogan Lovells (Washington, DC) served as advisors to Labcorp.

South Korean Firm to Buy QDx Pathology in New Jersey

South Korea-based LabGenomics has agreed to acquire QDx Pathology Services (Edison, NJ) for approximately $60 million. The deal is expected to be completed at the end of August.

QDx currently employs eight pathologists and has annual revenue of approximately $55 million. QDx specializes in traditional anatomic pathology services as well as PCR-based testing for Covid-19 and other respiratory viruses, gastrointestinal pathogens, sexually transmitted infections, and urinary tract infections.

QDx was founded by its Medical Director, M. Nasar Qureshi, MD, PhD, in 2006. The private equity firm Hadley Capital (Wilmette, IL) bought a majority stake in QDx in January 2017.

Following the acquisition, Hadley helped QDx to add financial staff, improve its IT systems, invest heavily in sales and marketing personnel, and expand geographically and with new insurance contracts. More recently, QDx moved from three locations into a single, much larger CAP-certified laboratory in central New Jersey.

In addition, QDx hired Tim Rich as Chief Executive in early 2022. Rich was formerly Chief Operations Officer at CellNetix Pathology and Laboratories (Seattle) and also Chief Executive Officer at PhenoPath Laboratories (acquired by Quest Diagnostics in 2018).

LabGenomics, based in Seongnam, South Korea, develops molecular diagnostics tests, including DNA chips, PCR kits and point-of-care-testing components. QDx marks its entry into the U.S. lab market. LabGenomics is likely to seek additional U.S. lab acquisitions, said Lee Jong-hoon, Co-Chief Executive of LabGenomics, at a press briefing on August 1.

“Fees for medical services are higher in the U.S. than in Korea, and the country’s CLIA labs expedite the commercialization of (diagnostics) products,” said Lee. “This is why we must foray into the U.S. diagnostics market.”

Crosstree Capital Partners (Tampa, FL) advised QDx and Hadley Capital on the sale to LabGenomics.

PathAI Lays Off 87 Employees

PathAI (Boston), which has a total of approximately 600 employees, has laid off 87 employees, according to a Massachusetts-filed WARN notice. Of the 87, 51 live in Massachusetts with the other 36 mainly remote workers outside the state. The layoffs were effective July 31.

PathAI develops AI software programs to assist pathologists and operates a CAP/CLIA-certified laboratory in Memphis. PathAI has raised a total of $255 million since being formed in 2016. Major backers include Labcorp, Kaiser Permanente, Merck and Bristol Meyers, as well as the private equity firms General Atlantic and General Catalyst.

HNL LAB MEDICINE TO GO 100% DIGITAL (*cont'd from page 1*)

HNL Lab Medicine, formerly named Health Network Laboratories, is an independent lab that is majority-owned by Lehigh Valley Health Network (LVHN). HNL has more than 1,100 employees, including 35 board-certified pathologists. It operates a full-service laboratory in Allentown and has more than 50 PSCs in Pennsylvania and New Jersey.

Jordan Olson, MD

Up until now, HNL has used digital pathology in very limited instances for intradepartmental consultations and taking still photomicrographs for tumor boards.

Here is a summary of our Q&A with Jordan Olson, MD, Chair of the Department of Pathology at LVHN and Medical Director at HNL.

What were some factors that convinced you that now is the right time for HNL to go digital?
Slide scanners and image management systems have evolved to a point where we can see the return on investment for making a large-scale commitment to digital pathology. In addition, with a pathologist shortage on the horizon and the rise of AI image analysis, it felt like the right time to make the push.

Roughly how many slides does HNL process each year?
We're doing about 600,000 surgical pathology slides per year, excluding cytology and hematology.

Which slide scanner have you chosen?
We'll be using Leica's Aperio GT 450—we have a lot of experience with this model. We expect to install 7 or more scanners. We'll also be using Proscia's Concentriq Dx as our digital pathology software platform to help upload, organize into patient cases, annotate, and store whole slide images.

Are HNL pathologists on board with going digital?
The overwhelming majority of our 35 pathologists are enthusiastic about going digital. One or two pathologists have expressed reservations, but generally the group sees digital as a more conducive and frictionless way of handling pathology. There is also the potential for pathologists to do at-home sign-outs. Radiologists have been doing this for years.

Can you describe your decision-making process?
It's critical to learn from the experience of early adopters. So myself and Sajjad Malik, MD, HNL's Division Director for Digital Pathology, made onsite visits to several labs on the East Coast. We also found members of CAP's Digital and Computational Pathology Committee to be a tremendous resource.

Our two biggest takeaways were:

1) Current regulations say we have to keep the glass slides. But we're still on the fence in determining how long we should keep our slide images in storage. Although IT storage is cheap and getting cheaper, each slide image requires between 1 and 1.5 gigabytes of compressed file storage. That adds up over time with volume.

2) We're also carefully planning how our new scanners will be integrated into the workflow in our histology lab. Digital pathology adds steps to the process, so we have been advised to keep the workflow very tight and figure it out beforehand.

Which types of cases will be digitized first?
We are initially targeting cases that involve only a small number of slides, including GI and liver biopsies as well as dermatology cases. Prostate biopsies will also be in the first wave. Our goal is to

scan 20% of our daily case volume by the end of this year and 100% within two years.

How will digital pathology help HNL lower costs and increase efficiency?
The logistics of moving glass slides each day for pathologists to read at six or seven different hospitals located throughout eastern Pennsylvania are immense. The fact that we will soon be able to get images to our pathologists as soon as they enter the lab each morning will be a huge plus for efficiency.

Describe your plans to start using AI on digitized slide images.
AI is advancing so fast. It seems like there is a new algorithm being announced every day. We're creating a committee of pathologists to begin beta testing at our lab in 2024. We plan on evaluating which AI programs will give us the best utility, but we won't rush putting it into practice if it doesn't seem figured out yet.

What is your estimated cost per digitized slide?
It's not cheap. But the flexibility it gives us combined with the shortage of pathologists….I don't see a way to not implement digital.

How Much Does Digitizing Slides Cost?

This is a question for which no one seems to have a simple answer. So here's a hypothetical example worked up by *Laboratory Economics*. It involves an independent pathology lab with 25 pathologists processing 500,000 surgical pathology slides per year.

We assume this lab will require six high-speed scanners at a fixed initial cost of $350,000 per scanner amortized over 10 years. This equates to a $2.1 million capital investment, or $210,000 annually if expensed over 10 years.

Our hypothetical pathology lab will hire two histotechnicians ($100,000 each for annual salary and benefits) to load and unload slides, and maintain the scanners.

Finally, we assume software licensing, image management and file storage fees of 50 cents per slide.

The grand total estimated cost is $660,000 per year, or $1.32 per digitized slide. Looking at it another way, the cost is equivalent to $26,400 per pathologist.

To put this into perspective, the technical slide-preparation component of a diagnostic read (CPT code 88305-TC) brings in $35 from Medicare to the lab. When you figure in the courier/logistics cost savings from digitization, improved turnaround time, and potential efficiencies from the application of AI, the case for the clinical adoption of digital pathology becomes more apparent.

Estimated All-Inclusive Costs of Digital Pathology

Expense Item	*Annual Cost*	*Cost per Digitized Slide*
Capital investment for 6 scanners (expensed over 10-year period)	$210,000	$0.42
Two histotechnicians	$200,000	$0.40
Variable software licensing, image management and file storage fees	$250,000	$0.50
Total Cost	**$660,000**	**$1.32**

Source: *Laboratory Economics'* estimates

70% of Life Sciences Companies Use Digital Pathology

Seventy-percent of pharmaceutical companies and contract research organizations (CROs) currently use digital pathology, according to a February 2023 survey of life science executives. The survey, which was conducted by Atheneum on Proscia's behalf, collected responses from 40 C- and VP-level respondents from the United States, Europe, the Middle East and Africa

The survey also found that 83% of non-users plan to adopt digital pathology by the end of this year. This would bring the level of use among pharma companies and CROs to 95%.

The top reasons for going digital include: Improve collaboration and operations (cited by 83%) and get new drugs to market faster (80%).

Top Reasons Life Sciences Companies Use Digital Pathology

Improve collaboration and operations	83%
Get new drugs to market faster	80%
Align with other functional areas that are digital	73%
Reduce costs	68%
Create new data assets for research	55%
Attract better talent	25%

Source: Proscia 2023 Life Sciences Digital Pathology Adoption Survey

The survey also found that 82% of organizations that use digital pathology have implemented AI applications. One hundred percent of non-users plan to deploy AI this year.

Implications for Clinical Use at Pathology Labs

Nathan Buchbinder, Co-Founder and Chief Product Officer at Proscia, says that the near-universal use of digital pathology at life sciences firms has implications for clinical use at pathology labs.

"The life sciences community has validated the technology and, in many cases, expanded the use cases, technical capacity, and value propositions of digital pathology. This serves as fodder to fuel clinical adoption," according to Buchbinder.

"We also see a flywheel effect as some of the digital pathology innovation in the life sciences translates directly into clinical practice. This can be observed with digital companion diagnostics and digital biomarker quantification. PD-L1 digital companions, as an example, enable a more consistent and efficient interpretation of a patient's biopsy and immunotherapy selection."

First Coast to Require Documentation for Digital Pathology

Medicare Administrative Contractor First Coast Service Options Inc. (Jacksonville, FL) is requiring that on or after Aug. 5, 2023, providers document how the digitization of glass microscope slides is reasonable and necessary. Providers must make a statement on Item 19 of the CMS-1500 claim form. An example of potentially reasonable and necessary digitization is if a slide requires an outside consultation that would necessitate mailing of the slide, but it represents the only slide demonstrating the pathology of interest (and the loss of the slide would mean loss of irreplaceable material).

Failure to provide a statement on claims that documents the need for the digitized slides may result in claims being rejected as unprocessable, according to First Coast. The requirement affects CPT codes 0751T-0763T. These are the new add-on codes, effective January 1, 2023, that Medicare is using to monitor the usage of digital pathology for primary diagnosis (see *LE*, July 2022, p. 1).

First Coast processes Medicare Part B claims in Florida, Puerto Rico and the U.S. Virgin Islands.

Spotlight Interview with White Plains Hospital Lab's Christina Hampton

White Plains Hospital (White Plains, NY), which has 292 beds and is part of Montefiore Health System, serves the Westchester County region (just above NYC). Its CAP-accredited laboratory has 230 employees, including seven employed pathologists, and performed a total of five million tests in 2022. *Laboratory Economics* recently spoke with Christina Hampton, Senior Director of Laboratory Medicine and Pathology at White Plains Hospital.


Christina Hampton

How are you coping with the lab employee shortage?
We did a staff survey and found that approximately 40% of our lab staff were at an age (55+) where they could potentially retire in 2018. This was a concern because not many new employees were entering the laboratory field. In addition, the pandemic accelerated retirements, so we have developed several successful strategies to offset this and we are now at a 15% retirement potential.

For example, in 2021, we upgraded the titles for our medical technologists to clinical laboratory scientists. The title change included a better compensation package which has helped us keep technical staff and improved recruitment. This title change was the first step in really recognizing the work that the staff do every day.

We're also doing more outreach to nearby colleges with CLS programs, including Mercy College and New York Medical College. Our laboratory provides rotations for these schools as well as Brooklyn Community College students entering medical technician roles.

Finally, our hospital has been sponsoring work visas and recruiting technical staff from outside the U.S. We have interviewed many candidates from all over the world, but most recent hires are coming from the Philippines.

Has automation helped?
Yes. We went live with Siemens Atellica clinical chemistry and immunoassay automated system on June 5, 2023. This system automates everything from decapping and resealing test tubes. It also enables remotely ordered and completed add-on testing. Automation will allow us to grow our volume without adding staff.

Have your test volume fully rebound to pre-pandemic levels?
We're up 40% from pre-pandemic test volumes in 2019. This year we expect to process roughly six million tests, up 20% from five million tests in 2022. Growth has been driven by inpatient testing, program growth with cardiac surgery and neurosurgery, and increased outreach testing with the expanding growth of our physician network White Plains Hospital Physician Associates (WPHPA).

Can you describe your lab outreach program?
Our lab outreach was founded 35 years ago and goes by Medical Labs of Westchester (MLW). Non-patient outreach testing represents about three million tests, or half of our hospital's total volume. MLW serves WPHPA, which has approximately 300 physicians, nurse practitioners and physician assistants, as well as nursing homes and assisted living facilities. MLW has its own dedicated billing staff that works closely with the hospital billing department.

Have you seen a recent uptick in Covid testing volumes?
We're currently performing about 100 Covid tests per day, which is an increase from an average of roughly 60 tests per day in July. To put this in perspective, at the peak of the pandemic in late December 2021, we had performed as many as 470 Covid tests per day.

Our excess Covid testing capacity has mostly been redirected to other areas. For example, our Abbott ID Now is performing flu, strep and RSV testing. Our Cepheid GeneXpert Infinity System is performing STD tests. And our BioFire PCR analyzer is being validated for blood culture identification testing for bacteria and meningitis panels.

UNITEDHEALTHCARE CUTTING BACK ON PRIOR AUTHORIZATIONS (*cont'd from page 1*)

The list of genetic test codes for which UnitedHealthcare is dropping prior authorization requirements overlaps with many of the same codes under UHC's new Z-code requirement (see *Laboratory Economics*, July 2023, p. 1).

Effective October 1, UHC is requiring Z-codes on commercial claims for 136 CPT codes as well as 106 proprietary lab analysis codes. Z-codes are five-character alpha-numeric codes assigned to molecular diagnostic tests by Palmetto GBA's MolDx program. Z-code assignment includes a technical assessment that reviews each test's analytical validity, clinical validity and clinical utility.

Thomas Cronin, Vice President of Client Services at Quadax Inc. (Cleveland, OH), believes UHC's new policies may result in fewer prior authorization requests and medical record reviews for genetic tests. Quadax specializes in revenue cycle management for labs and its biggest client segment is independent molecular labs.

Thomas Cronin

Cronin believes that many, if not most, molecular labs have already acquired Z-codes for their genetic tests. Palmetto GBA's MolDx program and Z-codes are already in use by four out of seven Medicare Administrative Contractors (MACs) for Part B claims. In addition, UHC has been requiring Z-codes for its Medicare Advantage claims for more than one year. Cronin says the biggest issue facing molecular labs is ensuring they have systems in place to incorporate Z-codes into their commercial claims to UHC.

Any potential future expansion by UHC of Z-code requirements on commercial claims could target custom PCR-based test panels for respiratory viruses, gastrointestinal pathogens and urinary tract infections. "Individual PCR-based tests are well established in terms of coverage and reimbursement....But Z-codes and their related technical assessments could serve as a quasi-coverage policy for custom panels," observes Cronin.

Will other insurance plans follow UHC's lead? Cronin notes that Palmetto's MolDx program has been around for 10 years and only a handful of commercial payers have adopted it for their Medicare Advantage plans (e.g., BCBS of NC, Fallon Health, Medical Mutual of Ohio and UHC). "It remains to be seen if other insurers will follow UnitedHealthcare," notes Cronin.

North Carolina Lab to Pay $2M to Settle False Claims Act Allegations

The U.S. Department of Justice has announced that Aspirar Medical Lab (Cary, NC) and its owner Pick Chay have agreed to pay $1.95 million to resolve allegations that they violated the law by billing the North Carolina Medicaid program for unnecessary urine drug tests and paying illegal kickbacks for these tests.

The DOJ alleged that from March 25, 2016, through September 19, 2017, Aspirar submitted claims to Medicaid for urine drug tests that were tainted by an illegal kickback arrangement with BPolloni Consulting LLC. Under the arrangement, Aspirar paid BPolloni for each urine drug test that BPolloni or another entity, Do It 4 the Hood Corp. (D4H), referred to Aspirar.

In addition to being tainted by illegal kickbacks, the United States alleged that claims for drug tests that Aspirar submitted to Medicaid were false because the tests were medically unnecessary. Specifically, the orders for the tests were not patient-specific and did not reflect a qualified medical provider's determination of the patient's need for the testing.

Aspirar remains in business. In addition to toxicology, Aspirar specializes in custom PCR-based test panels for urinary tract infections, respiratory pathogens and women's health (i.e., vaginal infections, vaginitis and bacterial vaginosis).

Quest Diagnostics Mid-Year 2023 Review

Quest Diagnostics (Secaucus, NJ) reported net income of $437 million for the six months ended June 30, 2023, down 26% from $589 million in the same period for 2022. Overall, Quest's reported half-year revenue fell by 7.8% to $4.669 billion. Quest's first-half requisition volume was down 1.8% to an estimated 103.8 million reqs. Revenue per requisition decreased by 6.3% to an estimated $41.27 per req, driven in large part by a decline in Covid PCR testing. Here's a summary of some key topics discussed during the company's July 26 conference call with analysts:

Employee Turnover

Quest CEO Jim Davis said that persistently high employee turnover in frontline jobs (phlebotomists, couriers, specimen processors and call centers) was hurting profit margins. He noted that annual turnover in these jobs had averaged 14% pre-pandemic, but was now averaging in the low 20% range. Davis estimated that every frontline employee that quits after two years of experience costs Quest between $8,000 and $10,000 per employee. Turnover could cost Quest $20 million in the second half of 2023, according to Davis.

Gene-Based & Esoteric Testing

First-half revenue increased the most at Quest's gene-based & esoteric testing segment, up 13% to $1.721 billion. Growth was strongest in areas such as cardiometabolic, women's health and neurology (including Alzheimer's identification).

Covid-19 Testing

Quest generated $160 million of revenue from Covid-19 testing in the first six months of 2023, down 83% from the same period last year. Quest expects Covid-19 testing revenue of $40 million in the second half of 2023. "I would encourage analysts to stop modeling Covid next year—we aren't going to talk about base business versus Covid next year," said Davis.

Direct-to-Consumer Testing

Quest's direct-to-consumer testing business recently turned profitable. In July, Quest began marketing a DTC blood test to detect abnormal levels of beta amyloid, a key Alzheimer's disease protein that can appear years before dementia symptoms arise, for $399 (plus a $13 physician service fee). Quest also recently introduced a DTC test (aka "Genetic Insights") that analyzes 36 genes to determine a patient's risk of nearly two dozen inheritable diseases for $199 (plus a $13 physician service fee).

Hospital Lab Outreach Acquisitions

Quest completed its acquisition of the outreach lab assets of New York-Presbyterian in an all-cash transaction for $275 million in April 2023. Davis said that Quest has a significant pipeline of potential outreach lab deals as health systems struggle financially from increased labor costs and the continuing shift to outpatient care.

Quest Diagnostics Mid-Year Financial Summary ($ millions)

Six months ended:	*6/30/2023*	*6/30/2022*	*% Chg*
Total revenue	$4,669	$5,064	-7.8%
Routine clinical lab testing	2,325	2,164	7.4%
Covid-19 testing	160	954	-83.2%
Gene-based & esoteric testing	1,721	1,526	12.8%
Anatomic pathology testing	326	281	15.8%
Other revenue*	140	139	0.4%
Operating cash flow	538	882	-39.0%
Capital expenditures	231	139	66.2%
Free cash flow	307	743	-58.7%
Net income	437	589	-25.8%
Diluted EPS	$3.83	$4.88	-21.5%
Est'd number of requisitions	103.8	105.7	-1.8%
Est'd revenue per requisition	$41.27	$44.04	-6.3%

*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 2023 Review

Labcorp (Burlington, NC) reported net income of $402 million for the six months ended June 30, 2023, down from $850 million in the same period for 2022. Overall, Labcorp's reported half-year revenue grew by 0.1% to $6.072 billion.

Looking specifically at Labcorp's lab testing business, revenue increased by 0.3% to $4.724 billion, including approximately 2.1% gained from acquisitions. On July 27, 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:

Covid-19 Testing
Labcorp's Covid testing revenue (PCR and antibody) totaled $117 million in the first half of 2023, down 85% from $795 million in the same period last year.

Core Test Volume Trends
Labcorp's core testing revenue (excluding Covid testing) was up by 18% to $4.607 billion in the first half of 2023, including the benefit from acquisitions.

Hospital Lab Outreach Acquisitions
Labcorp CEO Adam Schechter said the company has a "very strong pipeline" of hospital outreach lab deals. "First and foremost, hospitals want patient continuity. You need to make sure that there's no impact on their patients, if they do a laboratory agreement."

So far this year, Labcorp has reached agreements to acquire lab outreach assets from Tufts Medicine (see page 1) as well as Legacy Health (Portland, OR), Providence Health (Renton, WA) and Jefferson Health (Philadelphia, PA).

Employee Turnover
Schechter said that Labcorp's employee turnover is improving, but is still higher than pre-pandemic levels.

PAMA & SALSA
"We are hopeful that there's a path forward on SALSA [S. 1000/H.R. 2377: Saving Access to Laboratory Services Act] and ACLA is working on that….But at the same time, we realize we've got to be prepared in case PAMA does get implemented," said Schechter.

Schechter estimates that PAMA would cost Labcorp $75 million next year if implemented as scheduled in 2024.

Unless SALSA is passed into law, approximately 800 tests on the Medicare CLFS will receive rate cuts of up to 15% effective January 1, 2024.

Labcorp Mid-Year Financial Summary ($ millions)

Six months ended:	6/30/2023	6/30/2022	% Chg
Total revenue*	$6,071.5	$6,067.5	0.1%
Labcorp Diagnostics	4,723.6	4,709.5	0.3%
Biopharma Lab Services*	1,360.3	1,382.1	-1.6%
Operating cash flow	472.6	928.5	-49.1%
Capital expenditures	181.5	247.4	-26.6%
Free cash flow	291.1	681.1	-57.3%
Net income	401.8	850.2	-52.7%
Diluted EPS	$4.51	$9.11	-50.5%
Est'd number of requisitions	88.9	89.8	-1.0%
Est'd revenue per requisition	$55.85	$55.13	1.3%

*Excludes revenue from Fortrea CRO business (spun off on June 30, 2023)
Source: Labcorp and *Laboratory Economics'* estimates

EXACT SCIENCES TO SETTLE "GIFT CARD" LAWSUIT FOR $13.8M (*cont'd from page 1*)

Rosen is a retired pathologist and former Program Director of the CMS National Correct Coding Initiative (NCCI) program. He originally filed his lawsuit against Exact in June 2019 and filed an amended complaint (case: 8:19-cv-1526) in April 2021 in the U.S. District Court for the Middle District of Florida (Tampa). The Department of Justice declined to intervene in March 2021, but Rosen pushed forward anyway.

Rosen had alleged that Exact's $75 Visa reward card given to patients for returning their stool samples for testing is a kickback. Exact discontinued its gift card program several years ago (see *Laboratory Economics*, January 2023).

Exact to Pay $32.5M to Settle Alleged DOS Rule Violations

Separately, Exact Sciences has reached an agreement in principle with the DOJ to resolve a previously disclosed civil investigation concerning Genomic Health's compliance with Medicare Date of Service (DOS) billing regulations. Exact acquired Genomic Health in 2019.

Under Medicare billing rules, payment for lab tests performed on Medicare beneficiaries who were hospital patients at the time that a sample was obtained, and whose tests were ordered less than 14 days from discharge, must be bundled into the payment that the hospital receives for all services provided. Exact has agreed to pay $32.5 million plus interest to resolve DOJ allegations that it violated the DOS rule by improperly billing Medicare for certain tests performed on hospital patients.

TEN Healthcare to Pay $9M to Settle PCR Test Panel Fraud Claims

The U.S. Department of Justice has announced that Thyroid Specialty Laboratory (Fenton, MO), which does business as TEN Healthcare, has agreed to pay $1.9 million and relinquish another $6.9 million held in escrow to settle civil fraud claims. The settlement will resolve allegations that TEN billed Medicare, Medicaid and Tricare for polymerase chain reaction (PCR) test panels that were not medically necessary between June 2018 and July 2023.

The government alleged that TEN used requisition forms that included PCR tests that were not medically necessary as part of its upper respiratory infection (URI) and urinary tract infection (UTI) panels. The requisition forms ensured that ordering providers did not make an independent medical necessity decision about each test ordered. The panels included over 30 pathogens that lacked a common symptomology and, therefore, did not require PCR testing to rule out the included pathogens.

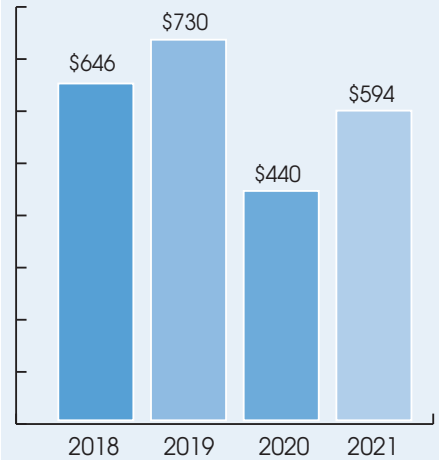
Additionally, after Medicare began rejecting the billing codes that TEN used to submit these panels, the company began using other billing codes to circumvent these rejections.

On May 19, 2020, CMS suspended payments to TEN that now total more than $6.9 million.

According to the agreement, it is "neither an admission of liability by the TEN Healthcare Entities nor a concession by the United States that its claims are not well founded."

Data from CMS shows that TEN had an average allowed payment of between $440 and $730 per Medicare beneficiary per year between 2018 and 2021.

TEN Healthcare Average Medicare Allowed Amount per Enrollee per Year



Source: CMS

Lab Stocks Up 3% Year-to-Date In 2023

Twenty-four lab stocks have risen by an unweighted average of 3% year to date through August 14. In comparison, the S&P 500 Index is up 17% year to date. The top-performing lab stocks thus far in 2023 are Exact Sciences, up 72%; Interpace Biosciences, up 57%; and NeoGenomics, up 51%. Labcorp is up 8% (after adjusting for spinoff of Fortrea) and Quest Diagnostics is down 14%.

Company (ticker)	Stock Price 8/14/23	Stock Price 12/30/22	2023 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
Exact Sciences (EXAS)	$85.08	$49.51	72%	$17,170	$2,301	7.5
Interpace Biosciences (IDXG)	1.63	1.04	57%	63	37	1.7
NeoGenomics (NEO)	13.94	9.24	51%	1,980	552	3.6
Natera (NTRA)	56.91	40.17	42%	6,200	931	6.7
Opko Health (OPK)	1.75	1.25	40%	1,540	868	1.8
Guardant Health (GH)	35.81	27.20	32%	4,350	510	8.5
DermTech Inc. (DMTK)	$2.30	$1.77	30%	47	14	3.3
Myriad Genetics (MYGN)	17.81	14.51	23%	1,530	699	2.2
Sonic Healthcare (SHL.AX)*	34.08	29.97	14%	18,370	8,670	2.1
Fulgent Genetics (FLGT)	33.38	29.78	12%	176	307	0.6
Enzo Biochem (ENZ)	1.60	1.43	12%	99	71	1.4
Labcorp (LH)	217.99	202.30	8%	23,710	14,881	1.6
Veracyte (VCYT)	25.36	23.73	7%	1,670	329	5.1
Exagen (XGN)	2.51	2.40	5%	36	53	0.7
Psychemedics (PMD)	4.82	4.90	-2%	29	24	1.2
Quest Diagnostics (DGX)	135.16	156.44	-14%	20,120	9,488	2.1
CareDx (CDNA)	9.35	11.41	-18%	260	309	0.8
Castle Biosciences (CSTL)	18.80	23.54	-20%	293	168	1.7
Aspira Women's Hlth (AWH)	3.55	4.95	-28%	32	9	3.7
Biodesix (BDSX)	1.46	2.30	-37%	143	42	3.4
GeneDx (WGS)	5.22	8.71	-40%	53	236	0.2
ProPhase Labs (PRPH)	5.77	9.63	-40%	103	79	1.3
Invitae (NVTA)	1.11	1.86	-40%	1,550	494	3.1
Biocept (BIOC)	1.10	15.90	-93%	6.4	6	1.0
Totals & Averages			3%	$99,531	$41,076	2.4

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

Source: *Laboratory Economics* from SeekingAlpha.com

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