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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

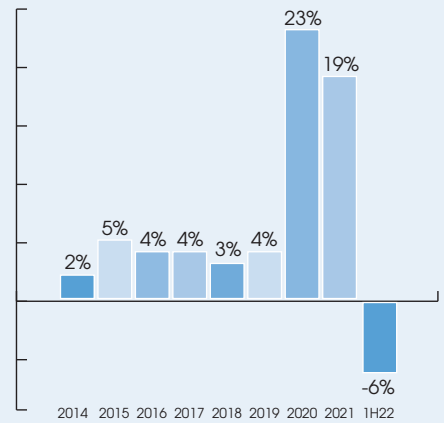
Are Nurses Qualified To Perform High-Complexity Testing?

CMS has issued a proposed rule that would make major changes to the Clinical Laboratory Improvement Amendments (CLIA) that regulate labs. The proposed changes would allow nurses to perform moderate- and high-complexity lab tests and individuals with "professional doctorates" or a "master's equivalency" to serve as directors of high-complexity laboratories. "I'm stunned the agency has equated the experience [of nurses] with waived testing in point-of-care settings as somehow similar to high-complexity testing," says Jim Flanagan, Executive Vice President of The American Society for Clinical Laboratory Science (ASCLS). He adds that, if implemented, this proposal would "open a new vector for diagnostic error." *Continued on page 5.*

Growth Cools At Publicly Traded Lab Companies

Demand for Covid-19 PCR testing decreased in the first half of this year leading to falling revenue at the nation's publicly traded lab companies. On a combined basis, 21 publicly traded labs reported a revenue drop of 6% to reach $14.3 billion during the first six months of 2022 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*. This followed the record-breaking growth these labs recorded in 2020 and 2021. *Continued on page 11.*

Revenue Growth at Publicly Traded Labs



Source: *Laboratory Economics* from company reports

UnitedHealth's Optum Launches Laboratory Benefit Management System

Optum Inc. (Eden Prairie, MN) has collaborated with Avalon Healthcare Solutions (Tampa, FL) to develop an automated laboratory benefit management (LBM) system aimed at reducing unnecessary routine clinical lab, genetic and pathology testing. The new LBM tool is being marketed to commercial, Medicare Advantage and managed Medicaid plans with 500,000+ members nationwide, including non-UnitedHealth plans. The LBM tool features automated payment denial for physician-ordered tests that are deemed to be medically unnecessary. *Full details on page 2.*

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Optum Launches Laboratory Benefit Management System (*cont'd from page 1*)
Optum is a subsidiary of UnitedHealth Group whose services include pharmacy benefit management (PBM) under the brand name OptumRx. OptumRx provides PBM services to more than 66 million health plan members and processes more than 1.3 billion pharmacy claims per year. In addition to UnitedHealth, OptumRx clients include Anthem, Health Net, Harvard Pilgrim Health Care, Tufts Health Plan, etc.

Optum's expansion into laboratory benefit management should benefit from its existing OptumRx client base. OptumRx clients will now have the choice to add the new LBM program.

Tanya Hendrickson, Senior Product Director, Healthcare, Payer Market Strategy at Optum, says the Optum LBM was developed in response to the extraordinary growth in genetic testing. Overall, Hendrickson estimates that outpatient lab expense averages roughly $20 per-member per-month (PMPM) across all member types (Medicare, commercial and Medicaid). Genetic testing currently accounts for an average of roughly $4 PMPM of overall lab test spending. Hendrickson says that genetic testing now comprises 20% of overall lab test expense versus only 5% ten years ago.

The Optum LBM utilizes information technology and connectivity developed by Optum. Automated software programs with evidence-based guidelines from Avalon are being used to weed out unnecessary tests.

The Optum LBM is also employing the DEX Z-code system from Palmetto GBA, the administrator of the MolDX Program. The Z-Code Identifier is a unique 5-character alpha-numeric code assigned by Palmetto GBA for use as an adjunct to non-specific CPT codes.

Examples of how the Optum LBM will work:

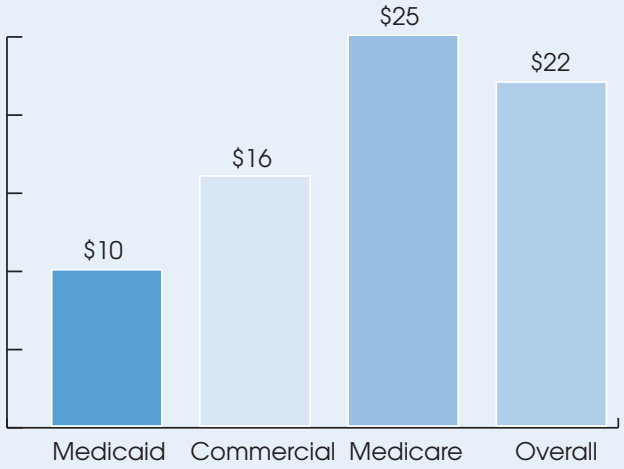
- **Routine Clinical Lab Testing:** Labs often market custom panels with add-on tests that are clinically unnecessary, according to Hendrickson. The LBM solution helps providers and health plans choose clinically appropriate care and avoid unnecessary tests. For example, some labs nudge physicians to order an expanded thyroid panel of seven tests, costing an average of $137 more than the two-test $30 basic panel (TSH and T4 Free) that a patient needs. The LBM will pay labs only for the smaller panel and will automatically deny payment for inappropriate add-on tests.
- **Genetic Tests:** Optum is requiring labs that bill for genetic tests using non-specific CPT codes (e.g., CPT 81479) to show their specific Z-code identifier on the claim as a requirement for payment. A health plan can use Optum's LBM solution to preauthorize the clinically appropriate panel at the same time it flags the testing that does not align with evidence-based care guidelines. Hendrickson says that the inclusion of DEX Z-codes increases automation and reduces the number of preauthorization's needed.

  There will also be limits placed on the number of tests that are reimbursed for genetic test panels, including panels for noninvasive prenatal testing (NIPT).
- **Anatomic Pathology:** Limits are being placed on the number of CPT 88305 units that will be reimbursed by specimen type. For example, Optum will pay for a maximum of six core biopsies (88305s) per prostate biopsy case. Many pathology labs routinely bill for 10-18 core biopsies per prostate biopsy case.

Hendrickson says that the Optum LBM is not designed to cut lab test reimbursement rates, but rather to reduce inappropriate test utilization. Optum estimates that there are roughly 13 billion lab tests performed each year in the United States and 30% are unnecessary.

John Adams, Chief Financial Officer at Avalon, anticipates that the Optum LBM will help health plans reduce their lab test spending by between 8% and 12% per year, or about $2 PMPM. He notes that this would equate to $48 million per year of reduced expense for a health plan with two million members (i.e., 2 million members x $2 PMPM x 12 months = $48 million). About one third of the savings will drop down to lower out-of-pocket costs for members, in terms of lower deductibles and co-pays, according to Adams.

Average Lab Test Expense PMPM at Health Plans*



*Includes clinical lab, genetic and anatomic pathology services (excludes hospital inpatient testing)
Source: Avalon Healthcare Services

Because of its automated evidence-based policy enforcement system, Adams believes the Optum/Avalon collaboration will help ensure members receive appropriate tests and place less of an administrative burden on labs than preauthorization programs.

bioAffinity Raises $7.8 Million From IPO

bioAffinity Technologies (San Antonio, TX) has raised gross proceeds of $7.8 million from an initial public offering (IPO) of 1.3 million units of common stock and warrants. Net IPO proceeds were approximately $6.2 million, after deducting underwriting discounts and commissions. The IPO was managed by WallachBeth Capital (Jersey City, NJ) and Craft Capital Management (Garden City, NY).

bioAffinity markets a noninvasive test (CyPath Lung) for the early detection of lung cancer. The CyPath Lung test uses flow cytometry to analyze cells in a person's sputum (aka phlegm).

bioAffinity has a royalty agreement with Precision Pathology Services (San Antonio, TX), an independent CAP-accredited laboratory that is marketing CyPath Lung as a laboratory-developed test. The target market is patients who are smokers and former smokers at high risk for lung cancer. Precision Pathology is offering the CyPath Lung test at a price of $880. In addition, bioAffinity is planning a clinical trial of 2,000 participants for CyPath Lung for pre-submission to the FDA for review.

bioAffinity reported a net loss of $1.6 million in the six months ended June 30, 2022, versus a net profit of $764,220 in the same period a year earlier; revenue was $1,306 versus zero. As of June 30, 2022, bioAffinity had an accumulated deficit of approximately $30.1 million since its inception in 2014.

bioAffinity has 14 employees. Maria Zannes, age 66, is Founder, President and CEO. Zannes is an attorney who had previously served as CEO of Biomoda Inc. (Albuquerque, NM). Biomoda had owned the CyPath technology but filed for Chapter 11 bankruptcy in late 2013. bioAffinity was then formed and purchased the patents and trademarks of CyPath.

Labcorp Completes Outreach Lab Deal With RWJBarnabas Health

Labcorp has completed its acquisition of RWJBarnabas Health's outreach laboratory business and select related assets (see *LE*, August 2022). RWJBarnabas Health (West Orange, NJ), which has 12 acute-care hospitals with 4,357 staffed beds, is New Jersey's largest academic health system. Financial terms of the transaction were not revealed.

Clinical lab outreach testing from RWJBarnabas Health will be shifted to Labcorp's regional laboratory in Raritan, New Jersey. Some STAT and same-day testing will be performed at select RWJBarnabas Health hospitals. Anatomic pathology services are not part of the deal and will not be affected.

In addition, any potential future reference testing relationship with RWJBarnabas Health would be independent of this transaction, according to a Labcorp spokesperson.

"This strategic business decision will provide a high-performing, streamlined outreach network to support our community," according to John Doll, Senior Executive Vice President and Chief Operations Officer of RWJBarnabas Health. The arrangement is also expected to reduce out-of-pocket lab costs for RWJBarnabas patients.

RWJBarnabas Health's decision to sell its clinical lab outreach business comes as it struggles with investment losses, rising labor costs and inflation. In the six months ended June 30, 2022, RWJBarnabas Health reported a net loss of $489 million vs. a net gain of $325 million in the same period a year earlier; total revenue was up 14% to $3.651 billion.

Investment losses at RWJBarnabas Health totaled $729 million in the six months ended June 30, 2022. In addition, salaries and employee benefits increased by $264,375 or 18%; physician fees and salaries increased by $79,207 or 22%; and supplies and other expenses increased by $191,781 or 17%.

RWJBarnabas Health collected total Medicare Part B CLFS revenue of $6.3 million in full-year 2021. *Laboratory Economics* estimates that Medicare Part B CLFS represents 25% of the overall revenue at RWJBarnabas Health's clinical lab outreach business (total annual revenue estimated at $25 million).

RWJBarnabas Health's Outreach Laboratory Business (Medicare Volume and Revenue for 2021)

Hospital Name (location)	Staffed Beds	Total Medicare Part B CLFS Test Volume	Avg. Collected Revenue Per Medicare Part B CLFS Test*	Total Medicare Part B CLFS Revenue
Community Medical Center (Toms River, NJ)	438	200,983	$7	$1,406,881
Cooperman Barnabas Medical Center (Livingston, NJ)	544	219,672	$5	$1,098,360
RWJ University Hospital (New Brunswick, NJ)	639	170,173	$5	$850,865
Monmouth Medical Center (Long Branch, NJ)	303	102,401	$7	$716,807
RWJ University Hospital (Somerville, NJ)	347	84,882	$7	$594,174
Clara Maass Medical Center (Belleville, NJ)	342	41,425	$9	$372,825
Newark Beth Israel Medical Center (Newark, NJ)	470	44,011	$8	$352,088
RWJ University Hospital Hamilton (Hamilton, NJ)	152	50,833	$6	$304,998
Monmouth Medical Center (Lakewood, NJ)	201	35,312	$6	$211,872
Jersey City Medical Center (Jersey City, NJ)	340	31,841	$6	$191,046
RWJ University Hospital (Rahway, NJ)	139	27,859	$5	$139,295
Trinitas Regional Medical Center (Elizabeth, NJ)	442	31,233	$4	$124,932
Grand Total	**4,357**	**1,040,625**	**$6**	**$6,364,143**

*Includes phlebotomy services

Source: *Laboratory Economics'* Hospital Outreach Laboratory Database

Are Nurses Qualified To Perform High-Complexity Testing? (*cont'd from p. 1*)
Comments on the proposal will be accepted through September 26, 2022. The proposed changes, if accepted, would be effective 30 days after the publication of the final rule. However, the publication date of a final rule is uncertain at this point. "The agencies will need to wade through more than 18,000 comments before they can distribute the final rules, which may change from what is proposed. I can't imagine they get through this until after the first of the year," according to ASCLS's Flanagan.

The proposed rule essentially places nursing degrees on the same level as degrees in clinical laboratory science, biology and chemistry. "We do not have any reason to believe that nurses would be unable to accurately and reliably perform moderate- and high-complexity testing," according to CMS.

However, Flanagan notes that the proposed rule "omits any requirement for training and demonstrated competency to perform high-complexity testing relative to those who have four-year degrees in clinical laboratory science, chemistry or biology." ASCLS does not believe nurses are seeking these responsibilities and fears that "this rule would be an open license for healthcare administrators to abusively push more complex and risky testing into point-of-care settings staffed by an already dangerously under-resourced nursing workforce."

The American Association for Clinical Chemistry (AACC) also opposes the proposal. AACC says that a nursing degree by itself does not qualify an individual to perform, supervise or direct laboratory testing. However, nurses could demonstrate testing competency through a variety of mechanisms, such as passing a curriculum of required laboratory-specific continuing education courses, and/or passing a competency exam (ASCP MLS, MLT or equivalent) for certifying staff to work in clinical laboratories as instrument operators and testing personnel.

Similarly, the American Hospital Association (AHA) has cautioned CMS "against softening standards designed to maintain the safety and quality of laboratory testing in the U.S."

High-Complexity Laboratory Director
CMS is also proposing to expand qualifications for a high-complexity laboratory director (HCLD) to include "professional doctorates" and individuals with "master's equivalency" who meet certain training, experience and certification requirements. Currently, this position is limited to certain MDs and board-certified PhDs. ASCLS is in favor of this proposal, says Flanagan.

However, AACC strongly objects to this proposal, saying that the Doctorate in Clinical Laboratory Sciences (DCLS), which CMS calls a "professional doctorate," falls short of meeting the requirements necessary for a person to serve as HCLD (as does master's equivalency).

CLIA Fee Increase
In addition, CMS is proposing a 20% across-the-board increase in biennial CLIA survey fees for certificate-of-compliance (CoC) labs. The proposed rule also includes a formula to increase user fees every two years to account for inflation as per the Consumer Price Index-Urban (CPI-U), if needed to meet program obligations. In addition, CMS is proposing a one-time $25 fee on certificate-of-waiver (CoW) laboratories, and to incorporate specific fees for other labs, including fees for follow-up surveys, substantiated complaint surveys and revised certificates.

The CLIA survey fee increase will have a modest impact on most lab budgets. For example, a CoC lab that performs total annual volume of between 10,000 and 25,000 laboratory tests would see its biennial survey fee rise from a current $2,336 by 20% to $2,803. The largest CoC labs (1,000,000+ annual tests) would see their biennial survey fee increase by $882 to $5,290.

CMS says that without the fee increases, the CLIA program will no longer be financially self-supporting by the end of 2023.

ASCLS and AHA have not commented on the proposed fee increases.

Meanwhile, AACC has expressed concerns about the size of the proposed survey fee increases. "CMS does not elaborate on how it will spend these funds, not does it consider the deep reimbursement cuts laboratories are incurring under the Protecting Access to Medicare Act," says the organization in its comments.

AACC does support the increase in the CoW user fee and suggests that some of the revenue be used to reinstitute the agency's two percent annual inspections of CoW facilities. It notes that of the more than 300,000 CLIA-certified labs in the United States, the vast majority are waiver laboratories that are not subject to inspection, and many have only recently entered the market.

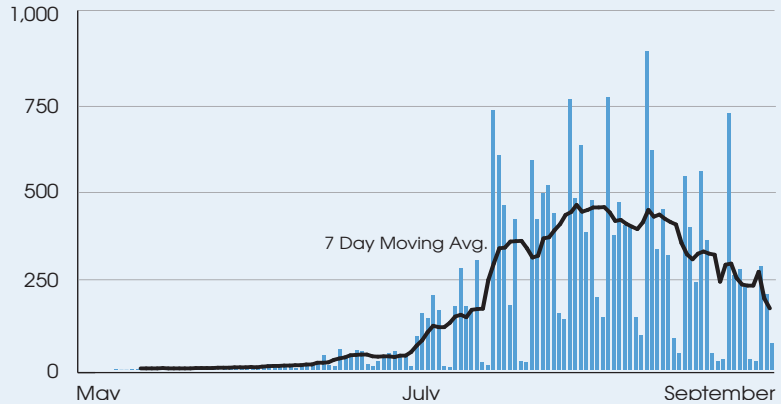
MACs Set Low Reimbursement Rates For Monkeypox Test

Palmetto GBA's MolDx program has set a disappointingly low reimbursement rate of $35.09 for Monkeypox testing (CPT 87593). Palmetto is the Medicare Administrative Contractor (MAC) for Part B services in Jurisdiction J (AL, GA, TN) and Jurisdiction M (NC, SC, VA, WV) and its MolDx rate decisions are followed by other MACs as well. Palmetto GBA's MolDx program determined the rate by cross walking it to CPT 87798 (infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified).

The American Clinical Laboratory Association (ACLA) had recommended that the Monkeypox test be cross walked to CPT 87662 (Zika virus, amplified probe technique), which is performed in a similar way and reimbursed by Medicare at $51.31. ACLA had further recommended that this rate be multiplied by 1.5 to accommodate for the additional costs associated with performing this test, which includes increased personal protective equipment, biosafety level 3 facility, reagent costs, increased waste disposal costs, reporting requirements to public health authorities, and increased specimen processing and performance times for technical staff. Including the 1.5 multiplier to account for higher costs would have set reimbursement at $76.97.

Two other MACs, First Coast Service Options (Florida and Puerto Rico) and Novitas (AR, CO, LA, MS, NM, OK and TX), have published a Monkeypox reimbursement rate of $51.31, which is the cross walk to the industry-suggested 87662, but without the 1.5 multiplier.

Daily U.S. Monkeypox Cases (May 18 through September 14)



Source: Centers for Disease Control and Prevention

As of September 14, the CDC reports a total of more than 23,000 Monkeypox cases had been recorded since the initial case was identified in Massachusetts on May 18, 2022. Two deaths—one each in Texas and California—have been linked to Monkeypox infections so far. However, the speed of the outbreak appears to be slowing from the peak in daily new cases in August.

Spotlight Interview with GreatLakes Laboratory Network's Mike Hiltunen


Mike Hiltunen

The GreatLakes Laboratory Network (GLN) is an alliance of 40 Michigan and Northern Indiana hospital-based laboratories created to secure ancillary contracts from which hospital laboratories were previously excluded and to provide a viable alternative to the national laboratories. The network provides single-source contracting and provides comprehensive billing, quality and utilization data to health plans. *Laboratory Economics* recently spoke with Executive Director Mike Hiltunen.

When was GLN formed and what are some of its larger members?
GLN members started initial investigatory work to form a network in 1995, and it was officially formed in 1998. The larger members are the University of Michigan Medical Center, Detroit Medical Center, Munson Medical Center, Sparrow Health and Holland Hospital.

What is Mayo Clinic Laboratories role in the network?
After the network was formed, members decided to select a reference laboratory partner to do the esoteric work that the hospitals were not able to perform. A primary objective was to find a partner who could bring information technology resources to link the laboratories together and outreach support services such as sales and marketing, as well as legal and administrative guidance. After reviewing a number of proposals, Mayo Clinic Laboratories was selected.

Are there other similar networks in the country?
Yes, in fact there is another network that formed in Michigan around the same time as GLN – Joint Venture Hospital Laboratories (JVHL). In 2004, GLN and JVHL entered into a joint operating agreement (JOA) to provide statewide coverage to the health plans in Michigan. The combined networks consist of 127 hospital-affiliated laboratories and currently provide access to 27 contracts serving over five million covered lives. There is also another similar laboratory network, Carent Laboratory Solutions, that serves hospital-based laboratories in Colorado and Montana.

Who are your biggest competitors?
Our largest competitors remain the large national reference laboratories; however, our hospital-based laboratories currently dominate the commercial HMO market with over 80% of the HMO market share in Michigan.

Do you track test volumes by all members in the network? If yes, are volumes growing?
Yes, we track test volumes by all members in the network. There was a significant drop of routine testing during the pandemic, which was supplemented by a large increase in COVID-19 testing. Currently, our testing volume for the routine testing is approaching pre-pandemic levels.

Are you planning to add other labs to the network?
Yes, we are always looking to add laboratories that fit into our model and are able to provide testing services to patients in our market. Currently, the vast majority of hospital-based laboratories in Michigan belong to one or both of the Michigan networks.

What if a lab wants to join the network?
There is an application process. If the laboratory meets the requirements, their leadership would sign a network participation agreement that spells out terms and conditions of membership.

What do you see as the biggest challenges for the laboratory industry?
I think one of the biggest challenges facing the laboratory industry is declining reimbursement. With the cuts made to Medicare payments due to the PAMA legislation, we are seeing some of the health plans

following suit. We also see health plans narrowing their networks to drive patients towards the low-cost providers. This makes it difficult for hospital-based laboratories, who don't belong to a network, to compete.

What do you see as the biggest opportunities for the industry?
I think one of the biggest opportunities for laboratories is becoming the driver for population health management. As healthcare reform efforts continue to evolve and we transition from fee-for-service reimbursement models to value-based payment models, healthcare organizations must be able to gather and analyze clinical data to reduce episode-of-care costs and establish and implement evidence-based, standardized care processes. Hospital laboratories add value to the broader continuum of care by providing insights on patient populations and monitoring key disease trends. However, this can only happen if the hospital laboratory has access to the total continuum of care. Belonging to a laboratory network enables the long-term success of the hospital-based laboratory and the healthcare organization overall.

Are hospital outreach labs ready to contribute to the next PAMA private-payer survey in early 2023?
The hospitals who are required to submit data are prepared to do so.

Any comment on the news that many large hospital-outreach labs around the country are being sold to Quest and Labcorp?
We're not seeing that many GLN laboratories looking to sell their outreach programs like we're seeing in other parts of the country.

SALSA Bills Slowly Gaining Support In Congress

The Saving Access to Laboratory Services Act (S. 4449/H.R. 8188), which would freeze Medicare CLFS rates next year and revamp the PAMA private-payer data analysis, is slowly gaining support in Congress.

The House version of SALSA was introduced by Rep. Bill Pascrell (D-NJ) on June 22 and now has seven cosponsors. The latest to sign on is Rep. Earl "Buddy" Carter (R-GA) on August 12.

The Senate version of SALSA was introduced by Sen. Richard Burr (R-NC) and has one cosponsor, Sen. Sherrod Brown (D-OH).

Without congressional intervention, more than 800 tests on the Medicare CLFS will receive up to 15% rate cuts effective January 1, 2023.

In a September 8 letter sent to Congressional leaders, more than 20 laboratory, hospital and physician organizations urged for the passage of SALSA into law before scheduled rate cuts take effect on January 1, 2023.

Enactment of SALSA would give CMS authority "to collect private market data through statistically valid sampling from all laboratory segments for the widely available test services where previous data collection was inadequate," the letter said. "The bill ensures true private market rates are included, provides a much-needed reduction in reporting burden, and protects labs and Medicare from dramatic rate increases or decreases with a gradual phase-in approach going forward."

Among the organizations signing the letter were the American Hospital Association, American Medical Association, American Association for Clinical Chemistry, American Clinical Laboratory Association and College of American Pathologists.

Spotlight Interview with Summit Health's Kahul Patel


Kahul Patel

Summit Health, a physician-owned multi-specialty group formed by the merger of Summit Medical Group and CityMD, opened a new 50,000-square-foot laboratory in Woodland Park, New Jersey in April. Summit Health has more than 2,500 providers, 12,000 employees, and over 340 locations in New Jersey, New York, Connecticut, Pennsylvania, and Central Oregon. *Laboratory Economics* recently spoke with Summit Health Laboratory Director Kahul Patel.

How many laboratories does Summit Health have?
In addition to our new lab in Woodland Park, Summit Health has four larger labs situated within our comprehensive healthcare settings in New Jersey – Berkeley Heights, Florham Park, Livingston, and Clifton. In total, we have over 200 lab employees, including phlebotomists.

Why did Summit Health decide to open a new laboratory in Woodland Park?
Mostly because of space. Our previous lab was embedded in our Berkeley Heights campus. We wanted to add a lot more functions, including automation, and we needed more room. We went from 7,500 square feet to 50,000 square feet. Since moving in on April 1, the lab has been servicing all 150+ CityMD urgent care centers and Summit Health primary care and multispecialty offices in the greater New York City area.

What does the new laboratory offer?
The new lab offers both clinical laboratory testing and anatomic pathology testing, including women's health, testing for urgent care centers, molecular, and Covid PCR testing. We also have a microbiology lab, and we have expanded our test menu to include drugs-of-abuse for pain management. We used to do mainly routine testing.

What are some of the new tests added to Summit's lab menu recently?
We've added on allergy testing, TB quantiFERON, H. pylori breath tests, autoimmune testing, and we've brought in-house dermatology immunohistochemical stains. We've probably added a total of about 40 new tests in the past 12 months.

What is your Covid PCR testing volume?
Currently, we are testing about 14,000 samples a day, which is a significant increase since the laboratory was moved to Woodland Park.

Are you experiencing any difficulty finding lab employees?
Yes, but the good thing for us is that automation has helped with manual processes that techs were doing. Our techs can now focus on abnormal results. Our tech resources can be deployed for more of the critical areas.

We also created lab assistant roles; we have lab assistant 1, 2 and 3 – it's like a career ladder. We may have someone with a biology degree assisting in some ways such as loading analyzers or checking the pending list, anything other than analyzing patient samples. It gives them a chance to move up, maybe go back to school to become a med tech.

In addition, we have a partnership with a local university—their students do their clinical rotations here, so when they graduate, we may be able to hire them. We do something similar with histology—there is an online course they can do for their books studies and then do their hands-on at our lab.

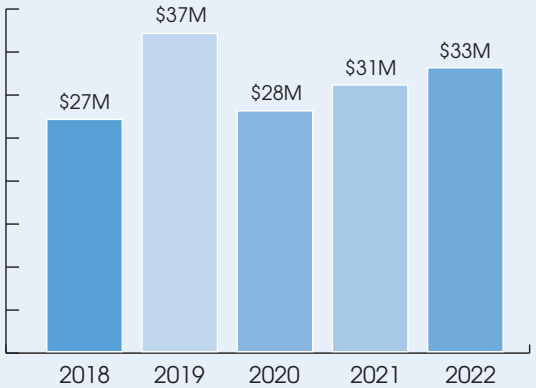
What are the most significant challenges you face?
We're continuously focused on logistics to make sure we get the samples to the lab in a timely manner and ensuring that the IT is able to continually support our expansion. Sample tracking is always on my radar, and we are exploring various options here, including the potential utilization of Radio-frequency identification (RFID) tags.

Exact Sciences Sells Oncotype Prostate Test

Exact Sciences (Madison, WI) sold its Oncotype DX Genomic Prostate Score (GPS) test to MDxHealth (Irvine, CA, and Herstal, Belgium) in early August. Exact received $30 million upfront, including $25 million in cash and $5 million worth of shares in MDxHealth. An additional $70 million will be paid to Exact if certain sales milestones are achieved by MDxHealth between 2023 and 2025.

Exact originally acquired the Oncotype GPS through its $2.5 billion purchase of Genomic Health in 2019. The Oncotype GPS analyzes 17 genes in paraffin-embedded tissue samples from patients with localized prostate cancer. The test result gauges how likely the cancer is to be aggressive and spread within the next 10 years. Low-and intermediate-risk patients can avoid prostatectomy or radiation—and their side effects—while high-risk men can be directed to immediate invasive treatment.

Annual Revenue for Oncotype GPS



Source: *Laboratory Economics* estimates based on info from Genomic Health, Exact Sciences and MDxHealth

Medicare reimburses Oncotype GPS through CPT code 0047U at a rate of $3,873. The Oncotype GPS test is expected to generate total estimated revenue of roughly $33 million in 2022.

MDxHealth markets proprietary diagnostics tests focused primarily on prostate and bladder cancer. Its tests include ConfirmMDx and SelectMDx for prostate cancer and AssureMDx for bladder cancer. MDxHealth operates a CLIA-certified lab in Irvine, California. The company anticipates overall revenue of $40-42 million in 2022, including $13 million in expected revenue for the acquired Oncotype GPS business over the August to December 2022 period.

Sema4 Announces Restructuring; 250 Job Cuts

Sema4 Holdings Corp. (Stamford, CT) has announced a restructuring that includes 250 job cuts—mostly at its headquarters and labs in Connecticut. In addition, Founder and President Eric Schadt, PhD, resigned effective August 12. Sema4 says its now focused on profitable growth with the goal of turning cash flow positive by the end of 2025.

Restructuring plans include:

- Exiting the somatic tumor testing business, including the planned closure of its clinical lab in Branford, Connecticut, effective December 31, 2022. This business line represents less than 1% of Sema4's revenue but approximately $35 million in annual expense.
- Eliminating approximately 250 positions, representing approximately 13% of its workforce. The company now has approximately 1,600 employees after the cuts.
- Consolidating hereditary cancer testing operations from Stamford, Connecticut to its automated GeneDx lab in Gaithersburg, Maryland at the end of the third quarter of 2022.

On April 29, Sema4 acquired GeneDx from OPKO Health for $322 million of cash and stock plus contingent consideration of up to $150 million if certain revenue milestones are met in 2022 and 2023 (see *LE*, February 2022).

Sema4 reported a pro forma (including GeneDx) net loss of $244 million in the six months ended June 30, 2022, compared with a net loss of $309 million in the same period a year earlier; revenue fell by 15% to $138 million. Sema4 had $285 million of cash on its balance sheet as of June 30, 2022.

Publicly Traded Lab Revenue Fell 6% In First-Half 2022 (*cont'd from page 1*)
Among five national clinical labs (Quest Diagnostics, LabCorp, Sonic Healthcare USA, BioReference and Enzo), combined revenue fell by 10% (after adjusting for acquisitions). In particular, BioReference saw its revenue drop by 42% (after adjustments for the sale of GeneDx). BioReference performed 2.9 million Covid PCR tests during the six months ended June 30, 2022, which was down 58% from 6.9 million Covid PCR tests in the same period a year earlier.

Covid-19 PCR testing volumes at BioReference and other labs have declined as testing has moved predominantly to rapid antigen testing. In response, BioReference has reduced its employee headcount from 8,000 at the peak of the Pandemic to a current 3,600 employees. In addition, BioReference says that it is reducing, delaying or eliminating some of its longer-term commercial initiatives, including initiatives around Scarlet Health and their digital health platforms. BioReference is working under the assumption that there will not be a new surge in Covid testing for the remainder of 2022.

Meanwhile, among 16 specialty and genetic testing labs, combined pro-forma revenue increased by 8%. Pro-forma revenue growth was fastest at DermTech (up 41%), Natera (up 33%) and Veracyte (up 32%).

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

Company	First-Half 2022	First-Half 2021	Reported Change	Pro Forma Change*
Quest Diagnostics (lab testing only)	$4,925,000	$5,117,000	-4%	-5%
Labcorp (lab testing only)	4,709,500	5,123,300	-8%	-9%
Sonic Healthcare USA[1]	735,800	757,400	-3%	-9%
Opko/Bio-Reference Labs	473,402	904,149	-48%	-42%
Enzo Clinical Labs (lab testing only)[2]	42,304	49,006	-14%	-14%
Total, 5 National/Clinical Labs	10,886,006	11,950,855	-9%	-10%
Exact Sciences	1,008,211	836,896	20%	19%
Fulgent Genetics	445,609	513,045	-13%	-20%
Natera	392,333	294,342	33%	33%
Myriad Genetics	344,200	362,500	-5%	0%
Invitae Corp.	260,313	219,933	18%	18%
NeoGenomics	242,241	237,257	2%	2%
Guardant Health	205,243	170,766	20%	20%
CareDx	160,050	141,588	13%	13%
Veracyte	140,647	91,808	53%	32%
Sema4	90,110	111,216	-19%	-35%
Castle Biosciences	61,690	45,571	35%	5%
Interpace Biosciences	19,728	20,989	-6%	-6%
Exagen	19,356	23,359	-17%	-17%
Psychemedics	13,021	11,800	10%	10%
DermTech	7,951	5,643	41%	41%
Aspira Women's Health	3,959	3,295	20%	20%
Total, 16 Specialty/Genetic Labs	3,414,662	3,090,008	11%	8%
Grand Total, All 21 Lab Companies	$14,300,668	$15,040,863	-5%	-6%

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.
[1]Sonic Healthcare USA revenue is for the six months ended June 30, 2022 at constant exchange rate of 1 Australian Dollar equal to 0.72 U.S. Dollar [2]Enzo's revenue is for lab services only for six months ended April 30, 2022.
Source: *Laboratory Economics* from company reports

Lab Stocks Down 47% Year To Date

Twenty-four lab stocks have dropped by an unweighted average of 47% year to date through September 14. In comparison, the S&P 500 Index has fallen by 18% so far this year. The top-performing lab stocks thus far in 2022 have been ProPhase Labs, up 50%; Psychemedics, down 6%; and Myriad Genetics, down 21%. Quest Diagnostics is off 28% and Labcorp is down 29%.

Company (ticker)	Stock Price 9/14/22	Stock Price 12/31/21	2022 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
ProPhase Labs (PRPH)	$10.77	$7.17	50%	$158	$131	1.2
Psychemedics (PMD)	6.57	$7.02	-6%	41	26	1.6
Myriad Genetics (MYGN)	21.94	27.60	-21%	1,700	672	2.5
Quest Diagnostics (DGX)	123.99	173.01	-28%	19,310	10,582	1.8
Labcorp (LH)	222.96	314.21	-29%	27,130	15,715	1.7
Enzo Biochem (ENZ)	2.20	3.21	-31%	103	112	0.9
Sonic Healthcare (SHL.AX)*	31.74	46.63	-32%	18,130	9,340	1.9
Castle Biosciences (CSTL)	28.35	42.87	-34%	517	110	4.7
Guardant Health (GH)	59.18	100.02	-41%	6,380	408	15.6
Natera (NTRA)	49.38	93.39	-47%	4,930	724	6.8
Exact Sciences (EXAS)	40.56	77.83	-48%	9,090	1,938	4.7
Veracyte (VCYT)	19.23	41.20	-53%	1,350	268	5.0
Opko Health (OPK)	2.09	4.81	-57%	1,790	1,426	1.3
Fulgent Genetics (FLGT)	42.80	100.59	-57%	466	925	0.5
CareDx (CDNA)	18.57	45.48	-59%	760	315	2.4
Exagen (XGN)	4.52	11.63	-61%	33	44	0.8
DermTech Inc. (DMTK)	5.48	15.80	-65%	40	14	2.8
Biodesix (BDSX)	1.67	5.29	-68%	70	31	2.2
NeoGenomics (NEO)	10.10	34.12	-70%	1,490	489	3.0
Aspira Women's Hlth (AWH)	0.51	1.77	-71%	46	8	6.2
Interpace Biosciences (IDXG)	2.15	$7.47	-71%	71	40	1.8
Biocept (BIOC)	0.92	3.62	-75%	0.4	63	0.0
Invitae (NVTA)	3.50	15.27	-77%	1,970	501	3.9
Sema4 Holdings (SMFR)	1.00	4.46	-78%	202	184	1.1
Unweighted Averages			-47%	$95,777	$44,068	2.2

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from YFinance and Seeking Alpha

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