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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

SALSA Bill Gaining Momentum

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 gaining support in Congress. Over the past 30 days, 12 more Reps. have joined as cosponsors and three more Senators have signed on. Unless SALSA is passed into law, more than 800 tests on the Medicare CLFS will receive rate cuts of up to 15% effective January 1, 2023.

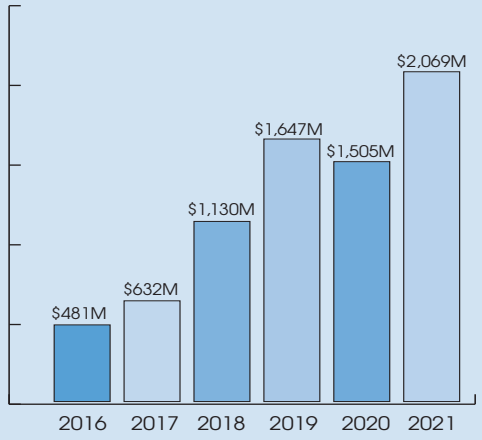
Continued on page 8.

Genetic Test Spending Surged 37% In 2021

National Medicare Part B Carrier allowed payments for genetic test codes increased by 37% to more than $2 billion in 2021, according to an *LE* analysis of newly released data from CMS. The growth represented a strong rebound from the 9% decline that occurred in 2020 due to the pandemic. Despite a concerted effort by MACs to curtail growth, Medicare Part B Carrier spending on genetic testing grew by an average annual rate of 34% from 2016-2021.

More details on page 5.

Medicare Part B Carrier Spending on Genetic Tests*



*Total Medicare Part B Carrier allowed payments for all Molecular Pathology Tests, Multianalyte Algorithmic Assays, Genomic Sequencing Procedures and certain Proprietary Lab Analyses codes

Source: Medicare Part B National Summary Data, 2016-2021

Quest To Acquire Summa Health's Outreach Lab Business

Quest Diagnostics (Secaucus, NJ) has agreed to acquire select assets of Summa Health's clinical lab outreach business, which does business as LabCare Plus, in an all-cash transaction. Summa picked Quest as a buyer after a competitive bid. The purchase price has not been disclosed.

More details on page 2.

Contents

Quest To Acquire Summa Health's Outreach Lab Business (*cont'd from page 1*)
Summa Health (Akron, OH) operates four hospitals and a multi-specialty medical group with 300 physicians at 100 offices in northeast Ohio. Summa Health will continue to own and operate its hospital labs, which serve inpatient and hospital-based outpatient departments. In addition, Summa will maintain its pathology department and services.

Summa's LabCare Plus outreach business is based at its flagship Summa Health System—Akron Campus (648 beds). LabCare Plus has 19 patient service centers in the greater Akron area. It generated $1.5 million in Medicare CLFS payments in 2021. *Laboratory Economics* estimates that the overall outreach business has revenue of $5-10 million per year.

Quest plans to shift the acquired outreach test volumes to its labs in Twinsburg, Ohio (22 miles north of Akron) and Pittsburgh (111 miles southeast).

The transaction is expected to close in the fourth quarter of 2022.

Labcorp Completes Mega-Deal with Ascension

Labcorp has completed a previously announced comprehensive laboratory deal with Ascension (see *LE*, February 2022).

As a part of the transaction, Labcorp purchased select assets of Ascension's clinical lab outreach business for $400 million and will manage the health system's hospital-based labs in Alabama, Florida, Kansas, Maryland, Michigan, New York, Oklahoma, Tennessee, Texas and Wisconsin.

Labcorp expects to bring in between $500 million and $600 million of annual revenue from the combined hospital lab management agreement and lab outreach asset acquisition.

A Labcorp spokesman says the arrangement does not involve anatomic pathology services. "Labcorp and Ascension worked together to preserve the important role of the pathologists and medical directors serving Ascension facilities," according to a statement from Labcorp.

St. Louis-based Ascension Health is the third-largest health system in the US with 143 hospitals in 19 states and annual revenue of more than $20 billion.

Recent Hospital Outreach Laboratory Transactions

Over the past three years, nine health systems have chosen to sell their clinical lab outreach businesses to either Labcorp or Quest Diagnostics. Transactions have been spurred by Medicare CLFS rate cuts, wage pressure and inflation, and the lure of upfront cash payments—often used to help offset health system operating losses.

Date	Buyer	Hospital Outreach Lab Target (location)
Pending	Quest Diagnostics	Summa Health's LabCare Plus (Akron, OH)
Oct-22	Labcorp	Ascension Health clinical lab outreach (AL, FL, KS, MD, MI, NY, OK, TX, WI)
Aug-22	Labcorp	RWJBarnabas Health (New Jersey)
Jun-22	Labcorp	Prisma Health's clinical lab outreach (Greenville, SC)
May-22	Labcorp	AtlantiCare's clinical lab outreach (southern NJ)
Jul-21	Labcorp	North Memorial Health clinical lab outreach (Robbinsdale, MN)
Jun-21	Quest Diagnostics	Mercy Health clinical lab outreach (AR, KS, MO, OK)
Jul-20	Labcorp	Franciscan Missionaries of Our Lady Health outreach lab (Baton Rouge, LA)
Apr-20	Quest Diagnostics	Memorial Hermann Diagnostic Labs (Houston, TX)

Source: *Laboratory Economics*

Think Twice Before Selling Your Hospital Outreach Lab, Advises Laughman


Keith Laughman

Keith Laughman has more than 30 years' experience in the lab business, including a 15-year term as President of Mayo Medical Labs. Following Mayo, Laughman became President of AmeriPath Reference Services and Specialty Reference Laboratories. He later helped to create and served as President and CEO of the reference lab startup Med Fusion (Dallas/Fort Worth). Both AmeriPath and Med Fusion were later sold to Quest Diagnostics. Most recently, Laughman has been the Managing Partner at CareTinuum Consulting Partners (Scottsdale, AZ). Below we summarize his views on the hospital outreach laboratory market.

Are hospital outreach lab businesses still viable given the Medicare CLFS rate reductions from 2018-2020 and the potential for further rate cuts?
Absolutely. Outreach lab services leverage existing hospital infrastructure with excess capacity to achieve a low variable cost per test. As a result, attractive contribution margins have remained even after lowered fee schedules.

In addition, as healthcare systems transition to value-based reimbursement models, the value of the clinical lab's outreach program supporting the care of patients across the community's continuum of care will become even more attractive.

So why do some health systems choose to sell their outreach labs?
It is often because leadership is attracted to the one-time cash payment and because they view their outreach activity as a diversification strategy that can be sold without negatively impacting the healthcare system. Both reasons miss the bigger picture.

The attraction to the one-time payment ignores the annuity that lab outreach can provide well into the future. This annuity will increase going forward under value-based care and at-risk reimbursement.

In addition, there seems to be a lack of understanding that by selling the outreach volume, currently performed in the health system's existing labs, they are setting the stage for increased unit costs for their inpatient testing.

It will likely also put pressure on the current hospital length-of-stay (LOS) because certain tests that previously could be performed in an affordable manner in-house, courtesy of the additional outreach volume, may now need to be sent to a reference lab, likely delaying inpatient care and increasing inpatient LOS.

If a health system feels compelled to sell its outreach lab business, what are some of the quality or turnaround time goals that should be included in the sales contract?
Service levels and quality metrics that were in place before the outsourcing must remain unchanged for two key reasons.

Test turnaround time is key because delayed test results delay care and are a key factor in a patient's dissatisfaction with their physician office visits.

In addition, specimen quality metrics are essential because as samples leave the community, there is an increased chance that they will be lost or damaged. In addition, transport to a distant commercial lab (often out-of-state) can put specimen integrity at risk, leading to the need for a second sample collection. This can cause additional delays, canceled tests, and provider and patient frustration.

Don't third-party payers benefit from lower fee schedules after a national lab acquires a hospital outreach lab business?
Yes and no. Although insurers are likely to get lower test prices, the aggregate cost of care, which is also a payer's responsibility, can be expected to increase due to the previously identified delays and lack of alignment between testing protocols and local patient care pathways. So, while payers may benefit from lower test prices, these savings will be far outweighed by increased costs for the non-lab aspects of care due to delayed results, medical errors, increased hospital readmissions, etc.

It is important to remember that lab costs only represent 3% of healthcare expense in the U.S. while generating approximately 70% of the objective data in a patient's medical record and influencing the majority of their healthcare costs.

Some health system/commercial lab joint ventures (e.g., Sonora Quest) have been long-lasting and successful. What makes these arrangements successful?
These programs differ from most current outsourcing/acquisition arrangements because they are true joint ventures. Health systems, in these scenarios, often maintain a majority stake in the venture allowing for enhanced organizational alignment, improved visibility regarding service and quality, and a strong voice at the table.

Some health systems have chosen to bring their lab outreach services back in-house. What are the challenges they face in transitioning lab services back to the hospital?
Based on what I have heard and my experience when I have been asked to make recommendations, reestablishing a previously outsourced lab to a level capable of supporting inpatient and the local community's testing needs is a true lab service restart for the health system.

This restart effort is due to a reduction in the hospital lab's equipment and staff attrition that occurred through layoffs and voluntary departures, and low morale and trust issues among the remaining staff that occurred after the outsourcing arrangement. As a result, considerable investment and management effort are needed to reestablish a high-quality lab operation and service culture.

In my opinion, it is well worth this effort when the health system value generated by a high-functioning, integrated, and aligned laboratory is fully recognized. This is especially true when its role in reducing patient care costs outside of the lab are fully considered. We saw this clearly play out with many community labs' innovative responses to the challenges posed by the pandemic.

What's the most common misconception hospital CEOs and CFOs have about hospital outreach labs?
Some health system CEOs and CFOs tend to view their lab outreach activity as a diversification strategy that can be sold without negatively impacting the healthcare system.

From my perspective, the lab, including its outreach program, should be viewed as a core competency.

The level of lab service required for any healthcare system that intends to thrive in value-based care, including keeping pace with new advanced diagnostics, can only be provided in a cost-effective manner by having access to the needed resources at an optimized unit cost. As we know, unit cost optimization in the lab can only occur through growth. Health systems benefit from their outreach growth by receiving profitable incremental net revenue and reduced healthcare delivery costs.

In addition, lab outreach programs are becoming vital to maintaining an integrated patient-centric medical record as more patient care migrates into the ambulatory setting.

Genetic Test Spending Surged 37% In 2021 (*cont'd from page 1*)

The data analyzed covers Medicare CLFS payments made to labs and physicians, but not payments made to hospitals through fiscal intermediaries. Academic medical centers and hospital labs represent a tiny portion (<2%) of all Medicare fee-for-service claims for genetic testing.

The fastest-growing genetic tests in 2021 were CPT 81414, up 845% to $20.6 million in Part B allowed payments, and CPT 81413, up 785% to $20 million. Both codes are used to test for genes associated with cardiac ion channelopathies—rare genetic conditions that affect the electrical functioning of the heart. Labs that performed the highest volume of these two codes included Sonoran Desert Pathology Associates (Monterey Park, CA), Ft Buyer LLC. (Pearland, TX), which is no longer in business, and Infinity Diagnostics (Teterboro, NJ).

Other fast-growing genetic tests included CPT 81238, up 413% to $18.6 million in Part B allowed payments. CPT 81238 is used for Factor IX (e.g., hemophilia B) genetic analysis. Hemophilia B affects about 4,000 people in the U.S. and is usually diagnosed around birth or within the first two years of life. Labs that performed the highest volume of CPT 81238 on Medicare patients included Claro Scientific Labs (Lafayette, CO) as well as Sonoran Desert Pathology Associates and Infinity Diagnostics.

Medicare Part B carrier allowed payments were highest for CPT 81479 (Unlisted molecular pathology procedure) at $409 million in 2021, up 41% from $209 million in 2020. Labs that performed the highest volume of CPT 81479 include CareDx (Brisbane, CA), Guardant Health (Redwood City, CA) and Caris MPI (Phoenix, AZ).

Why Is It So Hard to Make a Profit in Genetic Testing?

Despite the high growth in genetic testing, bottom-line profits at genetic testing lab companies remain elusive. Fourteen publicly traded genetic testing lab companies recorded combined losses of $3.9 billion in the six months ended June 30, 2022. On page 6, *Laboratory Economics* examines the role that high sales and marketing expenses play in the financial difficulties at genetic testing labs. And on page 7, we provide an update on claims denial rates for genetic tests.

Latest Financial Results at Genetic Testing Lab Companies

Company	First-Half 2022	First-Half 2021	Accumulated Deficit Since Inception
Invitae Corp.	-$2,705,320,000	$24,294,000	-$4,428,168,000
Exact Sciences	-$347,000,000	-$208,076,000	-$2,988,520,000
Guardant Health	-352,660,000	-207,233,000	-1,360,485,000
Natera	-297,856,000	-181,697,000	-1,678,582,000
Sema4 Holdings	-162,638,000	-237,936,000	-738,079,000
DermTech	-59,688,000	-32,170,000	-266,052,000
Myriad Genetics	-34,600,000	-44,200,000	-288,800,000
Biodesix	-31,410,000	-18,363,000	-333,383,000
Castle Biosciences	-26,271,000	-13,071,000	-120,038,000
Veracyte	-23,993,000	-50,906,000	-381,150,000
Aspira Women's Health	-17,511,000	-12,994,000	-489,239,000
Interpace Biosciences	-6,186,000	-7,653,000	-233,245,000
Biocept Inc.*	-2,768,000	2,599,000	-269,119,000
Fulgent Genetics	165,516,000	280,503,000	-22,417,000
Total for 14 companies	-$3,902,385,000	-$706,903,000	-$13,597,277,000

*Biocept results are for the three months ended March 31, 2022.

Source: *Laboratory Economics* from Securities and Exchange Commission 10Q filings

The High Cost of Marketing New and Complex Genomic Tests

Unlike a complete blood count (CBC) or lipid panel, new and complex genomic tests require a huge investment in sales and marketing to educate physicians and stimulate test orders.

Sales and marketing budgets at genomic testing labs tend to be substantially higher than at routine clinical and anatomic pathology labs.

For example, six of the biggest routine clinical and anatomic pathology labs (e.g., Quest Diagnostics, Labcorp, BioReference Labs, etc.) spent an estimated 5% of their revenue on sales and marketing expenses in the first six months of 2022. In comparison, 14 genomic testing lab companies spent an estimated 38% of their revenue on sales and marketing expenses.

Among all publicly traded lab companies, Exact Sciences, which markets the Cologuard and Oncotype DX tests, is far and away the leader in terms of spending on sales and marketing. Exact spent $448 million on sales and marketing in first-half 2022—an amount equal to almost half of its total revenue over that period. Included in Exact's sales and marketing expense was $237 million for personnel (1,000+ sales reps), $122 million for direct marketing costs, including TV, print and online advertising, and $89 million in other expenses.

National Lab Companies	*Total Revenue, First-Half 2022*	*Sales & Marketing Expense, First-Half 2022*	*Sales & Marketing Expense % of Revenue*
Quest Diagnostics	$5,064,000,000	$227,880,000E	4.5%
Labcorp (lab testing division only)	4,709,500,000	211,927,500E	4.5%
Sonic Healthcare USA	735,800,000	36,790,000E	5.0%
Opko Health/BioReference Labs	473,402,000	71,010,300E	15.0%
NeoGenomics	242,241,000	33,370,000	13.8%
Enzo Biochem (lab testing division only)*	42,304,000	6,345,600E	15.0%
Total 6 National Lab Companies	$11,267,247,000	$587,323,400	5.2%
Genomic Testing Labs	*Total Revenue, First-Half 2022*	*Sales & Marketing Expense, First-Half 2022*	*Sales & Marketing Expense % of Revenue*
Exact Sciences	$1,008,211,000	$448,103,000	44.4%
Fulgent Genetics	445,609,000	18,806,000	4.2%
Natera	392,333,000	156,933,200E	40.0%
Myriad Genetics	344,200,000	86,050,000E	25.0%
Invitae	260,313,000	122,893,000	47.2%
Guardant Health	205,243,000	138,035,000	67.3%
Veracyte	140,647,000	47,755,000	34.0%
Sema4 Holdings	90,110,000	65,665,000	72.9%
Castle Biosciences	61,690,000	21,591,500E	35.0%
Biocept**	33,921,000	6,175,000	18.2%
Interpace Biosciences	19,728,000	5,190,000	26.3%
Biodesix	17,498,000	8,749,000E	50.0%
DermTech Inc.	7,951,000	30,444,000	382.9%
Aspira Women's Health	3,959,000	8,077,000	204.0%
Total for 14 Genomic Testing Labs	$3,031,413,000	$1,164,466,700	38.4%

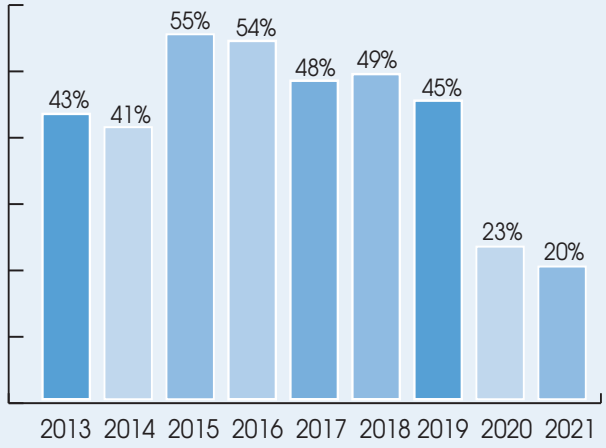
E=estimated based on each company's reported SG&A expense
*Enzo's results are for six months ended April 30, 2022
**Biocept's results are for six months ended March 31, 2022
Source: *Laboratory Economics* from latest 10Q financial reports

Genetic Test Claims Denial Rates Edge Lower

Twenty percent of genetic test claims were denied by Medicare Part B contractors in 2021, according to an exclusive analysis of the latest available Part B carrier data by *Laboratory Economics*. This is a substantial improvement from the historical denial rate for genetic test claims, which had averaged between 41% to 55% between 2013 and 2019. However, it is still more than double the average denial rates of 5-10% for routine clinical lab and anatomic pathology tests.

The cause of declining denial rates for genetic tests is not entirely clear. However, the U.S. Department of Justice's crackdown on genetic testing fraud, dubbed "Operation Double Helix," has put many fraudulent genetic testing labs out of business over the past three years. These labs were responsible for a high volume of claims denials and their removal has lowered the overall average denial rate. Operation Double Helix may have also "scared straight" many smaller genetic testing labs into more conservative Medicare billing practices, notes *Laboratory Economics*.

Medicare Part B Claims Denial Rates for Genetic Tests



Source: Medicare Part B aggregate denied claims vs. submitted claims for CPT codes 81105-81599, G0452 and Proprietary Laboratory Analysis (PLA) codes for 2013-2021

Medicare Part B Carrier Claims Denial Rates for Top 20 Genetic Tests for 2021

CPT	Short Description	Submitted Claims	Denied Claims	Percent Denied
81528	Cologuard colorectal cancer screening	511,657	13,855	2.7%
81479	Unlisted molecular pathology procedure	350,432	164,717	47.0%
81404	Molecular pathology procedure, Level 5	324,419	55,351	17.1%
81406	Molecular pathology procedure, Level 7	233,912	31,651	13.5%
81405	Molecular pathology procedure, Level 6	229,116	27,908	12.2%
G0452	Molecular pathology interpretation	202,533	37,272	18.4%
81408	Molecular pathology procedure, Level 9	168,948	27,410	16.2%
81403	Molecular pathology procedure, Level 4	133,852	11,836	8.8%
81401	Molecular pathology procedure, Level 2	120,677	13,472	11.2%
81407	Molecular pathology procedure, Level 8	107,766	11,071	10.3%
81162	BRCA1/BRCA2 full seq analysis & full dup/deletion analysis	68,176	17,186	25.2%
81291	MTHFR gene analysis	46,660	27,728	59.4%
81411	Aortic dysfunction/dilation gene analysis	39,702	4,408	11.1%
81413	Cardiac ion, genomic sequence analysis panel	39,562	5,283	13.4%
81241	Factor V gene analysis	37,874	31,385	82.9%
81238	F9 (coagulation factor IX), full gene sequence	34,691	3,628	10.5%
81240	Factor II gene analysis	32,639	26,645	81.6%
0097U	BioFire FilmArray Gastrointestinal Panel	31,643	8,917	28.2%
81490	Vectra DA rheumatoid arthritis test	31,633	1,661	5.3%
81286	FXN gene analysis	31,543	2,806	8.9%
Top 20 genetic tests		2,777,435	524,190	18.9%
Total for all Part B genetic tests		**3,608,848**	**725,378**	**20.1%**

Source: www.CodeMap.com and Medicare Part B national carrier data for 2021

SALSA Bill Gaining Momentum (*cont'd from page 1*)
The House version of SALSA was introduced by Rep. Bill Pascrell (D-NJ) on June 22, and now has 19 cosponsors. The latest to lend support have been Reps. Nanette Diaz Barragan (D-CA) and Tom Malinowski (D-NJ).

The Senate version of SALSA was introduced by Sen. Richard Burr (R-NC) and now has four cosponsors. The latest to sign on has been Debbie Stabenow (D-MI).

Most of Congress is currently focused on campaigning for the mid-term elections. Congress will return to Washington in mid-November. The hope is that SALSA can be inserted into a bigger year-end legislative package. SALSA has not yet been scored by the Congressional Budget Office. Congress will need to pay for the cost of SALSA by finding offsetting spending cuts or new tax revenue. This may be the biggest hurdle to getting SALSA passed into law.

FDA User Fee Reauthorization Does Not Include VALID Act

Legislation to reauthorize the FDA's user fee program passed Congress in late September but did not include a measure (aka the VALID Act) to give the agency authority over lab-developed tests (LDTs). The reauthorization, part of a larger measure to fund the government through the end of the year, initially included the VALID Act, but it was stripped from the final bill prior to passage.

From 2023 to 2027, the Medical Device User Fee Amendments (MDUFA) reauthorization allows the FDA to collect about $1.8 billion in user fees specifically for medical devices. In addition, it provides for annual hiring targets for new positions, requires the FDA to retain an independent contractor to conduct a MDUFA workforce data assessment and provides additional transparency in the form of new reporting to industry and the public on use of MDUFA resources.

VALID Act Not Dead Yet
Although removed from the larger spending package, the Verifying Accurate Leading-Edge IVCT Development (VALID) Act could still be attached to another bill. The measure would create a risk-based framework for in vitro clinical test (IVCT) regulation. High-risk tests would be required to go through pre-market review, but lower risk tests would go to market after passing through technological certification. LDTs currently in clinical use would be grandfathered in.

While the IVD community has been supportive of the legislation, the clinical laboratory community is opposed to the measure, arguing that LDTs are already regulated under the Clinical Laboratory Improvement Amendments (CLIA). The American Association for Clinical Chemistry (AACC) says it supports modernizing both the IVD and LDT regulatory processes through distinct approaches that optimize the regulation of each. AACC and other lab groups are working with the bill's sponsor to address their concerns about the measure, which is likely to come up for debate again before the end of the year.

The American Society for Microbiology, for example, has urged lawmakers to consider the vast differences between large commercial test developers and individual, nonprofit labs at academic and other medical centers that develop LDTs.

A spokesperson for the American Clinical Laboratory Association (ACLA) tells *Laboratory Economics* that the association is continuing to engage with the committee of jurisdiction about possible changes to the legislation.

"While the user fee package had long been considered to be a potential vehicle for additional provisions like the updated VALID Act, other legislation, like an end-of-year package, may be a viable path forward," according to ACLA.

Spotlight Interview with Bryan Health Laboratory Director Christina Nickel


Christina Nickel

Bryan Health, a health system that serves a four-state region (Nebraska, Iowa, Kansas and South Dakota), consists of six hospitals, a physician network, several urgent care locations, and an imaging and diagnostics center. The system has two full-service laboratories, plus a patient service center that offers on-demand testing. *Laboratory Economics* recently spoke with Laboratory Director Christina Nickel, MHA, MLS(ASCP), CPHQ.

How many employees does the laboratory department have?
About 170. We contract with pathologists, and we have one medical director for the east and west campus of Bryan Medical Center in Lincoln.

What are your test volumes? Are they growing?
Our volumes are growing. Last year we did 1.7 million tests. This year we are hoping for over 2 million. Hospital inpatient testing represents approximately 64% of test volume and outpatient is 18%. Nonpatient/outreach represent another 18% of volume, primarily for Bryan Physician Network (148 providers in 24 offices) and at our new Bryan Imaging and Diagnostic Center in Lincoln.

Are you having any supply chain issues?
We are having some random supply issues, such as specimen tubes. We have started sending out testing for gonorrhea and chlamydia because of supply problems. We send referred testing mostly to ARUP Labs.

Do you have particular areas of specialty?
We have consultation for transfusion medicine. We also have microbiology and do a lot of molecular testing. We don't do genetic testing. MALDI-TOF mass spectrometry is probably our biggest specialty area.

Do you plan to expand your test menu?
Yes, we are looking at flow cytometry and some other esoteric tests, such as electrophoresis. We are meeting with docs to ask what tests they wanted to see added to the menu.

Can you describe your new direct-to-consumer testing business?
We launched a DTC testing program in April 2021 under the brand name On-Demand Lab Tests. We anticipate volume of 33,000 billable tests in full-year 2022. The most popular On-Demand tests have been Covid testing (PCR at $50; antibody at $30) and rapid antigen at $25, as well as thyroid panel (TSH and T4 at $22) and A1c ($7).

Are your revenues growing?
Yes, but we are challenged with revenue integrity—a lot gets written off by the hospital. Billing is all done through the hospital. We would like to contract with someone to do lab billing so we can show we aren't just a cost center. We have had discussions with outside revenue cycle companies. The C-suite is supportive, but there is still some hesitation about bringing in outside services. They feel like they should be managing the collections, but they aren't able to focus on small dollars. They just don't have the bandwidth.

Are you having any problems with staffing?
Yes, we have issues with people getting sick, and it's just hard to find people. We have several openings for techs right now. Our local program that does the MLT program switched from quarters to semesters, which meant we had 18 months with no new graduates – that was hard,

especially during the pandemic. We are bringing in people with science degrees and training them on the job. We also have developed a career ladder, where someone can work as a lab assistant or a specimen processor and get enough training to become an MLT.

What are your greatest challenges?
The biggest challenge for us is the economy – hospitals were seeing lower volumes earlier in the year, but we're really struggling with our ED volumes, which are through the roof. We do have issues with payer mix—we don't have a lot of self-pay, and we're seeing less reimbursement on the dollar. The longer stays from some Covid patients really cost us. We don't get reimbursed more. Patient and testing volumes have been lower the last couple of months. I have never been told "no" on my capital budget requests, and this year I was told "no" on a number of things. Money is tight.

The other issue is burnout. We have been trying to support our frontline – they got incentives and pay increases, but the people on salary did not, and unfortunately, the folks on salary ended up covering a lot of shifts for illness, in addition to their regular hours to manage the department. It's exhausting.

What are your opportunities?
We are looking at improving lab test utilization, hoping to reduce expenses. The only way to make more money from inpatient work is to spend less.

We are implementing a program called CareSelect, which tracks orders and determines trends. It will allow us to follow up with the practices that are over-ordering.

We did one project with a pulmonology group that focused on their bronch lavage test. They were ordering a viral culture for the same sample that included PCR testing. That saved about $90,000 a year, improved the info they were getting to treat patients, improved turnaround times, and reduced length of stay. That's how I was able to get approval to start the CareSelect program.

PHE Extended; Rates for Covid Testing To Be Maintained Through 1/11/23

On October 13, the U.S. Department of Health and Human Services (HHS) extended the federal Public Health Emergency (PHE) through January 11, 2023. This is the 11th renewal of the PHE since its first declaration in January 2020. It means that the country will continue operating under pandemic-era policies until at least the next deadline: Jan. 11, 2023.

In late September, CMS issued notice that "When the Covid-19 PHE ends, payment rates [for high-throughput Covid PCR testing] will revert to those rates under the Clinical Laboratory Fee Schedule."

CMS first acted in April 2020 by increasing the Medicare payment to labs for high-throughput Covid-19 diagnostic tests (U0003 and U0004) from $51.31 to $100 per test. Effective January 1, 2021, CMS lowered the rate for these two codes to $75 but created an add-on payment code (U0005) for $25, if test results were provided within an average of two days or less.

The latest notice from CMS indicates that Medicare rates for high-throughput Covid-19 diagnostic tests (U0003 and U0004) will be lowered to a flat $51.31 in mid-January, assuming the PHE is lifted.

In addition, when the PHE is over, payment for specimen collection for Covid-19 testing will no longer be separately paid.

During the PHE, CMS has been paying labs specimen collection fees (G2023: $23.46) for Covid-19 testing provided to homebound Medicare recipients. Likewise, CMS has been paying labs a Covid-19 specimen collection fee (G2024: $25.46) for nursing home patients.

DOJ Continues Crack Down on Telefraud & Unnecessary Genetic Testing

A federal grand jury in Nashville on Aug. 5, 2022, returned a 40-count indictment charging eight people in a Medicare and Medicaid fraud conspiracy totaling more than $150 million in billed charges.

At the center of the indictment is Fadel Alshalabi, 54, of Waxhaw, NC. Alshalabi was originally charged in July 2021, with conspiracy and violation of the federal anti-kickback statute for his role in orchestrating a fraud related to genetic testing.

Alshalabi is the owner and Chief Executive of Crestar Labs LLC., which operates labs in Spring Hill, TN (dba Crestar Labs), Dallas (dba Martis Analytics and Diagnostics and CrestarDX) and Baltimore (dba Karemore Labs). The indictment alleges that Alshalabi and his labs entered into sham contracts with third-party marketers and paid kickbacks in exchange for patient samples.

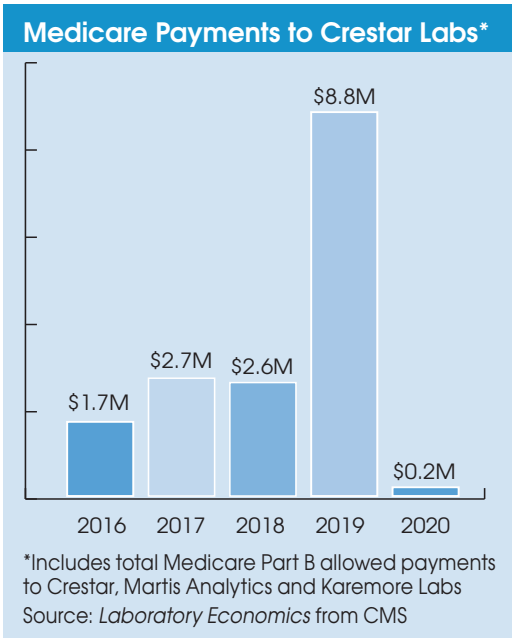
The Alleged Scheme

Third-party marketing firms targeted Medicare recipients through door-to-door marketing, attending senior citizen fairs and visiting nursing homes. They promised Medicare recipients free cancer tests and collected saliva samples. Test orders were then purportedly approved by telemedicine doctors who did not engage in the treatment of patients and often did not even speak with the patients for whom they ordered tests. Specimens were shipped to one of Alshalabi's labs for expensive genetic tests. Frequently, the patients or their treating physicians never received the results of the tests.

$16 Million in Medicare Payments

During the period of 2016 to July 2021, Alshalabi and his co-conspirators billed Medicare and Medicaid over $150 million. Alshalabi's three labs received Medicare payments totaling $16 million over the five-year period from 2016 to 2020.

Most of the alleged fraud seems to have occurred in 2019. Alshalabi's three labs received total Medicare payments of $8.8 million for testing performed on 2,787 beneficiaries in 2019; the average payment per beneficiary was $3,146. The most commonly performed tests included CPT 81408 (Molecular pathology procedure, Level 9; Medicare rate of $2,000), CPT 81242 (FANCC gene analysis; $37) and CPT 81317 (PMS2 gene analysis; $677).



Potential for Prison

The case is being investigated by the U.S. Department of Health and Human Services, Office of Inspector General, and the FBI. If convicted, Alshalabi faces up to 10 years in prison on the healthcare fraud and anti-kickback statute charges plus 10 years for money laundering charges.

Verify Orders, Review Relationships

To ensure compliance with federal and state laws, prior to performing testing, clinical labs should always verify that orders are properly completed and signed, advises Thomas Barnard, a lawyer with Baker Donelson (Baltimore). Labs should also be wary of arrangements that involve third-party marketers, says Barnard. "The government will closely scrutinize any relationship that appears to share in marketing, administration or funding," he adds.

Lab Stocks Down 55% Year To Date

Twenty-four lab stocks have dropped by an unweighted average of 55% year to date through October 14. In comparison, the S&P 500 Index has fallen by 25% so far this year. The top-performing lab stocks thus far in 2022 have been ProPhase Labs, up 45%; Psychemedics, down 11%; and Quest Diagnostics, down 27%. Labcorp is off 34% and Sonic Healthcare is also down 34%.

Company (ticker)	Stock Price 10/14/22	Stock Price 12/31/21	2022 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
ProPhase Labs (PRPH)	$10.41	$7.17	45%	$162	$131	1.2
Psychemedics (PMD)	6.22	$7.02	-11%	38	26	1.5
Quest Diagnostics (DGX)	126.11	173.01	-27%	18,620	10,582	1.8
Myriad Genetics (MYGN)	18.69	27.60	-32%	1,360	672	2.0
Labcorp (LH)	208.66	314.21	-34%	24,240	15,715	1.5
Enzo Biochem (ENZ)	2.12	3.21	-34%	94	107	0.9
Sonic Healthcare (SHL.AX)*	30.55	46.63	-34%	16,920	9,340	1.8
Castle Biosciences (CSTL)	22.02	42.87	-49%	374	110	3.4
Guardant Health (GH)	48.76	100.02	-51%	5,310	408	13.0
Natera (NTRA)	41.51	93.39	-56%	3,920	724	5.4
Exact Sciences (EXAS)	30.35	77.83	-61%	7,110	1,938	3.7
Veracyte (VCYT)	15.61	41.20	-62%	1,010	268	3.8
Fulgent Genetics (FLGT)	36.39	100.59	-64%	245	925	0.3
CareDx (CDNA)	16.45	45.48	-64%	616	315	2.0
Opko Health (OPK)	1.73	4.81	-64%	1,450	1,426	1.0
Interpace Biosciences (IDXG)	1.75	$7.47	-77%	69	40	1.7
Biocept (BIOC)	0.79	3.62	-78%	-1.7	63	NA
Biodesix (BDSX)	1.14	5.29	-78%	47	31	1.5
Aspira Women's Hlth (AWH)	0.38	1.77	-79%	29	8	3.9
DermTech Inc. (DMTK)	3.37	15.80	-79%	-47	14	NA
Exagen (XGN)	2.43	11.63	-79%	1	44	0.03
NeoGenomics (NEO)	7.05	34.12	-79%	1,100	489	2.2
Sema4 Holdings (SMFR)	0.86	4.46	-81%	133	191	0.7
Invitae (NVTA)	2.10	15.27	-86%	1,580	501	3.2
Unweighted Averages			-55%	$84,380	$44,071	1.9

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from YFinance and Seeking Alpha

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