

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Helio Genomics Rolling Out Liquid Biopsy Tests

Helio Genomics (Irvine, CA) introduced a blood-based test for liver cancer (brand name: HelioLiver) late last year. Fulgent Genetics (Irvine, CA) has the marketing rights to the laboratory-developed test (LDT) version of HelioLiver, which is being offered at a list price of \$649. The test combines the analysis of cell-free DNA methylation patterns in 77 sites from 28 genes along with three protein tumor markers to detect early-stage liver cancer in high-risk individuals.

Using its cfDNA methylation technology, Helio Genomics has also developed a blood-based screening test for colorectal cancer (HelioColon). HelioColon is expected to be launched as an LDT by year's end, according to Justin Chen Li, Chief Executive at Helio Genomics.

More details on page 7.

OIG Expands Scope Of Covid-19 Test Audits

At the end of May, the Office of Inspector General (OIG) announced plans to begin auditing labs that billed Medicare for the \$25 add-on payment for timely Covid-19 testing. OIG says it will review documentation for labs that billed the add-on CPT code U0005, which provides an extra \$25 for high-throughput Covid-19 tests that meet two-day turnaround times. The latest announcement expands the wide range of Covid-19 testing audits that the OIG is now pursuing.

Continued on page 4.

HRSA Fund Investigating Lab Claims For Covid Testing

The Health Resources and Services Administration (HRSA) uninsured program stopped accepting claims for Covid-19 testing effective March 23. Since its launch in early 2020, the HRSA fund has paid out a total of \$11.4 billion to more than 20,000 labs, hospitals and POLs for Covid-19 testing provided to uninsured individuals.

Now the HRSA program has begun making information requests to labs to identify overpayments and potential fraud. Multiple labs across the country have received information requests from HRSA and at least one lab has received a civil investigative demand (CID), a form of subpoena, from the U.S. Department of Justice, according to Elizabeth Sullivan, healthcare attorney at McDonald Hopkins (Cleveland, OH).

Continued on page 2.

CONTENTS

HEADLINE NEWS

Helio Genomics Rolling Out Liquid Biopsy Tests.....	1, 7
OIG Expands Scope of Covid-19 Test Audits	1, 4
HRSA Fund Investigating Lab Claims for Covid Testing.....	1-2

REGULATORY

Top 25 Labs Paid by HRSA Fund.....	3
California Lab Owners Indicted for \$214 Million Medicare Test Fraud	6

SPOTLIGHT INTERVIEWS

American Oncology Network's Curtiss McNair.....	5-6
Helio Genomics' Justin Chen Li.....	7

UBS CONFERENCE HIGHLIGHTS

Quest Diagnostics	8
Labcorp.....	8

MERGERS & ACQUISITIONS

Butterworth on Lab Acquisition Trends.....	9-10
Mana Capital to Acquire Cardio Diagnostics.....	10
Lab Acquisition Table.....	11

FINANCIAL

Lab Stocks Drop 47% YTD	12
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CODING & COMPLIANCE

CodeMap	13
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HRSA Fund Investigating Lab Claims For Covid Testing *(cont'd from page 1)*

The HRSA program was funded by federal legislation and designed to ensure that labs were paid when they provided Covid-19 testing to uninsured individuals. Reimbursement was set at Medicare rates and claims payment was administered by UnitedHealthcare.

Labs that billed the HRSA fund were required to agree to the program's terms and conditions, notes Sullivan. These terms require that "Providers must verify and attest that to the best of the provider's knowledge at the time of claim submission, the patient was uninsured at the time the services were provided."

In addition, the terms state that "any deliberate omission, misrepresentation, or falsification of any information contained in a request for reimbursement or future report may be punishable by criminal, civil, or administrative penalties, including, but not limited to revocation of Medicare billing privileges, exclusion from federal health care programs, and/or the imposition of fines, civil damages, and/or imprisonment."

HRSA Subject to False Claims Act and Whistleblower Action

Sullivan notes that the HRSA payments are subject to the False Claims Act and whistleblower action. Included with the Terms and Conditions is a "Fraud, Abuse and Waste" section which links directly to the HHS-OIG hotline page. On this page, HHS-OIG explains that "complaints from HHS employees, grantees or contractors about fraud, waste, abuse or mismanagement in HHS programs (whistleblower complaints)" will be investigated.

Responding to a HRSA Information Request

A thorough well-documented response to a HRSA inquiry should limit a lab's risk of a formal investigation, according to Sullivan. The response should show, among other things, that the lab had a process for verifying that an individual was uninsured prior to submitting a claim. Each lab should also be able to show that they have a self-auditing process in place and are refunding the HRSA program for erroneous test claims.

Which Labs Are At Risk?

Sullivan believes that HRSA has made information requests to labs that received high total payment amounts from the program as well as those that are statistical outliers in terms of locality, patient mix or claims volume.

For example, an estimated 9.2% of U.S. residents, or 30 million people, lacked health insurance when surveyed in 2021, according to the CDC's National Health Interview Survey. A lab that billed more than 20% of its overall Covid-19 test volume to the HRSA fund might trigger a formal investigation.

Top Labs Paid by the HRSA Fund

The HRSA fund has paid **Curative Inc.** (San Dimas, CA) a total of \$587 million for Covid-19 testing. Curative was founded by its CEO Fred Turner in March 2020. Curative acquired Korva-Labs Inc. (San Dimas, CA), a small CLIA-certified lab that had specialized in testing athletes for performance-enhancing drugs, in May 2020. Curative has transformed KorvaLabs into one of the nation's highest-volume Covid-19 testing labs.

Curative currently operates a network of over 17,000 collection sites across over 40 states and three CLIA-certified labs (CA, TX and Washington, DC). As of March 30, Curative reports that it has processed a total of more than 30 million Covid-19 tests from all payers.

Curative is a privately owned lab that is backed by the private equity firms Refactor Capital (Burlingame, CA) and DCVC (Palo Alto, CA) plus Chris Anderson, the owner of TED Talks.

Quest Diagnostics has been paid a total of \$519 million by the HRSA fund. This represents 8.5% of Quest's total revenue of \$6.1 billion from Covid-19 testing through March 31, 2022.

Fulgent Genetics has been reimbursed a total of \$505 million by the HRSA fund. This represents 32% of Fulgent's total estimated revenue of \$1.6 billion from Covid-19 testing through March 31, 2022.

Labcorp has received a total of \$486 million from the HRSA fund. This represents 8.1% of Labcorp's total estimated revenue of \$6 billion from Covid-19 testing through March 31, 2022.

CVS Pharmacy and its **MinuteClinic** division has been paid a total of \$365 million from the HRSA fund. The HRSA fund also paid CVS and MinuteClinic a total of \$471 million for vaccine administration plus another \$18 million for treatment of Covid-19 patients.

Top 25 Labs Paid by HRSA Fund

Laboratory	Location	Covid-19 Test Claims Paid by HRSA
Curative Labs	Washington, DC and San Dimas, CA	\$586,934,150
Quest Diagnostics	Nationwide	519,018,696
Fulgent Genetics	Temple City, CA	505,412,250
Labcorp	Burlington, NC	485,807,718
CVS MinuteClinic Diagnostic	Nationwide	365,311,711
Nomi Health	Salt Lake City, UT and Jacksonville, FL	334,978,320
Helix Opco LLC.	San Mateo, CA	227,335,100
Aegis Sciences Corp.	Nashville, TN	216,650,924
O'Hare Clinical Lab	Park Ridge, IL	187,153,096
Medstar Laboratory	Hillside, IL	164,969,065
Northshore Clinical Labs	Chicago, IL	164,871,700
Doctor's Clinical Lab	Rolling Meadows and Chicago, IL	153,496,686
AIT Laboratories	Denton, TX	115,417,101
GENETWORx Laboratory	Glen Allen, VA	105,192,696
MedLab2020	Orange, CA	103,327,865
Crestview Clinical Lab	Irvine and Porterville, CA	101,924,363
Infinity Diagnostic Labs	Teterboro, NJ	100,062,374
Dart Medical Laboratory	Brooklyn, NY	95,231,278
BioReference Laboratory	Elmwood Park, NJ	94,222,072
Centers Laboratory	Bronx, NY and Cedar Knolls, NJ	92,646,704
Infinity BiologiX	Piscataway, NJ	91,743,200
Dx Solutions LLC.	Nicholasville, KY	90,522,117
Signal Diagnostics	Los Angeles, CA	83,219,896
Lab Elite	Chicago, IL	77,229,981
AccessDx Laboratory	Houston, TX	55,880,784
Total, Top 25 Labs		\$5,118,559,847
Total, All 20,000+ Labs		\$11,362,068,129

Source: *Laboratory Economics* from <https://data.cdc.gov/Administrative/Claims-Reimbursement-to-Health-Care-Providers-and-/rksx-33p3>

OIG Expands Audits Of Covid-19 Testing *(cont'd from page 1)*

The OIG is tasked with fighting fraud and abuse within Department of Health and Human Services (HHS) programs including Medicare and Medicaid.

During the first two years of the Pandemic, the Medicare program focused on ensuring that labs had the resources to meet the demand for massive Covid-19 testing. This included generous reimbursement rates and a waiver of physician-authorization requirements for Covid-19 testing.

The Medicare Part B program spent \$1.5 billion on Covid-19 testing in 2020 alone. *Laboratory Economics* estimates that total Medicare Part B spending on Covid-19 testing to date now totals more than \$5 billion.

With the Pandemic seemingly near an end, the OIG has initiated a series of audits of Medicare Part B lab services that “focus on aberrant billing of Covid-19 testing.”

The OIG audits are concentrated on several key areas:

- **Were Covid-19 tests eligible for Medicare payment?** Medicare covers tests for beneficiaries who either have signs or symptoms of Covid-19 or have a known or suspected exposure to Covid-19. The patient record should show that the patient was reporting symptoms and/or had been exposed to Covid-19. Medicare does not cover non-diagnostic tests, such as employee screening programs or public health surveillance.
- **Was it appropriate to bill for specimen collection and travel?** If a lab travels to and collects samples for Covid-19 tests for homebound or nursing home patients, Medicare may be billed for travel and specimen collection. However, If the test is performed in the same location that the test sample is collected, Medicare will not pay for any travel expenses. Labs billing Medicare for specimen collection related travel are required to have logs supporting the mileage traveled.
- **Were Add-On Tests Medically Necessary?** Under revised rules finalized in September 2020, a beneficiary may receive Medicare coverage for one Covid-19 and related test without the order of a physician or other health practitioner, but then must receive a physician order for any additional testing. OIG has concerns that these relaxed rules led to potentially fraudulent billing for add-on tests for respiratory panels, allergy tests and genetic tests.
- **Was the \$25 Add-On Fee Used Appropriately?** Effective January 2021, CMS instituted a rule to incentivize labs to turn around Covid-19 test results faster. This was done by lowering the Medicare rate for high-throughput Covid-19 PCR tests from \$100 to \$75. CMS established a new code (CPT U0005) that would pay labs \$25 if 1) the Covid-19 test was completed within two calendar days and 2) the majority of all their Covid-19 high-throughput tests (from all payers) were completed in two days in the previous month. OIG plans to review labs supporting documentation to determine if the criteria for billing the add-on payment was met.

As *Laboratory Economics* has noted, more than 60,000 new CLIA labs, including 3,232 moderate- or high-complexity labs, were formed in 2020 and 2021 (see *LE*, May 2022). “A lot of opportunistic individuals with no experience got into the lab business and were faced with overwhelming Covid test volumes. It created the perfect storm,” according to Elizabeth Sullivan from McDonald Hopkins. “I’m hoping the regulators will show some leniency toward those labs that can demonstrate they operated in good faith.”

Spotlight Interview: American Oncology Network's Curtiss McNair

American Oncology Network LLC (AON) is a physician-owned network of oncology practices with a core lab in Fort Myers, Florida. AON was formed by Florida Cancer Specialists & Research Institute in 2018 with the goal of acquiring oncology/hematology practices outside of Florida [see *LE*, October 2019]. The AON Pathology Lab serves AON's 107 physicians and 85 nurse practitioners and physician assistants in 16 states. AON provides care for 100,000 unique patients per year. *Laboratory Economics* recently spoke with Curtiss McNair, Vice President, Laboratory Services, at AON. McNair joined AON in April 2021. He was previously the East Division Laboratory Director at BayCare Health System (Clearwater, FL) and Senior Laboratory Manager at DaVita Labs (DeLand, FL).



Curtiss McNair

How many people are employed by the AON Pathology Lab?

There are about 25 employees in the core lab and some lab techs who float around to different clinics in different states as quality supervisors. Because we are highly focused on hematopathology, we have five hematopathologists and one surgical pathologist. Our Medical Directors are Wilfredo Blasini, MD, and Ryan Olson, MD.

What kinds of cancer testing does the lab perform?

We focus on lymphoid and myeloma neoplasms. All of the pathology tests from AON practices are sent to our core lab in Fort Myers.

Who does AON use for its reference lab?

All of our next-generation sequencing goes to Genomic Testing Cooperative (Irvine, CA). NeoGenomics is our primary reference lab.

What were AON Pathology Lab's volumes last year?

In 2021, we performed about 3.2 million clinical lab tests, including about 1,500 bone marrow tests, 1,100 flow cytometry tests and 1,100 FISH cases. For the first quarter of 2022, we are up about 27% for flow cytometry and 16% in bone marrow testing.

When our network grows, our pathology volume grows. Because we are a "physician-owned" laboratory and not a reference lab, we can only provide pathology services to our own AON clinics and providers. Over the past 18 months, the AON network has grown from 88 physicians to 107 physicians.

How does your core lab improve oncology care?

Our pathologists have 100% access to medical records of AON patients, and our oncologists have 100% access to our pathologists. This synergy provides the most personalized care possible.

Are there any new tests you have recently added to your menu?

We recently brought in-house a cancer gene mutation panel called MPN (myeloproliferative neoplasms). We had previously sent out thousands of these tests per year.

Our MPN panel is based on HemeScreen technology developed by Precipio Inc. (New Haven, CT). HemeScreen includes four panels: MPN, AML, Anemia and CLL. We went live with the MPN panel in November of last year, and we are working toward going live with the other panels.

We would like to bring more NGS testing in-house, but right now we're focusing on going live with the new panels from Precipio.

Do you use digital pathology or artificial intelligence in the lab?

We don't currently use digital pathology or AI, but we are looking at getting into AI for histology.

Do you offer Covid-19 testing?

We test for Covid IgG antibody on the Vitros 3600 (Ortho Clinical Diagnostics).

Are you experiencing shortages in laboratory personnel?

Like most industries, we too are experiencing personnel shortages. It's been tough to find staff for the small labs within our local practices, as well as generalists to work in the core laboratory in Fort Myers. We've seen many hospital labs double the hourly rate they pay for some positions that are highly technical and difficult to find. We try to combat these shortages by ensuring that staff members are cross-trained among different departments and analyzers, and by treating our employees well and compensating them fairly.

California Lab Owners Indicted For \$214 Million Medicare Test Fraud

The U.S. Department of Justice has indicted Imran Shams and Lourdes Navarro, both 63 and owners of Matias Clinical Laboratory (Baldwin Park, CA), for their alleged roles in a \$214 million Medicare billing fraud scheme.

The DOJ says that the married couple arranged for Matias to pay kickbacks to third-party marketers in exchange for specimens and test orders. Matias would then perform testing and pay the marketers a percentage of the reimbursements it received, including from the Medicare program.

Matias (dba Health Care Providers Lab) billed the Medicare program for \$214 million of lab test claims between August 2018 and March 2022. This amount included \$143 million of fraudulent claims for Covid-19 and respiratory pathogen tests that were submitted without regard to medical necessity, according to the DOJ. As a result of these alleged fraudulent claims, Matias received total Medicare payments of \$29 million, including \$18 million for Covid-19 and respiratory pathogen tests.

The DOJ alleges that Shams and Navarro used the Pandemic for their own financial gain by bundling Covid-19 tests with more expensive respiratory testing, irrespective of whether the testing was medically necessary.

DOJ says that Shams and Navarro transferred money from Matias to shell companies, Nurse Plus and Proworx, to launder money. The pair then withdrew this money to fund real estate transactions and to purchase luxury items and goods and services for their personal use.

Furthermore, the DOJ says that Shams fraudulently concealed his role at Matias and his prior criminal convictions. Shams had been excluded from all participation in Medicare since being convicted in 2000 for felony grand theft related to Medicare and Medi-Cal billing fraud.

Separately, *Laboratory Economics* notes that the HRSA uninsured program has paid Matias/Health Care Providers Lab \$2 million for Covid-19 testing plus another \$15.9 million for treating Covid-19 patients.

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Helio Genomics Rolling Out Liquid Biopsy Tests *(cont'd from page 1)*

The DNA methylation pattern analysis technology used by Helio Genomics to detect cancer was initially developed at the Institute of Genomic Medicine at the University of California (San Diego). In 2014, another team, led by Shu Li, PhD, licensed this technology and formed the Laboratory for Advanced Medicine (now named Helio Genomics) to commercialize methylation cancer detection testing and bring it to the clinical market. Below we summarize our interview with Justin Chen Li, Chief Executive of Helio Genomics.



Justin Chen Li

How much money has Helio Genomics raised?

We've raised a total of \$151 million to date from three rounds of financing (A, B and B1). Investors include Samsung Securities and Fulgent Genetics. Our Executive Chairman Shu Li also owns a stake in the company.

Can you describe your partnership with Fulgent Genetics?

Fulgent invested \$20 million in our Series B financing in July 2021.

In addition, Fulgent has exclusive commercial rights to market the laboratory-developed-test (LDT) version of our HelioLiver blood test in the U.S. and Canada. Fulgent began marketing HelioLiver to gastroenterologists and hepatologists in December 2021. Fulgent processes and performs the test at its CLIA laboratory in Temple City, CA.

What's the intended market for HelioLiver?

It's a surveillance test for the 4.5 million people in the U.S. who are at high risk of liver cancer, including those with pre-existing cirrhosis, chronic hepatitis B or hepatitis C, excessive alcohol use, and nonalcoholic fatty liver disease.

The current surveillance practice involves an ultrasound every six months. But ultrasound readings are highly subjective, depending on the technician and radiologist, and have been shown to have a sensitivity of less than 50% for picking up early-stage (I & II) liver cancer.

What's the specificity and sensitivity for HelioLiver?

Validation study data recently published in *Hepatology Communications*, the peer-reviewed journal of the American Association for the Study of Liver Diseases, showed that HelioLiver had high specificity (91%) and high sensitivity (76%) in detecting early-stage liver cancer.

If caught at an early stage, liver cancer treatment options include ablation therapy (destroy small tumors without having to surgically remove them) or surgical resection (removal of the tumor with surgery).

Does HelioLiver have a CPT code and reimbursement?

The test was recently approved to receive a proprietary laboratory analysis (PLA) code and should get a Medicare rate by the end of the year.

Any plans for an FDA-cleared kit for HelioLiver?

HelioLiver has been granted the breakthrough device designation by the FDA and we plan to submit for clearance by the end of the year.

Is Helio Genomics developing other liquid-biopsy tests?

Yes. We're using DNA methylation pattern analysis technology for a colon cancer screening test. An LDT version of HelioColon should be on the clinical market by year's end.

We're also developing a lung cancer test to rule out the need for a biopsy for indeterminate nodules. Blood tests for breast and bladder cancer are also in the pipeline.

Quest and Labcorp at UBS Global Healthcare Conference

The top executives at Quest Diagnostics and Labcorp participated in Q&A sessions at the UBS Global Healthcare Conference 2022 in New York City on May 24. Here are some highlights.

Quest Diagnostics was represented by **Steve Rusckowski**, Chairman and CEO, and **James Davis**, CEO-elect and EVP, General Diagnostics. Rusckowski is retiring from his role as CEO at the end of October and Davis is taking his place.

Quest generated \$5.5 billion from Covid testing over the past two years “and generated more cash than we would have expected,” according to Rusckowski. Quest is investing its free cash into advanced diagnostics and consumer-initiated testing. In particular, Rusckowski noted that direct-to-consumer testing represented \$70 million of revenue (including Covid testing) for Quest in 2021. This is expected to grow to \$250 million by 2025 (excluding Covid). “The game is you’ve got to get the eyeballs to the site, give them a superb client experience [and] get the repeat business so that you’re paying less for paid searches [advertising],” noted Davis.

Rusckowski said non-Covid test volumes had mostly recovered back to prepandemic levels. Some areas of weakness include New York City, which is still down around 15%. In addition, drugs-of-abuse testing volumes remain depressed.

In terms of inflation, Davis noted that Quest is different from health systems since it doesn’t employ the jobs that are experiencing the highest degree of wage pressure [nurses]. Quest’s biggest area of employee shortages is in specimen processing. Quest employs about 7,500 specimen processors. They are paid an average of between \$15 and \$20 per hour and represent about 10% of Quest’s total wage spending. Overall, Davis expects Quest’s wage spending to grow by 2-3% this year.

Davis said that 80% of Quest’s supply spending was under long-term contracts. “I can assure you that those long-term contracts with our suppliers don’t contemplate price increases for reagents.” When instrument and reagent contracts come up for renewal, they go out for competitive bid which generally results in lower prices, according to Davis.

Quest will see a \$7-8 million increase in fuel spending this year, mostly related to increased gas prices spent on courier vehicles. The company’s 25

aircraft are mostly fuel-efficient small turbo-prop planes, said Davis.

Quest’s transition to digital pathology is in the pilot phase, according to Davis. “Over the next 10 years, we’ll be 100% digital in this company. Anywhere you go in the laboratory and you still see people looking under the microscope. It’s an opportunity for automation and the use of artificial intelligence.”

“We are seeing a lot of inflationary costs in that business [clinical trials drug development], but it takes time to get the costs out. We are working diligently and we’re making huge progress to get some of the costs out....Inflation hits you right away. It takes time to get some of the [offsetting] costs out,” said **Adam Schechter**, Chairman and CEO of **Labcorp**.

“I think everyone in the world is facing some level of [laboratory] staffing issues....In general, a lot of our staffing issues have come at the entry levels whether it be in drug development or in diagnostics.” The toughest positions to fill are in the front end of diagnostics, including laboratory technicians, phlebotomists and couriers, according to Schechter.

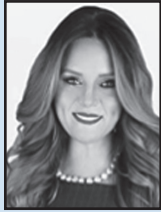
“My biggest surprise since I’ve taken this job, outside of Covid, has been how long it takes to get hospital deals done [both acquisitions and lab management agreements]....We finally, I believe, cracked the code on that,” said Schechter. Recent Labcorp hospital deals have included Ascension, Prisma Health, Franciscan Hospitals and AtlantiCare. “It took years for some of those to happen, but the pipeline there remains strong.”

Regarding future acquisitions, Schechter said, “I think there’s a lot of things to look at. The hospital deals are a bit easier than before due to the pressure that hospitals are feeling and what they’ve learned from trying to manage their own labs through Covid.”

Labcorp has performed a total of 74 million Covid-19 tests since the start of the Pandemic. Schechter is anticipating that the Public Health Emergency, and associated Covid-19 reimbursement rates, will remain in effect until the end of the year.

Butterworth's Views On Today's Laboratory Acquisition Trends

Melissa Butterworth co-founded, along with Dan Lucky, the M&A consulting firm Advanced Strategic Partners (ASP-Miami, FL) in 2007. Over the last 15 years, ASP has advised and/or closed deals with more than 80 clinical, anatomic, molecular and hospital outreach labs. Total deals closed have been valued at more than \$1.8 billion. Butterworth is also author of the newly updated book *The End Game: The Laboratory Owner's Exit Strategy*. We last spoke with Butterworth in late 2019 (see *LE*, October 2019). Below we summarize Butterworth's thoughts on several key topics in today's laboratory M&A market.



Melissa
Butterworth

What's the biggest mistake that lab owners make when selling their lab company?

Negotiating with only one buyer. Not seeking bids from multiple potential buyers almost guarantees you will not get the maximum value for your laboratory. We have managed bidding processes and received bids ranging from 1x to 3x annual revenue for the same laboratory. Buyers are willing to pay more for labs that can be consolidated into their existing infrastructure.

Who are the most active buyers?

Today, the most active buyers are Labcorp, Quest, Sonic, PathGroup, NeoGenomics and Eurofins Scientific. There is also a group of 15-20 opportunistic labs and private equity firms that are potential buyers.

What has changed in the lab M&A market since we last spoke?

The bigger labs have become more inclined to structure their acquisitions as asset purchase agreements rather than stock transactions. This allows the buyer to purchase certain assets, such as a client list and patient service centers, while avoiding most liabilities and any potential compliance risks from the selling lab.

Asset purchase agreements also tend to close much quicker. Because the exposure to unknown liabilities is limited, the buyer typically needs to expend less time and money on conducting due diligence.

Under an asset purchase, the seller often keeps ownership of their lab company's insurance contracts. These contracts have little value to the big labs because they already have contracts with nearly every insurance company.

Most insurance contracts are transferable and can be sold through a separate transaction to another lab. New Covid testing labs that have sprung up over the past two years are looking to diversify their test menus and need these contracts. It can take 9-12 months to file for and gain in-network status and some insurers have closed their networks completely.

How much are transferable insurance contracts worth?

Right now, there are multiple lab buyers seeking in-network payer coverage, so demand is high. The exact value depends on which payers are contracted and at what rates. We've seen some lab owners sell select assets to a big lab and then separately sell and transfer their insurance contracts to a smaller lab for as much as a few million dollars.

How are buyers valuing Covid testing revenue?

Buyers are placing very little to no value on Covid testing. They are projecting declining volume and reimbursement rate reductions for Covid testing as the pandemic winds down.

What are the multiples currently being paid for labs?

Molecular and genetic testing labs have seen as high as 4-6x their annual revenue, if a strategic buyer folds the testing into their existing infrastructure. We have seen anatomic pathology labs being valued at roughly 1.2-2x their annual revenue, hospital outreach at 1.3-2x, and clinical labs at 1-3.3x. These multiples exclude Covid-19 testing revenue.

What about contingent consideration (i.e., earnouts)?

I am not a fan of "earnouts" because they can be extremely subjective. We have structured earnouts in

deals where the lab owners have recently added substantial amounts of new business and want to get credit for it post-sale.

Roughly 20% of the deals we have helped negotiate have some component of an earnout, but only about 10% of those wound up getting paid some or all of the earnout amount.

It's best to base earnout payments on something the seller has some control over such as the volume of CPT codes or top line revenue. Don't base it on profitability because the buyer may factor in subjective expenses.

What are the average transaction costs associated with selling a lab?

An owner should expect that between 8% and 12% of the selling price will go to outside advisors, including accountants, consultants and lawyers. Another 2-3% is generally paid out as bonuses to key employees, including the CEO, CFO, COO, etc.

What turns off a potential buyer?

Buyers are wary of any hint of legal, billing or compliance risk. Claims billed to the HRSA Covid-19 Uninsured Program are getting scrutiny. Potential buyers are checking random samples of Covid-19 test claims to see if they were submitted properly (see pages 1-3).

What kind of layoffs can be expected after a lab is sold?

Lab assets sold and integrated into a national lab typically see layoffs in the range of 20% to 40% of their staff.

Mana Capital To Acquire Cardio Diagnostics For \$75 Million

Mana Capital Acquisition Corp. (Dover, DE) has agreed to acquire Cardio Diagnostics at an enterprise value of \$75 million. Cardio Diagnostics sells a proprietary heart health test (brand name: Epi + Gen CHD) direct to consumers.

Mana Capital is a blank check company, known as a special purpose acquisition company (SPAC), with one employee. Mana Capital raised gross proceeds of \$65 million from an IPO late last year. It doesn't have a business model of its own other than to make acquisitions.

Upon closing of the transaction, expected by August 26, Mana will be renamed Cardio Diagnostics Holdings and will be listed on the Nasdaq under a new ticker symbol "CDIO."

The technology behind Cardio Diagnostics' Epi + Gen CHD test was created at the University of Iowa by company founders Meesha Dogan, PhD, and Rob Philibert, MD, PhD. Following the transaction, Dogan, age 33, will be CEO at the combined company and Philibert, 60, will be President and Chief Medical Officer. As of May 25, Cardio had four full-time employees and one part-time employee.

Epi + Gen CHD is a laboratory-developed test for assessing an individual's risk of a heart attack within three years. The test panel consists of three DNA methylation (epigenetic) and five SNP (genetic) biomarkers. The test is being sold directly to consumers for \$199 through a partnership with the telemedicine firm InTeleLabs (San Diego, CA). InTeleLabs operates the website elicity.health.

Consumers order the test online and are shipped a finger-prick blood collection kit. Cardio Diagnostics has contracted with MOgene (St Louis, MO), a CLIA-certified lab, to process samples and perform testing. Test results are available 7-10 business days after each sample is received by the lab.

Cardio Diagnostics has not generated significant revenue since inception in 2017 and has an accumulated deficit of \$1.5 million as March 31, 2022. The company projects it will generate total revenue of \$1 million in 2022 with an increase to \$5 million in 2023.

Laboratory Acquisition Summary (latest 18 months through June 15, 2022)

Date	Buyer	Target/Location	Purchase Price*	Acquired Revenue	Price/Revenue
Pending	Mana Capital	Cardio Diagnostics (Chicago, IL)	\$75	\$1	75.0
Pending	Labcorp	Prisma Health's clinical lab outreach (Greenville, SC)	NA	NA	NA
Pending	Labcorp	Ascension Health clinical lab outreach (St Louis, MO)	400	150	2.7
May-22	Innovative Gx Laboratories	Nationwide Laboratory Services (insurance contracts only)	NA	NA	NA
May-22	LetsGetChecked	Veritas Genetics (Danvers, MA)	NA	NA	NA
May-22	EmeritusDX	Freedom Pathology Partners (Conshohocken, PA)	NA	NA	NA
May-22	GTCR	PathGroup (Brentwood, TN)	NA	>500E	NA
May-22	Fulgent Genetics	Inform Diagnostics (Irving, TX)	170	120E	1.4
May-22	Labcorp	AtlantiCare's clinical lab outreach (southern NJ)	NA	NA	NA
Apr-22	Convergent Laboratories	First Path Laboratory (Pompano Beach, FL)	NA	NA	NA
Apr-22	Sema4	GeneDx (Gaithersburg, MD)	472	130	3.6
Apr-22	Castle Biosciences	AltheaDx (San Diego, CA)	140	3	46.7
Apr-22	MAWD Pathology	Boyce & Bynum Pathology Professional Services (Columbia, MO)	NA	NA	NA
Mar-22	Diversified Medical	Dynasty Medical Laboratory (Hurricane, UT)	NA	NA	NA
Feb-22	Labcorp	Personal Genome Diagnostics (Baltimore, MD)	545	40	13.6
Jan-22	PathGroup	Pathology Consultants (Greenville, SC)	NA	NA	NA
Jan-22	Exact Sciences	PreventionGenetics (Marshfield, WI)	190	36	5.3
Dec-21	Sonic Healthcare	ProPath (Dallas, TX)	NA	110	NA
Dec-21	Northwest Pathology	Progenity's Avero Diagnostics (Irving, TX)	10.9	40	0.3
Dec-21	Castle Biosciences	Cernostics (Pittsburgh, PA)	80	NA	NA
Dec-21	Quest Diagnostics	Labtech Diagnostics (Anderson, SC)	85	NA	NA
Nov-21	EKF Diagnostics	Advanced Diagnostic Laboratory (San Antonio, TX)	10	12	0.8
Oct-21	Versant Diagnostics	Alliance Pathology Consultants (Elk Grove Village, IL)	NA	NA	NA
Oct-21	Versant Diagnostics	Addison Central Pathology (Chicago, IL)	NA	NA	NA
Sep-21	Labcorp	Myriad's Vectra autoimmune testing business (Salt Lake City, UT)	150	35	4.3
Aug-21	Fulgent Genetics	CSI Laboratories (Alpharetta, GA)	52	43E	1.2
Aug-21	ProPhase Labs	Nebula Genomics (San Francisco, CA)	14.6	NA	NA
Aug-21	PathGroup	DermLab (Birmingham, AL)	NA	NA	NA
Aug-21	OPKO/BioReference	Roche's Ariosa U.S. prenatal testing business	NA	NA	NA
Aug-21	Quest Diagnostics	Nationwide Laboratory Services (Boca Raton, FL)	26E	NA	NA
Aug-21	Veracyte Inc.	HalioDx (Marseille, France and Richmond, VA)	321	30	10.7
Aug-21	Ariana Sciences	American Pathology Partners (North Carolina and Florida)	NA	NA	NA
Jul-21	Eurofins Scientific	DNA Diagnostics Center (Fairfield, OH)	NA	55	NA
Jul-21	Labcorp	North Memorial Health clinical lab outreach (Robbinsdale, MN)	NA	NA	NA
Jul-21	Labcorp	OmniSeq (Buffalo, NY)	NA	NA	NA
Jul-21	PathAI	Poplar Healthcare (Memphis, TN)	NA	NA	NA
Jun-21	Labcorp	American Pathology Partners (Colorado and Texas)	NA	NA	NA
Jun-21	NeoGenomics	Inivata (Research Triangle Park, NC & UK)	415	NA	NA
Jun-21	Apollo Medical Holdings	Sun Clinical Laboratories (El Monte, CA)	4	NA	NA
Jun-21	PathGroup	Skin Diagnostics Group (Birmingham, AL)	NA	NA	NA
Jun-21	Quest Diagnostics	Mercy Health clinical lab outreach (AR, KS, MO, OK)	225	NA	NA
May-21	Castle Biosciences	Myriad's MyPath Laboratory (Salt Lake City, UT)	32.5	10E	3.3
Apr-21	Augustus Labs	Evergreen-Sheridan Laboratories (Palos Heights, IL)	NA	NA	NA
Apr-21	DiamiR	Interpace Biosciences (Connecticut lab)	NA	NA	NA
Mar-21	Veracyte Inc.	Decipher Biosciences (San Diego, CA)	595	40	14.9
Mar-21	Bio-Techne Corp.	Asuragen (Austin, TX)	320	30	10.7
Mar-21	C2i Genomics	QNA Dx (Cambridge, MA)	NA	NA	NA
Jan-21	ChristianaCare	Delaware Clinical & Laboratory Physicians (Newark, DE)	NA	NA	NA

Source: *Laboratory Economics*

Lab Stocks Down 47% Year To Date

Twenty-four lab stocks have dropped by an unweighted average of 47% year to date through June 10. 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 54%; Psychomedics, down 8%; and Quest Diagnostics, down 24%. Labcorp is down 29% and Sonic Healthcare is off 28%.

Company (ticker)	Stock Price 6/10/22	Stock Price 12/31/21	2022 Price Change	Enterprise Value (\$ millions)	Enterprise Value/Revenue	Enterprise Value/EBITDA
ProPhase Labs (PRPH)	\$11.01	\$7.17	54%	\$163	1.5	5.7
Psychomedics (PMD)	6.49	\$7.02	-8%	39	1.5	16.7
Quest Diagnostics (DGX)	131.25	173.01	-24%	19,900	1.9	7.4
Enzo Biochem (ENZ)	2.39	3.21	-26%	98	0.9	NA
Sonic Healthcare (SHL.AX)*	33.74	46.63	-28%	19,990	2.2	8.4
Labcorp (LH)	224.57	314.21	-29%	26,410	1.7	7.2
Myriad Genetics (MYGN)	17.10	27.60	-38%	1,150	1.7	NA
Exagen (XGN)	6.24	11.63	-46%	54	1.1	NA
Opko Health (OPK)	2.56	4.81	-47%	2,050	1.3	27.8
Exact Sciences (EXAS)	41.23	77.83	-47%	9,430	5.1	NA
CareDx (CDNA)	22.70	45.48	-50%	999	3.2	NA
Fulgent Genetics (FLGT)	49.92	100.59	-50%	501	0.5	0.8
Castle Biosciences (CSTL)	19.43	42.87	-55%	248	2.5	NA
Interpace Biosciences (IDXG)	3.26	\$7.47	-56%	72	1.7	NA
Veracyte (VCYT)	16.33	41.20	-60%	1,100	4.4	NA
Biocept (BIOC)	1.36	3.62	-62%	9	0.1	NA
Guardant Health (GH)	37.50	100.02	-63%	3,800	9.7	NA
Natera (NTRA)	34.20	93.39	-63%	3,090	4.6	NA
Biosesix (BDSX)	1.91	5.29	-64%	79	2.5	NA
Sema4 Holdings (SMFR)	1.59	4.46	-64%	446	2.2	NA
Aspira Women's Hlth (AWH)	0.59	1.77	-66%	46	6.4	NA
DermTech Inc. (DMTK)	5.17	15.80	-67%	3	0.2	NA
NeoGenomics (NEO)	7.71	34.12	-77%	1,140	2.4	NA
Invitae (NVTA)	2.42	15.27	-84%	1,460	3.0	NA
Unweighted Averages			-47%	\$92,277	2.6	10.6

*Sonic Healthcare's figures are in Australian dollars

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