

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

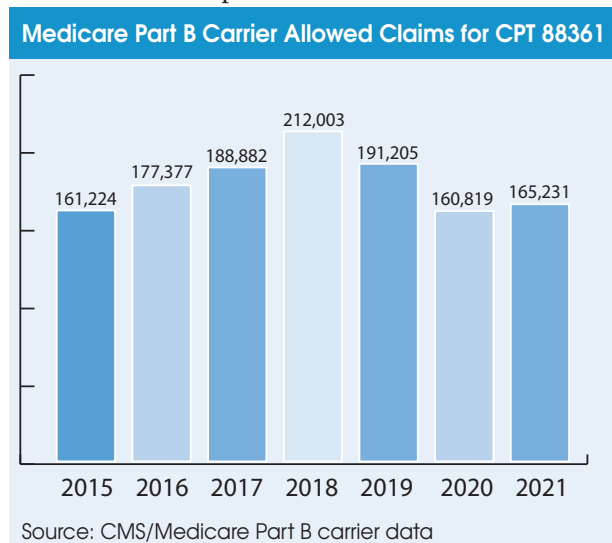
Capital Digestive Care Opens New Full-Service Lab

Capital Digestive Care (Silver Spring, MD), which is one of the largest gastroenterology practices in the nation, has opened a new 22,000-square-foot full-service laboratory. The lab has 60 employees, including 10 pathologists employed by the practice. It will serve CDC's 140 gastroenterologists at more than 25 office and outpatient surgery centers in Maryland, Virginia and Washington, DC.

Full details on page 6.

Did Digital Pathology Utilization Increase During The Pandemic?

The conventional wisdom says that digital pathology use surged as a result of the pandemic. However, Medicare data for CPT 88361 (computer-assisted IHC for breast cancer) tells a different story. The volume of Medicare Part B allowed claims for 88361 declined by 16% to 160,819 in 2020, followed by only a 3% rebound to 165,231 in 2021. CPT 88361 is the only code devoted specifically to bill Medicare for reading digitized slides. It therefore gives an indication



of digital pathology trends in the clinical market.

More details on page 4.

A Closer Look at UnitedHealth/Optum's New LBM

It looks like Optum's new laboratory benefit management (LBM) program is rapidly being adopted by health plans. "Since launching the LBM solution, we have seen rapid market adoption from health plans looking to manage the rising costs of routine and genetic lab tests. We are on track to add more than 20 million lives to the program," according to Rob Mayer, Senior Vice President and General Manager, Optum.

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A Closer Look at UnitedHealth/Optum's New LBM *(cont'd from page 1)*

During a September 15 webinar, executives from Optum Inc., which is owned by UnitedHealth, and Avalon Healthcare Solutions, provided more details on Optum's new laboratory benefit management (LBM) program.

The Optum LBM benefit is in the process of being rolled out across the country (see *LE*, September 2022). It covers routine lab tests, genetic testing and anatomic pathology services provided to commercial health plan members, Medicare Advantage and Medicaid managed care plans. The Optum LBM does not affect lab tests provided to hospital inpatients or at Emergency Departments.

John Hoffman, Vice President, Payer Market, at Optum, said that there are between 75,000 and 100,000 genetic tests on the clinical market today and 10 new tests are being introduced every day. "Some genetic tests simply have no clinical utility or validity, meaning they are in some cases useless and can result in false positives.... They can send you down the wrong treatment path, which can have horrible consequences for patients."

Hoffman noted that there are only 300 or 400 CPT codes for genetic tests. "How does a health plan have any idea what to cover, what to pay for and what to pay for it?"

When it comes to routine tests, which comprise 99% of all lab test volume, Hoffman said that demanding further pricing discounts from labs won't work anymore. Health plans must now manage utilization and know what they are paying for, according to Hoffman.

Hoffman said that the need for a solution to better manage lab spend and utilization led Optum to two partnerships executed in 2021. Optum partnered with Palmetto GBA, a regional MAC that manages the MolDX program and Dex Z-Code identifiers for genetic tests. Optum also partnered with Avalon, which has developed evidence-based lab policies with automated policy enforcement software tools.

Optum already has prepayment software installed at more than 100 health plans (covering 66+ million members) throughout the country, including its claims editing and/or prepay audit programs for its Optum Rx pharmacy benefit management program.

Thyroid Panel Example

CPT	Test	Allowed	Denied
84443	TSH	\$18	
84439	T4 Free	\$12	
82542	Iodine Serum		\$35
84482	T3 Reverse		\$54
84479	T3 Uptake		\$11
86800	Thyroglobulin		\$25
84436	T4 Total		\$12
Totals:		\$30	\$137

The Optum/Avalon prepayment lab policy program automatically denies inappropriate tests.

Source: Optum/Avalon

"The fact that we've got these assets already installed, so we can plug Avalon onto the back of them. This really reduces the speed to value and reduces the lift a [Optum health plan] customer has to take on as far as IT resources," explained Hoffman.

Routine Testing

Rahul Singal, MD, Chief Medical Officer at Avalon, said that Avalon has developed 70 different evidence-based policies to identify and automatically deny payment for inappropriate routine lab tests. The process takes place at the claims adjudication stage. The health plan will electronically send the claim to Optum-Avalon which will apply its evidence-based

rules logic to the claim. The software examines each individual lab test on the claim in a process that takes less than one second to complete. Individual test codes identified as unnecessary are auto-denied payment.

For example, Singal noted that many labs offer expanded thyroid panels with extra tests that can turn a simple \$30 thyroid panel (TSH and T4 Free) into a seven-test panel costing \$167. The Optum-Avalon software will only allow payment for the simple panel and will deny payment for the extra tests. “Some of these other tests that are stuffed into thyroid panels are really only indicated in very unique circumstances,” said Singal.

The Optum LBM has similar policies for approximately 70 other routine tests and panels, including folate testing, Lyme disease, HIV genotyping and phenotyping, Vitamin D and Covid testing.

Optum believes its LBM can lower health plan spending on routine tests by 8-10%.

Genetic Testing

The Optum LBM program will also focus on non-specific CPT codes, especially CPT 81479 (unlisted molecular pathology procedure), according to Tanya Hendrickson, Senior Product Director at Optum. She noted that more than 40,000 different tests are currently being billed by labs through CPT 81479. The FDA has not reviewed these tests and most health plans do not have the staff or expertise to properly review these tests, according to Hendrickson.

Optum has contracted with Palmetto’s MolDX program and is licensed to use its DEX Z-Code test assessment and identifier system. The Optum LBM is requiring labs that bill for genetic and other tests using CPT 81479 to obtain a specific Z-Code as a requirement for payment. Tests billed using CPT 81479, but without a specific Z-Code, will be auto-denied payment.

Lab billing of the Mopath Procedure Level 5 (81404) and Level 7 (81406) are also expected to be scrutinized under the Optum LBM.

Optum believes its LBM can lower health plan spending on genetic tests by 20-40%.

Anatomic Pathology

As previously reported, limits are being placed on the number of CPT 88305 units that will be reimbursed by specimen type. For example, the Optum LBM will pay for a maximum of six core biopsies (88305s) per prostate biopsy case. Evidence-based guidelines that place limits on the utilization of immunohistochemistry (CPT 88341 & 88342) are also part of the Optum LBM.

Can Labs Balance Bill Members?

In-network labs may not balance bill health plan members for routine tests that are denied payment, according to Singal. Routine tests that are denied payment are considered uncovered with no liability on the part of the member. Similarly, in-network labs cannot balance bill for genetic tests that did not receive prior authorization and were denied payment.

The Cost to Health Plans?

Hoffman said that the Optum LBM is being offered to health plans at different pricing plans, including per-member per-month (PMPM), shared savings, and full-risk pricing models.

Is there Any Benefit to Labs?

Hendrickson said the Optum LBM’s real-time clinical policy adherence enforcement will increase auto approval rates and reduce prior authorization requests.

Did Digital Pathology Utilization Increase During The Pandemic? *(cont'd from p. 1)*

Another indication that the digital pathology market has not taken off during the pandemic is the falling number of pathologists using it. A total of 736 pathologists billed Medicare for CPT 88361 in 2020 (the latest year of available data), which was down from 871 pathologists in 2019.

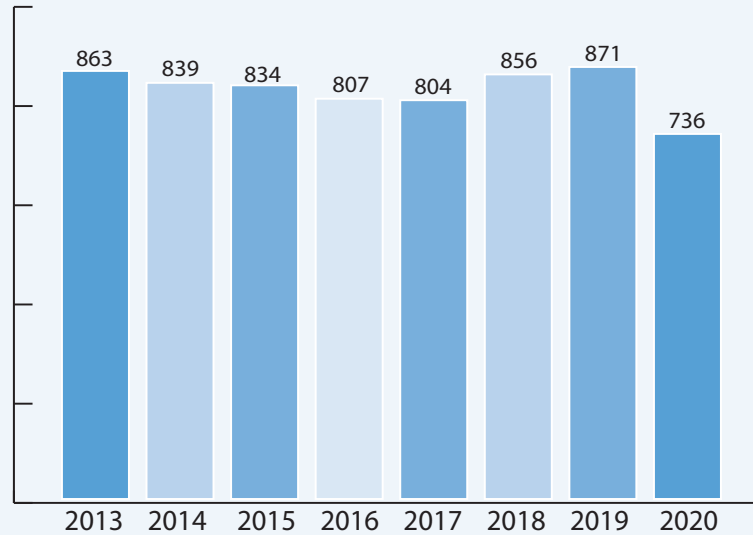
The number of independent labs billing Medicare for CPT 88361 declined from 96 labs in 2013 to 66 labs in 2019 but increased slightly to 69 labs in 2020.

The main barrier, irrespective of the pandemic, to more widespread adoption of digital pathology has been the added expense of digitizing slides without reimbursement. The problem is that digital pathology comes as an “add on” process that is produced from a traditional glass slide. Digital pathology does not eliminate the need to process, section, glass-slide-mount and stain biopsy specimens. A high-end conventional microscope costs between \$9,000 and \$12,000, while a complete digital pathology system can cost between \$100,000 and \$400,000.

In addition, pathologist practice patterns are hard to change, especially without a clear clinical benefit and/or compelling financial incentive.

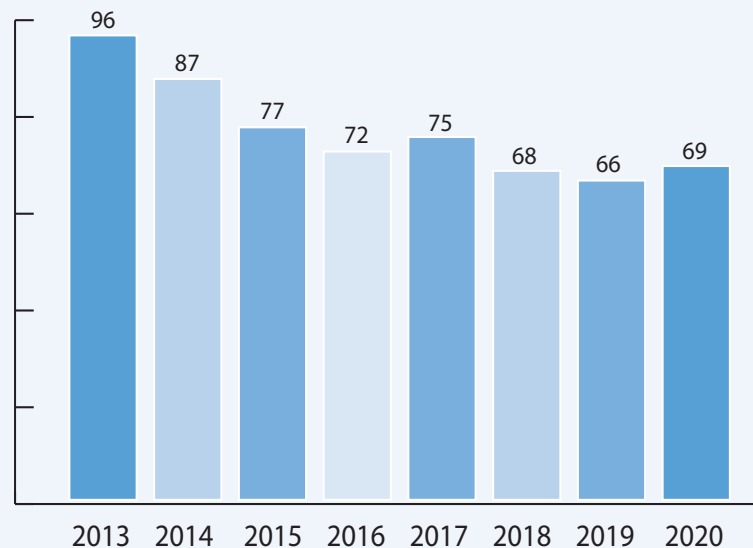
Artificial intelligence could be the game changer that jump-starts the digital pathology market. AI-based decision-support tools that boost pathologist productivity and reduce errors need digitized images to read. AI vendors (PathAI, Paige, Ibex Medical Analytics, etc.) claim their software can help pathologists read 30+% more slides per day. This may provide hospitals and labs with the return on investment necessary to justify an investment in digital pathology scanners.

Total Number of Pathologists Billing Medicare for CPT 88361



Source: Medicare Part B Carrier Utilization Data

Total Number of Independent Labs Billing Medicare for CPT 88361



Source: Medicare Part B Carrier Utilization Data

Spotlight Interview:

Molecular Diagnostic Testing Labs of America's Joey Campbell

Molecular Diagnostic Testing Labs of America (MDTLA-Tupelo, MS), which began as a Covid-19 testing lab in October 2020, now provides additional testing services to nursing homes in the southeast. *Laboratory Economics* recently spoke with Managing Partner Joey Campbell, one of three owners of MDTLA—the other partners are Tony Smith and Eddie Smith.



Joey Campbell

Tell us about MDTLA.

We are a full-service laboratory. The majority of clients we serve are nursing homes, but we do have a hospital we service. We serve 150 nursing homes, which we hope to increase to 200 by the end of the year. We do all kinds of testing—CBCs, lipids, PSAs, some pharmacogenetics, testing for therapeutic drug levels, UTI panels. We got started when Covid was running rampant. We still do Covid testing, but not as much. We use a qTower from Analytik Jena and a QuantStudio from ThermoFisher.

What is your background?

I've got over 20 years' experience in managing labs, including at CPC Reference Laboratories, Gamma Healthcare and Yalobusha General Hospital. My partners have the business experience. Tony Smith is a CPA and Eddie Smith is an MBA.

What geographic areas does MDTLA serve?

We cover the whole state of Mississippi, Louisiana, the edge of Alabama, and we are getting ready to sign our first client in Nashville. We hope to expand further into Tennessee. We have two lab locations, one in Tupelo, which is 2,500 square feet, and one in Gulfport, LA, which is 4,000 square feet.

How many employees do you have?

We have about 55 employees. Our medical director is Thomas Pittman, PhD and we are looking to hire our first pathologist.

Within molecular diagnostics, does the lab have a particular area of specialty?

UTIs, an STD panel, a fungus panel, a wound panel, respiratory and Covid. We also do some pharmacogenetic testing, but we send that out to Resolve Diagnostics in Nashville.

What were your volumes last year? Are they growing? By how much?

We process about 300 to 400 specimens per day. Our volumes in 2020 were 32,777, in 2021 they were 425,125 and this year so far, they're more than 581,000.

Are your revenues growing? By how much?

Since last year, our revenues have increased by at least 50%. We expect to grow about 80% over the next year.

Who are your biggest competitors? What sets you apart from them?

It's not Labcorp or Quest because they don't do a lot of nursing home business. American Healthcare Associates and AcuLabs are our primary competitors. We have about an 80/20 split between Medicare and commercial payers. The reason we get so much business is because we supply Monday through Friday collection while others have gone to one or two pickups a week. We also turn around results within 24 hours. Our competitors take longer. We also compete on quality of service. When someone calls our lab, they will actually speak to a Medtech.

Who do you use as your reference laboratory?

Sonic's American Esoteric Laboratories in Memphis. We are also looking to bring microbiology and certain genetic testing in-house.

Have you had issues with staffing?

Definitely. Two weeks ago, we had 10 people scheduled for interviews and nobody showed up. It's just hard to get good people. We train new employees to ensure they know how to collect samples. They don't have to be certified as phlebotomists. However, the majority of our phlebotomists are certified. That's something they pursue on their own.

Are you working with any colleges?

We have contacted Northeast Mississippi Community College. We are hoping to offer a rotation to their medical laboratory technician students, but we don't offer microbiology yet. We are in the process of validating it now. The University of Mississippi has a 3 plus 1 program where the last year of the med tech program is completed at the local hospital, which usually hires them.

Do you have any challenges getting reimbursed by payers?

Our biggest challenge is missing or incorrect information from the ordering physician. We are constantly having to call to get the correct codes. We do periodic training with the nursing homes, but it's still a challenge. We have three coders on staff and we use a third-party billing company (CGM Billing).

Capital Digestive Care Opens New Full-Service Lab *(cont'd from page 1)*

CDC had operated a 10,000-square-foot anatomic pathology lab in Silver Spring, MD, since 2009. The new lab includes an expanded menu of molecular diagnostics and clinical lab tests (368 tests on menu), including GI pathogen panel, PCR testing for C diff., HPV and CT/NG testing, and infusion level testing, according to Laura Vivian, Executive Laboratory Director. Henry Bell, MD, who is board certified in both anatomic and clinical pathology, is Laboratory Medical Director.

Overall, the new lab is expected to process more than 125,000 biopsy specimens and 180,000 special stains, immunohistochemistry (IHC) antibodies, and in situ hybridization (ISH) probes per year. The lab will also perform more than 300,000 clinical lab tests annually.

CDC is the first gastroenterology practice to have its lab designated as a Roche Center of Excellence. The lab has installed Roche's new BenchMark Ultra Plus system for automated IHC and ISH slide staining. In addition, Vivian says that the CDC lab plans to add whole-genome-sequencing for colorectal and esophageal cancer, as well as gut microbiome testing.

Vivian says that having a lab devoted specifically to CDC's gastroenterologists and patients allows for better integrated care. Result turnaround times for biopsies is less than 48 hours, while clinical lab tests are reported in under 24 hours, according to Vivian. CDC contracts with Stat Experts (Beltsville, MD) for specimen courier services.

SALSA Adds More Support in Congress. Will It Be Enough?

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, has added more support in the House of Representatives. Over the past 30 days, seven more Reps. have joined as cosponsors. A total of 27 Reps. now support the bill, including initial sponsor Bill Pascrell (D-NJ).

No new cosponsors were recently added in the Senate. A total of five Senators support the bill, including initial sponsor Richard Burr (R-NC).

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.

Labcorp Buys Accurate Diagnostics Labs in New Jersey

Labcorp has acquired Accurate Diagnostics Laboratories (South Plainfield, NJ) effective October 31. Accurate is an independent routine clinical lab that operates a main laboratory in northern New Jersey and has 15 PSCs in New Jersey and another four PSCs in New York City. Accurate was founded by its President and CEO, Rupen Patel, in 2000. Accurate serves hundreds of practice clients in the greater New York City area and has estimated annual revenue of between \$75 million and \$100 million. Specimen volume from Accurate is expected to be shifted to Labcorp's regional lab in Raritan, New Jersey (16 miles west of South Plainfield).

Mako Acquires ScientiaDx

Mako Medical Labs (Raleigh, NC) acquired ScientiaDx (SDx-Lyndhurst, NJ) on August 1. The SDx acquisition gives Mako a physical laboratory presence in the Northeast to begin equipping and building around, according to Josh Arant, Chief Operating Officer at Mako. He says that Mako will keep the SDx lab open and operating in New Jersey. Over the next 12 months, the combined Mako and SDx team will begin exploring larger spaces to accommodate a planned test menu expansion and specimen volume growth. SDx, which has 120 employees, currently specializes in drug and toxicology screening and Covid PCR testing. The company (originally named Gene Tox) was founded in 2016 by its Chief Executive Charles Gentile.

Avalon GloboCare Buys Majority Stake in Laboratory Services LLC

Avalon GloboCare Corp. (Freehold, NJ) has signed a definitive agreement to acquire a 60% stake in Laboratory Services LLC (Costa Mesa, CA) for \$31 million. The acquisition will mark Avalon's entry into the lab testing business.

Laboratory Services had 2021 revenue of more than \$25 million and net income of approximately \$10 million. The company has processed more than 600,000 tests since its laboratory in Costa Mesa gained its CLIA certificate in December 2020. Laboratory Services specializes in drug and toxicology testing, immunology tests, STD/STI's, molecular UTI testing and Covid PCR testing.

Sarah Cox, the co-founder and CEO of Laboratory Services, will become Chief Operating Officer of Avalon and will join its Board of Directors.

The acquisition price of \$31 million, consists of: 1) \$15 million in cash; 2) \$15 million in Avalon's Series B preferred stock; and 3) \$1 million payable on the first anniversary of the closing date. In addition, Avalon may pay up to \$10 million more if Laboratory Services reaches certain cash flow targets in 2022 and 2023.

Avalon, which has six employees, currently generates all of its revenue from rentals of an office complex it owns in northern New Jersey. In the six months ended June 30, 2022, Avalon reported revenue of \$588,452 versus \$570,006 in the same period last year; net loss was \$4.1 million versus \$4.7 million.

Ibex Raises \$10 Million from Kreos Capital

Ibex Medical Analytics (Tel Aviv, Israel), which has developed artificial intelligence software tools for prostate, breast and gastric cancer, has raised \$10 million from Kreos Capital (London, UK). The funding comes as an addition to Ibex's \$52 million raised to date. Existing investors include Octopus Ventures, 83North, aMoon, Planven Entrepreneur Ventures and Dell Technologies Capital. Ibex clients in the United States include CorePlus (Puerto Rico), Alverno Labs (Hammond, IN) and Advanced Pathology Associates (Rockville, MD).

Reditus Labs Shuts Down

Reditus Laboratories (Pekin, IL), which became one of the largest Covid-19 testing labs in the nation, was shut down on November 4. In the coming months, Reditus expects to liquidate its assets and dissolve as an entity.

A dispute over money between the owners of Reditus is ongoing, and the lab has been operating under a court-ordered receivership since April 2022.

Reditus had originally opened in June 2019 as a histology laboratory with 10 employees and a focus on dermatopathology. When the pandemic struck in early 2020, Reditus shifted its focus to Covid-19 PCR testing. During 2020-2021, the company grew to 300 employees and performed millions of PCR tests, mostly for the Illinois Department of Public Health and Illinois Department of Corrections. In total, Reditus was paid \$222 million from Illinois state contracts to administer Covid-19 PCR tests. Reditus initially charged the state of Illinois \$113 per test. The state later renegotiated the price to \$93.

Aaron Rossi, age 39, co-founder and former CEO of Reditus, is at the center of the controversy.

A Disgruntled Dermatopathologist

James Davie, MD, a co-founder and minority owner in Reditus, sued Rossi earlier this year. Davie, who is a dermatopathologist, claims that he helped with the start of Reditus and initially served as its Lab Director. Davie's lawsuit says that Rossi forced him out as Lab Director and withheld financial information from him.

Davie alleges that Rossi has wrought "financial destruction" on Reditus through "shady accounting" and the misuse of funds. The lawsuit claims Rossi was "pillaging" Reditus to fund a "nouveau riche over-the-top lifestyle."

Despite the enormous profits Reditus apparently made, Davie's lawsuit alleges no distributions were made to him in the years 2020 and 2021. As a result, Davie has not been provided any money to cover his expected federal and state income tax liabilities.

A Lavish Lifestyle

Meanwhile, an investigation by WGLT (a public radio station owned by Illinois State University) has revealed that there are 28 vehicles registered in Rossi's name or that of his company, AJR MD Consulting.

That includes six Porsches, six BMWs, two Mercedes-Benzes, a Ferrari, and a Tesla. Almost all of them are model years 2020, 2021, or 2022. In addition, there are 59 other vehicles registered to Reditus, including nine BMWs, a Porsche, and a Tesla, according to state records obtained through the Freedom of Information Act by WGLT.

Indicted for Tax fraud

In a separate case, a federal grand jury charged Rossi with tax fraud in March. According to the indictment, Rossi underrepresented his income to the IRS in 2015, 2016 and 2017. Rossi is also accused of defrauding his former employer, Central Illinois Orthopedic Surgery, from 2014 to 2018. Rossi was office manager there and also worked as a surgical assistant. Prosecutors say Rossi defrauded the business and its owners out of more than \$1 million. He used the money to lease a private jet, make payments on a personal credit card, and to buy an A/V system for his home, prosecutors said.

Pretending to be a Doctor

Federal prosecutors say part of the scheme involved Rossi falsely portraying himself as a physician, which he is not. He went to medical school in Barbados but never got licensed in Illinois and never did a residency. Prosecutors say he kept doing this even after the Illinois Department of Financial and Professional Regulation (IDFPR) told him to stop.

CS Conference Highlights for Fulgent, Labcorp and Exact Sciences

Four lab companies made presentations to investors at Credit Suisse's 31st Annual Healthcare Conference, November 7-10 in Rancho Cordova, CA. Here are some highlights:

Revenue that **Fulgent Genetics** (Temple City, CA) generated from Covid-19 testing helped the company build its balance sheet to \$918 million in cash and investments as of September 30, 2022, according to Chief Executive **Ming Hsieh**.

Fulgent was also able to expand its anatomic pathology business through the acquisition of Cytometry Specialists Inc., or CSI (Alpharetta, GA), for \$53 million in August 2021 and Inform Diagnostics (Irving, TX) for \$138 million in April 2022.

Integration of CSI was fairly easy given its small size (about 100 employees), according to **Brandon Perthuis**, Chief Commercial Officer at Fulgent. In addition, Fulgent opened a new 25,000 square-foot cancer testing lab in El Monte, CA in May 2022, dubbed CSI West, to improve turnaround times and enable expansion in the western U.S.

InformDx, with 550 employees and four lab locations, was a much bigger acquisition. "We did rightsize the business and put in new leadership," said Perthuis. A focus has been integrating the sales teams, combined ~25 reps, to cross sell InformDx's pathology services and Fulgent's genetic cancer tests. Perthuis noted that InformDx brought Fulgent more than 500 health insurance contracts covering 300 million lives—payer contracts had been a weakness at Fulgent. "We expect those contracts to be rolled up into Fulgent's corporate level and tax ID by the end of the year, so starting fresh in 2023 we can start selling our next-gen cancer tests to InformDx clients and third-party payers."

Labcorp performed an average of 24,000 Covid-19 tests per day in the third quarter, expects to average 15,000 to 20,000 per day in the fourth quarter, and anticipates a continued reduction in 2023, according to Chairman and CEO **Adam Schechter**.

However, Schechter said, "We're seeing a much higher rate of positivity for RSV than what we've seen in the past." He also noted that this past flu season was tough in Australia, which has opposite season to the U.S. "We can use them as a predictor, and they had a rough RSV season." Labcorp recently introduced a triple PCR test for Covid-19/RSV/Flu.

Labcorp recently closed on its acquisition of certain hospital outreach labs from Ascension plus management agreements for another 100 Ascension hospitals labs in 10 states. Labcorp has added 4,700 Ascension employees as part of agreement. Schechter said that Labcorp's pipeline of potential hospital lab deals is the strongest he's ever seen. "Every hospital is struggling right now, so if there's a way for them to monetize some of their assets we can help them do that."

Exact Sciences has invested heavily in sales and marketing over the years to build brand awareness of its Cologuard screening test for colon cancer and its Oncotype DX Breast Recurrence Score Test, according to Chairman and CEO **Kevin Conroy**. He said that Exact had reached the point where it should now be able to hold its sales and marketing expense constant, while growing its revenue. As a result, he believes the company is on track to break even on an adjusted EBITDA basis in third-quarter 2023.

Conroy said that Exact should also benefit from the FDA clearance (September 2019) of its Cologuard test for average-risk individuals ages 45 and older, which expanded on its previous indication for ages 50 and older. There are 19 million people in this age group (45-49) in the United States.

In the nine months ended Sept. 30, 2022, Exact reported a net loss of \$496 million versus a net loss of \$375 million in the same period a year earlier; revenue grew by 18% to \$1.5 billion.

RSV Hospitalizations for Children Soaring

The percentage of children (age 0-17) testing positive for Respiratory Syncytial Virus (RSV) that have been hospitalized reached a multi-year high of 13.1% in early November, according to the U.S. Centers for Disease Control and Prevention (CDC). That's more than double the peak average rate of pediatric RSV hospitalizations (4-6%) for the previous four flu seasons.

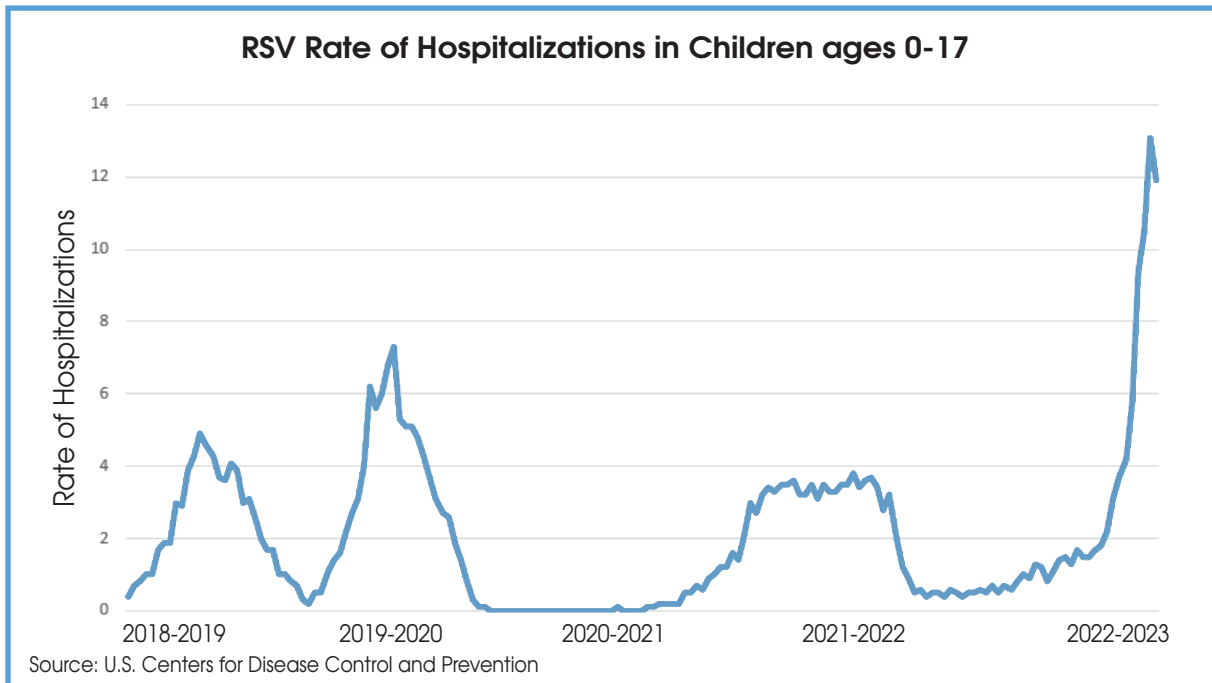
Peak RSV hospitalization rates have historically occurred around the holidays and first week of January. So the current trend looks ominous.

“Blame it on RSV immunity debt,” according to a recent online article in the *Journal of the American Medical Association* (November 11, 2022. doi:10.1001/jama.2022.21638). Most children are exposed to RSV in the first year of life, and almost all have been infected by two years. RSV infections in the first six months can be particularly severe, leading to bronchiolitis and pneumonia. Subsequent infections usually are milder, causing cold-like symptoms. “But there was essentially no RSV in 2020, and now kids are paying for it.”

RSV is typically responsible for 100–300 deaths in children younger than 5 years old each year, according to the CDC. However, this season may be worse given the high hospitalization rate.

Mark Roth, Chief Executive Officer at Lighthouse Lab Services (Charlotte, NC), notes that a large portion of RSV testing takes place at regional independent labs and large physician clinics (see table on page 13). His firm is in the process of helping approximately 15 independent labs add PCR-based RSV testing to their menus. Roth says that a lab needs to perform at least 200-300 RSV tests per month in order for it to be economical.

Currently, Roth says that most RSV testing is being performed as part of a panel that includes Covid-19 and flu tests. The Medicare rate for CPT 87637 (PCR testing for Covid-19/ influenza A & B/RSV) is \$143, while private payers reimburse in the range of \$100-150. Standalone RSV testing (CPT 87634) has a Medicare rate of \$70; private-payer rates range between \$50 and \$100. All-in reagent/supply costs for an RSV test average between \$10 and \$20, according to Roth.



Infectious Disease Panels Present Coverage, Reimbursement Challenges

Large panels that test for multiple infectious diseases may make sense from a diagnostic standpoint but getting payers to cover these panels is a challenge for clinical labs, many of whom are left “holding the bag” when it comes to payment.

According to coverage and coding experts, these large testing panels developed by IVD companies present significant problems, both in terms of federal and private insurance coverage. Some panels, for example, will test for 25 different antigens, but Medicare contractors typically cover only up to five antigens.



“We always try to encourage IVD companies to make sure their panels are covered before they develop them,” says Greg Root, Chief Operating Officer and General Counsel for CodeMap (Chicago). “But IVD companies are not focused on payment; they are focused on science.”

Greg Root

Medicare’s coverage policies for molecular diagnostic testing are fairly restrictive, adds Root, noting that CMS’s MolDX program has many local coverage determinations, but they can be confusing and can change often. The MolDX program is administered by Palmetto GBA, a Medicare contractor.



For routine testing, large panels are rarely warranted, says Diana Voorhees, Principal and CEO at DV & Associates (Salt Lake City). “Developers of the panels actively market their availability,” she says. “There may be times when a large panel is appropriate, but for routine testing it’s questionable.”

Diana Voorhees

Commercial payers largely follow what MolDX does when it comes to coverage of molecular diagnostics, adds Voorhees, who encourages test manufacturers and providers to consider appropriate coding and reimbursement, which may include a proprietary laboratory analyses (PLA) code, during development of a test or a panel. These codes are established by the American Medical Association’s CPT editorial panel. New PLA codes are released and posted online on a quarterly basis. However, even with a PLA code, many commercial payers require prior authorization before the test can be performed.

Thus, clinical labs face the age-old problem of lab testing: The doctor orders a test, but the lab doesn’t necessarily know if it will get paid for performing it. Denials are increasing, says Root, which is a natural reaction to the sheer volume of testing that’s occurring now.

“Labs have to be diligent and appeal and chase down those denials,” advises Root. “Figure out which tests or panels are causing the problems. The labs that handle this best are those with robust claims submission departments.”

Extensive Revisions

Another challenge faced by clinical labs is that coverage policies are revised and updated frequently, and it can be difficult to keep up with the latest changes. MolDX, for example, typically releases quarterly updates. Private payers often don’t release coverage policies at all.

“MolDX is constantly revising their coverage policies, and if people don’t stay on top of it, it’s easy to fall behind,” says Voorhees. “I think the staff at MolDX are trying to communicate and be transparent, but I think they are overwhelmed with the number of people trying to get technical assessments.”

Both Root and Voorhees advise labs to sign up for updates from MolDX and other payers that may issue coverage policies and to be aware that panels that test for a large number of antigens may not be covered.

Lab Stocks Down 50% Year To Date

Twenty-four lab stocks have dropped by an unweighted average of 50% year to date through November 13. In comparison, the S&P 500 Index has fallen by 17% so far this year. The top-performing lab stocks thus far in 2022 have been ProPhase Labs, up 68%; Psychemedics, down 12%; and Quest Diagnostics, down 13%. Labcorp is off 22% and Sonic Healthcare is also down 30%.

Company (ticker)	Stock Price 11/13/22	Stock Price 12/31/21	2022 Price Change	Enterprise Value (\$ millions)	Revenue for Trailing 12 mos. (\$ millions)	Enterprise Value/Revenue
ProPhase Labs (PRPH)	\$12.02	\$7.17	68%	\$182	\$143	1.3
Psychemedics (PMD)	6.17	\$7.02	-12%	35	26	1.4
Quest Diagnostics (DGX)	150.40	173.01	-13%	21,250	10,294	2.1
Myriad Genetics (MYGN)	21.94	27.60	-21%	1,580	661	2.4
Labcorp (LH)	245.31	314.21	-22%	28,020	15,259	1.8
Enzo Biochem (ENZ)	2.30	3.21	-28%	117	107	1.1
Sonic Healthcare (SHL.AX)*	32.75	46.63	-30%	17,710	9,340	1.9
Veracyte (VCYT)	28.65	41.20	-30%	2,000	284	7.1
Exact Sciences (EXAS)	44.81	77.83	-42%	10,020	2,005	5.0
Castle Biosciences (CSTL)	22.58	42.87	-47%	338	124	2.7
Guardant Health (GH)	48.25	100.02	-52%	5,740	431	13.3
Natera (NTRA)	35.46	93.39	-62%	3,840	776	4.9
Fulgent Genetics (FLGT)	35.92	100.59	-64%	306	803	0.4
Opko Health (OPK)	1.70	4.81	-65%	1,390	1,220	1.1
NeoGenomics (NEO)	10.95	34.12	-68%	1,590	497	3.2
CareDx (CDNA)	14.20	45.48	-69%	567	319	1.8
Biocept (BIOC)	0.83	3.62	-77%	3.0	62	0.0
Interpace Biosciences (IDXG)	1.65	\$7.47	-78%	67	40	1.7
Aspira Women's Hlth (AWH)	0.39	1.77	-78%	31	8	3.9
Biodesix (BDSX)	1.11	5.29	-79%	53	36	1.5
Invitae (NVTX)	3.17	15.27	-79%	2,040	520	3.9
Sema4 Holdings (SMFR)	0.90	4.46	-80%	183	191	1.0
Exagen (XGN)	2.25	11.63	-81%	-4	44	NA
DermTech Inc. (DMTK)	2.50	15.80	-84%	-41	15	NA
Unweighted Averages			-50%	\$97,018	\$43,204	2.2

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from YFinance and Seeking Alpha

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Top 25 RSV Testing Labs

Cabot Lab (Plano, TX) is the top RSV testing lab in the United States in terms of Medicare Part B Carrier allowed test volume for RSV testing (CPT codes 87631-87634 and 87637) in 2020 (the latest data available). Cabot Lab had allowed volume of 36,327 RSV test codes for Medicare patients in 2020. Overall, there were 305 independent labs and 316 physicians/physician offices that billed Medicare Part B for RSV testing in 2020.

Laboratory	Location	Medicare Part B RSV Test Volumes*
Cabot Lab LLC	Plano, TX	36,327
B. Gurevich, MD/Rush North Shore Medical Center Lab	Chicago, IL	23,960
T. Oxner, DO/West Shores Medical Clinic	Hot Springs, AR	23,903
J. Reagan, APRN/First Choice Healthcare	Walnut Ridge, AR	21,155
T. Gann, NP/Priority Family Medical Clinic	Prescott, AZ	14,399
MediTest Laboratories	Irvine, CA	10,186
Southwest Regional PCR Laboratory	Lubbock, TX	8,926
P. Cohen, MD/Internal Medicine	Syracuse, NY	8,795
T. Bernard, MD/Healthplex Family Clinic	Shreveport, LA	8,548
Sea Level Labs	Gulf Breeze, FL	8,323
E. Zompa, MD, PhD/West Isle Urgent Care	Galveston, TX	7,199
Kan-Di-Ki LLC (dba Diagnostic Laboratories and Radiology)	Burbank, CA	6,779
M. Srepetis, MD/Rapides Regional Physician Group	Alexandria, LA	6,237
Dx Solutions (dba Solaris Diagnostics)	Nicholasville, KY	5,947
A. Tomlinson, NP/Murfreesboro Medical Clinic	Murfreesboro, TN	4,536
Med Health Services Management	Monroeville, PA	4,191
Chabado Genomics Inc.	Torrance, CA	4,156
ARC Diagnostics	Owasso, OK	4,039
Genesys Diagnostics	East Lyme, CT	3,944
Quest Diagnostics	Baltimore, MD	3,596
H. Bell, MD/Howard County General Hospital	Columbia, MD	3,229
Redwood Laboratory	Dearborn, MI	3,207
A. Massa, NP/Jackson Family Care	Jackson, MO	3,142
Labcorp	Burlington, NC	3,117
C. Smith, MD/Smith Allergy & Asthma Specialists	Horseheads, NY	3,072
Total for Top 25 Part B Providers		230,913
Total for all Part B Providers		394,676

*Includes CPT codes 87631-87634 and 87637

Source: Medicare Part B Carrier Provider Utilization Data for 2020