

# LABORATORY ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## Agendia Seeks \$75 Million From IPO

Agendia (Irvine, CA), which markets genetic tests for breast cancer, has filed with the Securities & Exchange commission to raise up to \$75 million in an initial public offering (IPO). The IPO is being managed by Goldman Sachs, Citigroup, Cowen, and Stifel. Agendia intends to use the proceeds from the IPO to pay down debt, expand marketing activities, and hire more personnel.

*Continued on page 8.*

## Final 2022 Medicare Physician Fee Schedule Cuts Pathology Rates By 4%

The Final Medicare Physician Fee Schedule (MPFS) for 2022 reduces professional rates paid to pathologists by an average of roughly 4%, while technical fees paid to pathology labs will also fall by approximately 4%. These cuts are primarily due to a 3.71% reduction in the final 2022 conversion factor (CF) to 33.5983. The CF reduction is the result of the expiration of the 3.75% temporary 2021 payment increase Congress approved through pandemic-related legislation.

*Full details on pages 3-4.*

## Versant Diagnostics Buys Two Pathology Groups In Chicago Area

Versant Diagnostics (Oak Brook, IL) has acquired Alliance Pathology Consultants (Elk Grove Village, IL) and Addison Central Pathology (Chicago, IL). Both deals were completed on October 15. The acquisitions are the first two deals for the newly formed Versant, which expects to buy more pathology groups in the Chicago area in the coming months.

Versant aims to raise the revenue at its acquired pathology groups by building a sales and marketing team to increase referral volume from physician offices in the Midwest. Both Alliance and Addison are in the process of transitioning to digital pathology with artificial intelligence (AI)-based tools to raise pathologist accuracy and productivity in reading biopsy cases.

“Adding a sales and marketing infrastructure will help leverage the productivity that digital pathology with AI bring,” according to Jim Billington, Chief Executive at Versant.

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**Versant Diagnostics Buys Two Pathology Groups** (*cont'd from page 1*)

Prior to co-founding Versant, Billington, age 59, was an M&A consultant. His experience also includes President and Co-Founder of American Esoteric Laboratories, which was sold to Sonic Healthcare for \$187 million in 2007. Billington was also Senior Vice President of Operations at AmeriPath, which is now part of Quest Diagnostics.



*Jim Billington*

Ven Aduana, MD, age 66, is Chairman, Chief Medical Officer, and Co-Founder of Versant. Prior to Versant he was President and CEO of Alliance Pathology Consultants.

Alliance Pathology Consultants has 10 pathologists who cover the five hospitals of the Alexian Brothers Health Network within AMITA Health (Chicago, IL).

Addison Central Pathology has eight pathologists that provide professional pathology services to three AMITA hospitals. Addison's sole shareholder is its President Vickie Rezai, MD, who is retiring.



*Ven Aduana,  
MD*

Aduana notes that other pathology groups affiliated with AMITA's seven other acute care hospitals are in different stages of negotiation with Versant. A merger of all the AMITA-affiliated pathology groups into Versant would foster greater cooperation and use of subspecialty pathologists, notes Aduana.

Versant has received financing (both equity and debt) from Iron Path Capital (Nashville, TN). The total amount invested is undisclosed. However, Billington says Versant has raised enough to fund acquisitions for the next several years. "We're taking a disciplined approach to practice valuations, so the deals make sense for everyone."

Neither Alliance Pathology Consultants nor Addison Central Pathology operates its own histology lab. Alliance uses hospital-based labs, while Addison contracts with Alverno Clinical Laboratories (Hammond, IN) for slide preparation services. Alverno is an independent lab owned by AMITA Health and the Franciscan Alliance.

Alverno, which processes more than one million histology slides per year, has been transitioning its hospitals and contracted pathology groups to digital pathology over the past two years (see *LE*, June 2019). Some of Alverno's pathologists are already reading 98-99% of their cases on monitors versus the traditional microscope. Recently, Alverno announced plans to use Ibex's AI-powered Galen platform to assist pathologists with professional interpretations (see *LE*, August 2021). Alverno is expected to introduce AI-based tools for prostate cancer first and then breast cancer.

Billington says Versant has no immediate plans to open its own histology lab and will continue to contract with Alverno for technical services.

Alverno's digital pathology program is currently in the process of being phased in at Addison and is scheduled to be implemented at Alliance in early 2022. The slide prep for Alliance will also be transitioned to Alverno next year as part of the switch to digital pathology. Aduana estimates that the combination of digital pathology and AI will increase pathologist productivity by 30% with greater increases coming as the technology matures.

None of the AMITA hospitals currently has a dedicated pathology sales and marketing staff—outreach is driven by the initiative of individual pathologists. The development of a sales and marketing program focused on gaining physician office clients will help fill the extra capacity created by digital pathology and AI, notes Aduana.

Billington says Versant is currently recruiting a marketing executive to lead its sales team. "What I learned from my experience at AmeriPath and observation of Aurora Diagnostics (now owned by Sonic Healthcare) is the need to grow revenue at acquired practices."

**Final 2022 Medicare Physician Fee Schedule Cuts** (*cont'd from page 1*)

The College of American Pathologists (CAP) has been lobbying Congress throughout 2021 to set aside an additional \$3 billion to reduce the Medicare rate cuts to pathologists and other physicians next year. However, barring last-minute legislative action, the following changes will become effective January 1, 2021.

**Surgical Pathology**

The global rate for CPT 88305 (Level IV, tissue exam) will drop by 2% to \$69.88 in 2022; professional interpretation down 4% to \$36.29; technical component down 1% to \$33.60.

The global rate for CPT 88307 (Level V, tissue exam) will decline by 3% to \$282.23; professional interpretation down 4% to \$79.96; technical down 2% to \$202.26.

The global rate for G0416 (Surgical pathology for prostate biopsy) is being reduced by 2% to \$348.08; professional down 4% to \$172.36; technical flat at \$175.72.

**Immunohistochemistry**

The global rate for CPT 88342 (IHC, first stain procedure) has been finalized to decrease by 6% to \$99.45; professional interpretation down 5% to \$33.60; technical down 7% to \$65.85.

The global rate for CPT 88341 (IHC, each additional stain) will fall by 7% to \$87.02; professional interpretation down 5% to \$27.21; technical down 8% to \$59.80.

**Special Stains**

The global rate for CPT 88312 (Special stains, group 1) will decline by 2% to \$111.21; professional interpretation down 5% to \$25.53; technical down 1% to \$85.68.

The global rate for CPT 88313 (Special stains, group 2) will decrease by 2% to \$79.96; professional interpretation down 4% to \$11.76; technical down 2% to \$68.20.

**Flow Cytometry**

The rate for the high-volume flow cytometry code 88185 (Flow cytometry/tech comp, each additional marker) will drop by 7% to \$21.50.

**Digital Pathology**

CPT code 88361 (Quantitative IHC-computer assisted) is used to bill Medicare for the reading of digital HER2, ER and PR slides from a computer monitor. The global rate for CPT 88361 will fall by 5% to \$118.60 in 2022; professional interpretation down 4% to \$42.33; technical down 5% to \$76.27.

**Clinical Laboratory Fee Schedule**

Medicare CLFS rates were frozen in 2021. However, the PAMA rate cuts will resume next year; most high-volume test codes will be reduced by 10% to 15%.

In addition, after a two-year delay, the next PAMA data reporting period starts January 1, 2022. Starting then, most independent labs, hospital outreach programs and big physician-office labs (POLs) must submit their private-payer payment data to CMS or face substantial civil monetary penalties. CMS will use this data to calculate new Medicare CLFS rates for 2023-2025.

The American Clinical Laboratory Assn. (ACLA) is lobbying to have Medicare CLFS rates frozen for another year in 2022. Another one-year delay would give the lab industry time to try to get legislative changes to PAMA that ensure that data from all labs is accurately represented in rate calculations.

**Final Medicare Rate Changes for Key Pathology Codes for 2022**

<b>CPT/HCPCS</b>	<b>Short Description</b>	<b>Final 2022<sup>1</sup></b>	<b>Final 2021<sup>2</sup></b>	<b>% Rate Change</b>
88112-Global	Cytopathology, cell enhance technique	\$65.52	\$67.69	-3%
88112-26	Cytopathology, cell enhance technique	26.88	27.91	-4%
88112-TC	Cytopathology, cell enhance technique	38.64	39.78	-3%
88184-TC only	Flow cytometry/1st marker	67.20	69.79	-4%
88185-TC only	Flow cytometry/each add'l marker	21.50	23.03	-7%
88187-26 only	Flow cytometry, read 2-8	34.94	36.64	-5%
88188-26 only	Flow cytometry/read 9-15	61.15	62.81	-3%
88189-26 only	Flow cytometry, read 16 & greater	81.98	85.14	-4%
88305-Global	Tissue exam by pathologist	69.88	71.53	-2%
88305-26	Tissue exam by pathologist	36.29	37.68	-4%
88305-TC	Tissue exam by pathologist	33.60	33.85	-1%
88307-Global	Level V, tissue exam by pathologist	282.23	290.31	-3%
88307-26	Level V, tissue exam by pathologist	79.96	83.39	-4%
88307-TC	Level V, tissue exam by pathologist	202.26	206.92	-2%
88309-Global	Level VI, tissue exam by pathologist	428.71	441.75	-3%
88309-26	Level VI, tissue exam by pathologist	140.44	146.90	-4%
88309-TC	Level VI, tissue exam by pathologist	288.27	294.85	-2%
88312-Global	Special stains, group 1	111.21	113.05	-2%
88312-26	Special stains, group 1	25.53	26.87	-5%
88312-TC	Special stains, group 1	85.68	86.19	-1%
88313-Global	Special stains; group 2	79.96	81.65	-2%
88313-26	Special stains; group 2	11.76	12.21	-4%
88313-TC	Special stains; group 2	68.20	69.44	-2%
88331-Global	Pathology consult during surgery	100.46	104.68	-4%
88331-26	Pathology consult during surgery	60.14	62.46	-4%
88331-TC	Pathology consult during surgery	40.32	42.22	-5%
88341-Global	Immunohistochemistry (add'l stain)	87.02	93.86	-7%
88341-26	Immunohistochemistry (add'l stain)	27.21	28.61	-5%
88341-TC	Immunohistochemistry (add'l stain)	59.80	65.25	-8%
88342-Global	Immunohistochemistry (1st stain)	99.45	106.08	-6%
88342-26	Immunohistochemistry (1st stain)	33.60	35.24	-5%
88342-TC	Immunohistochemistry (1st stain)	65.85	70.83	-7%
88360-Global	Tumor immunohistochem/manual	118.94	124.92	-5%
88360-26	Tumor immunohistochem/manual	40.32	42.22	-5%
88360-TC	Tumor immunohistochem/manual	78.62	82.70	-5%
88361-Global	Tumor immunohistochem/computer	118.60	124.22	-5%
88361-26	Tumor immunohistochem/computer	42.33	43.97	-4%
88361-TC	Tumor immunohistochem/computer	76.27	80.25	-5%
88377-Global	Morphometric analy, ISH (quant or semiq)	399.82	424.65	-6%
88377-26	Morphometric analy, ISH (quant or semiq)	61.82	64.55	-4%
88377-TC	Morphometric analy, ISH (quant or semiq)	338.00	360.10	-6%
G0416-Global	Prostate biopsy, any method	348.08	354.16	-2%
G0416-26	Prostate biopsy, any method	172.36	178.65	-4%
G0416-TC	Prostate biopsy, any method	175.72	175.51	0%
G0452-26	Molecular pathology interpretation	\$44.69	\$46.41	-4%

<sup>1</sup>Payments based on the 2022 conversion factor of 33.5983; <sup>2</sup>Payments based on the 2021 CF of 34.8931

Source: *Laboratory Economics* from CMS

## Spotlight Interview with CAP President Emily Volk, MD

**E**mily Volk, MD, FCAP, Chief Medical Officer at Baptist Health Floyd (New Albany, IN), recently was sworn in as the 37th president of the College of American Pathologists (CAP). Volk is also Associate Professor of Pathology at the University of Louisville School of Medicine. *Laboratory Economics* recently spoke with Volk about the Covid-19 pandemic and more.



Emily Volk, MD

### **Given that it is possible to have breakthrough cases of Covid-19, why is it still so important to get vaccinated?**

I like to think of the vaccine as water being poured on kindling wood. You can still light it, but it's much harder, and the fire does not burn as hot. Without water, the kindling is very susceptible to picking up a spark. The vaccine operates in a similar way. A person might have a breakthrough case, but it is less likely to be severe or deadly, and that person is far less likely to develop long-Covid.

### **Do the Covid vaccines generate T-cells and B-cells that provide long-term protection against hospitalization and death?**

The vaccine trains the body to protect itself from the virus. For example, the vaccine primes the B-cells to produce antibodies that are ready to go into action when someone is exposed to the virus. Scientists are also learning that the mRNA vaccines encourage a strong T-cell response when a vaccinated person is exposed to Covid-19. T-cells don't prevent infection, because they kick into action only after a virus has infiltrated the body, but they are important for clearing an infection that has already started.

### **What is the role of rapid testing in helping to mitigate the pandemic?**

Rapid tests are useful in determining if you have the virus, especially if the prevalence of the virus is high—the performance characteristics of the rapid test is much better when used on populations with a high prevalence of disease. My concern is using frequent rapid testing as a substitute for vaccination.

I recognize that there are folks who need a religious or medical exemption, and businesses are looking for ways to mitigate risk of a handful of unvaccinated employees by using rapid testing on a regular basis, like weekly.

Unfortunately, there are many people who still are vaccine hesitant. I have talked to people who are hesitant, and when I listen with an open mind to their concerns, I have been able to contribute to folks deciding to get the vaccine.

### **What's the biggest mistake that consumers make when using at-home tests?**

Not following instructions properly. It is important that they read the instructions carefully and follow them exactly.

### **Have many people delayed routine cancer testing and screening due to the pandemic?**

What we've seen in the last 18 to 20 months is a striking decrease in the number of patients coming in for screening tests, which includes colonoscopies, pap smears and mammograms. Colon cancer, cervical cancer and breast cancer all do better when they are caught early. It is safe to go in for screenings as doctors' office and healthcare settings have extensive safety protocols in place.

### **How important will Covid testing be in the future?**

I think it will continue to be with us for a long time, just like influenza and whooping cough testing. We are already seeing manufacturers bundling Covid tests with respiratory pathogen panel tests. I think Covid testing will remain with us for some time.

**Are supply shortages for lab tests now under control?**

We are still seeing supply chain issues. The availability of various kinds of test tubes have been unpredictable. We had a blue top tube shortage locally over the summer. There are still some issues with pipette tips and medical grade plastics. It's better than it was in the beginning, but we are not out of the woods yet.

**What is CAP doing to address the shortages in the laboratory workforce?**

We have known about a need to build a pipeline for laboratorians in a variety of roles for some time now. There are shortages for many positions, even for pathologists. CAP is working closely with residency program directors and medical schools, and we have a social media campaign to let people know what being a pathologist is all about. As pathologists, we are the best kept secret in medicine. When medical students learn about pathology, they get excited. The CAP has made a concerted effort to shore up the pipeline. We are trying to make sure pathology is visible to people from diverse backgrounds. It's not only the right thing to do, it's the smart thing to do.

**Why do nurses make so much more money than MTs when both require four-year degrees?**

There are more nurses than medical technologists, and the nursing organizations have done a much better job of going after better salaries for their people. I think there is a real opportunity for medical technologists to come together to ask for better wages. The organizations that are focused on med techs need to be pushing for better salaries. Because they are in short supply, that may help drive up wages. Med techs are very talented people who should be paid accordingly.

**What are your expectations for the upcoming flu season, in terms of flu cases and Covid cases?**

Last year we did see a drop in flu cases because people were largely masking. I am not sure what is going to happen with flu this year. As more people are vaccinated against Covid, people are getting more lax about masking. We are not seeing many flu cases yet, but that could change.

**Why is clinical laboratory accreditation so important?**

It's like the good housekeeping seal of approval. People who go to CAP-accredited labs can rest assured that all steps are taken to ensure that their tests are reliable and accurate.

**ARUP And Quest Raise Minimum Hourly Wage To \$15**

**A**RUP Laboratories (Salt Lake City, UT) says that it will increase its minimum hourly wage to \$15 effective November 27. All new hires and approximately 600 employees who currently earn less than the new minimum will be paid \$15 per hour or more. In addition, about 2,800 hourly employees who already earn more than \$15 per hour also will get raises with the higher minimum hourly wage. ARUP has about 4,500 employees, most of whom work in University of Utah Research Park.

Effective November 7, Quest Diagnostics says that it will adjust its hourly rate to \$15 for the small number of employees who were below that level. In addition, Quest will make a non-taxable payment (\$500 for full-time employees and \$250 for part-time and per diem) to approximately 47,500 employees to offset financial challenges due to the pandemic.

Finally, Quest noted that another year of pandemic pressures and travel restrictions have made it very difficult for many of its employees to take their paid time off (PTO). Therefore, Quest said it is providing a payout of most unused PTO for its hourly employees to ensure they don't forfeit it at the end of the year.

Recently, Labcorp also announced it was raising its minimum wage to \$15 (see *LE*, September 2021).

## Highlights From Credit Suisse Conference: Quest Diagnostics And Labcorp

The Credit Suisse 30th Annual Healthcare Conference took place via webcast presentations on November 8-11. Below we highlight the Q&A presentations from executives at the nation's two largest commercial lab companies.

**Mark Guinan**, Executive Vice President and CFO at **Quest Diagnostics**, expects some level of Covid-19 testing to continue into next year. "But the amount of volume in addition to whether or not the PHE [Public Health Emergency] gets extended in January are the biggest wildcards." Longer term, Guinan expects Quest to report organic revenue growth of 2-3% per year plus another 2% from acquisitions.

Guinan said that commercial insurers, including UnitedHealth, are now willing to gradually transition their reimbursement rates after Quest acquires hospital-based outreach labs with higher fee schedules. "The commercial payers realize it's in their best interest when we buy a hospital outreach lab and so they're willing to step down those rates over a couple of years as opposed to the historical windfall they've received after we make an acquisition."

He said that commercial payers are also helping Quest target physician practices that order expensive lab tests from out-of-network labs and hospital outreach labs. "We can then go in with their [the payer's] imprimatur and explain to the physician practice how Quest can save money for their patients....It's become a much more strategic and collaborative relationship with all the national and large regional payers."

Guinan said that test volumes [excluding Covid-19] in the New York City area are still down by double digits as compared with 2019. "It might have to do with public transportation. The New York metro area is the most dependent area in the country for public transportation and until people get comfortable taking buses and subways again the way they used to, there will be access issues for patients."

Guinan said that despite increased wages and compensation, there is a labor shortage in the lab industry. "The good news is we never completely shut down, so we never had to

completely rebuild our workforce. But we are seeing higher rates of turnover especially in the specimen processing part of the lab. There's also quite a bit of demand for drivers and some for phlebotomy and med techs....Some people have made personal decisions to step out of the workforce....There's just not enough people applying when we're looking to hire people."

**Adam Schechter**, Chairman and CEO at **Labcorp**, said that the company has run into supply chain issues in many different places. "We are holding a bit more inventory than we normally would....We've had to worry about everything from test tubes to dry ice to pipette tips to nasal swabs....For almost everything we've had to find ways to innovate to overcome the supply issues we face....But there's no doubt that material costs are going up."

"And there's no doubt that the cost for people is going up....A lot of it is for entry-level positions that we need to fill. There's a lot of competition that didn't exist before....We're seeing competition and wage increases across the business.... We've got to find other ways to reduce costs significantly to offset those additional [salary, wage and benefit] costs," said Schechter.

In terms of Covid-19 PCR testing, Schechter said that Labcorp averaged 114,000 tests per day in September and saw declines in October. "I would expect to see a continued decline unless we see a significant flu season." Schechter said Labcorp's base business (excluding Covid-19) has rebounded to 2019 levels and is growing slightly.

Schechter said Labcorp's acquisition pipeline is as strong as he's ever seen it. "We're always looking for hospital lab acquisitions, local labs and regional labs...They are accretive typically in the first year, they return their cost of capital in a couple of years, and we know how to integrate them."

**Agendia Seeks \$75 Million From IPO** *(cont'd from page 1)*

Agendia, which has 248 employees, operates a CLIA-certified lab (13,000 sq. ft.) that offers two proprietary genetic tests, MammaPrint and BluePrint.

- **MammaPrint** (CPT 81521) measures the activity of 70 genes to determine the likelihood of a patient's breast cancer recurring. MammaPrint has a Medicare rate of \$3,873. The test was cleared by the FDA in 2008.
- **BluePrint** (CPT 81479 for unlisted molecular pathology procedure) analyzes 80 genes to determine the underlying genomics driving the growth of a tumor. BluePrint does not have a fixed Medicare rate.

**Latest Financial Results**

Agendia posted a net loss of \$24.1 million for the nine months ended September 30, 2021, versus a net loss of \$15.7 million for the same period last year; revenue was \$43.9 million, up 8% from \$40.5 million. Agendia has accumulated losses totaling \$319 million since being spun off from the Netherlands Cancer Institute of Antoni van Leeuwenhoek Hospital in Amsterdam in 2003.

Mark Straley (age 60) has been Chief Executive at Agendia since 2015. Previously he was President of the Anatomic Pathology Division at Thermo Fisher Scientific.

Agendia's largest shareholders include the private equity firms Norgine Ventures (London, England), Athyrium Capital Management (New York City) and Korys Investments (Halle, Belgium).

**Competition**

Exact Sciences' Oncotype DX is far and away the market leader in breast cancer gene expression testing. Exact's Oncotype DX test is expected to generate more than \$500 million of revenue in 2021.

Agendia's other competitors include Hologic's Breast Cancer Index, Veracyte's Prosigna and Myriad Genetics' EndoPredict test.

**Comparison of Breast Cancer Gene Expression Tests**

Test Name	Description	Laboratory Vendor	CPT Code	Medicare Rate	FDA Cleared	U.S Launch
Oncotype DX	21-gene assay; Recurrence score of 0-100 provides 10-year prognosis.	Exact Sciences/ Genomic Health	81519	\$3,873	No	2004
MammaPrint	70-gene analysis; provides risk classification for 10-year prognosis.	Agendia	81521	\$3,873	Yes	2008
Breast Cancer Index	11-gene predictor for risk of late recurrence at 5 to 10 years.	Hologic/ Biotheranostics	81518	\$3,873	No	2014
Prosigna (PAM50)	50-gene microarray; gives numerical value of 0-100 for probability of recurrence within 10 years.	Veracyte/ NanoString	81520	\$2,510	Yes	2014
EndoPredict	12-gene molecular score for early and late recurrence.	Myriad Genetics	81522	\$3,873	No	2017

Source: *Laboratory Economics* from companies

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## Enzo Biochem Hires New CEO; Investors Push For More Change

**H**amid Erfanian, age 52, has become Chief Executive Officer Enzo Biochem (New York City) effective November 8. Erfanian was most recently Chief Commercial Officer of Euroimmun, an IVD manufacturer owned by PerkinElmer (Waltham, MA). Former CEO Elazar Rabbani, PhD, age 78, will remain Chairman and will also serve as Enzo's new Chief Scientific Officer.

Erfanian is set receive a base salary of \$600,000 with eligibility for a bonus of between 30% and 100% of his base salary. Furthermore, Erfanian will receive 260,000 shares of Enzo stock plus options to purchase 700,000 more shares. Finally, he will get \$60,000 for relocation expenses.

### Restless Investors Seek More Change

Meanwhile, Bradley Radoff, a private investor who owns 7.5% of Enzo's outstanding shares, says the CEO change does not go far enough. In an open letter to Enzo's board, he said the shift was merely a way to prolong the 45-year tenure of Rabbani, who helped found Enzo in 1976. Radoff is urging the board "to take swift action to prevent Dr. Rabbani from perpetually controlling the company, as if it is his own private fiefdom."

Rabbani did not receive a majority of shareholder votes cast for his re-election at Enzo's last annual meeting in January 2021. However, Enzo's board refused to accept Rabbani's resignation and he remains Chairman.

Other Enzo investors, including Harbert Discovery Fund (10.7% stake), Roumell Asset Management (6% stake), and James Wolf (5.4% stake), have also been pressuring the company to make changes (see *LE*, January 2021).

## Castle Biosciences To Buy Cernostics For Up To \$80 Million

**C**astle Biosciences (Friendswood, TX) has signed a definitive agreement to acquire Cernostics (Pittsburgh, PA) for \$30 million. Furthermore, Castle will pay up to an additional \$50 million in cash and/or common stock if Cernostics reaches certain milestones in 2022. The acquisition is expected to be finalized year's end.

Cernostics is a privately held company that has raised a total of \$21 million since being formed in 2008. Key investors include Illumina Ventures and UPMC.

Cernostics markets a laboratory-developed test named the TissueCypher Barrett's Esophagus Assay. The test uses spatial biology (3D analysis of tissue) and artificial intelligence to analyze digitized images of tissue biopsies. The test is designed to predict future development of high-grade dysplasia and/or esophageal cancer in patients with Barrett's esophagus, a disorder in which the lining of the esophagus is damaged by stomach acid.

TissueCypher has its own unique CPT PLA code (0108U) and is reimbursed by Medicare at \$2,513. The proprietary test is only available from Cernostics' CLIA-certified lab in Pittsburgh.

Cernostics, which has 16 employees, will remain based in Pittsburgh and CEO Mike Hoerres will continue with Castle after the acquisition. Castle plans to hire 13-15 sales reps to begin marketing its TissueCypher test directly to gastroenterologists and cardiothoracic surgeons.

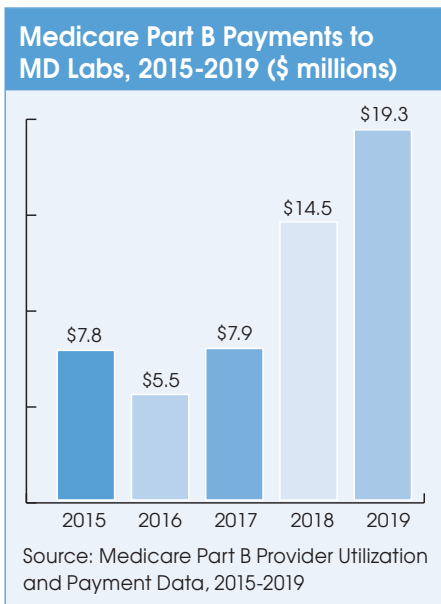
Castle, which has 201 employees, is headquartered in Friendswood, Texas (near Houston) and operates a CAP-accredited laboratory in Phoenix. Its lead testing product is DecisionDx-Melanoma, which analyzes 31 genes to predict metastatic risk in patients diagnosed with cutaneous (skin) melanoma. DecisionDx-Melanoma is an Advanced Diagnostic Laboratory Test (ADLT) that is reimbursed by Medicare at \$7,193 (CPT 81529).

For the nine-month period ended September 30, 2021, Castle reported a net loss of \$24.9 million versus a net loss of \$5.4 million in the same period last year; revenue increased by 52% to \$69 million.

## MD Labs To Pay Up To \$16 Million To Resolve Fraudulent Billing Allegations

Nevada-based MD Spine Solutions (doing business as MD Labs) and its two owners have agreed to pay up to \$16 million to settle allegations that MD Labs submitted false claims to Medicare and Medicaid, according to the U.S. Department of Justice. The co-owners, Denis Grizelj and Matthew Rutledge, have admitted that MD Labs regularly billed federal healthcare programs for medically unnecessary urine drug tests (UDTs) between 2015 and 2019.

Typically, a relatively inexpensive UDT called a presumptive test will be used first to quickly determine the need for a confirmatory UDT. However, MD Labs had regularly performed and billed for both UDTs at the same time without physician-designated reflex orders in place. Since the presumptive test was no longer being used to call for secondary testing, many confirmatory UDTs were medically unnecessary, according to the DOJ.



The settlement states that MD Labs, Grizelj and Rutledge will pay the government no less than \$11.6 million and up to \$16 million based on MD Labs' financial performance through 2026. CMS also suspended Medicare payments to MD Labs effective April 13, 2021.

The DOJ's case against MD Labs was initially set into motion in December 2018 by a whistleblower, Omni Healthcare (Melborne, FL), which will get 15% of the settlement amount. Omni Healthcare is a multi-specialty group with seven offices located in the Orlando area.

The settlement amount is small potatoes compared with the total Medicare payments of \$55 million that MD Labs received between 2015-2019, notes *Laboratory Economics*.

## Arkansas Lab Owner Indicted in \$100 Million Billing Fraud

A federal grand jury in the Western District of Arkansas has indicted Billy Joe Taylor, age 42, for an alleged scheme that billed Medicare for over \$100 million dollars in fraudulent lab test claims between February 2017 and May 2021.

Taylor is the owner of several lab companies, including Vitas Laboratories (Barling, AR), Beach Tox (Torrance, CA), Nations Laboratory Services (Tecumseh, OK), Corrlabs (Southern Pines, NC) and Imaginus Diagnostic Laboratory (Spiro, OK).

Taylor allegedly used access to beneficiary and medical provider information from prior lab orders to submit fraudulent claims for urine drug tests, Covid-19 tests and respiratory pathogen panels, that were not actually ordered or performed. The complaint also alleges that hundreds of claims were submitted for beneficiaries after they had died or otherwise ceased providing samples.

Taylor used the proceeds of the fraud to live a lavish lifestyle, including purchasing numerous luxury cars, real estate, jewelry and guitars, according to the indictment.

Taylor is charged with 16 counts of health care fraud, and one count of engaging in a monetary transaction in criminally-derived property. Each of the counts is punishable by a maximum penalty of 10 years in prison. He is scheduled for his arraignment on November 23 before the U.S. District Court for the Western District of Arkansas.

## Toxicology Labs Average \$475 Per Medicare Patient

The top 25 independent toxicology lab companies received an average of \$475 of revenue per Medicare patient they served in 2019, according to data analyzed by *Laboratory Economics* from the Medicare Part B program.

The biggest toxicology lab in the country is **Aegis Sciences Corp.** (Nashville, TN), which received \$47.8 million of Medicare payments for 387,812 tests provided to 117,943 patients in 2019 for an average of \$405 per patient. Aegis billed an average of 3.3 CPT codes per Medicare beneficiary it served. Its three highest volume codes in 2019 were G0482 (drug test, definitive; 15-21 classes), CPT 80307 (testing for presence of drug) and G0481 (drug test, definitive; 8-14 classes).

**Vitas Laboratory** (Barling, AR) collected the highest average Medicare payment per beneficiary at \$4,459. The company billed an average of 28 CPT codes per Medicare beneficiary it served. Its three highest volume codes in 2019 were G0483 (drug test, definitive; 22+ classes), CPT 80307 and CPT 80053 (comprehensive metabolic panel). The owner of Vitas Laboratory, Billy Joe Taylor, was recently indicted for allegedly defrauding Medicare (see page 10).

### Top 25 Toxicology Labs by Medicare Part B Payments, 2019

Laboratory	Location	Number of Medicare Patients	Total Medicare Payments	Avg. Paid Per Patient
Aegis Sciences Corp.	Nashville, TN	117,943	\$47,781,949	\$405
Millennium Health	San Diego, CA	95,730	\$39,385,355	\$411
MD Spine Solutions (dba MD Labs)	Reno, NV	27,977	\$19,330,709	\$691
Precision Toxicology	San Diego, CA	34,423	\$15,240,737	\$443
Ethos Holding Corp	Newport, KY	21,653	\$11,342,530	\$524
Medscan Laboratory	Williston, ND	15,458	\$8,927,802	\$578
Dominion Diagnostics	North Kingstown, RI	18,111	\$8,436,057	\$466
Lifebrite Laboratories	Brookhaven, GA	14,497	\$8,151,724	\$562
American Institute of Toxicology	Denton, TX	17,101	\$7,306,106	\$427
Radeas	Wake Forest, NC	10,930	\$6,210,781	\$568
Genotox Laboratories	Austin, TX	9,766	\$6,135,899	\$628
National Labs Inc.	Hayward, CA	9,830	\$5,941,017	\$604
Vitas Laboratory	Barling, AR	1,227	\$5,471,156	\$4,459
American Forensic Tox Services	Huntington, NY	14,150	\$5,020,326	\$355
Regional Toxicology Services	Tacoma, WA	13,962	\$5,003,315	\$358
Synergy Medical Laboratories	Old Bridge, NJ	3,588	\$4,933,897	\$1,375
Labsource	Greenville, SC	9,172	\$4,933,598	\$538
Drugscan Inc.	Horsham, PA	15,808	\$4,904,034	\$310
Compass Laboratory Services	Memphis, TN	9,648	\$4,903,581	\$508
Helix Diagnostics	Waterford, MI	5,758	\$4,792,856	\$832
South Georgia Toxicology	Valdosta, GA	7,164	\$4,491,173	\$627
Infiniti Labs Inc.	Tampa, FL	6,451	\$4,457,054	\$691
Medical Tox Labs	Tampa, FL	5,720	\$4,324,631	\$756
Labcorp	Rsrch Tri Park, NC	23,397	\$4,223,493	\$181
Acutis Diagnostics	East Northport, NY	7,912	\$4,085,643	\$516
<b>Totals &amp; Average</b>		<b>517,376</b>	<b>\$245,735,422</b>	<b>\$475</b>

Source: *Laboratory Economics* from Medicare Part B Provider Utilization and Payment Data for 2019

## Lab Stocks Up 5% Year To Date

Twenty-three lab stocks have risen by an unweighted average of 5% year to date through November 12. In comparison, the S&P 500 Index is up 26% thus far in 2021. The top-performing lab stocks so far have been Interpace Biosciences, up 154%; Fulgent Genetics, up 70%; and Psychomedics, up 67%. Labcorp is up 46%, Quest Diagnostics, +26%, and Sonic Healthcare, +20%.

Company (ticker)	Stock Price 11/12/21	Stock Price 12/31/20	2021 Price Change	Enterprise Value (\$ mill)	Enterprise Value/Revenue	Enterprise Value/EBITDA
Labcorp (LH)	\$297.23	\$203.55	46%	\$32,740	2.0	7.1
Quest Diagnostics (DGX)	150	119.17	26%	21,850	2.0	6.4
Sonic Healthcare (SHL.AX)*	38.51	32.15	20%	20,800	2.4	8.1
Exact Sciences (EXAS)	91.7	132.49	-31%	16,680	9.5	NA
Guardant Health (GH)	103.8	128.88	-19%	10,580	30.9	NA
Natera (NTRA)	115.04	99.52	16%	10,070	17.8	NA
NeoGenomics (NEO)	41.92	53.84	-22%	5,300	11.0	60.0
Invitae (NVTA)	21.96	41.81	-47%	5,080	11.7	NA
Veracyte (VCYT)	48.15	48.94	-2%	3,030	19.2	NA
Opko Health (OPK)	4.12	3.95	4%	2,880	1.6	14.7
Myriad Genetics (MYGN)	30.24	19.77	53%	2,240	4.0	NA
CareDx (CDNA)	47.68	72.45	-34%	2,180	7.9	NA
Fulgent Genetics (FLGT)	88.82	52.10	70%	2,160	2.4	3.3
Castle Biosciences (CSTL)	51.68	67.15	-23%	1,180	13.6	NA
Progenity (PROG)	2.97	5.31	-44%	504	6.7	NA
DermTech Inc. (DMTK)	25.17	32.44	-22%	446	48.9	NA
Aspira Women's Hlth (AWH)	2.35	6.71	-65%	239	39.9	NA
Biodesix (BDSX)	7.81	20.16	-61%	190	2.5	NA
Enzo Biochem (ENZ)	3.39	2.52	35%	143	1.2	17.8
Exagen (XGN)	12.87	13.20	-3%	141	3.0	NA
Interpace Biosciences (IDXG)	7.98	3.14	154%	85	2.2	NA
Psychomedics (PMD)	8.5	5.09	67%	53	2.4	35.8
Biocept (BIOC)	3.95	4.44	-11%	50	0.9	NA
Unweighted Averages			5%	\$138,621	10.6	19.2

\*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from company reports and Capital IQ

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