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# LABORATORY

# INDUSTRY REPORT™

Vol. 14, Iss. 18, September 18, 2014



## HIGHLIGHTS

### TOP OF THE NEWS

- Veracyte acquires Allegro Diagnostics for \$21 Million ..... 1
- LabCorp launches new division to focus on NGS testing ..... 1
- Mayo Medical Laboratories enters into development deal with European firm ..... 3

### INSIDE THE LAB INDUSTRY

- In a tough market, PeaceHealth Laboratories tries to drum up new revenue ..... 4

### INDUSTRY BUZZ

- Pathway Genomics enters into pact with Susan J. Komen Foundation ..... 8

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## Veracyte Acquires Allegro Diagnostics For \$21 Million

**V**eracyte Inc. is adding winds to its sails by entering the growing pulmonology market.

The South San Francisco, Calif.-based company has acquired Allegro Diagnostics in a deal valued at \$21 million, a rare instance of late when a purchase price is disclosed in the lab sector. The transaction includes \$7.8 million in cash and \$13.2 million in Veracyte stock.

Allegro had been developing a test called Bronchogen, which acts as a complementary assay for bronchoscopic procedures. The test helps clinicians determine whether a patient with lung nodules can be effectively monitored using CT scans rather than through more invasive procedures required for a pathology diagnosis. It closely monitors molecular changes that occur in a patient's airways as a result of smoking. Bonnie Anderson, Veracyte's chief executive officer, said the test can be used with surgery to detect lung cancer.

Although the test is not yet commercially available, it has been tested in two validation studies involving nearly 1,000 patients. It was

*Continued on page 2*

## LabCorp Launches New Division to Focus On NGS Testing

**L**abCorp, the nation's second-largest laboratory, has announced a plan to enlarge its focus on the well-paying realm of molecular diagnostics. The company has launched a division called Enlighten Health Genomics that will capitalize on next-generation sequencing technology.

"Enlighten Health Genomics is an important part of LabCorp's strategy to capitalize on our unique assets, create new sources of revenue from our core capabilities and meaningfully differentiate us from competitors," Dave King, LabCorp's chief executive officer, said in a statement. "The launch of this business is another tangible step in the development of Enlighten Health, our initiative to create innovative tools and capabilities to enhance patient care."

No details were released about Enlighten Health's management, but it will have a scientific advisory board, chaired by Duke University genetics professor David Goldstein.

*Continued on page 7*



## Upcoming G2 Events

### Lab Institute 2014 Inflection Point for Labs

Oct. 15-17, 2014  
Hyatt Regency on Capitol Hill  
Washington, D.C.  
[www.LabInstitute.com](http://www.LabInstitute.com)

### Getting a Piece of the Private Payer Market: Lab Contracting Trends, Pricing Realities, and Business Outlook

Half-Day Symposium  
Oct. 17, 2014  
Hyatt Regency on Capitol Hill  
Washington, D.C.  
[www.LabInstitute.com/Symposium](http://www.LabInstitute.com/Symposium)

### ■ VERACYTE ACQUIRES ALLEGRO DIAGNOSTICS FOR \$21 MILLION, *from page 1*

deemed to be more than 90 percent effective in diagnosing patients with an intermediate risk for lung cancer. About 8 million Americans are considered high risk for developing the disease based on their history of heavy smoking and might need ongoing testing, Anderson said.

The functionality of Bronchogen is similar to that of Afirma, Veracyte's test for thyroid cancer, which can provide a detailed diagnosis and help avoid unnecessary thyroid biopsies and removals. The company claims Afirma can reduce surgery rates for thyroid cancer victims as much as 50 percent. Anderson said pulmonology has a similar "diagnostic ambiguity" to endocrinology and therefore provided an opportunity for its next business expansion.

"With Allegro and its novel, clinically validated lung cancer test, we plan to accelerate our entry into the pulmonology market, enabling us to improve care for patients with lung nodules while creating long-term growth opportunities," Anderson said. "Allegro is a natural fit for us, and we believe this move further establishes our leadership in molecular cytology, using genomics to resolve diagnostic ambiguity preoperatively and thus spare patients from unnecessary invasive procedures and reduce associated health care costs."

The test is expected to become commercially available by the middle of next year and would provide "meaningful revenue" to the company's top line by 2017, according to Anderson.

Veracyte was already developing a test for idiopathic pulmonary fibrosis, or IPF, but Anderson indicated it would not be available until at least 2016. However, the launch of Bronchogen is expected to enhance the chances for the IPF assay because the focus on sales growth would be on the same pulmonologists.

One Wall Street analyst said the deal only provides upside for Veracyte.

"It's a great area for the company to be getting into," said J.P. McKim, an analyst with William Blair & Co. in Chicago. "It kind of goes along with the prevention of overtesting and overtreatment and allows those people to kind of avoid unnecessary surgery, which in essence saves payers money."

McKim added that the money-saving factor is among the reasons Veracyte has been able to obtain relatively quick coverage approval for Afirma from a large number of insurers. It has coverage for about 135 million lives, up from 125 million in the prior quarter and 100 million a year ago, according to a recent report McKim and fellow analyst Amanda Murphy recently published on Veracyte.

"We believe Veracyte is uniquely poised to commercialize and gain reimbursement for our test, given the rapid success the company has achieved with its Afirma solution," said Michael D. Webb, Allegro's chief executive officer.

William Blair has other reasons to be bullish on Veracyte. It recently renegotiated its contract with biotech giant Genzyme to provide marketing and sales support for Afirma. It will pay Genzyme 15 percent of the revenues from test sales, down from 32 percent, until 2027.

“We believe that the amended agreement brings not only forward profitability for the company, but also additional sales reps in house (more feet on the street) to penetrate complex accounts with a more-specialized/-focused rep,” McKim and Murphy wrote, projecting that Veracyte will have a 35 percent market penetration by 2017, compared to its current penetration of about 15 percent. Although the company’s stock price has retreated significantly from its 52-week high of more than \$18 a share in the spring and is now trading at around \$11 a share, the analysts maintained their “outperform” rating on Veracyte’s stock and expected that more payer contracts will be announced later in the year.

*Takeaway: Veracyte’s decision to acquire Allegro Diagnostics will accelerate the company’s entry into pulmonology testing.* 

### Mayo Medical Laboratories Enters Into Development Deal With European Firm

**T**he Minnesota-based Mayo Medical Laboratories has entered into a deal with a European firm to develop what it calls a “novel” series of new molecular assays based on next-generation sequencing.

Under the terms of the agreement, the Mayo Clinic’s division of clinical microbiology will supply appropriate tissue samples to Advanced Biological Laboratories for use in developing new laboratory-developed tests. The two organizations will also develop a sequencing database as the result of their collaboration.

Additionally, Mayo Medical Laboratories will also have access to Advanced Biological’s genotyping platforms, which include both Sanger and next-generation sequencing. Its two primary products, the ViroScore Suite and DeepChek, have yet to receive approval from the U.S. Food and Drug Administration and therefore can only be used for research purposes. However, the platforms are widely available in Europe through a distribution agreement Advanced Biological has with Roche Diagnostics International.

Advanced Biological, which is based in Luxembourg, is a spinoff company from that country’s Public Research Center for Health. It focuses specifically on molecular testing and ongoing monitoring of infectious chronic diseases, specifically HIV, the HPV virus, and hepatitis. Those three medical conditions are treatable with drug regimens, but caring for patients in the long term is often complicated and expensive.

“Properly validated and characterized laboratory-developed tests offer valuable direction to clinicians and virologists. They guide the selection of optimal treatments and diagnostic monitoring for patients suffering from genetically variable virological diseases of either an acute or chronic nature,” said Advanced Biological Chief Executive Officer Chalom Sayada, M.D. “When developed in a timely manner, these tests can be crucial to improved clinical outcomes and decreases in treatment failures, adverse events, and health care costs.”

Financial terms of the deal were not disclosed.

*Takeaway: Mayo Medical Laboratories is willing to go overseas and enter into untraditional partnerships in order to expand its testing portfolio.* 

# Inside The Lab Industry



## In a Tough Market, PeaceHealth Laboratories Tries to Drum Up New Revenue

If Ran Whitehead did not have the best high school-age job in the history of American adolescence, it was near the very top of the list.

The chief executive officer of PeaceHealth Laboratories in Oregon grew up in Southern Florida in the 1960s and was drummer for a band called the Avengers. It played a circuit of local clubs and opened at the renown Miami club Hullabaloo for a headlining California band, the Turtles, whose biggest hit was the iconic 1967 tune “Happy Together.”

When the Turtles drummer needed to take a leave of absence, Whitehead was offered the job. It paid \$1,500 a week (more than \$10,300 in today’s dollars). He also appeared on the band’s *Happy Together* album cover, which was its biggest seller by far.

But the gig ended, and although Whitehead wanted to continue in music and show business, his parents wanted him to have a Plan B. He decided to pursue a career in health care himself (his father was a physician), and the Turtles money paid for a portion of his education at the University of Michigan, where he studied to be a medical technologist. He later earned an MBA from Duke University.

**“The leadership is quite strong, with a good commercial lab and hospital background.”**

**—Noel Maring,  
Vice President,  
Sonic Laboratories**

“It was hard to leave the entertainment world, but in retrospect, my parents were right,” Whitehead said.

After lab management jobs with such organizations as SED Medical Laboratories and Home Healthcare Laboratories of America, Whitehead joined PeaceHealth Laboratories in 2001 as its chief operating officer. He’s been its CEO since 2003.

Whitehead still records albums with local musicians in his spare time. He believes his years in show business have helped him manage PeaceHealth’s 800-plus employees.

“Your job is to evince fire and promote programs and that is a form of entertainment. I try to use what I learned to charm, influence, and make a good presentation,” he said. Whitehead also sits in with bands hired for workplace events, a disarming tactic that helps create a greater bond with his workers.

But if there any hints of hippiedom within PeaceHealth Laboratories, it appears to be limited to its name.

“The leadership is quite strong, with a good commercial lab and hospital background,” said Noel Maring, a vice president with Sonic Laboratories in Texas, who spent nearly two decades as a senior manager with Spokane, Wash.-based PAML, one of PeaceHealth’s competitors. “They have a strong knowledge of both sides of the business, and how to integrate outreach testing with a hospital environment.”

Maring believes the PeaceHealth structure is a model for other health systems. “All their hospital labs and the core lab are centrally managed under one leadership team, allowing for standardization, economies of scale, and maximizing efficiencies,” he said.

### **A Difficult Operating Environment**

And PeaceHealth Laboratories, its management and staff are navigating a difficult environment together, happy or not. The organization, which operates 12 labs in Oregon, Washington, and Alaska, has been battling cuts in reimbursement from Medicare and private payers. Annual test volumes, at around 7.5 million, have been flat for several years (although an uptick in the last quarter suggests to Whitehead that business may finally be on the road toward improvement). “I think the employment picture has improved,” he said, meaning that more people have insurance and therefore are more likely to seek lab testing.

***“They have excess and growth capacity and have some areas of well-developed expertise.”***

***—Francisco Velázquez, M.D.,  
Chief Executive Officer,  
PAML***

Although Whitehead’s organization is affiliated with the 10-hospital PeaceHealth health care system, it operates as an independent lab. As such, it is paid on the Medicare fee schedule and does not enjoy the higher rates paid to hospital laboratories. And while Medicaid expansion under the Affordable Care Act has been unrivaled in Oregon (anyone receiving food stamps was automatically enrolled), it only covers about 60 percent of the costs of providing services.

### **New Product Lines**

To that end, Whitehead and the rest of the PeaceHealth Laboratories staff have been trying to drum up new product lines that can grow business outside of the traditional revenue streams.

According to the CEO of one of PeaceHealth Lab’s biggest competitors, the company is in a good spot to grow organically.

“They have excess and growth capacity and have some areas of well-developed expertise,” said Francisco Velázquez, M.D., PAML’s chief executive officer.

Among those areas, according to Velázquez, is medication testing and monitoring. Indeed, one of PeaceHealth’s biggest initiatives has been in that realm.

That began several years ago. PeaceHealth Laboratories is licensed as a toxicology lab, but its margins in workplace testing had eroded due to price cutting and competition. One of PeaceHealth’s scientists proposed using a different set of testing protocols and algorithms in order to create a more precise test.

The result is PtProtect, for which PeaceHealth Laboratories obtained a patent in 2011. The resulting testing panel can detect opioid use at levels as low as two nanograms per decileter, compared to about 50 nanograms per decileter for panels from other labs. As a result, PtProtect can detect

## INSIDE THE LAB INDUSTRY

opioid use in 37 percent more patients than other traditional tests, according to PeaceHealth Laboratories' marketing material. According to Whitehead, the test retails for about \$500 and average reimbursement is about \$300—on the high end for drug assays.

Sales of the PtProtect test have enjoyed double-digit annual growth since the panel was launched in 2012, with sales remaining mostly in the Pacific Northwest and Western United States, suggesting that there remains a lot of room to boost sales. But efforts to license the panel to other labs have remained a work in progress, although Whitehead said it has commanded a lot of interest.

"We definitely have a plan to expand this, either through licensing or through arrangements with large health care providers," Whitehead said. He added that PeaceHealth had just hired a national sales representative to encourage licensing and wider use of the PtProtect panel.

Meanwhile, tweaks have also had to be made to the test, according to Whitehead. Some users, for example, no longer wish to test for marijuana, which is now legal for medical use in 23 states and the District of Columbia. It is also legal for recreational use in Washington state, where PeaceHealth has a significant presence.

PeaceHealth Laboratories is also planning to launch another panel late this year that will focus on medication adherence—ensuring patients are taking their prescribed drugs and in the case of painkillers, not selling them. It will provide similar levels of sensitivity as the PtProtect panel. Whitehead said he hopes the panel, which will be branded as RxAdhere, will eventually reduce hospital readmissions, of which about half are linked to prescription drug adherence issues.

The lab is also making inroads into testing and health care delivery using smartphones and other smart devices. It is working with the Finnish company iStoc, although any assays that come out of the collaboration are likely a few years away.

### **Tiptoeing Toward Price Transparency**

Meanwhile, PeaceHealth has also made inroads with individual patients, many of whom are facing rising out-of-pocket costs for their health care even when they are well insured. Its EasyAccess program, launched about four years ago, offers discounts of around 30 percent to 50 percent on the retail price of tests if patients are willing to pay.

"It's not a huge part of our business, but it is helpful for patients who are uninsured or underinsured," Whitehead said. One of the biggest surprises: About a quarter of its users had never patronized PeaceHealth Laboratories before, creating a new revenue stream from people who are generally grateful for its opening access.

"We have gotten many letters from people who are thanking us for this service. These are people who probably would not have gotten their lab tests done otherwise," Whitehead said.

*Takeaway: Creating unique product lines may be a way for enterprises such as PeaceHealth Laboratories to grow revenues in a tough operating environment.*



### ■ **LABCORP LAUNCHES NEW DIVISION TO FOCUS ON NGS TESTING**, *from page 1*

“We believe that patients with serious genetic conditions require a thorough interpretation of their genome. Our goal is to offer innovative and affordable diagnostic solutions to broad patient populations, making genomics a routine part of clinical decisions,” Goldstein said in a statement.

An enhanced focus on molecular diagnostics makes business sense. Although coverage for many tests has been held up by a regulatory thicket on the Medicare side, many tests command prices of hundreds or thousands of dollars apiece, meaning that large chunks of revenue can be generated without dependence on a heavy volume.

Meanwhile, LabCorp, like its counterpart Quest Diagnostics, has been struggling with flat revenue. In 2013, its revenue, \$5.8 billion, was less than 2 percent higher than it had been in 2012 and essentially unchanged from 2011.

“LabCorp has historically been increasing its footprint in molecular testing and genomic analysis through both internally expanding their menu and acquisitions, and clearly sees this as an important market for product expansion,” said Lâle White, chief executive officer of XIFIN, a San Diego-based firm that focuses on laboratory reimbursement issues. “Genomic analysis is essential to the test menu of any comprehensive lab, not just to preserve market share and grow revenue, but because it is the fastest-growing segment of lab services and represents the future of diagnostics, personalized medicine, disease management, and population health management.”

White added that labs are also pressured to turn to esoteric assays “since there is a continual compression of reimbursement for older assays that are performed with greater automation and thus commoditized. As the result of the rapid advancements in technology, molecular and genetic testing are simply beginning to outpace the commoditization of . . . basic chemistry testing.”

In addition to the Enlighten Health division, LabCorp also said that it would introduce a whole-genome sequencing service called ExomeReveal later this year. It would focus on “genome-wide interpretation for children with serious childhood genetic diseases as well as additional diagnostic information for patients of any age,” the company said in a press release.

But that was pretty much the limit of what LabCorp was willing to say. The Burlington, N.C.-based lab has a reputation for being exceedingly tight-lipped, particularly for a publicly traded company of its size, and it did not deviate from that path in this matter. Its mandated regulatory filing with the Securities and Exchange Commission regarding Enlighten Health did not include anything beyond the spare press release it had issued.

Company spokesperson Stephen Anderson said any queries would have to be cleared by LabCorp’s legal department. However, the company did not respond by time of publication to both e-mail and telephonic requests for comment.

*Takeaway: In a bid to grow revenues, LabCorp has launched a new division that will focus on the lucrative niche of molecular health and next-generation sequencing.* 

## Pathway Genomics Enters Into Pact With Susan J. Komen Foundation

**P**athway Genomics, the San Diego-based molecular laboratory, has entered into a pact with one of the nation's best known breast cancer charity programs.

The deal with the Susan J. Komen Cancer Foundation includes funding for the organization's future "Race for the Cure" events in San Diego, Los Angeles, Denver, and Seattle. It will also include money to reach medically underserved women in Washington, D.C. That city has the highest death rate from breast cancer in any city in the United States.

The financial terms of the deal agreement were not disclosed.

"The Susan G. Komen organization does an extraordinary job serving uninsured, low-income, and medically underserved women and men of our communities, and we're delighted to help as long-term partners in that mission," said Pathway Genomics Chief Executive Officer Jim Plante.

Pathway has worked closely with Komen in the past, hosting a fund-raiser in Southern California for the Dallas-based charity earlier this year. But Pathway, which began heavily promoting the BRCA test to women earlier this year, needs to make inroads into likely users in the midst of rising competition among labs offering a form of the assay. A patent on the basic breast cancer gene, once held by Myriad Genetics, was overturned by the U.S. Supreme Court last year.

Meanwhile, Komen has been under financial duress after it decided two years ago to stop making monetary contributions to Planned Parenthood. It quickly reversed that decision after a public backlash, and the executive who had pushed the decision resigned. Nevertheless, Komen suffered a drop-off in donations, prompting it to cancel half of its Race for the Cure events last year.

"Pathway Genomics' partnership builds on our view that we can help significant numbers of women, and solve important problems in breast cancer, through partnerships," said Komen Chief Executive Officer Judith A. Salerno, M.D. "Pathway Genomics' partnership will allow us to reach the most vulnerable women and men in our communities to provide educational programs and help and support for those facing the disease."

*Takeaway: Pathway Genomics is using philanthropy as a potential path for raising the awareness of its BRCA assay.* 

<i>References</i>			<b>Note our change of address and phone numbers effective immediately. To subscribe or renew LIR, call now +1-603-357-8101, 800-531-1026 (AAB and NILA members qualify for a special discount, Offer code: LIRN11)</b>
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