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# LABORATORY

# INDUSTRY REPORT™

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## HIGHLIGHTS

### TOP OF THE NEWS

Anthem Makes Offer  
Indiana's Hospital Labs  
Apparently Can't Refuse ..... 1

PAML and BloodworksNW  
Enter Into a Strategic  
Collaboration ..... 1

Foundation Medicine  
Enters Into Collaborative  
Agreement with NCI ..... 2

Cyrex Laboratories  
Introduces Food-Related  
Autoimmune Test Panel ..... 3

### INSIDE THE LAB INDUSTRY

Despite Big Write-offs,  
Quest & LabCorp Report  
Strong First Quarters ..... 4

### INDUSTRY BUZZ

Quest Launches New Tests  
for Blood-Based Cancers ..... 8

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### Lab Institute

October 14-16, 2015

Hyatt Regency Washington DC  
on Capitol Hill

[www.labinstitute.com](http://www.labinstitute.com)

## Anthem Makes Offer Indiana's Hospital Labs Apparently Can't Refuse

**A**nthem Blue Cross Blue Shield of Indiana has introduced a hospital reference laboratory network with uniform prices for patients, a move stirring concern that it could dramatically ratchet down reimbursements for laboratories elsewhere in the country.

Anthem introduced the network in March, saying its impetus was a study released last year showing vast differences in pricing among hospital labs in California, where one lab might charge \$10 for an assay for which another lab would charge \$10,000.

In a statement issued by the health plan, it said a test that may have cost \$400 at an out-of-network laboratory would cost as little as \$45 for a patient picking one of the reference labs, reducing their out-of-pocket costs from as much as \$120 to \$4.50.

*Continued on page 7*

## PAML and BloodworksNW Enter Into a Strategic Collaboration

**P**AML, the largest standalone laboratory in the Pacific Northwest, has entered into a strategic alliance with another major player in the region.

PAML said late last month it had entered into a letter of intent with Seattle-based Bloodworks Northwest (BloodworksNW), which changed its name last year from Puget Sound Blood Center. BloodworksNW has been in operation since the mid-1940s, and has gradually expanded its blood banking operations to include a significant menu of laboratory tests.

The two companies labeled the work they will do together as more of a collaboration "on innovation" than a joint venture or a merger.

"This letter of intent underscores the potential for synergy between our two organizations, and the role we both play providing specialized lab services to support the highest quality of patient care," said BloodworksNW Chief Executive Officer James P. AuBuchon in a

*Continued on page 2*

**■ PAML AND BLOODWORKSNW ENTER INTO A STRATEGIC COLLABORATION, from page 1**

statement. “By combining our strengths, we can improve the efficiency and scope of clinical services, improve access to specialized transfusion and transplantation testing, and ensure that healthcare expenditures deliver the maximum value.”

PAML Chief Executive Officer Francisco Velázquez said some form of collaboration between the two companies makes sense.

“PAML and BloodworksNW share a common geography, and we are very strong providers in our areas, and we provide services to a lot of the same hospitals, and cover a lot of the same patient populations,” he said. “If we work together, we can avoid duplications.”

One area of potential overlap is in obstetrics/gynecology. PAML provides a lot of initial prenatal bloodwork services, but BloodworksNW often provides prenatal testing for expectant mothers that is beyond the routine.

“One of the things we want to do is to immediately strengthen that process so patients can get access to all of the testing they need in one stop as opposed to making two to three stops for each patient,” Velázquez said.

He added that BloodworksNW also has a significantly stronger menu than PAML in red blood cell-based genomic testing, as well as in testing for specialty coagulation blood disorders and the human leukocyte antigen (HLA). Consolidating test menus to some extent is also expected to strengthen customer service for both labs, according to Velázquez.

The two entities are also expected to collaborate on direct-to-consumer testing and data sharing to improve BloodworksNW’s blood drives and blood banking, as well as to create more efficiencies among their respective staffs of hematologists.

Although the two labs will continue their discussions as to where else their services could complement one another’s, no cash has changed hands as part of the letter of intent, and there are no plans for a merger, according to Velázquez.

“If we help each other reach specific segments of the market and eliminate the overlap, everyone wins,” he said.

*Takeaway: A collaboration between PAML and BloodworksNW will likely consolidate their market dominance in the Pacific Northwest.* 

## Foundation Medicine Enters Into Collaborative Agreement with NCI

**T**hey’re called “exceptional responders.” They are cancer patients who had an unexpected and long-lived reaction to a form of treatment that few other patients—typically less than 10 percent—show.

Little hard scientific information is actually available regarding these patients and their reactions, but Foundation Medicine, which specializes in genomic analysis of cancer cases, is trying to change that.

The Cambridge, Mass.-based Foundation has announced that it has entered into a collaboration with the National Cancer Institute (NCI) to study exceptional responders.

Foundation's FoundationOne genomic profile of solid tumors will be used to analyze the tumors that will be collected for the study in an attempt to determine if there is some genetic variations that have led to the odd responses these patients have had.

Tumor tissue samples from more than 300 patients labeled exceptional responders will be collected for the study. They will come from NCI-supported clinical trials, clinical studies at private sector hospitals, and cases submitted by oncologists.

FoundationOne will work in collaboration with the Baylor College of Medicine and Nationwide Children's Hospital. Nationwide Children's will prepare the samples for analysis. And in addition to FoundationOne's analysis, whole exome and transcriptome RNA sequencing will be conducted at the Baylor College of Medicine.

"At Foundation Medicine, we are focused on understanding the unique molecular changes that contribute to a patient's individual disease to inform treatment decisions," said Foundation Medicine Chief Medical Officer Vincent Miller, M.D., in a statement. "The [Exceptional Responders Initiative] represents a significant opportunity to utilize advances in precision medicine to better understand outcomes, which can be applied to the future selection of treatments for patients with cancer. Every oncologist can point to a small number of their patients who have had unusually favorable responses to systemic therapies," said Miller. "By beginning to leverage this experience, largely rooted in community practice, we hope to learn more quickly and generate critical hypotheses which can then be validated in larger cohorts."

Financial terms of the collaboration with NCI were not disclosed.

*Takeaway: Foundation Medicine will be teaming with the federal government to capitalize on one of the yet-to-be explained mysteries of personalized medicine.* 

## Cyrex Laboratories Introduces Food-Related Autoimmune Test Panel

**A**n Arizona laboratory has launched a panel that can test for dozens of food-triggered autoimmune disorders.

Phoenix-based Cyrex Laboratories said that its Array 10 panel can test 180 raw and cooked foods for triggering autoimmune disorders in patients. The panel was created specifically to determine a food's reaction to a patient in real-world circumstances.

Some 50 million Americans are living with some form of autoimmune disease, which include rheumatoid arthritis, Crohn's disease and lupus. Foods containing gluten, sugar, chocolate, dairy, and tomatoes are among the triggers for autoimmune conditions. However, diagnosing such disorders can often take years because of the vast array of causes.

"It's time we start paying attention to what we are putting into our bodies and how our bodies react to our diets. In addition to genes, environmental triggers such as toxic chemicals, infectious agents and food proteomes all play a significant role in autoimmune disease," said Aristo Vojdani, Cyrex's chief scientific advisor, in a statement.

*Takeaway: Cyrex Laboratories is attempting to use a new test to simplify the diagnosis of autoimmune disorders.* 

# Inside The Lab Industry

## Despite Big Write-offs, Quest & LabCorp Report Strong First Quarters

The first quarter of the year looked pretty good for the two national laboratories, as Quest Diagnostics reported strong revenue growth and LabCorp began reaping the benefits of its huge acquisition last year of pharmaceutical firm Covance.

For the first quarter ending March 31, the New Jersey-based Quest reported net income of \$61 million on revenue of \$1.84 billion. That compares to first quarter 2014 net income of \$122 million on revenue of \$1.75 billion. Income was negatively impacted by an \$80 million write-off associated with the early retirement of debt in association with the company's recent \$1.2 billion debt refinancing, as well as restructuring and integration costs. Altogether, Quest forecasts taking \$115 million in charges related to the refinancing.

*The performance for the quarter was strong despite the harsh winter weather in the Northeast, which Quest Chief Financial Officer Mark Guinan estimated impacted earnings by 8 cents per share, or about 8 percent overall.*

But the write-downs did not eclipse strong growth: Requisitions were up 5.6 percent for the quarter, although revenue per test was down 0.7 percent.

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The performance for the quarter was strong despite the harsh winter weather in the Northeast, which Quest Chief Financial Officer Mark Guinan estimated impacted earnings by 8 cents per share, or about 8 percent overall. Yet despite the winter being the second harsh one in a row, the adjusted earnings per share for the quarter was \$1.05, up from 93 cents during the first quarter of 2014.

During a conference call with analysts, Quest Chief Executive Officer Steve Rusckowski indicated a variety of encouraging developments for the company. Among them was stability in test volumes from providers, as well as a continuing expansion of the Medicaid program as part of the Affordable Care Act (ACA). That has continued to drive growth in Quest's Medicaid test volumes, according to Rusckowski, although the company did not break out revenue by payer for the

Quest and LabCorp Earnings

Companies	1Q 2015 Revenue	1Q 2014 Revenue	1Q 2015 Net Income	1Q 2014 Net Income	2014 EPS	2015 EPS Guidance
Quest Diagnostics	\$1.84 Billion	\$1.75 Billion	\$70 Million	\$111 Million	\$3.81*	\$4.70-\$4.85
LabCorp	\$1.78 Billion	\$1.43 Billion	\$700,000.00	\$113.1 Million	\$5.91*	\$7.55-\$7.90

\* Diluted

# Inside The Lab Industry

quarter. Revenue from gene-based esoteric testing also grew at the fastest rate recorded in more than a year. The company's risk assessment and clinical trials division saw revenue grow by 11 percent. And Invigorate, Quest's cost-streamlining program, is expected to report total savings of \$1.3 billion by 2018.

Rusckowski also noted that the recent legislation repealing the Sustainable Growth Rate formula (SGR) did not include any cuts to laboratory reimbursements under the Medicare program. LabCorp Chief Executive Officer Dave King also acknowledged that fact during a conference call with analysts.

*LabCorp's acquisition volume grew by 6 percent, of which 5.2 percent was organic growth, although revenue per requisition was down 0.6 percent.*

Quest stood by its 2015 forecast of 2 to 3 percent revenue growth for the year. It did not provide any revenue forecasts for its recently announced joint venture with Quintiles, but did say that it would likely be neutral to revenues. Clinical trials testing currently represents only about 2 percent of Quest's annual revenues.

Meanwhile, North Carolina-based LabCorp, long the second-largest of the national laboratories based on revenue, began booking revenue from its acquisition of Covance on Feb. 19, or just a few days into the second half of the first quarter. As a result, it quickly closed a revenue gap with Quest that was close to \$2 billion annually.

For the first quarter, LabCorp reported net income of \$700,000 on revenue of \$1.8 billion. That compares to first quarter 2014 net income of \$113.1 million on revenue of \$1.43 billion. Like Quest, LabCorp's minuscule net income for the quarter was tied to a hefty write-off—\$138.7 million. Much of that was tied to closing the Covance deal (\$113.4 million), with another \$19.3 million tied to restructuring costs. Another \$6 million in write-offs was tied to LabCorp's Project Launchpad initiative, a cost-saving revamp of operations that is expected to save the company \$150 million over the next three years. It projects \$50 million in savings for calendar 2015.

About \$269 million of the quarter's revenue was attributable to Covance's operations, or about 15 percent. That is expected to rise in future quarters as the company's revenue is fully integrated into LabCorp's top line. With the Covance numbers mixed in, net revenue for the company grew 24.8 percent. But even with it removed, LabCorp reported growth of about 4.9 percent. However, Covance's overall revenue of \$625 million was down from \$637 million for the first quarter of 2014.

LabCorp's acquisition volume grew by 6 percent, of which 5.2 percent was organic growth, although revenue per requisition was down 0.6 percent.

# Inside The Lab Industry

*"If the study is successful Covance and LabCorp will have helped a client get a new treatment against deadly infections to doctors and patients sooner meeting an important medical need and vividly demonstrating how only months after the merger we are already capitalizing on the promise of our combined company."*

— Dave King, CEO, LabCorp

Despite the fact that LabCorp's revenue for the quarter was still a shade behind Quest Diagnostic's, CEO King referred to the enterprise as the "world's leading health-care diagnostics company." He noted in a conference call with analysts that "when we announced the acquisition of Covance, we said that the timing was excellent because the lab business was showing strength after a couple of very challenging years from a regulatory and reimbursement perspective ... our operating performance in the first quarter in my judgment demonstrates the wisdom of our decision."

King noted that the synergies between LabCorp and Covance are helping it land a major testing contract to help an unnamed biotech firm develop an antibiotic to fight MRSA, an infection that has been plaguing hospital patients in recent years.

"If the study is successful Covance and LabCorp will have helped a client get a new treatment against deadly infections to doctors and patients sooner meeting an important medical need and vividly demonstrating how only months after the merger we are already capitalizing on the promise of our combined company," King said.

For calendar 2015, LabCorp issued guidance that included revenue growth of 39 percent to 42 percent, down from prior guidance of 40 to 44 percent growth. That included LabCorp Diagnostics' growth of 3 to 5 percent, and Covance revenue growth of flat to 2 percent.

Amanda Murphy, an analyst with William Blair & Co., said the numbers from Quest were in line with expectations and LabCorp's organic growth was better than originally expected.

However, LabCorp's stock dropped about 7 percent after the earnings report, to \$118 a share. Quest's stock price took a similar downward bump, from \$76 per share to \$71 per share after its earnings were released. Both companies' stock remained steadily in that trading territory.

***Takeaway: Quest and LabCorp reported solid growth for the first quarter outside of acquisitions and joint ventures, although write-offs and some shareholder doubts have blunted them somewhat.*** 

**■ ANTHEM MAKES OFFER INDIANA'S HOSPITAL LABS APPARENTLY CAN'T REFUSE, from page 1**

“Members have many choices when it comes to getting lab work done,” David Lee, M.D., vice president of provider solutions for Anthem Blue Cross and Blue Shield, said in a statement. “But they probably aren’t aware that some options may be significantly more cost effective. That’s the reason for our new reference lab network.”

*“Joining the Anthem reference lab network assures both physicians and patients that there is easy access to the high quality IU Health lab services they have come to expect.”*

— Harold Berfiend

That Anthem is reorganizing its lab network in the Hoosier State could be seen as discomfiting news for hospital labs nationwide. A combination of factors, including state and federal regulations and greater negotiating leverage, often means that hospital labs are paid significantly more for performing the same test than standalone laboratories. The health plan and one of the new network’s participants, the Indiana University Health System (IU), positioned the change as a gain for consumers.

“Joining the Anthem reference lab network assures both physicians and patients that there is easy access to the high quality IU Health lab services they have come to expect,” said Harold Berfiend, IU Health’s vice president of pricing and contracting, in a statement. “More patients are taking an interest in managing their healthcare dollars and services. This is another step toward transparency for consumers and physicians.”

But Anthem—which operates plans in 14 states—and IU Health were both conspicuously quiet about how the new network would function and plans for future expansion. An Anthem spokesperson said Lee was unavailable and did not respond to a request seeking more details. An IU Health System spokesperson declined comment after written questions were submitted by *Laboratory Industry Report*.

According to the *Indianapolis Business Journal*, 63 hospital labs are participating in the network. They have agreed to cut their rates for bloodwork and biopsies by between 50 and 80 percent. The publication said it is was a reduction “nearly unheard of” and suggested the hospitals were made a “Godfather”-like offer that they can’t refuse.

Mark Birenbaum, administrator of the National Independent Laboratory Association, noted that some hospital labs are paid five to 10 times what commercial labs receive for the same work. He added that the response by Anthem is logical given the stark differences in reimbursement. “With these high-deductible health plans a lot of patients now have, many of them are just going to other labs directly and paying out of pocket,” he said.

However, Birenbaum said such a shift could create dramatic downward pressures on Medicare prices after 2017, when the Protecting Access to Medicare Act (PAMA) goes into effect. PAMA dictates that Medicare’s reimbursement rates to labs would be based on commercial rates. Birenbaum expects Anthem to roll out new hospital lab networks to other states.

“That is going to drive down the PAMA rate even further, and that could hurt everybody,” he said.

***Takeaway: Anthem is introducing a new reference lab network that could dramatically alter how much hospital labs are paid for services.*** 

# INDUSTRY BUZZ

## Quest Launches New Tests for Blood-Based Cancers

**N**ew Jersey-based national laboratory Quest Diagnostics has launched a new genomic test devoted to monitoring the progress of several forms of blood cancer.

Known as LeukoVantage, the genomic test focuses on hematologic malignancies. They include acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) and myeloproliferative neoplasms (MPNs). The test is based on next-generation sequencing, polymerase chain reaction (PCR) and other techniques that are used on blood or bone marrow. It is able to detect the mutations in 30 genes that are most closely connected to myeloid neoplasms.

For cases of MPN, LeukoVantage can identify molecular markers that may suggest not only a prognosis, but the use of targeted therapies like JAK2 inhibitors. It can also detect gene mutations in the vast majority of AML patients, allowing oncologists to tailor a treatment plan using induction chemotherapy. And for MDS, the assay can be used to determine how far the disease has progressed. And for AML and MDS, LeukoVantage can be used to determine whether epigenetic modifying drugs may be more fruitful than relying on traditional chemotherapy.

“LeukoVantage is an outgrowth of Quest’s commitment to advancing oncology care based on actionable molecular insights,” said Frederick K. Racke, M.D., Quest’s medical director of hematology oncology, in a statement. “There is growing evidence that several genetic alterations involved in myeloid neoplasms not only provide significant diagnostic and prognostic value, but may also help guide treatment decisions. LeukoVantage builds from the latest science and Quest’s deep experience in genomics and hematology to deliver insights that can help the physician potentially diagnose the patient more quickly and reliably and establish an appropriate treatment plan.”

About 156,000 new cases of blood-related cancers are diagnosed in the United States annually, with about 55,000 deaths each year. Company officials indicated the launch of LeukoVantage was in part an extension of its launch of OncoVantage last year in collaboration with Memorial Sloan-Kettering Cancer Center.

*Takeaway: Quest Diagnostics is upping its game on the detection and treatment of hematologic cancers.* 

### References

**Anthem Blue Cross Blue  
Shield of Indiana**  
800-382-5520

**BloodworksNW**  
206-292-6500

**Cyrex Laboratories**  
602-759-1245

**Foundation Medicine**  
617-418-2200

**LabCorp**  
336-584-5171

**National Independent  
Laboratory Association**  
314-241-1445

**PAML**  
509-755-8999

**Quest Diagnostics**  
800-222-0446

**William Blair & Co.**  
312-236-1600

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