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# LABORATORY

# INDUSTRY REPORT™

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## Upcoming G2 Events

### Lab Revolution

April 6-8, 2016  
 Sheraton Wild Horse Pass  
 Resort & Spa, Chandler, AZ  
[www.labrevolution.com](http://www.labrevolution.com)

### Lab Institute 2016

October 26-28, 2016  
 Hyatt Regency Washington on Capitol Hill,  
 Washington, DC

## Lab Sector Jobs Grow by 25 Percent Over Last Decade

**L**aboratories have been a significant generator of jobs over the past decade, with the entire sector growing by 25 percent.

That's according to the U.S. Bureau of Labor Statistics (BLS), which began publishing lab-specific jobs data for the first time in January. It was one of 27 new categories—including seven in health care—that the agency broke out to begin calendar 2016, according to an agency spokesperson.

*Continued on page 7*

## Abbott's Acquisition of Alere Continues Mergers of Lab, Pharmaceutical Interests

**T**he merging of diagnostic laboratories into the folds of big pharma has continued with point-of-care firm Alere being acquired by Abbott for \$5.8 billion.

The all-cash deal, announced on Feb. 1, was for \$56 per share—a more than 50 percent premium above Alere's stock price. Alere had previously been a subsidiary of health care giant Johnson & Johnson in 2001. The company rebranded itself as Alere in 2010.

Alere, which specializes in in vitro tests for influenza, hospital-acquired infections, toxicology and cardiology, introduced in 2014 a point-of-care molecular test that can differentiate between influenza A and B strains within 15 minutes.

Despite such innovations, Alere has experienced relatively flat revenue growth in recent years. It reported revenue of \$2.16 billion in 2010 and is on track for \$2.5 billion for 2015, down from \$2.56 billion for 2014 and \$2.62 billion in 2013. The company also lost \$37.7 million in 2014. It has blamed currency fluctuations and decreases in sales of its pain management/toxicology tests, although its cardiology business has demonstrated recent significant growth.

“The combination of Alere and Abbott will create the world's premier point of care testing business and significantly strengthen and

*Continued on page 2*

## ■ ABBOTT'S ACQUISITION OF ALERE CONTINUES MERGERS OF LAB, *from page 1*

grow Abbott's diagnostics presence," said Abbott Chief Executive Officer Miles D. White in a statement. "We want to offer our customers the best and broadest diagnostics solutions. Alere helps us do that."

*"Abbott is marking out point-of-care as an area that it can compete and win in."*

— Bruce Carlson,  
Kalorama Information

The deal is reminiscent in size, scale and fit of LabCorp's acquisition of Covance, which not only made LabCorp the biggest lab in the country, but gave it entree into the growing world of drug development and related testing.

"Our leading platforms and global presence in point-of-care diagnostics, combined with Abbott's broad portfolio of market-leading products, will accelerate our shared goal of improving patient care," said Alere Chief Executive Officer Namal Nawana in a statement.

According to Abbott, the transaction will make it the biggest point-of-care lab company in the U.S., with related revenue in that segment of about \$7 billion per year.

Despite Alere's significant 2014 losses, Abbott said the deal would be accretive to its 2017 bottom line by about 12 cents a share, increasing to more than 20 cents by 2018.

Bruce Carlson of the research firm Kalorama Information said that the deal would give Abbott supremacy in point-of-care testing. "Abbott is marking out point-of-care as an area that it can compete and win in," he said in a statement. "This should not be surprising as point-of-care in some areas like infectious disease is growing at one and half times the global in vitro diagnostics market."

*Takeaway: Abbott's acquisition of Alere is another example of the fusing of pharmaceutical and laboratory firms.* 

## ACLA Uses Cancer Initiative to Lobby on PAMA, LDTs

The American Clinical Laboratory Association (ACLA) has applauded the Obama Administration's proposal for a \$1 billion cancer "Moon Shot Task Force" that would drive researchers closer to a cure for the disease. But the lobbying organization also asked that more earthly matters not be ignored at the expense of the new initiative.

According to a Feb. 9 letter sent to Vice President Joe Biden by ACLA President Alan Mertz, the lobbying group asks specifically for more attention regarding regulatory intrusion into the way labs conduct business and how they are reimbursed from government payers.

Specifically, the ACLA asked that the U.S. Food and Drug Administration (FDA) not be allowed to regulate laboratory-developed tests—a contentious issue in the laboratory sector. The FDA has issued draft guidance on regulation, to which labs have objected. "Often LDTs are the only available options for clinicians and patients, particularly when it comes to cancer. Additional FDA oversight through the proposed Guidance would institute an arduous and unnecessary regulatory barrier," Mertz wrote. "Therefore, in order to support the goals of the Cancer Moonshot Task Force and facilitate the continued unfettered development of new diagnostics, the FDA should withdraw" the draft guidance.

The ACLA also asked the Obama administration to keep in mind its concerns regarding the draft guidance under the Protecting Access to Medicare Act (PAMA). The organization has been particularly concerned that the proposed mechanism for setting new Medicare reimbursement rates leaves out most hospital-based laboratories, which are often paid at higher rates.

“ACLA supported the legislative changes and has sought to collaborate with the Centers for Medicare & Medicaid Services since the enactment of PAMA,” Mertz wrote. “We are hopeful that a predictable market-based payment model, which reflects the broad scope of the laboratory market, will encourage continued advancements in diagnostic innovation.”

*Takeaway: Labs are using the Obama administration’s desire to fund cancer eradication efforts to support their own agenda.* 

## PAML Campaign Encourages Men to Seek Routine Testing

**P**AML, the largest independent medical laboratory in the Pacific Northwest, has entered into a public service campaign with a regional television station that could boost the number of basic tests it performs in the short term.

The campaign, in conjunction with CBS affiliate KREM in Spokane, is known as “Real Men Wear Gowns.” It includes a 30-second television commercial that shows various men in the Spokane area—the city where PAML is based—wearing hospital gowns over their clothes as they go about their workday.

The lab’s director of marketing, David Love, said “Real Men Wear Gowns” was based on a nationwide public service campaign.

Officials said the intent is to prod men to undergo more routine testing, such as for heart disease and prostate cancer.

According to PAML spokesperson Amy Stoltz, more than half of men do not undergo routine medical checkups, and they are 25 percent less likely to visit a physician than a woman does. “Women are doing better here, but on the men’s front, we’re not seeing that traction,” she said.

The campaign is currently focused on heart disease prevention. Stoltz said the focus of the year-long program would change every quarter.

PAML has been known for its creative direct-to-consumer marketing, notably through Cinch, its direct-to-consumer testing platform that focuses on younger patients.

However, PAML officials said the campaign was not an attempt to boost laboratory test volume. Many routine tests, such as urinalysis, are low margin assays that depend greatly on volume to drive profitability. The lab’s director of marketing, David Love, said “Real Men Wear Gowns” was based on a nationwide public service campaign. Providers in Portland, Ore. and Atlanta are also running similar campaigns, although PAML is the only laboratory that is acting as a sponsor.

Love declined to disclose PAML’s budget for the campaign.

*Takeaway: PAML is engaged in a high-profile public service campaign, a rarity for a clinical laboratory.* 

# Inside The Lab Industry

## Healthy Financial Outlook for Publicly Traded Labs in 2016

**M**ost of the publicly-traded clinical laboratories ended 2015 on a fairly strong note. Their guidance suggests more of the same for 2016.

The two large national laboratories, LabCorp and Quest Diagnostics both report solid numbers for the fourth quarter ending Dec. 31.

### LabCorp

The North Carolina-based LabCorp reported fourth quarter 2015 net income of \$114.5 million on revenue of \$2.3 billion. The net is down slightly from fourth quarter of 2014's \$119.9 million, but on an adjusted basis—excluding amortization, restructuring charges and other special charges—it was up 20 percent, to \$1.98 per share from \$1.65 per share. That's reflective of the company's ongoing assimilation of drug testing giant Covance. Revenue for the quarter was up 46 percent, to \$2.24 billion from \$1.51 billion.

*"We are enthusiastic about our prospects for 2016."*

— Dave King,  
CEO, LabCorp

The Covance deal, which closed in mid-February 2015, added \$2.2 billion in revenue, or 36.7 percent of LabCorp's year-over-year growth. Organic revenue growth was relatively strong, at 4.6 percent.

For calendar 2015, LabCorp reported net income of \$436.9 million on revenue of \$8.68 billion. For calendar 2014, it reported net income of \$511.2 million on revenue of \$6 billion.

With an acquisition helping to boost revenue nearly 40 percent in its first year, Chief Executive Officer Dave King is upbeat about the future. "The year was transformative for LabCorp," he said in a statement. "We significantly expanded the company's capabilities, global presence and avenues for future growth."

LabCorp's 2016 guidance includes a bullish revenue growth forecast of 7.5 to 9.5 percent, as well as growth in earnings per share of 7 to 12 percent.

The Covance division is forecast to grow revenues by 6.6 to 9.6 percent, excluding impacts from currency fluctuations and the expiration of an agreement with Sano-fi. The laboratory diagnostics division is forecast to grow revenue by 3.5 percent to 5.5 percent. It reported 1.6 percent growth in test volume for 2015.

"We are enthusiastic about our prospects for 2016," King said.

Amanda Murphy, an analyst with William Blair, noted in a report after LabCorp's earnings announcement on Feb. 18 that "while the company's top-line guidance for 2016 well exceeded consensus, implied adjusted (earnings per share) growth fell below expectations." Murphy had forecast revenue growth of 7.5 percent for this calendar year. The general consensus among Wall Street analysts is growth of 7.6 percent.

# Inside The Lab Industry

## Quest Diagnostics

The New Jersey-based Quest reported net income of \$188 million on revenue of \$1.84 billion for the quarter. It earned \$190 million on revenue of \$1.88 billion for the fourth quarter of 2014.

*“Just three years ago this business was shrinking by more than 4%. We slowed the organic decline to 2% in 2014 and have now grown organically on an equivalent basis for the fifth consecutive quarter.”*

— Steve Rusckowski,  
CEO, Quest

But for calendar 2015, Quest earned \$709 million on revenue of \$7.49 billion. That compares to calendar 2014 net income of \$556 million, an increase of about 28 percent. 2014 Revenue was \$7.43 billion.

Quest’s net earnings for 2015 were \$4.92 per share. Its 2016 guidance now calls for earnings of between \$5.02 and \$5.17, excluding expenses for amortization. Revenue is expected to be between \$7.52 billion and \$7.59 billion, an increase of 1.5 percent to 2.5 percent. That number is excluding revenue from Quest’s joint clinical trials initiative, both for 2015 and moving forward. In 2015, clinical trials revenue accounted for \$85 million in the company’s revenue, or little more than 1 percent of the total.

In a conference call with analysts, Quest Chief Executive Officer Steve Rusckowski noted that the company had cut costs by \$200 million last year. “Just three years ago this business was shrinking by more than 4%. We slowed the organic decline to 2% in 2014 and have now grown organically on an equivalent basis for the fifth consecutive quarter,” he said.

Particularly healthy are Quest’s gene-based and esoteric testing lines. They now represent nearly a quarter of the company’s revenue, \$1.8 billion, and grew 5 percent year-over-year.

Quest also said it is in the midst of rolling out a new data analytics platform known as Quantum. Rusckowski said more details about the platform would be disclosed at the HIMSS conference at the end of the month. However, he noted that Quantum has already seen “strong interest” and that clients have already been signed up.

The company did not deny there were potential shadows on the horizon. Rusckowski began the call noting the sector’s concern about the final content of the PAMA regulations excluding hospital labs from future reimbursement formulas, as well as the Food and Drug Administration’s move to regulate laboratory developed tests.

“We understand the FDA’s concerns,” about the potential dangers of LDTs, “but we continue to believe what the FDA has proposed would result in labs being subject to both CLIA and FDA regulations that may be overlapping, duplicative, and sometimes contradictory in their requirements,” Rusckowski said. “This has the potential to raise healthcare costs for patients and potentially, hinder medical innovation.”

Meanwhile, earnings from the smaller publicly-traded labs also trickled out.

# Inside The Lab Industry

## Myriad

Salt Lake City-based Myriad Genetics has overcome the 2013 loss of its patent on BRCA testing and is back in growth mode. Powered by new revenue from its Prolaris prostate cancer test, Myriad reported net income of \$30.3 million on revenue of \$193.3 million for its fiscal second quarter ending Dec. 31. That compares to net income of \$24 million on revenue of \$184.4 million for the fiscal second quarter of 2015.

*“Our new products are making significant strides towards broader market adoption and reimbursement on a worldwide basis.”*

— Mark C. Capone, CEO, Myriad

For the first six months of fiscal 2016, Myriad reported net income of \$57 million on revenue of \$376.8 million. That first figure is up 42.5 percent from the \$40 million in net income on \$353.2 million in revenue for the first half of fiscal 2015.

“Our new products are making significant strides towards broader market adoption and reimbursement on a worldwide basis,” said Myriad CEO Mark C. Capone in a statement.

Although Myriad stayed with its current fiscal 2016 revenue guidance of \$750-\$770 million, it raised its earnings guidance from \$1.60 to \$1.65 per share to \$1.63 to \$1.68 per share.

## Genomic Health

Redwood City, Calif.-based Genomic Health reported a net loss for the fourth quarter of \$3.2 million on revenue of \$63.9 million. That’s a significant improvement over the \$6.2 million loss on revenue of \$58.8 million for the fourth quarter of 2014.

For calendar 2015, Genomic Health reported a net loss of \$33.8 million on revenue of \$286.8 million, including \$41.4 million from overseas sales. That’s compared to a loss of \$24.6 million on revenue of \$275.7 million in 2014.

Genomic Health CEO Kim Popovits told analysts that its prostate cancer test volume grew by 75 percent during the year, and all test volume grew 19 percent overseas.

“We expect the strong momentum generated across our business in 2015, combined with new compelling global prospective outcomes evidence for the Oncotype DX breast cancer test and recent Medicare coverage for the Oncotype DX prostate cancer test, to lead to double-digit test and revenue growth in 2016,” Popovits said.

Genomic Health provided 2016 guidance of \$320 to \$335 million in revenue, an increase of 12 to 17 percent over 2015. It forecasts a net loss of between \$12 million and \$18 million.

***Takeaway: Publicly-traded national and esoteric labs ended 2015 on a healthy note, and appear headed on the same path for 2016.*** 

■ **LAB SECTOR JOBS GROW BY 25 PERCENT OVER LAST DECADE**, *from page 1*

Altogether, labs employed 256,000 people in January. A decade ago, the sector had just over 200,000 jobs.

The growth among labs has been driven by a variety of factors, including the rise of esoteric molecular tests and toxicology testing. However, labs have not been the biggest driver of job growth in health care. Jobs at nursing care facilities, for example, have doubled over the past decade. The overall health care sector has grown by about 50 percent over the past decade.

Whether or not growth in the lab sector continues remains to be seen. According to the BLS, labs lost 3,700 jobs in January—a 1.5 percent drop in total employment.

Laboratory Sector Job Growth, Seasonally Adjusted (In Thousands)	
Year	Jobs
2006	208.9
2007	213.6
2008	216.2
2009	223.4
2010	229.9
2011	232.9
2012	239.9
2013	245.0
2014	253.8
2015	259.7
2016*	256.0

\* As of January 31  
Source: Bureau of Labor Statistics

However, sector officials say that demand has not slackened at all. Francisco Velázquez, M.D., chief executive officer of PAML in Spokane, Wash., noted that his company’s workforce grew by 4.6 percent in 2015.

“We closed the year at an 8.6 percent growth in our patient encounters/requisitions that was similar to last year,” Velázquez said. He added that similar growth was forecast in 2016.

“We’re busier than we have ever been,” said Chris Harol, a principal with Lighthouse Recruiting, a North Carolina-based firm that focuses on job placements in labs, primarily technicians and lab managers.

Harol noted that placement in toxicology labs has been strong, but there has been a recent slowdown in openings at hospital laboratories.

Moreover, BLS officials said they were not concerned about the trend.

“The estimated 3,700 decline in January is not an extreme movement,” said Tyler Donovan, a BLS analyst. He added that the data would be revised twice more over the next several months “to account for survey respondents whose data was not included in the initial estimate.”

**Takeaway: Laboratories have been a significant job generator, although they have lagged other portions of the health care sector as an economic engine.** 



WEBINAR ANNOUNCEMENT

**Genetic Test Utilization Management: Practical strategies for achieving efficiency, cost savings & appropriate test selection**

*With Cheryl Hess, MS, CGC, Genetic Counselor, NextGxDx; and Jessie Conta, MS, LCGC, Genetic Counselor, Department of Laboratories, Seattle Children’s Hospital*

Utilization management in the area of genetic testing is complicated due to the explosion of the number of tests available and the increasing number of laboratories offering such tests, differences in cost for comparable assays and the need for clarity concerning tests’ necessity and contribution to patient care. This conference will illustrate that utilization management can be an opportunity to bring together all parties in the health care delivery system to improve healthcare value for physicians, patients, hospitals, laboratories and payers.

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- ▶ Three common challenges when considering UM interventions
- ▶ Practical tactics regarding how and where to intervene in the test ordering process
- ▶ The importance of UM allies within commercial laboratories
- ▶ The value of data metrics and analytics in driving UM success

**When:** Feb. 24, 2016, 2-3:30pm EST (11am-12:30pm PST) **To register, visit** [www.g2intelligence.com](http://www.g2intelligence.com) **Or call Customer Service at** 1-888-729-2315

# INDUSTRY BUZZ

## Connecticut Lab Developing \$200 BRCA Test

Just a few years ago, it could cost upward of \$4,000 to undergo a molecular test for the BRCA gene.

The prices began to drop following a 2013 U.S. Supreme Court decision that prohibited the patenting of a single gene, breaking a monopoly on the test. Other labs began offering the assay, but the price tag was still often more than \$1,000.

Now, a pathologist has claimed in a new academic study that BRCA testing could be performed for as little as \$200 as part of routine pap smears and HPV testing that is given to women in the U.S. tens of millions of times a year. This particular test would focus only on three “founder” genetic variants that point to an increased cancer risk. The testing would mostly extend the current capabilities of pap smear and HPV tests.

According to a study recently published in the *International Journal of Molecular Sciences*, “with a robust PCR mixture, crude proteinase K digestate of the fixed cervicovaginal cells in the ... pap cytology specimens can be used as the sample for target DNA amplification without pre-PCR DNA extraction, purification and quantitation.” Using a simplified template for such a BRCA test, the cost can be brought down to \$200, the study claimed.

As a result, “selective patients in a high-risk population can be tested and each provided with a set of DNA sequencing electropherograms to document the absence or presence of these founder mutations in her genome to help assess inherited susceptibility to breast and ovarian cancer.”

The study was co-authored by Sin Hang Lee, M.D., director of the Connecticut-based Milford Molecular Diagnostics Laboratory and undertaken in collaboration with researchers in China.

Milford Molecular specializes in molecular-based tests for Lyme disease, a particular scourge in the Eastern U.S. The company said it was in the process for applying for a CLIA permit to begin marketing a Pap smear/HPV-based BRCA test.

A company spokesperson did not respond to a request seeking comment.

**Takeaway: A small laboratory in Connecticut may have developed a low-cost test for BRCA genetic testing.** 

## References

### Abbott

224-667-6100

### Alere

858-805-2000

### American Clinical Laboratory Association

202-637-9466

### Kalorama Information

800-298-5603

### LabCorp

336-229-1127

### Lighthouse Recruiting

800-838-0602

### Milford Molecular Diagnostics

203-878-1438

### Myriad Genetics

801-584-3600

### PAML

509-755-8600

### Quest Diagnostics

973-520-2700

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