



Your Independent Source for Business & Financial News

LABORATORY

INDUSTRY REPORT®



Kimberly Scott, Managing Editor, kscott@G2Intelligence.com

Vol. 12, Iss. 11, October 26, 2012

HIGHLIGHTS

TOP OF THE NEWS

- Studying the molecular payment possibilities..... 1
- Quest, GE chiefs offer similar takes on industry's future..... 1

BUSINESS/FINANCIAL

- A great time to buy a lab—if you can find one..... 3
- Quest, LabCorp report quarterly earnings—and a flat growth horizon..... 7

INSIDE THE LAB INDUSTRY

- Uncertainties drive Lab Institute dialogues: Industry reps, power players speak out..... 4

INDUSTRY BUZZ

- Watch out for these hotspots in 2013..... 8

Studying the Molecular Payment Possibilities

Predicting how the Centers for Medicare and Medicaid Services (CMS) will rule on the payment structure for the newly minted molecular pathology codes has made many in the lab sector resemble ancient scholars parsing Aramaic texts.

However, a prominent expert on the topic bluntly believes they should be priced on the clinical laboratory fee schedule (CLFS) rather than the physician fee schedule (PFS) in 2013.

The former is far more advantageous to the laboratory industry, which would be able to use gap-filling or crosswalking based on historic pricing of similar procedures to determine some levels of reimbursement—although that would only last a year before prices are set more permanently.

“It could be a colossal year for gap-fill,” said Bruce Quinn, M.D., a senior health policy specialist with Foley Hoag LLP in Washington, D.C. Although Quinn thought gap-fill was the likeliest scenario, he noted there were many other possibilities.

Continued on page 6

Quest, GE Chiefs Offer Similar Takes on Industry's Future: Labs Need to Evolve

As the patient changes, so will the demands on the laboratory industry.

That was the primary message from the two keynote speakers at G2 Intelligence's 2012 Lab Institute earlier this month: Steve Rusckowski, the new chief executive officer of Quest Diagnostics, and Pascale Witz, president and chief executive officer of GE Healthcare's medical diagnostics arm.

Rusckowski illustrated the shift in patient expectations through his 91-year-old mother Veronica, who had her blood drawn by a Quest technician at her home when she had not been feeling well. She had no idea what the blood draw was for and was not curious to find out.

By comparison, his two 20-something children, steeped in social media and instant communications (Rusckowski's daughter was a Harvard classmate of Facebook founder Mark Zuckerberg), are far more inquisitive of clinicians and have far more information at their fingertips.

Continued on page 2

G2 Intelligence **Upcoming Conferences**

Lab Leaders' Summit
Nov. 14, 2012
Union League Club of New York
New York City
www.lableaderssummit.com

Laboratory Investment Forum 2012
Give and Take in the Laboratory Market: Political and Market Forces Shaping the Investment Climate
Nov. 15, 2012
Bloomberg Tower
New York City
www.labinvestmentforum.com

Volume to Value
Redefining Lab Services in a Changing Market
Feb. 25-27, 2013
Westin Beach Resort & Spa
Fort Lauderdale, Fla.
www.g2labvalue.com

www.G2Intelligence.com



Steve Rusckowski,
Chief Executive
Officer,
Quest Diagnostics



Pascale Witz,
President and Chief
Executive Officer,
GE Healthcare's
medical
diagnostics arm

■ QUEST, GE CHIEFS OFFER SIMILAR TAKES ON INDUSTRY'S FUTURE, *from page 1*

"Patients once saw the lab as a black box," he observed, noting that it was mostly seen as a conduit for test results, therefore making it "a bit of a mystery." But now, with more highly informed patients, labs need to change how they deliver data.

Witz concurred, noting that the recent dramatic drop in pricing for performing genomic sequencing has upended the industry's mission. "Mass-market medicine has come to an end. We are now in a world of patient-based decisions," she said. "How are we going to work with that?"

Witz said that the mission of laboratories will be refocused in part to using their diagnostic capabilities to deliver the "right drug to the right patient at the right time."

Rusckowski noted that labs have begun to shift how they use data, pointing out the number of "collaborations" between lab and pharmaceutical firms has increased fourfold between 2005 and 2010, with much of the focus on oncology, neurology, and infectious diseases.

Witz observed that molecular diagnostics' driving most of the laboratory industry's growth in recent years is a reflection of the "need to have much more sophisticated diagnostics" in order to better focus courses of disease treatment for individual patients.

She also asserted that the current aging of the population will continue to grow demand for this segment, with the number of people over the age of 65 growing 140 percent by 2030. More than half will live in developed countries where such diagnostic tests are affordable. As a result, health care costs will continue to grow.

That's where Rusckowski sees laboratories as a potential savior.

"The laboratory test delivers the majority of information that leads to health care [decisionmaking]," he said, "but laboratories only cost about 3 percent of health care delivery—a remarkably low percentage." That cost ratio will need to be relentlessly communicated to patients in the coming years, he added. And labs will have to directly engage patients via mobile health care applications they can use on their smartphones and tablets.

In the meantime, labs will also have to continue to please their traditional constituencies: hospitals, doctors, and health plans.

Despite the ongoing and impending changes, both speakers indicated the industry had exciting times ahead. Witz said her company would continue to offer products that would increase the efficiency of labs. Rusckowski noted the industry should use its capabilities to filter out data to make crucial clinical decisions and share them with both patients and providers.

"I'm optimistic about the future," Rusckowski concluded. "The opportunity before us is to help shape the future of health care in this country."

Just hours later, Quest announced a major restructuring of its company to make it more competitive in the current marketplace. The company announced Oct. 11 that it would eliminate its current corporate structure and replace it with two major business groups focusing on diagnostic information services and diagnostic solutions. **G2**

A Great Time to Buy a Lab—If You Can Find One

It's a good time to invest in laboratories, but finding potential acquisitions is getting tougher, according to a major investment banker in the sector.

Timothy Johnson, a managing director with England & Co. in Washington, D.C., noted during a presentation at G2 Intelligence's Lab Institute 2012 on Oct. 11 that 2011 set a record for mergers and acquisitions, with 34 in total.

However, "activity has slowed (since)," said Johnson. The main reason is that the pool of most attractive targets—laboratories with annual revenues between \$50 million and \$100 million—has been shrinking.

That's primarily because the two powerhouse national laboratories—Quest Diagnostics and LabCorp—have relied heavily on acquisitions to fuel their growth over the past decade, and they have gobbled up many of their midsized competitors. According to Johnson's data, LabCorp's total year-over-year revenue growth has averaged 8.5 percent over the last 10 years, while Quest's growth has averaged 6.4 percent. But without acquisitions, LabCorp's growth has averaged 4.8 percent, while Quest's growth has been 2.1 percent.

"Both companies have performed very well," Johnson noted, but he made it clear that organic growth has been secondary to their success.

Meanwhile, the interest in acquiring labs remains intense, both from national players and outside investors.

"I get calls literally every week from groups wanting to partner in the lab sector," Johnson said. The main reasons: Laboratories are in a mature business sector, and most have strong cash flow.

"Few sectors of the economy have grown as fast," he observed. "Lots of private equity money has been raised over the past three to five years, and it needs to be redeployed."

Among potential future targets for acquisitions, Johnson referenced Myriad Genetics in Salt Lake City, Genomic Health in Redwood City, Calif., NeoGenomics in Fort Myers, Fla., and Enzo Clinical Labs in Farmingdale, N.Y. However, he added that some of the midsized players may be takeover resistant.

Hospital Labs Next Focus

That resistance, along with a shrinking number of acquisition targets, means hospital-operated laboratories may become more attractive to acquire in the near term, primarily because they still control 54 percent of the industry's total market share.

"If national laboratories want to continue to grow, hospital laboratories will be the next business they will focus on," Johnson said.

However, some independent laboratories still have alternatives to being acquired that private equity firms may also find attractive. They include options such as recapitalization, wherein the equity firm may get a stake as large as 90 percent in exchange for cash. 

Inside The Lab Industry



Uncertainties Drive Lab Institute Dialogues: Industry Reps, Power Players Speak Out

The word that could be used to best describe the future of the laboratory sector in 2013 and beyond is “uncertain.”

A nagging worry about a variety of issues affecting the laboratory business and the practice of pathology was on the minds of sector leaders participating in G2 Intelligence’s Lab Institute 2012 in Arlington, Va., earlier this month.

In a town hall meeting moderated by Dennis Weissman, G2 founder and executive editor, and Stephanie Murg, managing director, dilemmas ranging from how the payment system for laboratory services will evolve over the next few years to the composition of the White House and Congress after the November elections held sway. Audience members asked about a myriad of topics, including the use of hospitalist pathologists and litigation regarding the ability of physicians to make referrals for their patients out of the specified provider network.

But Weissman issued perhaps the most telling statement near the beginning of the hour-long town hall: “The system is going to morph into something we don’t recognize in the future.”

Weissman’s reference was to the momentum bundled payment arrangements are gathering with the tremendous growth of accountable care organizations (ACOs), along with how health plans are forcing patients to pay more out of pocket and potentially drain revenue from laboratories.

The Value Proposition

In order to survive what is predicted to be a tumultuous future, L. Eleanor J. Herriman, M.D., G2’s managing director of advisory services, noted that labs have to make a value proposition to providers.

“We’re only 3 percent of spend—you have to change the conversation toward talking about downstream costs and the impact you have on downstream costs and the model you can bring to bear and what those tests can do,” she said. “In a value market, if you’re only 3 percent of spend, it doesn’t matter.” Herriman added that this was particularly important given the rise of ACOs.

And while “value proposition” was an extremely popular term at the conference, the sector may have to surmount the myriad challenges of contracting with ACOs before showing their worth.

David Dexter, chief executive officer of Sonora Quest Laboratories in Tempe, Ariz., agreed in the “G2 Powers Players” session with industry CEOs that laboratories must demonstrate their value, but the sector’s tendency toward slack pricing is working against it.

“The industry hasn’t done itself a favor going down the road to do heavy discounting to get pull-through work or higher-profitability work,” he said. “Unfortunately, you set the bar low, you pay a price.”

Dexter added that most ACOs form a contracting arm, and labs have to negotiate rates with executives who are unfamiliar with the sector.

“The system is going to morph into something we don’t recognize in the future.”
—Dennis Weissman

"I've negotiated with six different ACOs recently. They're all different," he said, adding that Medicare ACOs are mostly offering capitated payments. And laboratories are often a very low priority with ACO management.

"The very last entity that gets contracted is lab," Dexter observed. "If you're last in line and all the dollars have been divvied up, there are only so many dollars left."

Payer Pressures

Similar pressures are mounting from payers. Weissman noted that in New England, Aetna has begun tiering lab services. "If Aetna gets the best price (from the lab), you're in tier one," he said. "But if you don't give them the best price, you're in tiers two or three—and guess what? The patient pays more and more out of pocket."

"You have to find ways you can be a proactive partner with the payer."

—David Dexter

Joe Skrisson, chief operating officer of Dynacare Laboratories in Milwaukee, said the pressure from payers has been relentless since the moment he joined the company a year ago.

"I've had every payer say they want to renegotiate our contract, reduce our payer rates, and so on," he said. Within three years, he expects 20 percent or more of the lab's business to be "at-risk" rather than fee-for-service. However, Skrisson believes the changes will actually reward labs that focus on quality and outcomes.

Leveraging different platforms can help as well. Francisco "Frank" Velazquez, M.D., chief executive officer of PAML in Spokane, Wash., noted that his company has stakes in the IT arena, as well as the supply chain and consumer arenas, and such diversity will help provide a more uniform product with added value—one that can also provide much more information in terms of mining crucial data.

Meanwhile, Dexter recommended that laboratories closely network with the payers in order to determine what they're looking for—and calculate what leverage laboratories might have in future negotiations. That includes introducing new lab tests, technologies and initiatives. In one instance, Sonora Quest is involved with insurer UnitedHealth and McKesson regarding the preauthorization of genetic testing.

"You have to find ways you can be a proactive partner with the payer," he said, adding that more friendly ways to engage with a health plan's CEO—such as involving yourself in their favorite charity—can also help.

"In the past we've had an almost quasi-adversarial relationship," Velazquez said of working with payers. He added that one of the biggest challenges is working on reversing "the lack of visibility of the diagnostic industry for the most part."

Although everyone agreed better visibility will help labs' position, they are also on the same page about the status quo vanishing.

"There's a lot of destructive change coming. But you should embrace that," Skrisson said. 

■ **STUDYING THE MOLECULAR PAYMENT POSSIBILITIES**, *from page 1*

The battles over these decisions seem to have a biblical scale in and of themselves, Quinn's presentation at G2 Intelligence's Lab Institute earlier this month suggested. His animation about the issues seemed to grow in direct proportion to their granularity—Quinn even dug up 30-year-old court cases about specific coding rules relevant to the molecular issues.

Under the PFS, rates might be set using relative value units (RVUs), or there may simply be contract pricing. However, there is no clear exit strategy for CMS if it adopts that policy, Quinn noted, and there are legal issues surrounding the use of RVUs.

In January 2013, the 101 new codes will replace the current system of "code stacking." CMS is expected to announce in early November how it plans to set pricing for these new codes—either on the CLFS, the PFS, or some combination of the two.

The code set consists of 92 codes in Tier 1, which includes the most commonly performed tests. The remaining nine codes are in Tier 2, which includes the more complex testing. The American Medical Association (AMA) approved the codes via its Current Procedural Terminology Editorial Panel.

Quinn observed that CMS has muddied the issues. "They have put question marks everywhere," he said, noting that the agency did so because "they saw problems with every solution," such as high pricing if crosswalking was adopted. As a result, Quinn believes crosswalking is the least likely scenario.

However, pushback from the College of American Pathologists (CAP), the AMA, and the Association for Molecular Pathology guarding their respective constituencies has also added to the indecision.

Making the Case for CLFS

But CMS is expected to issue a final decision on or around Nov. 1. Quinn believes the MDx codes should fall on the CLFS, primarily because he estimates 80 percent of the work under the codes is being performed by laboratory professionals rather than physicians themselves.

"If 80 percent of molecular interpretations are signed out by Ph.D.s, how can you say that the physicians (need to be directly involved)? It just makes my head spin," he said.

Yet Quinn noted that the pathology lobbies have still been pushing for their greater role—and corresponding placement of the molecular codes on the PFS. He noted that CAP's attorneys have argued genetic tests are surgical pathology because they involve the microscopic study of organs and tissues. Blood is an organ, and DNA is microscopic—therefore it fulfills the legal definition, Quinn joked in a line that drew laughter from attendees.

"That's not the point. The law says that clinical lab tests need to be on the [CLFS]," Quinn said, and that it has to be proven otherwise.

Quinn did note that the CMS could allow code stacking for one more year as a potential option—one that seemed within the realm of possibility given the agency's seeming reluctance to make a solid decision.

"We'll all know in [a few] weeks what is going to happen," Quinn said. "I don't know what CMS is going to do." 

Quest, LabCorp Report Quarterly Earnings—And a Flat Growth Horizon

It's a tale of two bottom lines for Quest Diagnostics and LabCorp in the third quarter, but ultimately the sector's two largest national laboratories are facing the same futures and hard questions.

The slightly smaller LabCorp reported bouncier numbers, with net income for the quarter ending Sept. 30 reaching \$148 million, compared to \$137.6 million for the third quarter of 2011, an uptick of 8 percent. However, revenue was all but flat, up 1.1 percent, to \$1.42 billion, compared to \$1.4 billion in the prior year's third quarter.

Quest, however, saw its profits slide slightly. Net income was \$171.6 million, compared to \$181.8 million in the year-ago quarter, a drop of 5.6 percent. Revenue was also down slightly, from \$1.85 billion from \$1.9 billion.

Quest Chief Executive Officer Steve Rusckowski, installed earlier this year, has embarked on a cost-cutting program to improve cash flow. Earlier this month, the company reorganized into two divisions focused on diagnostic information services and diagnostic solutions. New senior managers were also brought in, and

as many as 600 positions are expected to be cut by the end of 2013.

Quest and LabCorp at a Glance (\$MM)				
	Quest		LabCorp	
	3Q 2012	3Q 2011	3Q 2012	3Q 2011
Total Revenues	\$1,851.4	\$1,906.4	\$1,419.4	\$1,404.5
Net Income	171.6	181.8	148.4	137.6

“The new organization will allow us to aggressively drive operational excellence and improve our customer

focus, which will, over time, enable us to restore growth,” Rusckowski said.

Analysts noted both companies have relied heavily on growth through acquisitions, but few midsized labs of the type that have fueled their expansion over the past decade remain available. Quest's testing volumes were down 1.1 percent, and revenue per requisition was down 1 percent. LabCorp reported that testing volumes increased only 1.4 percent and that revenue per requisition was down 0.3 percent.

Both LabCorp and Quest's stocks have been flat the past six months, trading in the \$90 and \$60 range, respectively. “We believe DGX's valuation will not improve until organic volume growth returns,” said Piper Jaffrey analysts Kevin Ellich and Bradley Maiers in a recent report.

“LabCorp seems to be performing better on the volume front than its larger competitor and pointed to improving volumes throughout the quarter, which is encouraging,” said Amanda Murphy and Sylvia Chao of William Blair.

Quest to Acquire UMass Outreach Lab

In separate news, Quest recently entered into an agreement to purchase the clinical outreach laboratory of the University of Massachusetts Memorial Medical Center. Financial details of the transaction were not disclosed. The deal is expected to close in the next three months. Though it is selling its lab business, UMass will continue to be involved in the business under a partnership with Quest's Cambridge Laboratory and its Athena Diagnostics neurology testing subsidiary. 



INDUSTRY BUZZ

Watch Out for These Hotspots in 2013

The laboratory sector is certain to be buffeted in the coming year by a combination of payment changes, the rise of accountable care organizations (ACOs), and the tug of consumer demand. That was the consensus of a panel of G2 Intelligence executives who convened at the annual Lab Institute earlier this month to discuss “hotspots” expected to impact pathology practices and laboratories in 2013.

Dennis Weissman, G2’s founder and executive editor, observed that the industry should expect a total 4.65 percent reduction in Medicare reimbursement, with a 2.65 percent cut under the Part B lab fee schedule and an additional 2 percent cut as part of last year’s deal Congress made in order to raise the debt ceiling.

Weissman added that nontraditional means of payments—such as those bundled in an accountable care organization—will also receive added attention during the year, as will greater pressure on consumers by their health plans to pay more of their laboratory costs out of pocket.

“Fee-for-service is always a big issue, but I think the bigger issue is non-fee-for-service (payments). We’ll start seeing some impact (next year),” he said, adding that the continued rise of ACO projects will drive that.

L. Eleanor J. Herriman, M.D., G2’s managing director of advisory services, noted that there are 300 to 350 ACOs currently operating. Another 500 to 600 are in the application process. “It’s really explosive growth,” she said, adding that their proliferation will put pressure on hospitals regarding how they want to manage their laboratory services within an ACO context.

G2 Managing Director Stephanie Murg believes the next generation of genomic sequencing (non-Sanger-based) would have a “make-or-break” year in 2013. She noted that sequencing has made rapid breakthroughs in the last couple of years and is becoming an accepted bench-to-bedside technology rather than a test of last resort. Although the tests themselves are coming down in price, Murg noted that labs may be pressured by the resources required to sort and analyze the data they provide. “The challenge for clinical laboratories is how all this data really applies to patient care,” she said. 

References

Foley Hoag, LLP 202-223-1200	Sonora Quest Laboratories 602-685-5000	LabCorp 336-436-5076
Quest Diagnostics 800-222-0446	Dynacare Laboratories 414-805-7600	Piper Jaffray 800-333-6000
GE Healthcare 800-292-8514	PAML 509-755-8600	William Blair 212-237-2700
England & Co. 202-386-6500		

To subscribe or renew LIR, call now +1-973-718-4700, 800-401-5937 (AAB and NILA members qualify for a special discount. Offer code: LIRN11)

Online: www.G2Intelligence.com/LIR

Email: customerservice@G2Intelligence.com

Mail to: G2 Intelligence
1 Phoenix Mill Lane, FL3,
Peterborough, NH 03458-1467 USA

Fax: +1-603-924-4034

Multi-User/Multi-Location Pricing?
Please email jping@G2Intelligence.com or call 973-718-4703.

LIR 10/12b

October 26, 2012 © 2012 Kennedy Information, LLC, A Bloomberg BNA Business, 800-401-5937. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

Notice: It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to \$150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. Reporting on commercial products herein is to inform readers only and does not constitute an endorsement. *Laboratory Industry Report* (ISSN 1060-5118) is published by G2 Intelligence, 1 Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467 USA. Tel: 800-401-5937. Fax: 603-924-4034. Web site: www.G2Intelligence.com.

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Ron Shinkman, Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, COO and Publisher
Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 973-718-4700.