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LABORATORY

INDUSTRY REPORT®



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Palmetto Relents on Some New Molecular Prices

Lab industry lobbying has led to a minor uptick in some molecular coding prices unveiled earlier this year by one of the regional Medicare administrative contractors (MACs), but observers say many test prices remain well below the threshold of covering expenses.

The uptick in several Tier 1 codes by Palmetto GBA and a single Tier 2 code by Noridian comes just days before the Centers for Medicare and Medicaid Services (CMS) is expected to unveil the draft prices for more than 100 molecular pathology codes, which were moved on Jan. 1 to the clinical laboratory fee schedule. Medicare contractors were instructed to use gap-filling to determine pricing for the codes.

Earlier this month, Palmetto upped the payments on eight higher-volume codes—from 9 percent for KRAS, code 81275, to as high as 189 percent for the Cytochrome P450 2D6 test, code 81226. For the former test, the price rose from \$225.88 to \$246.40, while the latter jumped from \$278.93 to \$426.43.

The average nonweighted increase was 75 percent, although three of the codes received a bump below 15 percent.

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www.mdxconference.com

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Thermo Fisher to Acquire Life Technologies in Huge Deal

In what is likely to be the largest laboratory industry transaction for 2013, Massachusetts-based Thermo Fisher Scientific has gone bicoastal, coming to terms to acquire California-based Life Technologies for \$13.6 billion in cash and an assumption of \$2.2 billion of its debt.

The deal, which is expected to be finalized in early 2014, will create a giant company with nearly \$15 billion in annual revenue and 50,000 employees—and control of billions of dollars worth of molecular tests and complex equipment such as sequencers.

“The acquisition of Life Technologies enhances all three elements of our growth strategy: technological innovation, a unique customer value proposition, and expansion in emerging markets,” said Marc

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■ THERMO FISHER TO ACQUIRE LIFE TECHNOLOGIES IN HUGE DEAL, *from page 1*

N. Casper, Thermo Fisher's chief executive officer. "Our customers in research and applied markets will now be able to achieve even higher levels of innovation and productivity by working with the combined company. We're especially excited about the new opportunities we will have to leverage our complementary offerings."

It also suggests to some industry observers that molecular testing, once the unsettled frontier of the laboratory sector, is beginning to show signs of consolidation.

"There's been a gradual consolidation of the diagnostic space. We've seen it for the past five years," said Peter Lawson, an analyst with Mizuho Securities in New York.

However, Lawson does not see the market closing ranks.

"There is still plenty of space and time for a series of deals," he said.

Ross Muken, a senior managing director with the ISI Group in New York, agreed that there remains a significant opportunity for other players. "Molecular testing is still wide open. Certain areas like cancer are almost the wild, wild west."

Neither analyst believes that the deal will have much effect on the pricing of a primary lab product of both players: gene sequencers.

"There may be a blip for a year or two if there is a lack of innovation or a retrenchment," Lawson said, "but the trend [in price] has been downward."

As part of the acquisition, Mark P. Stevenson, Life Technologies' president and chief operating officer, is expected to have a "significant leadership role" in the combined company, a statement said, but no other details were disclosed. 

Quest and LabCorp: What the Future Holds For the Nation's Two Largest Lab Companies

Quest Diagnostics and LabCorp could be described as the New York Yankees and the Boston Red Sox of the laboratory world. They both have a long history and much success. And while they remain profitable, both teams have fallen on more difficult times as of late—the same fate that has befallen these two national labs.

The first-quarter earnings reports for both labs included flat revenues: LabCorp's were up a grand total of 1.5 percent, to \$1.44 billion from \$1.42 billion, while Quest's were down about 6.4 percent, to \$1.78 billion from \$1.9 billion.

Both labs made a significant amount of money during the quarter—LabCorp reported net income of \$147.2 million while Quest's net was \$143.6 million. However, those numbers were down 9 percent for LabCorp and 15 percent for Quest compared to the first quarter of 2012.

LabCorp forecast revenue growth of 2 percent to 3 percent. Quest says its 2013 revenue will be flat. Both labs are in the middle of plans to streamline operations. Quest is consolidating operations and cutting jobs. LabCorp is automating its labs and merging some of its operations. Both are also buying back stock.

These giants of the lab industry are in a tough operating environment, one that was greatly impacted by the recession that began in December 2007 and represented the single biggest economic contraction since the 1930s. Added to that are

“We believe . . . buyback [will] play an increasingly important role.”

—Deutsche Bank

recent across-the-board reimbursement cuts to Medicare, steep cuts to the technical component of code 88305, and cuts in molecular test reimbursement.

According to a recent study by the Kaiser Family Foundation, the recession was the greatest single factor behind the historic slowdown in health care spending, which rose only 3.9 percent annually between 2009 and 2011—far below its six-decade average growth of nearly 9 percent per year.

With laboratories accounting for approximately 3 percent of all health care spending, they lack the leverage experienced by other health care segments, such as hospitals or outpatient clinics. Moreover, many of their components could be construed by clinicians as elective. As a result, traditional lab spending been hit hard in recent years, and the bottom lines of Quest and LabCorp reflect that.

Not All Bleak

The future for the two giants is not all bleak, however. For example, the Kaiser Family Foundation study concluded that health care spending growth will eventually rebound to its prerecession levels. The long-term financial outlook for both companies reflects the most positive future.

Deutsche Bank, which has a hold recommendation for both Quest and LabCorp stock, has forecast net earnings per share for Quest of \$4.27 for 2013 and \$4.96 for 2014, up from prior forecasts of \$4.25 for 2013 and \$4.92 for 2014.

However, some of the earnings per share growth, at least for the near term, are based on streamlining operations and buying back shares. For Quest, “we believe market expectations are for buyback to play an increasingly important role in achieving 2013 EPS guidance,” it recently reported. As for LabCorp, Deutsche Bank is forecasting just 1.8 percent in revenue growth for 2013 and 2.7 percent for 2014.

But William Blair & Co. is giving the operational edge, however slight, to LabCorp. “Medicare reimbursement cuts, weather, and fewer business days were a negative in the quarter offset by some acquisition-related tailwinds. The company’s reported volume and revenue per requisition growth were better than those reported by its large-cap peer,” wrote William Blair analysts Amanda Murphy and Sylvia Chao. 

Inside The Lab Industry



Molding the Lab Business Along the Patient-Centric Medicine Model

For decades, the typical business model for outreach laboratories has been to perform a test, turn around results, and send out a bill.

But as was discussed during G2 Intelligence's recent Volume to Value conference in Fort Lauderdale, Fla., that era is drawing to a close.

Instead, labs must be more patient-centric. It is a term that could comprise a variety of meanings.

According to the National Institutes of Health, the patient-centric model is "health care that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients' wants, needs and preferences." It can also include medical homes—a single locale where a patient's care is coordinated, often through an accountable care organization (ACO).

"It's reached a tipping point" in terms of acceptance, said John T. Daly, M.D., the chief medical officer for COLA.

The current payment models are also being forced to change. Paul Epner, an industry consultant in Chicago and director of the Society to Improve Diagnosis in Medicine, noted that the costs for diagnostic services such as lab are growing faster than most other components of health care delivery. The result: Labs will be pressured to cut costs and improve efficiency.

"The problem is, there's no patient involved—just inputs and outputs . . . putting your head down and doing the labwork," Epner said.

Specific Role for Labs Remains Unclear

However, the specific role of laboratories in a patient-centric model remains for the most part undefined.

"We are in a period of uncertainty," Daly said. He noted that the payment policies being promoted by the Centers for Medicare and Medicaid Services in order to encourage patient-centric care are putting financial pressures on smaller labs and pathology practices. Such trends are also exacerbated by the fact that more and more pathologists are becoming employees of providers rather than owning stakes in their own practices.

Moreover, the longtime business models for most labs and pathology practices have contributed to the perception among most hospital and health system managers that "they are a commodity," Daly said, putting them at risk of being marginalized in the move over to patient-centric care.

Outreach labs also typically cover a sometimes sprawling geographic service area—one that can offer a variety of branches where patients can undergo draws for testing. Multiple locales do not necessarily serve the medical home model well.

“At the same time, it’s a moment for opportunity,” Daly said.

Patient Finances, IT, and the Sonora Quest Experience

Although lab and pathology leaders have been encouraged to use their skills to enhance the value of the care they provide, another patient-centric focus could be on finances. As cost-shifting by payers continues to grow, so do their deductibles and out-of-pocket costs. This may be prompting some patients to become more proactive regarding the care they receive.

Daly noted that IT is a critical component of patient-centric care and could be used to create algorithms to prompt specific tests and lab formularies.

However, hospitals and outreach labs have not been equal in the IT realm. The latter’s ability to electronically assemble data on an individual

patient and use it to its clinical and financial advantage has been easier said than done.

*“For me, it was obvious — we had to form our own patient IDs.”
—David N. Moore, Sonora Quest*

David N. Moore, chief information officer for Sonora Quest

Laboratories in Tucson, Ariz., observed that until recently, few labs had the ability to even differentiate between two patients with similar names—a distinct problem for his outreach network.

Although Sonora Quest is majority-owned by Banner Health, one of the state’s major hospital networks, it also provides outreach services to about half of Arizona’s major hospitals. Banner has also formed seven ACOs within Arizona, putting pressure on Sonora Quest to be able to service their patient populations.

Those pressures were compounded by recent changes in Arizona law that allowed patients to access their own laboratory records. So Sonora Quest was insistently prodded to update its IT infrastructure, according to Moore.

“All those requirements were tied in to the need to be able to track patient data,” Moore said. “For me, it was obvious—we had to form our own patient IDs.”

The results have not only made its lab network more able to compete within a patient-centric model, it has also been a boon to Sonora Quest’s bottom line.

As a result of its own internal upgrades and working with Arizona’s regional health information exchanges, Sonora Quest has been able to streamline the search for complete patient records from a couple of weeks to several minutes, according to Moore. Sonora Quest currently receives about 600 patient requests for records each week.

At the same time, Sonora Quest has become much more effective in collecting copayments from patients at the time of service. It's a critical issue given that the ACO Banner formed with the Arizona Blues includes a \$50 laboratory copayment. And while just 3 percent of patients who enter Sonora Quest's 73 service centers owe the lab any money, it still amounts to \$14,000 per day.

Now, every patient's balance is assessed when they check in. And a large number pay what they owe immediately, Moore said.

However, Moore also noted that by upgrading its IT, Sonora Quest can also support hospitals and ACOs in a variety of patient-centric metrics. They include monitoring incoming orders in conjunction with a patient's electronic medical records in order to warn of the possibility of missed tests and provide accurate lab utilization and cost data for specific periods of time.

Creating a Value Chain

But just getting a handle on costs or volume is not going to be enough to adapt to a patient-centric model of care. Epner noted that lab tests are only as valuable as they are to the entity consuming them. If a hospital or other provider ignores or misreads a lab test, it is of no value—either to the provider or the patient. Ditto for unnecessary tests.

"We can turn out an accurate result for a test that should have never been ordered—and we are not necessarily providing value for anybody," Epner said.

As a result, Epner encouraged labs such as Sonora Quest to provide specific volume and cost data—but it must be given to physicians individually with the intent of changing their behavior to the benefit of their patients. Epner cited a couple of studies that focused on physicians receiving specific feedback on a regular basis about their testing patterns and volume. In both of those studies, doctors who had engaged in inappropriate testing improved their performance.

"We can turn out an accurate result for a test that should have never been ordered—and we are not providing value for anybody."

—Paul Epner, Society to Improve Diagnosis in Medicine

Epner also noted that Kaiser Permanente's Southern California division has created 18 outpatient "safety nets" with the intent of cutting costs and improving care. Focused testing has proven vital in improving levels of accurate prostate cancer and chronic kidney disease diagnoses—as well as cutting down on malpractice suits. And labs are being called in for testing when certain patients show high refill rates for certain kinds of prescriptions—uncovering potential drug abuse and overdose issues.

"This is the kind of value where you are changing patient outcomes," Epner said. "You're not necessarily going to run more tests—although sometimes you are—but you are focused on the appropriateness of care and solving patient problems." 

■ PALMETTO RELENTS ON SOME NEW MOLECULAR PRICES, *from page 1*

The rise in the payments is primarily the result of lobbying by the California Clinical Laboratory Association (CCLA). Palmetto covers the Golden State and Nevada. The CCLA worked in conjunction with XIFIN, a San Diego-based revenue cycle management firm, and Diana Voorhees, whose Salt Lake City-based consulting firm specializes in coding issues.

Officials said that XIFIN worked as an intermediary to deliver cost data from 15 labs in California to Palmetto, guaranteeing that proprietary financial information did not wind up in the hands of rival labs.

“They were able to use us as an honest broker,” said Rina Wolf, XIFIN’s vice president of commercialization strategies, consulting, and industry affairs.

However, the new prices still in many instances won’t be profitable for the labs, according to CCLA President Michael Arnold.

Palmetto’s Molecular Test Repricing				
CPT	Test	Palmetto Initial Price	Palmetto Revised Price	Percentage Increase
81210	BRAF	\$57.51	\$97.45	69%
81225	Cyp2c19	\$135.26	\$319.12	136%
81226	Cyp2d6	\$147.50	\$426.43	189%
81227	Cyp2c9	\$96.78	\$169.50	75%
81235	EFGR	\$116.25	\$225.00	94%
81241	F5	\$68.64	\$78.39	14%
81270	Jak2	\$72.81	\$82.88	14%
81275	KRAS	\$225.88	\$246.40	9%

Source: XIFIN Inc.

“It’s produced some results, but it’s been insufficient so far,” Arnold said, although he conceded some headway has been made.

In the meantime, Arnold said the venture capital community—which is heavily involved in molecular testing and laboratories—has been expressing concern about the low pricing that the MACs have disclosed

under the new codes. If they remain in place, it could impact future investment in the sector, he indicated.

One California lab, Hunter Laboratories in Campbell, has a bigger problem: For the moment at least, Palmetto is denying payment for ApoE, a test to assess the risk of cardiovascular disease.

According to Hunter CEO Chris Riedel, Palmetto is “flat out wrong” about the value of the test, which he said is especially valuable for cardiologists and lipidologists.

“I don’t blame Palmetto as much as I do CMS, which gave the MACs a short timetable to get this done,” Arnold said.

He noted that some of the other MACs were also influenced by Palmetto, which was the first to release its pricing.

In the meantime, CMS is expected to release draft molecular code pricing from the MACs any day now. Stay tuned to www.G2Intelligence.com for updates. 



INDUSTRY BUZZ

Flu Season Boosts Quidel's Bottom Line

Those touched by influenza tend to count the days until they're feeling better. Quidel Corp.'s shareholders likely don't want it to end.

The San Diego-based firm that focuses on rapid diagnostic assays credits the recent flu season with a huge jump in its bottom line for the first quarter, ending March 31.

Revenue for the first quarter of 2013 reached \$62 million, compared to \$38 million in the year-ago quarter, an increase of 63 percent.

Net income for the quarter was \$12.4 million, or 36 cents per share. For the first quarter of 2012, net income was \$50,000.

"This year's influenza season, which began earlier in the previous period, continued well into the first quarter. Demand for our respiratory products, including QuickVue, Sofia, Quidel Molecular, and Diagnostic Hybrids, remained elevated through much of February until the percentage of patient visits attributable to influenza-like illness (ILI) fell as the epidemic ebbed," said Quidel Chief Executive Officer Douglas Bryant.

The company's stock reached a high for the year of \$24.50 in mid-March but has since dropped to about \$21 a share. However, four of the six stock analysts covering the company have buy recommendations on Quidel's shares.

Along with the uptick in earnings, Quidel also reported receiving Food and Drug Administration clearance to market a quick turnaround assay for *C. difficile*, a hospital-acquired infection that kills about 14,000 patients in the United States every year.

Nonetheless, Standard & Poor's analyst Phillip M. Seligman remains relatively skeptical about Quidel's future performance. He believes it will face the same headwinds hitting other laboratory operations. And Wedbush Morgan recently downgraded its stock, citing competition from other companies for molecular testing.

"Although we believe many supply categories are historically largely recession-resistant, there are concerns about demand trends in areas typically viewed as non-elective, such as basic hospital supplies, sterilization equipment, beds and stretchers, and blood collection products, that are tied to hospital spending budgets," Seligman wrote recently. However, he added that there was an "uneven pickup" in spending beginning in 2011 and continuing through last year. 

References

California Clinical Laboratory Association 916-446-2646	Palmetto GBA 800-633-4227	Sonora Quest 602-685-5000
Hunter Laboratories 800-762-9722	Quest Diagnostics 800-222-0446	Thermo Fisher 781-622-1000
Life Technologies 760-603-7200	Quidel 858-552-1100	XIFIN 858-793-5700

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