

LABORATORY INDUSTRY REPORT®

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Labs Get Delay on Physician Signature Requirement

Clinical laboratories are breathing a small sigh of relief after the Centers for Medicare and Medicaid Services (CMS) announced Dec. 21 that it would delay for three months enforcement of the physician signature requirement on laboratory requisitions. The requirement was to have taken effect Jan. 1, 2011.

In a statement posted on its Web site, CMS said that because many physicians, nonphysician practitioners, and clinical laboratories may not be aware of, or understand, the policy, it will focus in the first calendar quarter of 2011 on developing educational and outreach tools to educate those affected. As these tools become available, CMS says it will post the information on its Web site and use the other channels it has to communicate with providers to ensure the information is widely distributed. The agency will not begin enforcing the requirement until April 1.

While the clinical laboratory community had hoped for a repeal of the requirement—or at least a delay of one year—groups representing labs say they are grateful for a three-month reprieve.

Continued on page 2

Genoptix Puts Itself on Auction Block Quest, Sonic Possible Suitors

Now that specialized laboratory Genoptix (Carlsbad, Calif.) has put itself up for sale, industry observers are speculating about which companies might be interested in acquiring the cancer testing company.

According to a report on *Bloomberg*, Genoptix has hired Barclays Plc to run an auction. Among the possible suitors are Quest Diagnostics (Madison, N.J.) and Sonic Healthcare (Sydney, Australia), says Amanda Murphy, an analyst with William Blair & Co. (Chicago).

Following several years of strong growth, Genoptix has struggled in recent months. After what appeared to be a strong start this year, the company in May lowered its 2010 revenue expectations, leading several investment banks to downgrade the company's stock. As of Dec. 17, the company's stock was down 46 percent from the beginning of the year.

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■ LABS GET DELAY, *from page 1*

“Implementation on Jan. 1, 2011, would have resulted in a crisis in access to laboratory services for the nation’s seniors,” said the American Clinical Laboratory Association (ACLA) in a statement issued Dec. 21. “ACLA maintains that the policy is unworkable and is committed to working with CMS to examine a feasible alternative approach to meeting CMS’s objective of ensuring that laboratory requisitions are appropriately documented.”

How Did We Get Here?

A rule adopted by CMS in 2000 established the policy that there are alternatives to physicians signing laboratory requisitions. This policy was reiterated in numerous communications from CMS as recently as March 2010, according to ACLA. In a surprising turnabout in this policy, CMS in July proposed requiring a physician signature on all laboratory requisition forms. The agency then finalized this policy in its final rule implementing changes to the 2011 Medicare physician fee schedule.

In its proposal, CMS stated that the new requirement would eliminate uncertainty about whether documentation was required, would not increase the burden on physicians because “it is our understanding that physicians are already annotating the medical record or signing the paperwork provided to the laboratory,” and would minimize compliance problems for labs during audits.

Labs and groups commenting on the proposal noted that the requirement would increase the burden not only on physicians but also on labs, which have no way of enforcing the requirement and are the only provider at financial risk if the requisitions are not signed.

Part of the confusion about the new policy has to do with establishing the difference between a requisition and an order, explained Peter Kazon, an attorney with Alston & Bird (Washington, D.C.). Kazon spoke on this issue Dec. 16 during a webinar sponsored by Washington G-2 Reports.

According to CMS, a requisition is the “actual paperwork, such as a form, that is provided to a ... laboratory that identifies the test or tests to be performed for a patient.” Physicians are not actually required to use a requisition. Instead, they can use an “order,” which CMS defines as “a communication from the treating physician/practitioner requesting that a diagnostic test be performed.” An order could be an annotated medical record or a documented telephone request—in this case the policy is not implicated. If the order is a written document, then it must be signed by the treating physician or practitioner.

“In other words, it doesn’t really matter what you call it,” says Kazon. “If it’s on paper, then it has to be signed by the doctor.”

What Does This Really Mean?

The new policy raises—but does not necessarily answer—a number of questions about implementation. Kazon and Alan Mertz, president of ACLA, addressed some of the more common questions during the Dec. 16 webinar.



What is the impact of this rule on electronic or telephonic orders?

CMS states that this requirement does not apply to telephone or electronic orders. For a telephone order, both the treating physician, or his or her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records.

Does this affect test requirements for anatomic pathology services paid for on the physician fee schedule (PFS), rather than the clinical lab fee schedule (CLFS)?

It's unclear what CMS is saying here. CMS states that it is not changing its policy with regard to signature requirements of other types of services, such as those paid based on the PFS. In last year's proposed "clarification," CMS said it was not addressing questions related to physician pathology services. Kazon advises that once this policy goes into effect, labs should plan on getting a signature on all written orders for laboratory services, regardless of whether they are paid based on the CLFS or PFS.

What happens if a lab bills without a signed requisition?

CMS says you need a physician signature to have a valid order. If you don't have a valid order, then it raises the very substantial questions about whether a laboratory should bill for the service.

Can a laboratory go back to a physician to obtain a signature if the requisition comes in unsigned?

It appears likely. In certain circumstances, CMS has permitted laboratories to obtain an "attestation statement" signed by the physician to support that he or she ordered certain testing (see Transmittal 327, issued March 10, 2010). However, this is a key issue that CMS will have to clear up prior to implementation.

What will the likely impact of this rule be on nursing homes?

It seems likely that this rule could have a significant impact on labs that specialize in servicing nursing home patients. In many instances, nursing homes order tests after a telephone consultation with the patient's physician. Because this physician is usually not on site, it will make it difficult for the nursing home to obtain a signature prior to ordering the test. Also, this difficulty is magnified because often testing is ordered based on a standing order, which may cover a plan of care for the patient. If the standing order is otherwise valid, and signed

by the physician, then it is possible that that could serve as the order, although CMS has not spoken to that issue. However, according to Kazon, CMS has been dismissive of the concerns raised by nursing home labs, even though this could be a particularly difficult area in which to apply the new physician signature rules.

Are stamped signatures permissible on requisitions?

No. In transmittal 327, CMS states that a signature must be handwritten or electronic. Stamped signatures are not permissible.

The CMS statement announcing the delay is available at www.cms.hhs.gov/ClinicalLabFeeSched/.

Correction

The December issue of *Laboratory Industry Report* contained an error on pg. 9. The third and fourth columns in the chart, "Market Share Versus Best Value" are erroneous. The chart should have included only the first two columns: national market share and best value.



Congress Averts 25% Cut in Physician Payments Pathology 'Grandfather' Extended for Another Year

As expected, the House and Senate in mid-December passed legislation stopping the 25 percent cut in Medicare reimbursement for physicians that was supposed to take effect Jan. 1. President Obama signed the bill into law Dec. 15. The measure, H.R. 4994, also makes changes in other Medicare payment policy, including extending the ability of independent clinical laboratories to receive direct payments for the technical component of certain pathology services through Dec. 31, 2011.

The Medicare and Medicaid Extenders Act of 2010 freezes physicians' reimbursement for all of 2011, averting the 25 percent cut that was scheduled to take effect Jan. 1. The physician payment policy would cost \$14.9 billion, according to a summary of the legislation from the Senate Finance Committee.

Congress recently has passed a series of very short-term payment fixes—some as short as one month—rather than longer ones, because of the high cost associated with longer fixes. Physician groups continue to push for a long-term solution to the problem.

H.R. 4994 also would extend reasonable cost reimbursement for Part B lab services to hospital patients in certain rural areas until July 1, 2011. Other extensions include, in part, the Medicare Modernization Act (MMA) Section 508 hospital geographic reclassifications, the Medicare work geographic adjustment floor, and the exceptions process for Medicare therapy caps. In addition, it would include a repeal in the delay of Version Four of the Resource Utilization Groups (RUG-IV) for nursing homes.

The total price of the bill is \$19 billion. It would be paid for by modifying policy concerning overpayments of the health care affordability tax credit in the health care reform law. 🏛️

CMS Seeks Comment on RAC Expansion

The Centers for Medicare and Medicaid Services (CMS) has issued a solicitation for comment regarding implementation of the Recovery Audit Contractors (RAC) program for Medicare Parts C and D.

The solicitation, published in the Dec. 27 *Federal Register*, seeks comments on several implementation issues, including methods the RACs can use to identify overpayments and underpayments within the Parts C and D programs. Comments are due by Feb. 25.

"Given the fundamental differences between Medicare fee-for-service and the Medicare Parts C and D programs and since this is the first time we have attempted to expand RACs to other parts of the Medicare program, we are soliciting the views of industry stakeholders on how to best implement the RAC program requirements established in section 6411(b) of the Affordable Care Act for the Medicare Part C and Part D programs," the comment solicitation said.

The Patient Protection and Affordable Care Act expanded the RAC program to all of Medicare. Previously, it had been confined to Medicare Parts A and B. 🏛️

Sales Rep Salaries Increasing Despite Tough Economy Women Still Earn Less Than Male Counterparts

The median base salaries for industry sales representatives increased an average of 4 percent in 2010 when compared to the previous year, according to Washington G-2 Reports' 2010 Lab Sales and Marketing Compensation Survey (see Table 1). Results of the survey were presented at the 2010 Lab Compete Sales and Marketing Conference held Dec. 8-10 in Las Vegas.

"This is somewhat surprising given the difficult economic times," said Peggy McKee, CEO of PHC Consulting (Celina, Texas), a medical sales recruitment company that assisted G-2 with the survey.

Table 1
Base Salaries (averages)

Position	This Year	Last Year
Account Executive	\$79,000	\$76,000
Account Mgr/Director	113,000	101,000
Sales Representative	58,000	58,000
Business Development	90,000	90,000
Regional Sales Manager	94,000	92,000
Outreach Manager	83,000	80,000
Other	99,000	95,000

Source: 2010 Washington G-2 Reports' Lab Sales and Marketing Compensation Survey

The survey was conducted during the summer of 2010. Results reflect responses from approximately 100 survey participants. Of those responding, 59 percent were male, and 69 percent were at least 40 years old. Only 5 percent of those responding were 20 to 29 years old, and 22 percent were age 30 to 39. The vast majority (88 percent) of the sales and marketing professionals have a four-year college degree, while 33 percent hold an advanced degree.

The largest number of respondents (34 percent) came from laboratories with revenues of \$10 million to \$49 million. Only 9 percent work for labs with revenues of \$500 million or more, and 17 percent come from labs with revenues of less than \$5 million. Almost a third (32 percent) of respondents represent routine clinical laboratories, 19 percent esoteric/specialty, 35 percent both types of labs, and 14 percent other.

Performance and Incentives

Not surprisingly the survey found that the larger the lab, the greater the number of sales reps and the greater the annual sales per rep. Reps working for labs with revenues of less than \$5 million per year, for example, had average annual sales of \$591,996, while those working for labs with revenues

Table 2

Average Sales Per Representative

Company Revenue	Average Sales Per Month	Annual Sales Per Rep	Number of Reps
Under \$5 million	\$49,333	\$591,996	4
\$5 to \$9 million	50,556	606,672	7
\$10 to \$49 million	60,667	728,004	7
\$50 to \$99 million	62,727	752,724	14
\$100 to \$499 million	66,500	798,000	50
\$500 million or more	75,556	906,672	60

Source: 2010 Washington G-2 Reports' Lab Sales and Marketing Compensation Survey

of \$500 million or more had average annual sales of \$906,672 (see Table 2). McKee speculated the higher sales per rep at larger organizations could be related to additional tools and support provided to each rep.

According to the survey, all of the largest labs provide their sales professionals with a cell phone and laptop, while only 71 percent of small labs provided cell phones and 65 percent provided laptops. However, the smaller labs were more likely than their larger competitors to provide Internet service for their salespeople (see Table 3).

Less than half of account executives (45 percent), account managers (38 percent), and sales representatives (38 percent) responding to the survey said their company provides them with a car. A smaller number of ac-

Table 3

Tools/Perks Provided

Company Revenue	Cell Phone	Laptop	Internet
\$500 million or more	100%	100%	67%
\$100 to \$499 million	100%	91%	80%
\$50 to \$99 million	69%	92%	75%
\$10 to \$49 million	82%	88%	79%
\$5 to \$9 million	67%	92%	64%
Under \$5 million	71%	65%	73%
Overall	80%	86%	74%

Source: 2010 Washington G-2 Reports' Lab Sales and Marketing Compensation Survey

Table 4
Total Compensation Last Year

Account Executive	\$117,000
Account Manager/Director	137,000
Sales Representative	80,000
Business Development	97,000
Regional Sales Manager	123,000
Outreach Manager	94,000
Other	106,000

Source: 2010 Washington G-2 Reports' Lab Sales and Marketing Compensation Survey

count executives (18 percent) and an equal number of account managers and sales representatives (38 percent) said they are given a car allowance. The average car allowance was \$550.

Compensation

A large percentage of account executives (73 percent), sales representatives (77 percent), and regional sales managers (83 percent) are paid under a variable compensation plan. That type of plan was somewhat less common for account

managers (54 percent), outreach managers (57 percent), and business development (31 percent).

Total compensation in 2010 ranged from an average low of \$80,000 for a sales representative to an average high of \$137,000 for an account manager (see Table 4).

As might be expected, sales professionals with more advanced degrees earned a higher salary on average than those with a high school diploma or some college. High school graduates earned an average of \$35,000, those with some college earned \$82,682, those with a four-year-college degree earned \$114,191, and those with a masters' degree or higher earned \$133,121.

Age appeared to be less of a factor in determining compensation. Although respondents age 20 to 29 years earned an average of \$98,953, those 30 to 39 years old actually earned more (\$114,831) than people age 40 to 49 years old (\$110,806). Respondents age 50 to 59 years earned an average of \$129,074, while those 60 years of age and older earned an average of \$109,333.

While women typically earn less than men in most occupations, the wage

Table 5
Compensation by Gender, 2010

	Average	Median
Male	\$131,483	\$120,000
Female	94,297	87,000

Source: 2010 Washington G-2 Reports' Lab Sales and Marketing Compensation Survey

gap in laboratory sales was even wider than the national average for all occupations. Experts estimate that women earn 77 percent of what men earn. However, the G-2 sales compensation survey found that females working in laboratory sales earned on average 40 percent less than their male counterparts (see Table 5). 🏠



■ GENOPTIX PUTS ITSELF ON AUCTION BLOCK, *from page 1*

According to the *Bloomberg* report, Stephen Shankman, an analyst at UBS Investment Research in New York, says Genoptix's sales may grow only 5.5 percent this year, to \$194.5 million, after jumping nearly 59 percent in 2009.

And to add insult to injury, the company has been named as a defendant in a shareholder class-action lawsuit alleging that the company issues false and misleading statements about the company's operations and prospects. As a result of the false and misleading statements, the price of the company's stock was artificially inflated, the lawsuit alleges.

Genoptix at a Glance (\$MM)

	2006	2007	2008	2009	2010*
Revenue	\$24,018	\$59,332	\$116,170	\$184,378	\$195,234
Net income	-3,759	3,317	31,356	30,634	18,082
Earnings per share	\$-0.33	\$0.96	\$1.43	\$1.71	\$0.99

*estimate

Source: William Blair & Co. and company reports

The stock traded at a high of \$38.79 on April 30, 2010. But on May 6, the company surprised investors when it announced its financial results for the first quarter of 2010. The company reported net income of \$5.3 million, or 29 cents per diluted share, and revenue of \$47.4 million, falling far short of analysts' estimates, which expected the company to report diluted EPS of 41 cents per share and revenue of \$53.3 million.

In June, the company reduced its revenue guidance for 2010 from between \$235 million and \$240 million to \$210 million and reduced its diluted EPS guidance from between \$1.80 and \$1.85 per share to \$1.20 per share. Upon release of the news, shares of the company stock declined an additional \$5.69 per share to close at \$17.19 on June 16, 2010.

In releasing results for the third quarter, Genoptix once again lowered its full-year revenue guidance to between \$192 million and \$195 million. Revenues for the third quarter were \$49.5 million, while net income was \$4.4 million or 24 cents per diluted share.

Revenues for the first nine months of 2010 totaled \$147.9 million, an increase of approximately 9 percent over revenues for the same period in 2009. Average days sales outstanding was 77 days for the third quarter. 🏠

FTC Challenging LabCorp's Acquisition of Westcliff

The Federal Trade Commission (FTC) is challenging LabCorp's acquisition of Westcliff Medical Laboratories, saying the deal would lead to lower quality and higher prices in the Southern California region.

In a complaint filed Dec. 1, the FTC alleges the acquisition "will have the effect of substantially lessening competition for the sale of clinical laboratory testing services to physician groups in Southern California." It notes that LabCorp, based in Burlington, N.C., and Westcliff, based in Santa Ana, Calif., were two of only three significant clinical laboratory testing service vendors for the vast major-



ity of physician groups in Southern California. The transaction allegedly would leave LabCorp and Quest Diagnostics in control of approximately 89 percent of the market.

The commission indicated that it plans to seek injunctive relief in a district court to prevent LabCorp from integrating Westcliff assets while the case is litigated in the administrative proceeding. LabCorp had agreed on June 25 to hold Westcliff assets separate during the FTC staff's investigation of the transaction. A trial before an administrative law judge is scheduled to begin on May 2, 2011.

"Competition is one of the keys to keeping health care costs under control and ensuring that patients receive high-quality care, and laboratory services are an essential part of that," said Richard Feinstein, the FTC's Bureau of Competition director. "Physicians use lab testing to help diagnose patients and accurately evaluate their conditions, and the FTC is committed to protecting competition in this important sector."

Challenged Conduct

The agency's complaint alleges that the merger agreement and acquisitions violate the Federal Trade Commission Act and the Clayton Act. According to the complaint, an immediate impact of the integration of the Westcliff assets "is that LabCorp intends to increase prices to Westcliff customers." When Westcliff competes head-to-head with LabCorp, the complaint maintains, consumers benefit. "Westcliff has been willing to extend low-priced capitated contracts to customers that LabCorp and Quest have been unwilling to service in that manner," the complaint says.

Further, the elimination of a price-cutting maverick competitor means that the acquisition, if completed, will allow LabCorp to exercise market power both unilaterally by increasing prices on its own, or in coordination with its only remaining significant competitor, Quest. The FTC notes it is unlikely that a new competitor would enter or expand into the Southern California market for the sale of clinical laboratory testing services to physician groups sufficient to restore the competition lost as a result of LabCorp's acquisition of Westcliff. 🏠

Recent Events Bode Well for Myriad's Future

A Dec. 17 appeals court decision upholding patents on diagnostic tests owned by San Diego-based test manufacturer Prometheus could bode well for Myriad Genetics (Salt Lake City), which is battling its own challenge to patents.

In a closely watched case, the Court of Appeals for the Federal Circuit in Washington ruled that Prometheus's patents satisfy the test for patentable subject matter. The court had ruled on the case in 2009, but the ruling was appealed to the Supreme Court, which remanded the case for reconsideration in light of its ruling in *Bilski et al. v. Kappos*.

The *Prometheus v. Mayo* case is the first to be considered by the Federal Circuit in the realm of diagnostics following the Supreme Court's decision *In re Bilski*. The Prometheus patents involve initial dosing of thiopurine drugs (used for treating autoimmune disorders and some leukemias) and then measuring metabolites of



the drug in the blood to determine the patient's optimal dose.

In its initial ruling in 2009, the Federal Circuit had determined that these methods met the "machine or transformation" (MOT) test and thus were patentable. *In re Bilski*, the Supreme Court ruled that while the MOT test may be useful, it should not be considered the sole test for determining patent eligibility of methods.

In its revised opinion issued in December, the Federal Circuit maintained its earlier decision that the methods met the MOT test and therefore were valid. This is the same court that will hear the appeal of a lower court decision that invalidated certain of Myriad's gene patents.

"The recent decision in *Prometheus* gives us some view about how the Federal Circuit might consider the *Bilski* decision as it applies to the diagnostics space," writes Amanda Murphy, an analyst with equity research firm William Blair & Co. (Chicago) in a research note. "It seems that the court continues to maintain a broader view on method patent eligibility and application of the MOT test and more specifically as it related to diagnostics – which provides support for the view that the Federal Circuit will likely issue a partial reversal in the ACLA case (at least as it relates to Myriad's method claims)."

Company Launches New Test

In separate news, Myriad Genetics on Dec. 20 announced the launch of its new test for hereditary pancreatic cancer, Panexia. The test will be offered at a list price of \$3,025 and targets the roughly 9,000 patients diagnosed with familial pancreatic cancer annually (representing an incremental \$26 million annual revenue opportunity).

Panexia provides a comprehensive analysis of the PALB2 and BRCA2 genes for assessing a person's risk of developing pancreatic cancer. It is the ninth molecular diagnostic test launched by Myriad.

More than 20 percent of pancreatic cancer has been reported to have a familial component, and PALB2 and BRCA2 are the genes most commonly identified in the subset of families with pancreatic cancer. Individuals with a mutation detectable by Panexia have up to an 8.6-fold higher risk than the general population of developing pancreatic cancer.

This marks two new tests launched in 2010. Myriad launched its test for prostate cancer recurrence, Prolaris, earlier this year.

Myriad at a Glance (\$MM)

	2007	2008	2009	2010*
Revenue	\$145,285	\$222,854	\$326,527	\$362,649
Net income	55,862	47,846	84,615	152,302
Earnings per share	0.68	0.51	0.86	1.54

*estimate
Source: William Blair & Co. and company reports

"Given Myriad does not provide much visibility into its pipeline, we are encouraged that the company continues to have success converting its R&D efforts into commercial assays and expand its market opportunity," writes Murphy. 🏛️



Lab Index Shows Strong Gains at Year End, Up 15%

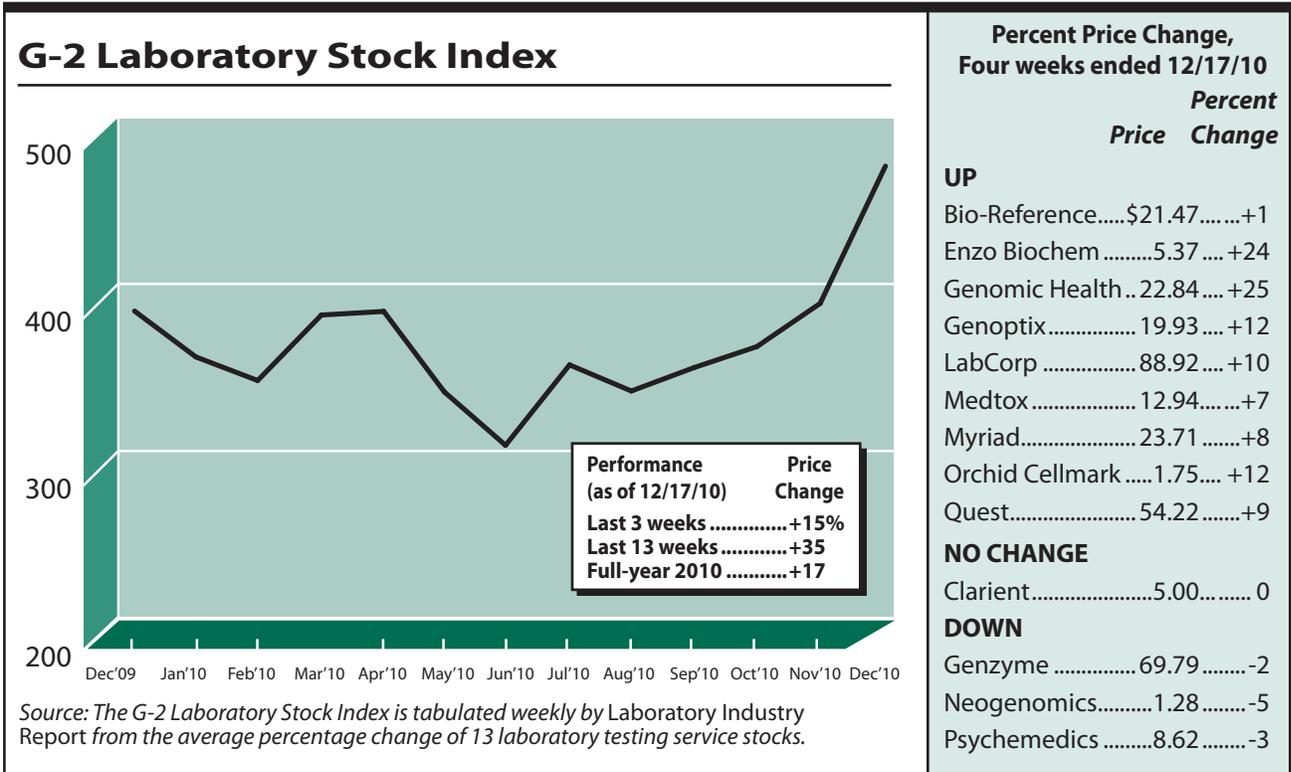
The G-2 Reports' Laboratory Stock Index surged ahead in December, rising 15 percent in the three weeks ended Dec. 17, 2010, driven in part by large gains by Enzo Biochem and Genomic Health. For the year, the index is up an unweighted average of 17 percent. In comparison, the Nasdaq composite is up about 16 percent, and the S&P 500 is up 12 percent.

Nine of the 13 publicly traded lab companies posted gains during the period, while three declined and one remained virtually unchanged.

Shares of **Enzo Biochem** (New York) soared 24 percent to \$5.37 after the company reported that its first-quarter 2011 loss narrowed on a mix of lower costs and a boost in laboratory service revenue. Revenues for the quarter ended Oct. 31, 2010, increased 2 percent to \$25.7 million. Enzo Clinical Labs increased revenues by 6 percent while reducing operating expenses by 62 percent. Overall, Enzo lost \$1.1 million, or 3 cents per share, during the quarter compared with a loss of \$1.8 million, or 5 cents per share, a year earlier.

Genomic Health (Redwood City, Calif.) continued to perform well, with shares climbing 25 percent to \$22.84. The company recently announced seven new studies focusing on its Oncotype DX breast cancer test. The studies, presented at the 33rd annual CTRC-AACR San Antonio Breast Cancer Symposium, further confirm the clinical value associated with the Oncotype DX Recurrence Score in accurately predicting chemotherapy benefit and recurrence risk in early-stage breast cancer patients. Separately, the company announced the first results of a large prostate cancer study that identified 295 genes strongly associated with clinical recurrence following radical prostatectomy. 🏠

For up-to-the-minute laboratory and diagnostic firm data and financial news—go to www.g2reports.com





CardioDx Test Honored as Top 10 Medical Breakthrough

CardioDx's Corus CAD, a blood-based gene expression test, has been honored as one of *Time* magazine's Top Ten Medical Breakthroughs of 2010.

Corus CAD is the first and only clinically validated blood-based test to help clinicians confidently identify which of their stable symptomatic patients are likely to need further assessment for obstructive coronary artery disease, according to CardioDx.

"At the moment, the most reliable way to check the status of the heart's vessels is by an angiogram, an invasive procedure that involves snaking a thin tube into the vessels from an artery in the leg," says the *Time* article (www.time.com). "But researchers have now identified a preliminary panel of 23 genes that code for blood proteins, which was 83 percent accurate in detecting blood-vessel obstructions typical of heart disease. When doctors added this blood test to existing measures of heart attack risk—including symptoms of chest pain and family history of health problems—it improved by 16 percent their ability to classify patients as being at high or low risk, compared with traditional methods alone." 🏛️

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- Genoptix 760-268-6200
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- Myriad Genetics 801-584-3600
- PHC Consulting 972-382-3132
- Prometheus 888-423-5227
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