

LABORATORY

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Congress Extends Physician Fee Fix Through Dec. 31 Lawmakers Working on a Longer-Term Solution

The House and Senate by unanimous consent have passed legislation canceling the 24.9 percent cut in Medicare physician payments that was set to take effect Dec. 1, instead continuing the 2.2 percent fee update currently in effect. President Obama late Nov. 30 signed the extension into law.

As *LIR* went to press, lawmakers were working on a one-year payment fix through 2011, which they hope to pass in early December before adjourning for their winter break. Lawmakers have been resistant to approving legislation canceling the cut without paying for it.

The American Medical Association, the American Society for Clinical Pathology, the College of American Pathologists, and other medical specialties had called on Congress to grant an extension of current pay rates plus 1 percent at least through 2011 at a cost of \$15 billion.

In a Nov. 29 statement, President Obama praised Congress for preventing the payment cuts from taking effect this month and urged

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Reference Testing Market Growing 8% Per Year

The national market for reference testing services is growing at about 8 percent per year, with the market in 2010 estimated at about \$6.2 billion, according to the latest report from Washington G-2 Reports, *U.S. Laboratory Reference Testing: Market Profile and Pricing Trends 2010*.

Washington G-2 Reports e-mailed surveys in the spring of 2010 to approximately 10,000 hospital and independent laboratories. This represents almost all CLIA-certified hospital and independent laboratories in the United States. The surveys were not distributed to the five major reference laboratory companies—Quest Diagnostics, LabCorp, ARUP Laboratories, Mayo Medical Laboratories, and Specialty Laboratories—since many of the survey questions were related to the quality of services and prices offered by these labs.

Among the highlights of the survey:

- ❑ The national market for reference testing services is estimated

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■ CONGRESS EXTENDS PHYSICIAN FEE FIX, *from page 1*

them to “pass a one-year extension to ensure seniors maintain access to the doctor they know and trust over the coming year.”

The steep reduction in Medicare physician fees is caused by the Sustainable Growth Rate (SGR) formula used to calculate the annual update to the Part B physician fee schedule. The SGR has triggered negative updates for most of the past decade, but Congress has repeatedly intervened since 2003 to block cuts with a series of short-term fixes. 🏛️

Extensions Urged for Pathology Grandfather Protection, Other Expiring Medicare Policies

Fourteen leading health care provider groups, including the American Clinical Laboratory Association (ACLA) and the College of American Pathologists (CAP), have appealed to Democratic and Republican leaders in the House and Senate to take immediate action to extend a host of Medicare policies that expire Dec. 31.

Two of the policies are laboratory-specific: an extension of the pathology “grandfather” protection and an extension of reasonable cost reimbursement for clinical lab services provided by certain small rural hospitals.

The provider groups made their appeal in a Nov. 1 letter to Senate Majority Leader Harry Reid (D-Nev.) and minority leader Mitch McConnell (R-Ky.) and House Speaker Nancy Pelosi (D-Calif.) and John Boehner (R-Ohio), minority leader.

The expiring policies also affect the physician fee schedule, ambulance services, the exceptions process for therapy caps, and extensive rehabilitation services needed to return Medicare beneficiaries to their homes and communities.

There is a chance that the extensions could be attached to an SGR fix before the lame-duck session adjourns in early December. Otherwise, they would be taken up again when the new Congress opens in January. Provider groups advocate extensions of at least through 2011, retroactive to Jan. 1. CAP and ACLA, while calling for an extension of the pathology grandfather protection for at least a year, support making the protection permanent.

Failure to pass legislation to extend these various Medicare policies, the provider groups said in their appeal to congressional leaders, “will prompt limited access to services for beneficiaries in rural and other underserved areas, payment cuts to health care professionals, as well as the creation of an unsustainable health care environment.”

The groups backed an extension under the Part B fee schedule “of the floor on geographic adjustments to the work portion of the physician service through the end of 2010, with the effect of increasing practitioner fees in rural areas. It also would provide immediate relief to areas negatively impacted by the geographic adjustment for practice expenses and require the secretary of HHS to improve



the methodology for calculating practice expense adjustments.”

The pathology grandfather protection allows independent clinical labs to bill Medicare Part B directly for the technical component (TC) of anatomic pathology services to hospital inpatients and outpatients. It expires Dec. 31, and the Centers for Medicare and Medicaid Services (CMS) has declared its intent to eliminate such billings after that date.

CMS has long advocated this policy change, contending that the TC is reimbursed through the hospital’s prospective payment and the lab should seek payment for the service from the hospital, not Part B.

Congress has repeatedly blocked the agency from moving ahead by enacting a series of short-term extensions of the “grandfather” protection, most recently last year by approving a one-year extension, through Dec. 31, 2010. The protection is of special benefit, advocates say, to rural hospitals that cannot afford to perform the pathology work in-house but must send it to an outside clinical lab.

The grandfather protection applies to hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to eliminate such billings. Further, it applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology. 🏠

Genomic Health Delivers Second Profitable Quarter

Cancer testing company Genomic Health (Redwood City, Calif.) reported its second profitable quarter Nov. 8, with total revenues increasing 18 percent to \$46.3 million when compared to the third quarter of 2009.

During the third quarter, Genomic Health delivered more than 14,730 Oncotype DX test results, an increase of 17 percent compared with the same period last year.

Net income was \$3.7 million in the third quarter of 2010, compared with a net loss of \$502,000 for the same period last year. Basic and diluted net income per share was 13 cents and 12 cents, respectively, compared with a net loss of 2 cents per share in the third quarter of 2009.

“Our strong third-quarter results reflect an increase in revenues and test volume across all segments of our business and increasing reimbursement worldwide,” said Kim Popovits, president and chief executive officer. “We delivered profit for the second consecutive quarter while continuing to invest in our global commercial infrastructure as well as multiple research and development initiatives aimed at expanding our reach to cancer patients in new markets throughout the world.”

During the third quarter, Genomic Health delivered more than 14,730 Oncotype DX test results, an increase of 17 percent compared with the same period last year. The company also established contracts with the Blue Cross Blue Shield plans of Delaware, Florida, and Montana, and with Blue Cross of Northeast-



ern Pennsylvania, for estrogen-receptor positive node-negative breast cancer, including patients with micrometastases. In addition, it established a contract with EmblemHealth for certain estrogen-receptor positive breast cancer patients providing in-network benefit coverage for approximately 3.3 million lives in the Northeast. 🏛️

Bio-Reference to Collaborate with Mass General on Test Development

Bio-Reference Laboratories (Elmwood Park, N.J.) said Nov. 30 that it has entered into a definitive agreement with Massachusetts General Hospital (MGH) to collaborate on the development of clinical diagnostic tests that will expand the use of personalized medicine for the identification and treatment of solid tumors.

The agreement will build upon a solid tumor genotyping and pharmacogenomics testing platform that MGH has been offering to its patients for the past few years. This genotyping platform will allow for the simultaneous assessment of more than 100 cancer mutations in clinical tumor specimens, allowing for the optimal choice of targeted therapies in each patient.

In addition, the agreement is expected to accelerate research, especially involving clinical correlations with drug responses that will be accessible to other entities, including pharmaceutical companies that are expected to cooperate in the development of personalized medicine therapies.

“Personalized therapies in the treatment of solid tumors hold great promise that still remains largely untapped,” said Marc Grodman, M.D., chief executive officer of Bio-Reference. “This joint initiative seeks to utilize our joint resources to help realize that potential.” 🏛️

Medicare Payment for Key Pathology Codes Set to Increase

If lawmakers act to stop a reduction in the physician fee schedule conversion factor, Medicare reimbursement rates for a number of key pathology codes will go up an average of 13 percent in 2011.

Currently the conversion factor is \$36.8729. While lawmakers have averted a cut through Dec. 31 of this year, the conversion factor will drop to \$25.51 on Jan. 1, 2011. However, lawmakers are expected to take action in early December to prevent the cut from taking effect (*see article on p. 1*).

If Congress keeps the conversion factor at the current level, global reimbursement rates for most pathology codes will rise by 10 percent or more in 2011. For example, global reimbursement for CPT 88305 (tissue exam by pathologist) would rise by 11 percent to \$115.04. Global reimbursement for CPT 88185 (flow cytometry) would increase 16 percent to \$54.94. The reimbursement rate for CPT 88367 (FISH—computer assisted) would increase by 16 percent to \$279, while the rate for CPT 88307 (tissue exam by pathologist) would rise 16 percent to \$246.31. 🏛️

Is a Clinical Digital Pathology Solution Ready for Primetime?



Gene Cartwright, CEO

Though digital pathology offers clear benefits for clinical use, widespread use of the new technology is still a few years off. A number of companies are working on developing a digital pathology solution, and some, including Omnyx (Pittsburgh), a joint venture between GE Healthcare and the University of Pittsburgh Medical Center (UPMC), are actually in the testing phase of digital pathology.

“Digital pathology is an obvious idea, but it’s extremely difficult to do because the images are so large,” says Omnyx CEO Gene Cartwright, who discussed digital pathology during Washington G-2 Reports’ 28th annual Lab Institute, held Oct. 13-15 in Arlington, Va. “I think everyone would want digital pathology if it worked,” says Cartwright. “The problem is those solutions don’t really exist today. A clinical digital pathology solution is not quite ready, but it will be ready very soon.”

In October, Omnyx announced that it was initiating clinical research testing of a digital pathology platform that it thinks will help transform the 125-year-old practice of pathologists using glass slides. The new technology is a combination of patented scanners that boost scan speed by using one camera to scan the slide and a second to simultaneously focus new imaging software for highest-quality images, along with an information technology backbone that digitizes a pathology department’s workflow.

UPMC, Montefiore Medical Center, Stanford University Medical Center, and University Health Network are currently installing, testing, and providing feedback on the new platform and will collect data for a submission to the Food and Drug Administration (FDA). GE Healthcare and UPMC have invested \$40 million in the project to date. The digital pathology market is expected to grow to more than \$2 billion over the next several years.

Omnyx is just one company working on a digital pathology solution. Others working in this area include Leica, Olympus, Aperio, Roche, Bioimagine, 3DHistech, and Philips.

So just how will digital pathology transform the industry? By helping streamline the entire pathology workflow, improving efficiency, enhancing quality, and bringing about faster diagnosis for patients, says Cartwright.

“Once you create a digital image, you can send it anywhere,” he explains. “You can send it to the most appropriate person. You can send it for a consult that will get you the right answer. There is real quality improvement that can be gained if you have a digital pathology solution.”

Despite the need for a more efficient and faster pathology workflow, less than half of labs responding to a recent survey conducted by *Laboratory Economics* said they already are or are planning to use digital pathology in the next two years. Of those already using it, the majority say they use it for education and training. Less than a quarter use it for primary clinical diagnosis.

Among the barriers to adoption are concerns that the image navigation is not fast enough or that scanning speed is not fast enough. Another barrier is

that many pathologists are reluctant to give up their microscopes, which Cartwright says could be a reaction to the first two concerns.

When asked why they don't plan to use digital pathology, respondents to the *Laboratory Economics* survey said that it was too expensive (52 percent), the "microscope works fine" (36 percent), integration concerns with laboratory information system (23 percent), too slow (15 percent), and reimbursement issues (13 percent).

Requirements for a Workable Solution

For a clinical digital pathology solution to work, it must meet a number of requirements, notes Cartwright:

- Fast image scanning.** Scanning should be able to take place in 30 seconds to one minute.
- Automated imaging scanning operation.** "You can't have a system where a technician has to baby-sit it," says Cartwright. "It's got to be completely automatic."

Identified Opportunities for Time Savings for Pathologists

Matching

- Matching paperwork to case
- Matching new slides ordered to cases
- Tracking receipt of ordered slides
- Rechecking slide to case match

Reduced Error Correction

- Transporting case to correct pathologist
- Obtaining correct or missing paperwork
- Reducing duplicate slides ordered
- Picking up wrong slides/missing slides

Querying for Priority Cases

- Checking if STAT cases have arrived
- Checking if frozen section cases are ready
- Visibility of overdue cases

Transporting Cases

- Giving and retrieving case for Pre-Signout Q/A
- Packaging cases for consult

Searching for Cases

- Searching for cases when receiving phone call
- Searching for "orphan" slides
- Pulling cases when reviewing for final signout
- Passing cases between residents and fellows

Retrieving Prior Cases

- Sending request for prior case
- Context switch away from current case
- Tracking receipt of requested prior cases

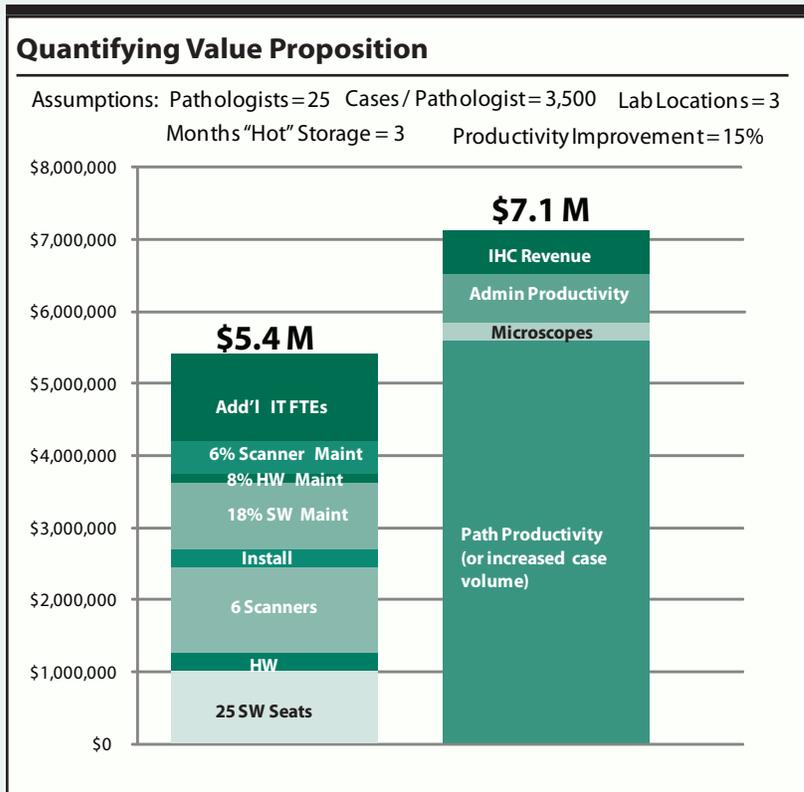
Organizing Cases

- Tracking cases for conferences
- Tracking which cases are ready for review

Communication

- Sending ROI images vs. coscheduling time at scope

- ❑ **Diagnostic level of image quality.** Quality has to be at least as good as what a pathologist would see on a slide.
- ❑ **Fast imaging streaming over existing networks.** The Omnyx platform does not stream the entire image, only the part of the image that the pathologist needs to see.
- ❑ **Enterprise, scalable information technology (IT) architecture.**
- ❑ **Intuitive user interface.** If you use digital pathology, it should make you more efficient, not less efficient, says Cartwright.
- ❑ **Deep integration to LIS systems.** All information that a pathologist needs to make a diagnosis should be easily accessible in one user interface.
- ❑ **Regulatory approvals.** Nothing has been approved yet in the United States for primary diagnosis for digital pathology. While it has been approved in a number of other countries, the FDA has set a very high standard for digital pathology solutions.
- ❑ **Value proposition.** There is no separate reimbursement for using digital pathology, but labs and pathologists can achieve productivity savings through decreased time spent on slides, quality improvement resulting from an increase in subspecialist routing and secondary consults, use of packaged algorithm assays, and improved turnaround time. Cartwright estimates a 15 percent improvement in



efficiency through use of digital pathology. In addition, there is the potential for revenue generation through an increase in "incoming" consults and reimbursement for quantitative IHC.

How long until a digital pathology solution is common in laboratories? It's still probably a few years out, says Cartwright, but it definitely is coming. The clinical research testing will allow Omnyx and other companies to make the platform faster and more cost-effective. After that, the companies will still have to get FDA approval, which will take some time. 🏢



■ **REFERENCE TESTING MARKET**, from page 1

at approximately \$6.2 billion in 2010. This includes about \$3.6 billion from hospital laboratories and \$2.6 billion from independent laboratories and physician office labs (esoteric tests only). This represents an increase of approximately 24 percent since 2007 (or about 8 percent a year) when the national market for reference testing services was approximately \$5 billion.

Pricing Data for Seven Frequently Referred Tests

Test Name	Avg.	High	Median	Low
Vitamin D	\$25.58	\$50.00	\$16.00	\$15.00
Chlamydia/GC DNA Probe	\$40.28	\$94.00	\$38.00	\$13.50
Antinuclear Antibody (ANA)	\$15.65	\$66.00	\$9.70	\$5.00
AFP/Quad	\$66.09	\$111.50	\$66.00	\$30.00
HIV Viral Load	\$7.57	\$9.00	\$7.00	\$6.10
Methyl Malonic Acid	\$28.10	\$40.00	\$29.00	\$15.00
Cystic Fibrosis	\$186.20	\$300.00	\$111.00	\$85.00

Source: U.S. Laboratory Reference Testing: Market Profile and Pricing Trends 2010

□ Overall, participating laboratories send out an average of 9.3 percent of their annual billable tests to reference laboratories; the median is 6 percent. Hospital/health system labs send out an average of 9.6 percent. Independent/commercial labs send out an average of 6.6 percent. Pathology groups send out an average of 9.8 percent, and physician-office labs (POLs) send out an average of 18.3 percent.

- Overall, laboratory survey respondents spent an average of \$1,368,848 each in 2009 on reference testing services, with a median of \$659,500. Hospital/health system laboratories spent an average of \$1,516,610. Independent/commercial laboratories spent an average of \$1,197,038. POLs spent an average of \$10,000. Overall, survey respondents reported a 9.7 percent increase in reference laboratory expenses in 2009. Hospital/health systems reported a 4 percent increase, independent/commercial labs reported a 20.7 percent increase, and physician office labs reported a 2.3 percent increase.
- In our survey, 38.7 percent of laboratory respondents indicated they were licensed to use Roche Diagnostics' polymerase chain reaction (PCR) technology, which is the most widely used equipment for performing molecular diagnostics. This has shown a dramatic increase since 2002, when only 18 percent of survey respondents indicated they were licensed for PCR and in 2005, when only 34.9 percent were.
- Out of all survey participants, 78.2 percent reported that they were actively seeking to broaden their esoteric test menus and, as a result, reduce sendout tests to reference laboratories. This is statistically insignificant from the survey results from 2005, which were 78 percent, and only marginally higher than in 2004 (74 percent) and 2002 (68 percent).
- Some 38.5 percent of respondents in our current survey said the biggest barrier to expanding their esoteric testing menu was that "low test volumes do not justify bringing in-house." This is up slightly from 2005 (35 percent), almost identical to 2004 (39 percent), and much less than in 2002 (46 percent). Most categories have remained stable over the last four surveys, from



2002 to 2010, although more cite “budget constraints and lack of capital to purchase necessary equipment” in 2009 (20.5 percent) than they have since 2002, when 26 percent cited that. It’s possible that the response is a reflection of the overall economy affecting capital acquisitions in the health care industry in 2008, 2009, and 2010

rather than the specific expenses of esoteric testing equipment.

One area that did show a significant drop was “esoteric testing reagents are too expensive to justify expanding menu.” In 2002, 2004, and 2005 this was fairly consistent, 10 percent, 11 percent, and 10 percent, respectively.

Market Share Versus ‘Best Value’

Reference Lab	National Market Share	Best Value	Median	Low
ARUP	18.9%	26.9%	\$16.00	\$15.00
Quest Diagnostics	25.7%	25.4%	\$38.00	\$13.50
Mayo Med Labs	16.2%	14.9%	\$9.70	\$5.00
LabCorp	10.8%	10.4%	\$66.00	\$30.00
Other	24.3%	20.9%	\$7.00	\$6.10
Specialty Labs	4.1%	1.5%	\$29.00	\$15.00

Source: U.S. Laboratory Reference Testing: Market Profile and Pricing Trends 2010

However, in 2009 only 1.3 percent cited reagent expense as an obstacle.

- ❑ Just over 38 percent of survey respondents indicated they use a group purchasing organization (GPO) to buy the majority of their reference testing services. This is a significant change from our surveys in 2002, 2004, and 2007, in which 56 percent, 44 percent, and 43 percent indicated they used GPOs to buy reference testing services.
- ❑ Survey results indicate wide price variation for the most frequently referred tests. There appears to be no correlation between lab size as defined by annual test volume and differences in prices. For example, a simple blood test for Vitamin D has a high of \$50, a low of \$15, and an average of \$25.59 (see chart on page 8).
- ❑ Almost 26 percent of survey participants cited Quest Diagnostics as their primary reference laboratory. “Other” was next, cited by 24.3 percent, followed by ARUP with 18.9 percent. Mayo Medical Labs was cited by 16.2 percent, LabCorp by 10.8 percent, and Specialty Labs by 4.1 percent.
- ❑ Survey participants were asked which national esoteric testing laboratory offers the best value, i.e., service plus price. Almost 27 percent cited ARUP, followed by Quest Diagnostics with 25.4 percent. “Other” labs were cited by 20.9 percent, followed by Mayo Medical Labs with 14.9 percent and LabCorp with 10.4 percent. Specialty Labs was cited by 1.5 percent.

Editor’s note: This article is excerpted from Washington G-2 Reports’ latest research report. U.S. Laboratory Reference Testing: Market Profile and Pricing Trends 2010 is available for purchase for \$995 (\$895 for G-2 Reports subscribers). To order, go to www.g2reports.com and click on “Books and Reports.” 

Medicare Makes Changes to Physician Quality Reporting System

The final Medicare physician fee schedule (MPFS) rule, released Nov. 2, 2010, implements key changes affecting the Physician Quality Reporting System (PQRS), formerly called the Physician Quality Reporting Initiative or PQRI. There is a 60-day comment period ending on Jan. 2, 2011. Below are brief highlights of the final decisions regarding 2011 PQRS that may be of interest to providers of diagnostic imaging and radiation oncology. All changes in the rule are effective Jan. 1, 2011, unless otherwise specified.

- ❑ Adds 20 individual PQRS measures (including new measures for reporting through registries and electronic health records (EHRs), and a new radiology measure, *Reminder System for Mammograms*);
- ❑ Makes 10 additional individual PQRS measures available for reporting through EHR systems, in addition to the 10 measures already available (the measures focus on primary care and preventive services);
- ❑ Reduces the reporting sample requirements for claims-based reporting of individual measures from 80 percent to 50 percent;
- ❑ Establishes procedures for correcting unsatisfactory quality reporting (including plans for interim feedback reports for claims-based reporting in future years) and creates an informal review process when CMS has determined that an eligible professional (EP) did not satisfactorily submit PQRS data;
- ❑ Authorizes PQRS incentive payments of 0.5 percent for 2012 through 2014 and requires PQRS payment adjustments beginning in 2015 for EPs (and group practices) that do not satisfactorily report PQRS data by reducing the MPFS payment by 1.5 percent in 2015 and 2 percent in 2016 and thereafter;
- ❑ Establishes an additional 0.5 percent incentive payment for EPs beginning in 2011 if they (1) satisfactorily report PQRS data for 12 months and (2) participate in a maintenance of certification program more frequently than is required to qualify for or maintain board certification status, which must include completing a practice assessment and patient survey on experience of care as part of that program;
- ❑ Establishes a framework for a new Physician Compare Web site; and
- ❑ Requires a plan to integrate PQRS reporting with the reporting elements required by the EHR Incentive Program (also known as Meaningful Use).

The final physician fee schedule rule, published in the Nov. 29 *Federal Register*, is available at www.gpo.gov. 



Lab Index Still Rising, Up 5% in November

The G-2 Reports' Laboratory Stock Index gained some more ground in November, rising 5 percent in the four weeks ended Nov. 26, 2010. For the year, the index is up an unweighted average of 2 percent. In comparison, the Nasdaq composite is up about 12 percent, and the S&P 500 is up about 7 percent.

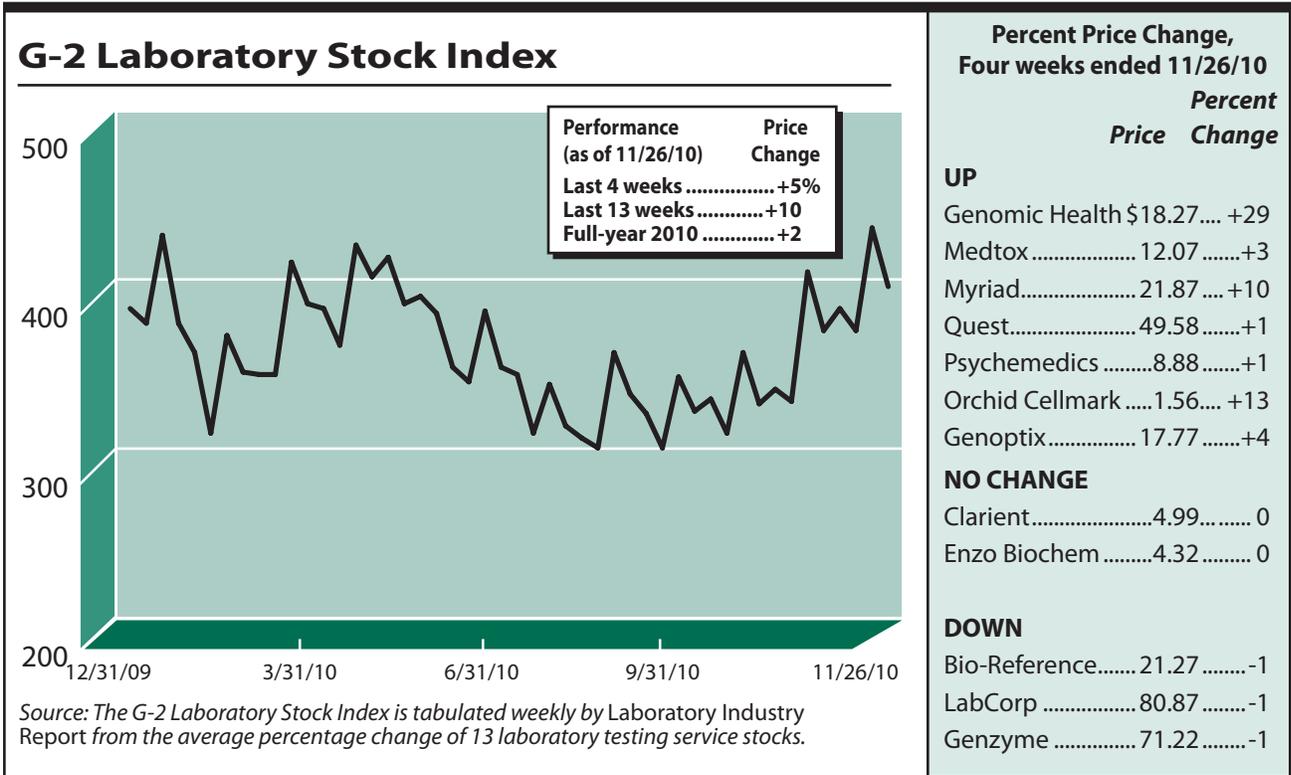
Eight of the 13 publicly traded lab companies tracked by the index posted gains during the period, while three experienced declines in their share prices. Two companies stayed virtually the same.

Shares of **Genomic Health** (Redwood City, Calif.) soared 29 percent to \$18.27 on reports that the company had its second profitable quarter with net income of \$3.7 million (*see related article on pg. 3*).

Neogenomics (Fort Myers, Fla.) shares rose 13 percent to \$1.35 after the company reported revenue growth of 19 percent in the third quarter. Revenue for the three months ended Sept. 30, 2010, was \$8.7 million, compared with \$7.3 million for the same quarter in 2009. Test volume increased approximately 29 percent compared to the same period the previous year.

Shares of **Myriad Genetics** (Salt Lake City) rose 10 percent to \$21.87. The company on Nov. 2 reported that revenues for the three months ended Sept. 20, 2010 (first quarter of fiscal 2011) increased 7.9 percent to \$91.9 million when compared to the same period last year. Oncology revenues increased 4.3 percent to \$66 million, while women's health revenues rose 18.4 percent to \$25.8 million. Revenue from the BRACAnalysis test, the company's flagship diagnostic product, grew 7.2 percent to \$80.7 million. 🏢

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Sonic to Acquire CBLPath for \$123.5 Million

Australian-based Sonic Healthcare said Nov. 8 that it has reached an agreement to buy CBLPath (Rye Brook, N.Y.), one of the fastest-growing anatomic pathology reference laboratories in the country, for \$123.5 million. Sonic said the acquisition would immediately improve earnings per share and be funded from more than \$400 million in existing debt facilities.

CBLPath has expanded in recent years across the United States. Sonic says it has clinical laboratory operations in eight of the 10 states where CBL made most of its revenue. The company has annual revenue of more than \$80 million.

Both companies say significant revenue synergies are expected to be realized from cross-sell opportunities in 2012 and beyond. In addition, they say there are a number of cost synergies that Sonic can offer CBLPath, particularly in the areas of logistics, purchasing, and billing.

The deal is expected to close in December 2010 and is conditional upon CBLPath shareholder approval and antitrust clearance. More than 40 percent of CBLPath is owned by Galen Partners, a private equity firm, with the balance owned by management, staff, and other private investors. 🏠

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 Myriad Genetics 801-584-3600
 Neogenomics 239-768-0600
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