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G2 INTELLIGENCE

LABORATORY INDUSTRY REPORT®

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Issue 01-12/January 2012

HIGHLIGHTS

Congress Defers Medicare Physician Pay Cut; Deal Also Extends Pathology Grandfather Protection

In last-minute maneuverings, congressional lawmakers Dec. 23 approved an amended version of payroll tax legislation that also would defer for two months a Medicare pay cut for physicians that had been due to be implemented Jan. 1. The deal narrowly averted a 27.5 percent reduction in Medicare reimbursement for physicians, including pathologists. President Obama signed the measure into law shortly after its approval.

The agreement also extends for two months the pathology grandfather protection that allows independent labs to bill Medicare directly for the technical component of pathology services to hospital inpatients and outpatients. That protection was set to expire Dec. 31.

House Speaker John Boehner (R-Ohio) and Senate Majority Leader Harry Reid (D-Nev.) negotiated an end to the impasse on Dec. 22. Under the agreement, the House approved the Senate's version of

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FTC Approves LabCorp's Acquisition of Orchid Cellmark but With Conditions

Following numerous extensions of its tender offer, LabCorp (Burlington, N.C.) in early December finally received approval from the Federal Trade Commission (FTC) to acquire Orchid Cellmark, but only under certain conditions.

The FTC will require LabCorp and Orchid Cellmark to divest a portion of Orchid's paternity testing business to resolve the FTC's complaint alleging that LabCorp's $85.4 million acquisition of Orchid would have an anti-competitive impact in the market for paternity testing services used by government agencies. The paternity testing business will be sold to DNA Diagnostics Center (DDC).

Government agencies contract with lab testing companies to provide DNA testing services and use those tests to resolve paternity issues. LabCorp and Orchid are the two most significant providers of these paternity testing services and have an overwhelming majority of the $27 million market. They consistently have been head-to-head competitors for these contracts, the FTC complaint alleged.

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■ **Congress Defers Medicare Physician Pay Cut**, *from page 1*
payroll tax legislation that freezes physicians' pay for two months and extends Medicare pay provisions for numerous other providers. The House version of the bill would have canceled the cut for two years and given physicians a 1 percent pay hike in 2012 and 2013.

Though physicians are pleased they received a temporary reprieve, the American Medical Association (AMA) chastised Congress for failing to pass a long-term fix to the sustainable growth rate (SGR). The AMA wants lawmakers to replace the SGR with stable fee increases over the next five years in the transition to a system based on payment and delivery alternatives to traditional fee-for-service. A repeal of the SGR is estimated to cost $300 billion over 10 years.

Because of the high cost of repealing the SGR altogether, it's likely that lawmakers will end up extending the freeze on physicians' pay and the pathology grandfather protection through the end of 2012, predicts Alan Mertz, president of the American Clinical Laboratory Association.

Lab Copay Averted for Now

Though lawmakers were looking at a lab copay or lab coinsurance as a possible option to raise money to help offset the budget deficit, the lab and pathology communities successfully lobbied senators and congressmen to stave off any further cuts to clinical laboratories. The Congressional Budget Office had raised the possibility of adding a new 20 percent coinsurance from Medicare beneficiaries. A variation of this option was a flat copayment of $1 to $2 per lab test.

Mertz notes that labs have already been squeezed as much as they can. Since 1995, labs have seen a 7.7 percent cumulative increase in the clinical laboratory fee schedule while physicians have had a 26 percent increase. "At some point it doesn't make sense to keep cutting labs," Mertz tells G2 Intelligence. "It's like robbing Peter to pay Paul and Peter is broke."

Mertz believes the lab copay may be off the table, at least for now, and says he is pleased that labs did not see major hits to payment in 2011. "We were facing so many potential threats this past year, but we managed to escape the year without any major cuts. The fight will start over again in 2012."

Lâle White, executive chairman and CEO of XIFIN, a billing and revenue management company based in San Diego, criticized lawmakers for "punting the ball into next year" and creating billing nightmares for providers.

"It is clear that while our politicians understand bad public policy and [pretend] to care about health care costs, they have absolutely no appreciation for the enormous outlays associated with constantly changing rules and regulations that require health care providers and payers to jump through hoops programming systems and setting up procedures to deal with their short-term follies," White wrote on XIFIN's blog. "Unable to differentiate between temporary busy work and enduring productivity, lawmakers are undoubtedly patting themselves on the back for creating jobs." G2

Medicare Lab Fees to Rise 0.65 Percent in 2012

The payment rates for clinical laboratory tests on the Medicare Part B fee schedule will increase 0.65 percent as of Jan. 1, 2012, welcome news after a cut of 1.75 percent in 2011 and a 1.9 percent cut in 2010. The last increase was in 2009 (4.5 percent) following an update freeze from 2004 to 2008.

The fee increase for calendar year 2012 is based on the revised update formula enacted in the health care reform law. It is calculated using the consumer price index minus a productivity adjustment and an additional 1.75 percent reduction.

The increase also boosts the national minimum payment amount for a cervical or vaginal Pap smear in 2012—$14.97, up from $14.87 this year. The affected codes are 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, and P3000.

CMS had previously indicated that it wanted more input on these [molecular pathology] codes before recognizing any or all of them. Now, it has given them a status "B" indicator and is asking clinical labs to report this on claims along with "stacked" molecular diagnostic and genetic testing codes.

For payments made on a reasonable-charge basis for laboratory services the annual inflation-indexed update is 3.6 percent. This includes codes for blood products, transfusion medicine, and reproductive medicine.

There is no change in the $3 specimen collection fee nor in the amount of the travel allowance. It remains at $1.005 per mile (P9603) and $10.50 on a flat-rate basis (P9604). These codes are billable only for traveling to perform a specimen collection for either a nursing home or homebound patient. If there is a revision to the standard mileage rate for 2012, CMS said, the agency will issue a separate instruction on the lab travel fees.

The surprise in the Dec. 9 transmittal to contractors on the 2012 lab fee schedule is how the Centers for Medicare and Medicaid Services (CMS) intends to address payment and claims processing issues connected with the Jan. 1, 2012, rollout of 101 new CPT molecular pathology test codes by the American Medical Association.

Molecular Pathology Procedure Test Codes

CMS had previously indicated that it wanted more input on these new codes before recognizing any or all of them. Now, it has given them a status "B" indicator and is asking clinical labs to report this on claims along with "stacked" molecular diagnostic and genetic testing codes.

"For payment purposes under the Medicare lab fee schedule," CMS said in the Dec. 9 transmittal, "these test codes will be assigned a B indicator—Payment for covered services are always bundled into payment for other services not specified." There will be no relative value units or payment amounts for these codes and no separate payment is ever made. "When these services are covered, payment for them is subsumed by the payment for the services to which they are incident (an example is a telephone call from a hospital nurse regarding care of a patient)."

Each of these new test codes represents a test that is currently being utilized and which may be billed to Medicare, CMS noted. "When billed to Medicare, we

understand that existing CPT codes are 'stacked' to represent a given test. For example, Laboratory A has a genetic test that is generally billed in the following manner—83891 (one time) + 83898 (multiple times) + 83904 (multiple times) + 83909 (multiple times) + 83912 (one time)—in order to represent the performance of the entire test. If the new CPT test coding structure were active, Laboratory A would bill Medicare the new, single CPT test code that corresponds to the test represented by the 'stacked' codes in the example above rather than billing each component of the test separately."

As of Jan. 1, 2012, CMS is asking labs to submit Medicare claims for these molecular pathology procedures that "reflect both the existing CPT stacked test codes that are required for payment and the new, single CPT test code that would be used for payment purposes if the new CPT test codes were active."

Referring to the example above, CMS said, "Laboratory A would report the existing stacked set of codes that are required to receive payment [*i.e.*, 83891 (one time) + 83898 (multiple times) + 83904 (multiple times) + 83909 (multiple times) + 83912 (one time)] along with the new, single CPT test code that corresponds to the test represented by the stacked test codes. While the allowed charge amount will be $0.00 for the new molecular pathology procedure test codes that carry the 'B' indicator, Medicare requests that claims also reflect a charge for the non-payable service." G2

PAML Names Velázquez New CEO

Providence Health & Services and Catholic Health Initiatives, co-owners of PAML (Pathology Associates Medical Laboratories) have named Francisco (Frank) Velázquez, M.D., as the new chief executive officer for PAML, the largest medical laboratory in Spokane, Wash. Velázquez will begin on Jan. 23, 2012, replacing longtime PAML executive Tom Tiffany, Ph.D.

Velázquez brings an outstanding background to his new role as CEO of PAML. He is an experienced physician executive with a strong clinical background and business leadership skills. He holds a medical degree from the University of Central del Caribe School of Medicine in Bayamon, Puerto Rico; completed fellowships in both anatomic pathology and laboratory medicine; is board-certified in clinical pathology; and holds a master's degree in health care management and policy from Harvard University.

Velázquez comes from Quest Diagnostics where he served as managing director of Nichols Institute and managing director/vice president for Focus Diagnostics in San Juan Capistrano and Cypress, Calif. He had direct oversight of the reference laboratory testing business at both laboratories as well as the clinical trials at Focus Diagnostics. Prior experience includes executive, faculty and medical leadership roles at universities in Texas and Boston.

Tiffany will work alongside Velázquez during the first quarter of 2012 to ensure a smooth transition. G2

Routine Clinical Adoption of Pharmacogenomic Testing Poised for Gradual Expansion Outside of Oncology

Researchers are optimistic that pharmacogenomic (PGx) testing will make gradual inroads into clinical practice over the next five years, but they say the most notable progress will be in disciplines outside of oncology. Clinical utilization of PGx testing will be propelled by institutional efforts to make health care more cost-effective while improving patient outcomes through personalized medicine.

Oncology is ahead of other medical disciplines in routinely utilizing genetic testing to improve the efficacy of targeted therapeutics, but experts say the field of infectious disease has seen some dramatic changes too, with PGx testing for HIV and Hepatitis C patients becoming the new standard of care.

"The area with a lot of activity in applying pharmacogenomics is in infectious disease, specifically virology," says Howard McLeod, Pharm.D., director, Institute for Pharmacogenomics and Individualized Therapy at University of North Carolina Chapel Hill. "Since [researchers have] found that HIV drugs [are] toxic to a small fraction of the population and that a particular germ line marker can predict who is at risk . . . it is practically malpractice to not use that test."

The U.S. Food and Drug Administration (FDA) recommends and doctors now routinely do pretreatment screenings on HIV-infected patients for the HLA-B*5701 allele, a genetic variant that causes increased risk for hypersensitivity reactions to the anti-viral drug abacavir (Ziagen).

Testing has also permeated disease management for Hepatitis C. While a combination interferon-ribavirin therapy is considered standard of care in treating Hepatitis C, the variability in sustained virological response to the treatment has frustrated disease-management efforts. But the recent incorporation of IL28B genotyping into treatment decisionmaking promises to increase the number of patients for whom treatment is successful while minimizing the number of patients in whom it is deleterious.

Adoption Spreading to Cardiology, Rheumatology, and Neuropsychiatry

Clinical adoption of PGx testing is anticipated to be more gradual in other practice areas, particularly in cardiovascular medicine, where testing for variants in drug metabolism will have to catch up with the brisk dispensation of common prescriptions for statins, anti-aggregants, and blood thinners.

"There are a number of institutions beginning to work on implementation [of PGx programs] most commonly in cardiology and within cardiology using clopidogrel (Plavix) testing," says Julie Johnson, Pharm.D., professor of pharmacy and medicine at the University of Florida (Gainesville).

In 2010 the FDA added a black-box warning to clopidogrel's label to alert physicians about the increased risk for adverse outcomes in patients with mutations in the gene CYP2C19 that lead to poor drug metabolism. In November Transgenomic (Omaha, Neb.) launched the PGxPredict:CLOPIDOGREL Pan-

el, a comprehensive test that analyzes two genes, CYP2C19 and ABCB1, and can predict response to clopidogrel in about 50 percent of patients that are poor metabolizers. ABCB1 is covered by a pending patent owned by Transgenomic. The test lists for a price of $750.

"Eight to 10 percent of patients that should be tested are [tested] and that figure could be as low as 5 percent," says Craig Tuttle, CEO, Transgenomic, of utilization of genetic testing to inform clopidogrel dosing decisions. "The challenge is to education physicians."

Genetic testing for the anti-coagulant warfarin is typically cited as an example of the failure of PGx testing to gain routine clinical acceptance, despite evidence showing that it can cut health care spending by reducing costs associated with bleeding events.

Non-Oncology PGx Biomarkers with FDA 'Boxed Warnings' or 'Warnings and Precautions'

BIOMARKER	CLINICAL AREA	DRUG
CCR5	Infectious disease - antivirals	Maraviroc
CYP2C19	Cardiology	Clopidogrel
CYP2D6	Psychiatry, analgesics, neurology, urology	Atomoxetine and Iloperidone, Codeine, Dextromethorphan and Quinidine, Tolterodine
HLA-B*5701	Infectious disease-antivirals	Abacavir
HLA-B*1502	Neurology	Carbamazepine
PML/RARα	Dermatology	Tretinoin110

Source: FDA

"If we look at warfarin there are several barriers. . . . Usually warfarin needs to be started quickly. The delay by ordering the test is undesirable, " explains Johnson. "In academic medical centers warfarin is monitored in specialty anti-coagulation clinics and a lot of clinicians there are comfortable in how they monitor patients. The problem is for patients outside of academic medical centers, where 80 percent to 85 percent of warfarin patients are treated. They stand to benefit the most because they may not be followed as closely. But usually [adoption of new tests] starts in academic settings and moves to the outside."

While cardiovascular medicine's biggest challenge might be altering physician practice, neuropsychiatrists are eagerly anticipating the arrival of PGx tests on the clinical scene.

A study published online Dec. 4 in *Nature Genetics* shows that rare, recurrent copy number variations (CNVs) affecting metabotropic glutamate receptor (GRM) genes were overrepresented in attention deficit/hyperactivity disorder (ADHD) cohorts, appearing in about 10 percent of cases. The current research suggests that selective GRM agonists could be tested as a potential therapy for ADHD in patients harboring particular CNVs. The results could also help in the creation of a diagnostic to assist in identifying which patients would most benefit from the treatment, explains Hakon Hakonarson, M.D., Ph.D., director of the Center for Applied Genomics at the Children's Hospital of Philadelphia.

A separate group of researchers made the discovery that dopamine transporter (DAT) and dopamine receptor D4 polymorphisms may be associated with individual variability in methylphenidate dose-response in the therapy used to treat ADHD. Lead author Tanya Froehlich, M.D., says her group's findings, published in October in *Journal of the American Academy*

of Child and Adolescent Psychiatry, are "not overwhelming enough that we could [right now] make a clinical test to predict [treatment response] with great certainty," but she says they plan to build a multifactoral model and that further testing using a large, multisite sample is needed.

"It is partly economic," says McLeod of the PGx activity in rheumatology. "The new drugs are very expensive and only 20 percent of patients get benefit. Insurance companies see it a lousy return on investment. Insurance companies are involved in funding studies looking for a marker. A 50-50 scenario or better would be a more sensible way forward."

Crescendo Bioscience (South San Francisco, Calif.) has released several studies this year supporting its Vectra DA test, a multi-biomarker blood test to assess RA disease activity and treatment response. In the May supplement of *Annals of Rheumatic Disease*, a study showed that following initiation of methotrexate or anti-tumor necrosis factor therapy, RA patients showed changes in their Vectra DA score in as little as two weeks after starting treatment, and individuals' scores were linked to their subsequent clinical response.

"The difference between rheumatology and oncology is that in rheumatology [assessment] is based on clinical impressions—feeling and squeezing joints. . . . Rheumatologist believe there is a better, more quantifiable way to measure disease activity," says David Chernoff, M.D., Crescendo's chief medical officer.

In the near future, Chernoff says, he envisions testing to become routine on all newly diagnosed RA patients and in the next three to five years RA may be able to be diagnosed presymptomatically.

Slow, Steady Progress Expected

With increased emphasis on cost-effectiveness and bundled reimbursement, experts say that institutional implementation of PGx programs will likely drive clinical utilization of testing. Greater understanding of the clinical understanding of genetic variations, increased utilization of electronic medical records (EMRs), and improvements in decision support systems will further enhance the value PGx testing.

"Because it is likely that in the not-too-distant future patients will have their full DNA sequence linked to their medical record, it is reasonable to anticipate that all medical specialties will soon be in a position to use this information, especially for genetic variation influencing drug metabolism," says Russell Wilke, M.D., associate professor of medicine in clinical pharmacology at Vanderbilt University Medical Center. "One big obstacle has been limited availability of adequate decision support."

"In the current setting ordering a test adds a delay. Implementation programs are trying to create a model system where the genetic information is available and the lag is avoided," says Johnson. "With preemptive genotyping it changes the question to, 'Can I justify ignoring this information?' The physician community is not opposed to [testing], they just want somebody to make it easier for them."

■ **FTC Approves LabCorp's Acquisition of Orchid Cellmark**, *from page 1*

Under the proposed settlement, Orchid will provide certain contract and service information needed by DDC to compete in the market, and LabCorp will provide assistance in assigning all current government paternity testing contracts to DDC. The settlement also requires LabCorp to service existing government contracts for paternity testing until the paternity testing business is successfully transferred and Orchid's government contracts are assigned to DDC. In addition, DDC will have access to the staff and facilities at Orchid's Dayton, Ohio, facility and LabCorp will not be allowed to keep any of Orchid's confidential business information for use in competitive endeavors.

The pending issue with the FTC dates back to May 2011. LabCorp in April announced that it would purchase Orchid for $2.80 per share, for a total of $85.4 million. Orchid provides DNA testing services for forensic, family relationships, and security applications, with its business split between the United Kingdom (63 percent) and the United States (37 percent).

The deal is expected to give LabCorp a leading position in identity testing in the United States and also establish its presence in this field in the United Kingdom. LabCorp in recent years has made a concerted effort to diversify its test revenues. The company has set a target of garnering 45 percent of its revenues from the specialty business in the next three to five years.

Orchid's revenue growth has fluctuated over the last several years but grew 7.9 percent in 2010. With 2010 revenues of $63.7 million, the purchase price is about 1.3x revenues.

Pathology Inc. Merges With West Coast Clinical Labs

Pathology Holdings Inc., parent company of its flagship laboratory Pathology Inc., is merging with West Coast Clinical Laboratories (WCCL), a leading California provider of full-service laboratory testing focusing on women's health and reproductive donor testing, the company announced in December.

Pathology Inc., a wholly owned subsidiary of Pathology Holdings Inc., is a full-service laboratory offering both clinical and anatomic pathology (AP) testing, with nationally recognized pathology expertise in gynecology, genitourinary pathology, gastrointestinal pathology, dermatopathology, hematopathology, and cytopathology. Pathology Inc. performs an array of tests focusing on women's health including comprehensive liquid-based Pap testing, associated molecular diagnostic assays, and computer-assisted interpretation techniques. The women's health market represents one of the largest anatomic pathology segments, with the U.S. cervical cancer screening market alone estimated at over $1.7 billion.

WCCL offers a comprehensive menu of clinical and AP testing services for OB/gyns, family practitioners, and primary care physicians, as well as specialists including gastroenterologists, urologists, and dermatologists. WCCL has been serving the Los Angeles community for over 20 years. Specializing in fertility testing, WCCL provides Food and Drug Administration donor testing for in

vitro fertilization clinics and OB/gyns and offers STAT testing services, facilitated through 14 patient service centers throughout Los Angeles County.

"We are thrilled to have West Coast Clinical Laboratories merging with our organization," says Pathology Inc. President and CEO Vicki DiFrancesco. "This is an exciting opportunity for our customers to participate in a novel partnership combining expertise from two laboratories that have been successfully servicing the women's health community in California for decades. The resulting synergies will provide expanded specialized services for our clients."

Affymetrix to Acquire eBioscience for $330 Million

Affymetrix Inc. (Santa Clara, Calif.) has signed a definitive agreement to acquire eBioscience Inc., a privately held San Diego-based company with an industry-leading position in flow cytometry and immunoassay reagents for immunology and oncology research and diagnostics.

Under the terms of the agreement, Affymetrix will acquire eBioscience for $330 million in cash subject to certain customary adjustments. The transaction is subject to customary closing conditions and is expected to close in January 2012.

Affymetrix expects the acquisition of eBioscience to:

- Create significant new commercial opportunities in the key post-genomic applications of immunology, oncology, cell biology, stem cell biology, and diagnostics;
- Diversify the company's revenues to complement its genomics franchise;
- Augment the company's growing business in molecular diagnostics;
- Expand the company's product portfolio to include multicolor flow cytometry reagents and a broad spectrum of reagents for the analysis of cytokines, growth factors, and other soluble proteins;
- Enhance the operational and new product opportunities for Panomics RNA and protein analysis products; and
- Leverage the commercial capabilities of both companies to generate new opportunities for growth.

"The acquisition of eBioscience is transformational for our business, and we are enthusiastic about the opportunities it creates," said Dr. Frank Witney, president and chief executive officer of Affymetrix. "With eBioscience, Affymetrix will significantly expand its addressable markets by adding an industry-leading portfolio of cell-based and immunoassays. These new products are a critical part of our customers' workflow in our key target markets of translational medicine, oncology, and immunology. We believe that these markets represent a nearly $3 billion annual opportunity, which will put Affymetrix on a solid path to sustained growth and profitability."

"The combination of Affymetrix and eBioscience has significant benefits," adds Tim Barabe, executive vice president and chief financial officer of Affymetrix.

"With 2011 sales expected to exceed $70 million, gross margins in excess of 70 percent and EBITDA greater than 30 percent, eBioscience makes Affymetrix a much stronger company, both operationally and financially. The purchase price represents approximately 4.5 times 2011 revenue and 14 times 2011 EBITDA."

The transaction will be funded using a combination of roughly 50 percent cash-on-hand and 50 percent committed debt to avoid dilution and maximize value to shareholders.

Affymetrix has obtained a fully underwritten senior secured financing commitment in the amount of $190 million (including a $20 million revolving credit facility) led by administrative agent GE Capital, Healthcare Financial Services and including, as lenders, Silicon Valley Bank, CIT Healthcare LLC, and CIT Bank. Affymetrix will be required to retain cash-on-hand of approximately $95 million to cover its outstanding convertible debt that can be put to the company in January of 2013. GE Capital Markets, Silicon Valley Bank, and CIT Capital Securities LLC will serve as joint lead arrangers and bookrunners for the transaction.

Affymetrix expects to maintain eBioscience's management team and operations in San Diego.

Payment to Begin Under Medicare Lab Test Demo

As of Jan. 1, 2012, Medicare will begin paying a set national rate for certain complex clinical laboratory tests selected for a new demonstration project on separate payment for these tests.

Participation is voluntary and open to clinical laboratories, both hospital-based and independent.

The project, authorized under Section 3113 of the health care reform law, will run for two years or until a total payment limit of $100 million is reached. Dates of service must be between Jan. 1, 2012, and Dec. 31, 2013.

The demo applies to a diagnostic lab test ordered by the beneficiary's physician less than 14 days following the date of the patient's discharge from the hospital.

Under standard Medicare "date of service" rules, such testing is considered bundled into payment to the hospital, and the lab must seek reimbursement from the hospital, not directly from Part B. Under the demo, the payment (inpatient and outpatient) to the hospital or critical-access hospital is unbundled.

Participants in the demo will be paid directly under a separate fee schedule at national payment amounts that the Centers for Medicare and Medicaid Services (CMS) has established for covered tests. CMS has identified 36 CPT codes that meet the statutory criteria, including molecular diagnostics and genetic testing codes: 23 in the chemistry series, 10 in immunology, one in microbiology, and two in anatomic pathology.

For tests on the fee schedule list, labs directly billing Medicare must submit claims with a project identifier 56 or an approved temporary G code, CMS said in a previous program transmittal.

Lab Index Gains 9% in December, Up 1% for Year

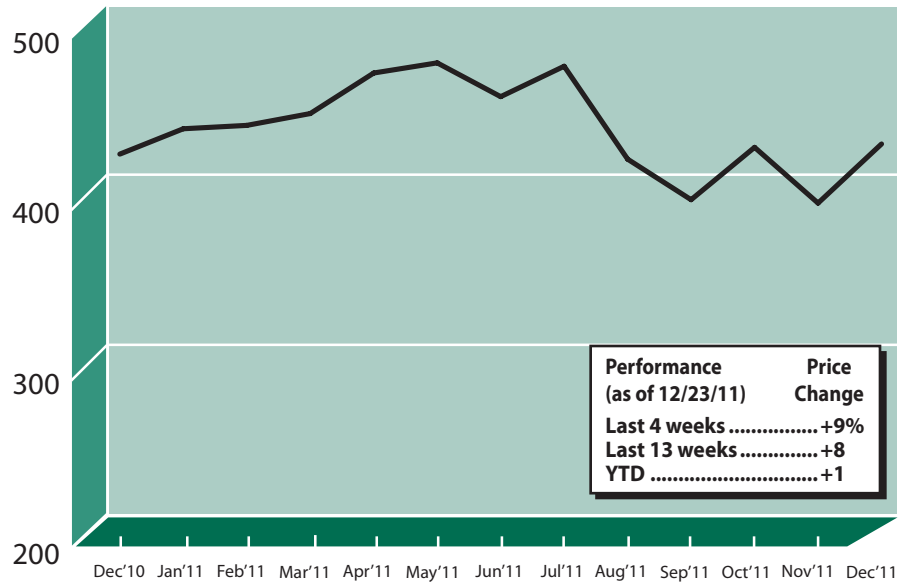
The G2 Intelligence Laboratory Stock index continued its roller coaster ride, rising 9 percent in the four weeks ended Dec. 23, 2011. Of the nine stocks in the index, eight gained in value while one stayed virtually the same. As of Dec. 23, the index was up 1 percent for the year. Orchid Cellmark was removed from the index in December due to its acquisition by LabCorp.

Shares of **Bio-Reference Laboratories** (Elmwood Park, N.J.) gained back much of November's losses rising 34 percent to $16.08. On Dec. 8 the company reported its best-ever quarterly and annual fiscal year results for revenues, earnings, and cash. For the fourth quarter, Bio-Reference reported revenues of $151.3 million, an increase of 20 percent over the same quarter in 2010. Net income after tax for the quarter totaled $10.5 million, or 37 cents per share, an increase of 22 percent from the previous year. Revenue per patient was $82.35, and the number of patients increased 19 percent to 1,822. CEO and Chairman Marc Grodman upped the company's guidance for the coming year, expecting net revenues to increase by more than 15 percent and net income to increase about 20 percent.

Enzo Biochem (New York) shares rose 10 percent to $2.18. The company Dec. 12 reported revenues for the first quarter of 2012 of $25.8 million, a slight gain over last year's comparable quarter. Net loss was $4.5 million or 12 cents per diluted share, an increase over 2010. Largely due to organic growth and greater service volume, Enzo Clinical Labs' revenues increased 15 percent, or $1.8 million, to $14.2 million.

Share of **Myriad Genetics** (Salt Lake City) increased 4 percent to $20.31. In a recent presentation, Myriad President Mark Capone noted that the company had $402 million in revenues in 2011, $158 million in operating profit, and $189 million in cash that was deployed through a $200 million share buyback.

G2 Laboratory Stock Index



Source: The G2 Laboratory Stock Index is tabulated weekly by Laboratory Industry Report *from the average percentage change of 9 laboratory testing service stocks.*

Percent Price Change, Five weeks ended 12/23/2011

	Price	Percent Change
UP		
Bio-Reference	$16.08	34%
Enzo Biochem	2.18	10
LabCorp	87.32	8
Medtox	14.73	15
Myriad Genetics	20.31	4
Neogenomics	1.40	1
Quest Diagnostics	58.97	8
Psychemedics	0.00	2
NO CHANGE		
Genomic Health	25.32	0

INDUSTRY BUZZ

Palmetto Addressing MolDx Concerns

Palmetto GBA is working to address some of the concerns raised by the lab industry over its new coverage and payment program for molecular diagnostics tests, but the Medicare contractor has no plans to delay the March 1, 2012, implementation date for the program, dubbed MolDx.

Mike Barlow, vice president and program manager for Palmetto's J1 jurisdiction, tells G2 Intelligence that he has met with several "major" labs to discuss their concerns and is in the process of modifying the program to address some of the issues raised. For example, Palmetto will eliminate or make optional some of the information requested from labs as part of the application process to receive a Z-Code™ from McKesson.

One of the concerns raised by the American Clinical Laboratory Association (ACLA) was that the application required labs "to submit more than 32 separate pieces of information, far more than would be necessary for the mere assignment of a code." Barlow counters that the instructions accompanying the Z-Code application specifically tells labs not to provide any proprietary information. For example, in the field for "Test Information—Contributing Components," the instructions state "Do not include intellectual property."

"We are only asking for things that are already available publicly," says Barlow. "It's information that could be found in the scientific literature or on [labs'] Web sites or in their marketing materials."

References

Affymetrix 408-731-5000

American Clinical Laboratory Association 202-637-9466

Bio-Reference Laboratories 201-791-3600

Crescendo Bioscience 650-351-1354

eBioscience 888-999-1371

Enzo Biochem 800-522-5052

LabCorp 336-436-5274

Orchid Cellmark 800-362-8378

Myriad Genetics 801-584-3600

Palmetto GBA 866-931-3903

Pathology Associates Medical Laboratories 800-541-7891

Pathology Inc. 877-922-7284

West Coast Clinical Labs 800-908-0083

XIFIN 858-793-5700

 Laboratory Industry Report (ISSN 1060-5118) is published by G2 Intelligence, 1Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467 USA. Tel: 800-401-5937. Fax: 603-924-4034. Web site: www.G2Intelligence.com.

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