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LABORATORY

INDUSTRY REPORT®



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2011 a Big Year for Lab M&A; What Will 2012 Bring?

Mergers and acquisitions in the clinical laboratory and anatomic pathology markets topped \$3 billion in 2011 with almost 30 deals ranging from small fold-in acquisitions to huge purchases such as Quest's acquisition of Athena for \$740 million and Miraca's acquisition of Caris Life Sciences for \$725 million.

Industry experts predict another active year in M&A, though the total dollar figure might not exceed that of 2011. However, some business experts have speculated that Quest Diagnostics (Madison, N.J.) is ripe for a takeover. Acquisition of Quest by a large, global company or a private equity firm would most certainly shake up the lab industry.

For more on mergers and acquisitions in 2011 and the outlook for 2012, see *Inside the Lab Industry* beginning on page 5.

Quest Gets Greater Access to New Mexico Market With Purchase of S.E.D. Medical Labs

Quest Diagnostics (Madison, N.J.) has increased its penetration of the New Mexico laboratory market with the acquisition of S.E.D. Medical Laboratories from Lovelace Health System. S.E.D. is a full-service and drugs-of-abuse testing lab founded in 1972.

In addition to acquiring the laboratory outreach program, Quest will manage inpatient labs for the four Lovelace hospitals and serve Lovelace Health Plan members. S.E.D. Labs serves 1 million patients and processes 7.5 million tests annually.

Terms of the deal were not disclosed, but estimates are that the company sold for less than one times annual revenues of about \$75 million.

Amanda Murphy, an analyst with equity research firm William Blair (Chicago) says this transaction does not appear to be indicative of an increasing trend for hospital outreach management outsourcing or increased interest on the part of Quest to increase its presence in hospital lab management contracts. "Rather, this asset was viewed as a means to gain increased access to a specific geography (i.e., New Mexico)," she writes in a research note.

Continued on page 2



2012 Conferences

Pathology Institute 2012

Pathology Under Attack: Practice Models and Business Strategies for a New Era

Feb. 9-10, 2012
Westin Beach Resort & Spa
Fort Lauderdale, Fla.
www.G2Path.com

MDx Next: Spring 2012

Gaining the MDx Edge: Putting Molecular Diagnostics to Work in the Clinical Lab

April 17-19, 2012
Fairmont Copley Plaza
Boston
www.mdconference.com

www.G2Intelligence.com

■ QUEST GETS GREATER ACCESS TO NEW MEXICO MARKET, *from page 1*

The Albuquerque market traditionally has been dominated by S.E.D. Labs and Tricore Reference Labs, which was formed by the University of New Mexico, Presbyterian Hospital, and St. Vincent's Hospital in 1998. Tricore employs more than 1,100 people in New Mexico and El Paso, Texas, and operates more than 50 satellite centers. 

Quest Diagnostics Sued for Gender Bias

Quest Diagnostics (Madison, N.J.) has been hit with a \$100 million federal lawsuit filed by female representatives accusing the company of gender discrimination.

The suit was brought in U.S. District Court in Newark by sales managers Erin Beery and Heather Traeger, two employees of the company's AmeriPath division. Beery is currently executive territory manager for AmeriPath in Indianapolis. Traeger is senior executive territory manager for AmeriPath in Bradenton, Fla. They are seeking to have the court extend the lawsuit to other female sales representatives who have been employed by Quest since Feb. 17, 2010.

Beery and Traeger allege a wide range of discriminatory practices by Quest. The complaint details various of discriminatory practices in the selection, promotion, and advancement of sales reps at Quest and AmeriPath, including discrimination on the basis of pregnancy and caretaking responsibilities in violation of Title VII of the Civil Rights Act of 1964 and other federal statutes.

According to Beery and Traeger, high-ranking company officials within Quest's predominantly male management team foster an environment detrimental to the success and advancement of female employees. They describe "old boys' club" attitudes that pervade the enterprise, including forcing women to work under less favorable circumstances than their male counterparts and denying them the educational and job advancement opportunities afforded men in similar positions.

"There is no question that male employees and, in some cases, women without primary childcare responsibilities, have advanced and continue to advance more rapidly to better and higher-paying jobs at Quest," said Sharon Eubanks, a member of the plaintiffs' legal team. "The managers who are maintaining and promoting the current male-dominated management structure have a disproportionate impact on the promotion and compensation decisions that affect female sales reps."

Beery and Traeger are seeking declaratory and injunctive relief; backpay; front pay; compensatory, nominal, and punitive damages; and attorneys' fees and legal expenses for themselves and the class.

Quest denies the allegations and intends to vigorously fight the lawsuit, according to a company spokesperson. "We are committed to equal opportunity for all employees and we take seriously our policies requiring equal treatment regardless of gender," the company says in a statement. "We are proud to be routinely recognized as a top employer in communities around the United States." 

Pathology Test Charges Rise 18% From Previous Year; Lab Tests See Much Smaller Increase

The average charge allowed for the top 11 pathology tests paid under Medicare Part B in 2010 increased almost 18 percent, from \$54.80 to \$64.43, when compared with 2009. In comparison, the average charge for the top 89 clinical laboratory tests, excluding pathology, increased just 2 percent, from \$12.11 in 2009 to \$12.37 in 2010.

According to an analysis of the top 100 clinical laboratory and pathology procedures paid under Medicare Part B during 2010, the average charge allowed for the top 89 laboratory and 11 pathology tests was \$17.59, compared to \$17.25 in 2009. The data come from the annual Part B Extract and Summary System (BESS) files for current procedural terminology (CPT) codes in the 8000 series. Lab and pathology services are represented in the CPT code range 80047-89399.

For calendar year 2010, the top 100 laboratory and pathology services encompassed 334.9 million Medicare-allowed services. For these services, Medicare-allowed charges to both providers and suppliers totaled \$5.89 billion. This represents a \$210 million increase in allowed charges in 2010 and a 34 cent rise in the average allowed charge, when compared to the previous year.

Of the top 100 procedures examined in the CPT 8000 series, 89 were laboratory codes and the remaining 11 were pathology codes. Laboratory codes are generally paid via the Medicare clinical laboratory fee schedule, while pathology codes are under the Medicare physician fee schedule.

The 89 laboratory codes included among the top 100 procedures accounted for a significant majority of Medicare-allowed services (301.35 million or about 90 percent). However, these tests constituted only about 63 percent (\$3.73 billion) of the total allowed charges, making for an average allowed charge per procedure of \$12.37. This compares to \$12.11 in 2009 and \$11.36 in 2008.

Key Findings

Surgical pathology, Level IV (CPT 88305) continues to rank as the highest-volume pathology procedure paid under Medicare Part B. CPT 88305 remains the first and only CPT code to top the \$1 billion mark in allowed charges for a single year. With over 19 million allowed services and an average allowed charge of \$67.21, CPT code 88305 totaled almost \$1.28 billion in allowed charges. This was despite the fact that the average allowed charge actually dropped slightly from the previous year's charge of \$67.46.

Of the top 100 procedures, 73 had allowed services of 1 million or more, up from 64 procedures the previous year. Of those, eight were pathology procedures:

- ❑ Level IV—Surgical pathology, gross and microscopic examination (CPT 88305)
- ❑ Immunohistochemistry (including tissue immunoperoxidase), each antibody (CPT 88342)
- ❑ Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each marker (CPT 88185)

- Drug screen, single drug class method (eg, immunoassay, enzyme assay), each drug class (CPT 80101)
- Special stains; Group II, all other, except immunocytochemistry & immunoperoxidase stains (CPT 88313)
- Special stains; Group 1 for microorganisms, including interpretation of report, each (CPT 88312)
- Level III—Surgical pathology, gross and microscopic examination (CPT 88304)
- Cytopathology, selective cellular enhancement technique with interpretation, except cervical or vaginal (CPT 88112)

Top 100 Medicare Part B Outpatient Laboratory and Pathology Procedures for 2010			
Description	Allowed Services	Allowed Charges	Average Allowed Charge
Totals for Top 89 Laboratory and 11 Pathology Tests	334,939,148	\$5,890,748,248	\$17.59
Totals for Top 89 Laboratory Tests	301,346,043	\$3,726,487,912	\$12.37
Totals for Top 11 Pathology Tests	33,593,105	\$2,164,260,336	\$64.43
% of Pathology Services/Charges included in Test Totals	10.03%	36.74%	N/A
<small>Source: Centers for Medicare and Medicaid Services, 2010 Part B National Summary Data file for the American Medical Association CPT codes 80000-89399 along with selected HCPCS codes.</small>			

The highest average allowed charge for a pathology procedure in 2010 was \$179.16 for Morphometric analysis, in situ hybridization (quant or semi-qual), each. Use of this FISH test, which is typically used to bill for Urovysion bladder cancer testing, increased 34 percent between 2009 and 2010. The second-highest average allowed charge was \$91.03 for Level V—Surgical pathology; gross and microscopic examination. This is a slight increase from 2009’s average charge of \$90.25 but still below the 2005 charge of \$95.72.

As in past, the highest-volume laboratory procedure in 2010 was blood count, CBC, auto and auto differential WBC count (CPT 85025) with 31.9 million allowed services. This code generated \$350.99 million in allowed charges, with an average allowed charge of \$11.01, a decline from 2009’s level of \$11.21.

The top five high-volume laboratory tests (those with more than 1 million allowed services) with the highest allowed charges are as follows:

- Parathormone (CPT 83970) \$59.08
- Natriuretic peptide (CPT 83880) \$48.00
- Vitamin D, 25 hydroxy, includes fraction(s), if performed \$41.88
- PSA, total (CPT 84153) \$26.30
- Extractable nuclear antigen, antibody to, any method, each antibody (CPT 86235) \$25.04 

Inside The Lab Industry



M&A in Lab Industry Tops \$3 Billion in 2011; Industry Consolidation Expected to Continue in 2012

The clinical laboratory industry continued its consolidation in 2011 with almost 30 mergers and acquisitions worth more than \$3 billion. While 2012 might not top that total dollar figure, experts predict that the number of deals could exceed that of 2011.

“There’s every chance that 2012 will be as active as 2011 was,” says Dennis Weissman, a senior adviser to England and Co., an investment bank based in Washington, D.C. Weissman, who founded Washington G-2 Reports, also serves as executive editor of G2 Intelligence. “I think there may be an equal or larger number of transactions, but that doesn’t mean the dollar amount would equal last year because there were some major purchases, and there aren’t that many big companies still available.”

Already in 2012, Quest Diagnostics has acquired S.E.D. Medical Labs in Albuquerque (*see article on p. 1*) for an estimated \$75 million. And more deals could be in the works. According to a PricewaterhouseCooper (PwC) report released in December, pent up demand for mergers and acquisitions is high, and large companies are looking to find growth opportunities.

“There’s every chance that 2012 will be as active as 2011 was.”

**–Dennis Weissman,
Senior Advisor,
England and Co.**

While volatile equity markets slowed mounting U.S. deal activity in the third and fourth quarters of 2011, the M&A activity was driven by well-prepared dealmakers focused on executing acquisitive growth strategies and availability of businesses with strong fundamentals—a key trend expected to continue into 2012, according to PwC’s Year-End US M&A Outlook.

“Despite lingering concerns for the global economy and financing obstacles, there continues to be a steady pulse of deal activity in the U.S. through the end of the second half of the year from both corporate and financial investors,” says Martyn Curragh, U.S. transaction service leader with PwC. “The hunt for growth remains a top priority for [corporations] of all sizes, while private equity also continues to put capital to work at higher levels than last year.”

Lab Activity Up in 2010, 2011

After slowing significantly in 2008 and 2009, M&A activity in the clinical laboratory, diagnostic, and anatomic pathology markets picked up significantly in 2010, with total acquisitions of about \$2.3 billion. Several factors contributed to this increase, including a thawing of capital markets, concern about the potential end of tax cuts implemented under President Bush, and a slowdown of organic growth due largely to the weak economy.

The reduction in the capital gains tax rate was supposed to expire at the end of 2010, which drove a number of deals, but Congress extended these cuts for another two years. They are now set to expire at the end of 2012, which means

there could be even more M&A activity in 2012 as companies try to complete deals before the tax rate increases in 2013.

Perhaps the two most significant trends to emerge in 2011 were the entrance of nontraditional players in the diagnostics space and more global companies buying U.S. labs and diagnostic companies. Early in 2011, Swiss pharmaceutical giant Novartis paid \$470 million to acquire pathology testing company Genoptix, marking the re-entry of pharma into specialty laboratory testing. Also in 2011, Swiss food giant Nestlé acquire Prometheus Laboratories, a company specializing in gastrointestinal and cancer diagnostics for an estimated \$567 million. Toward the end of the year, Miraca Holdings, Japan's largest clinical diagnostics and lab testing services provider, acquired Caris Life Sciences for \$725 million.

Is Quest Ripe for a Takeover?

While Quest Diagnostics (Madison, N.J.) traditionally has been the company on the acquisition side of deals, some have speculated that the company could actually be ripe for a takeover. In recent years, Quest has underperformed its biggest competitor, LabCorp.

Since Surya Mohapatra took the helm of Quest in 2004, the company's share price has grown much more slowly than that of LabCorp. Between the January 2004 and January 2012, Quest's stock price grew 70 percent while LabCorp's stock price grew 131 percent.

According to analysts at Deutsche Bank Securities, LabCorp's outperformance since 2004 has been underpinned by better earnings per share growth, better revenue growth, higher operating margins and free cash flow margins, and higher return on invested capital. Despite Quest's struggles, the company has strong fundamentals and cash flow of almost \$1 billion annually, which is attractive to a potential buyer.

In an online article on InvestorPlace.com, writer Tom Taulli says Quest is one of the top three takeover candidates for 2012, along with Salesforce.com and Range Resources. While Quest has had difficulties with its growth rate, in part because people are putting off medical care, the lab industry will remain a critical component of the U.S. health system as aging baby boomers use more medical services, he says.

"Interestingly enough, some signs show that Quest is already preparing for some type of buyout. It has announced cost-cutting efforts and has boosted its dividend. Also, the CEO has departed," writes Taulli. "All in all, Quest would be a smart acquisition for a private equity group. Consider that cash flows should remain fairly stable for the long-haul, which is likely to make it easy to finance a transaction."

With a market cap of more than \$9 billion, Quest would be expected to sell for at least \$11 billion to \$12 billion, which clearly limits the companies big enough to purchase the firm. A possible suitor could be GE Healthcare, which has deep pockets with revenues of about \$18 billion and has been looking to move more into the diagnostic space. Already a major player

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in molecular imaging and radiology, GE Healthcare has made clear that it would like to combine molecular diagnostic technologies with its molecular imaging technologies. In 2010, GE Healthcare paid \$587 million to acquire

Clariant Inc., an anatomic pathology company focused on cancer diagnostics.

At the J.P. Morgan Healthcare Conference, held in San Francisco in early January, GE Healthcare's presentation focused largely on the role of diagnostics as the future of personalized medicine, which led to some speculation that the company was actively seeking additional acquisitions in diagnostics. During her presentation, Pascale Witz, president and CEO, GE Healthcare, Medical Diagnostics, noted that "personalized medicine is at the core of our efforts in medical diagnostics. We are working to combine in vivo and in vitro testing for integrated solutions from risk stratification and early detection through prediction and monitoring."

Suitors could also include other large, global firms with an interest in health care or large, well-funded private equity groups.

The sale of Quest to a private-equity firm could have a profound impact on the dynamics of the lab market, Weissman tells *Laboratory Industry Report*. "It could be a lot more agile than a publicly traded company, which could be a pretty big jolt for the industry." 

2011 Lab and Pathology M&A Deals

Date	Buyer	Target	Purchase Price (\$MM)
Jan. 11	Aurora	Austin Pathology Associates	30
Jan. 11	Aurora	Western Pathology Consultants	7
Jan. 11	Pathology Inc.	Central Coast Clinical Laboratories	NA*
Feb. 11	Novartis	Genoptix	470
Feb. 11	Sonic Healthcare	Central Coast Pathology Consultants	NA
March 11	LabCorp	Clinical Laboratory Management	NA
March 11	Quest	Celera Corp.	341
March 11	Quest	Athena	740
May 11	Myriad Genetics	Rules Based Medicine	80
June 11	Aurora Diagnostics	DermPath New England	NA
June 11	LabCorp	Clearstone Central Laboratories	NA
June 11	Signal Genetics	DiagnoCure US Laboratory	6
June 11	Solstas Lab Partners	Select Diagnostics	NA
June 11	US Clinical Labs	Vidalia Lab Services	NA
July 11	Nestle	Prometheus	567+
July 11	Linden LLC	Strata Pathology Services	80
July 11	Solstas Lab Partners	NextWave Diagnostics Labs	NA
July 11	Solstas Lab Partners	Wilmington Pathology Laboratory	NA
Aug. 11	Aurora Diagnostics	Global Pathology Laboratory Services	NA
Aug. 11	Solstas Lab Partners	Southern Diagnostics	NA
Aug. 11	Solstas Lab Partners	Oracle Diagnostics	NA
Aug. 11	US Clinical Labs	Augusta Lab	NA
Sept. 11	Shore Capital Partners	ClearPath Diagnostics	NA
Nov. 11	Miraca	Caris Life Sciences	725
Dec. 11	LabCorp	Orchid Cellmark	85.4
Dec. 11	Pathology Inc.	West Coast Clinical Labs	NA
Total			\$3.1 billion-\$35 billion

* Not available

Source: G2 Intelligence

Quest Beats Expectations for Fourth Quarter

Quest Diagnostics (Madison, N.J.) on Jan. 24 reported better-than-expected fourth-quarter results, with earnings rising 14 percent compared to the final quarter of 2010 and revenues increasing 3 percent. The company also announced a \$1 billion share repurchase program.

The company earned \$189.5 million, or \$1.19 per share, in the three months ended Dec. 31. That compares to earnings of \$165.7 million, or 96 cents per share, for the fourth quarter of 2010. Analysts had projected earnings of \$1.06 per share.

Clinical testing revenues increased 2.6 percent, with revenue per requisition up 2.2 percent and volume, measured by the number of requisitions, up 0.4 percent. The acquisitions of Athena and Celera contributed 3.2 percent to consolidated revenue growth and 2.6 percent to clinical testing revenue growth.

For the fourth quarter of 2011, adjusted operating income was \$336 million or 17.9 percent of revenues, compared to \$313 million or 17.2 percent of revenues for 2010. Cash flow from operations was \$338 million, compared to \$340 million in 2010. During the fourth quarter of 2011, the company repurchased \$50 million of its common shares.

For the full year, revenues increased 1.9 percent from 2010. For the year, income from continuing operations was \$472 million, or \$2.93 per diluted share, compared to \$723 million, or \$4.06 per diluted share, in 2010.

For 2012, Quest is projecting revenues to grow between 2 percent and 2.5 percent and diluted earnings to be between \$4.40 and \$4.55. Operating income as a percentage of revenues is expected to approach 18 percent. The company expects cash from operations to approximate \$1.2 billion and capital expenditures to be between \$225 million and \$250 million. 

Quest at a Glance (\$MM except earnings per share)				
	Three Months Ended Dec. 31		Twelve Months Ended Dec. 31	
	2011	2010	2011	2010
Revenue	\$1,879.30	\$1,824.00	\$7,510.50	\$7,368.90
Net income	\$189.50	\$165.70	\$470.60	\$720.90
Earnings per share	\$1.19	\$0.96	\$2.93	\$4.06
<i>Source: Quest</i>				

LabCorp to Offer Risk Stratification Tool for Ovarian Mass Malignancy

LabCorp in January announced the nationwide availability of a new Food and Drug Administration-cleared risk stratification tool for determining whether an ovarian mass is at high or low likelihood of being malignant.

The tool, ROMA (Risk of Ovarian Malignancy Algorithm), combines the results for Fujirebio HE4, Abbott's ARCHITECT CA 125 II, and menopausal status into a numerical score that, along with clinical and radiological evaluation, can aid in determining whether a woman over the age of 18 who presents with an ovarian mass and for whom surgery is planned is at high or low likelihood of finding malignancy in surgery. 

Qiagen Expands With New Deal

In an attempt to expand its companion diagnostic portfolio for several types of new anti-cancer drugs, Qiagen recently entered into two different agreements with U.S. biotech companies—Insight Genetics Inc. and Personal Diagnostics Inc. Through the agreement, the company seeks to obtain worldwide exclusive rights for biomarkers for gene mutation.

In collaboration with Nashville-based Insight Genetics, Qiagen will provide a genetic test with a biomarker for non-small cell lung cancers (NSCLCs) that express the abnormal anaplastic lymphoma kinase (ALK) gene. Meanwhile, under the agreement with Maryland-based Personal Genome Diagnostics, Qiagen's 89 percent subsidiary Ipsogen obtained rights to genetic testing for mutations of the IDH1 and IDH2 genes for brain cancers, acute myelogenous leukemia (AML), and other malignancies.

Qiagen's current initiative to expand its biomarker portfolio through the addition of the ALK and IDH1/IDH2 biomarkers is expected to continue to strengthen its position in the molecular diagnostics market, notes an analyst blog on Zacks.com. This should bring in incremental sales for the company globally. Qiagen also plans to develop companion diagnostics to make these biomarkers available in combination with new medicines.

"We are encouraged by Qiagen's focus on strategic initiatives to drive growth and profitability in the companion diagnostics market," writes a Zacks analyst on the blog. "Its innovative tests in the genomic/esoteric arena, specifically in the area of cancer with a focus on the high-margin esoteric testing business, are expected to accelerate sales growth in the next several quarters."

"We are encouraged by Qiagen's focus on strategic initiatives to drive growth and profitability in the companion diagnostics market. Its innovative tests in the genomic/esoteric arena, specifically in the area of cancer with a focus on the high-margin esoteric testing business, are expected to accelerate sales growth in the next several quarters."

—Zacks analyst

However, Qiagen is facing mounting competition in the molecular diagnostic space especially from players like LabCorp and Myriad Genetics. LabCorp has already expanded its companion diagnostic portfolio with the ALK biomarker for Pfizer's Xalkori, notes Zacks. Xalkori received Food and Drug Administration approval along with a test (Vysis ALK Break Apart FISH Probe Kit) for certain patients

with late-stage NSCLC who express the ALK gene. This companion diagnostic test is exclusively available through LabCorp.

Myriad is also aiming to establish itself as a strong player in the companion diagnostic market. In 2011, the company entered into an agreement with BioMarin Pharmaceuticals to conduct BRCA1 and BRCA2 mutation testing on patients to be enrolled in the latter's phase I and II clinical study of BMN 673, a PARP-inhibitor drug candidate for the treatment of genetically defined cancers. Myriad also has agreements with Abbott Laboratories and AstraZeneca. 

Quest Gets FDA Approval for New JCV Antibody Test

The Food and Drug Administration (FDA) has granted a de novo classification petition to Quest Diagnostics' STRATIFY JCV Antibody ELISA testing service.

STRATIFY JCV is the first blood test to be FDA market-authorized for the qualitative detection of antibodies to the polyomavirus JC virus (JCV) for stratifying risk for progressive multifocal leukoencephalopathy (PML), an infrequent but serious brain infection in patients with multiple sclerosis (MS) receiving TYSABRI (natalizumab), a highly effective therapy for relapsing forms of MS.

Market authorization follows FDA approval of a product label change for TYSABRI. The new label identifies JCV antibody status as a PML risk factor; other risk factors include duration of treatment with TYSABRI and prior immunosuppressant therapy use.

STRATIFY JCV was developed under an extensive collaboration for the U.S. market with Biogen Idec, co-manufacturer with Elan Corp., plc, of natalizumab. The test employs technology licensed from Biogen Idec and is exclusively offered through Quest Diagnostics' Focus Diagnostics laboratory in the United States. It is based on a test validated and performed by Focus Diagnostics in clinical trials. 

Lab Report on Drug Tests Not Eligible for Trademark

A printed medical report detailing toxicology lab results is not marketed separately from the lab tests themselves and therefore the report itself is not eligible to be registered as a trademark, the Trademark Trial and Appeal Board ruled Dec. 14, 2011 (*In re Ameritox Ltd.*, T.T.A.B., No. 77852949).

The board agreed with a trademark examining attorney that the reports "are merely a conduit through which the results of applicant's laboratory services are reported." As such, the board said that the reports were not "goods in trade," and thus were ineligible for trademark protection under the Trademark Act.

Ameritox Ltd. (Midland, Texas) offers drug screening tests to doctors and other medical professionals. In addition to conducting the toxicology screenings, Ameritox also sends its customers a detailed report that identifies the tests that were performed and the results of those tests. Ameritox sought a trademark for this report, which it calls RX Guardian. According to Ameritox's use-based application, the mark will identify "printed reports featuring medical laboratory results provided to medical practitioners for record keeping purposes."

The examining attorney refused registration of the report after determining that the reports were simply a portion of Ameritox's services. The examining attorney could find no evidence indicating that the reports were sold separately in commerce from the laboratory tests. Therefore, the application was refused on the grounds that the proposed mark did not apply to "goods in trade." Ameritox appealed, but Administrative Trademark Judge Marc A. Bergsman said "it is not the report per se that protects the medical professionals; it is applicant's underlying drug testing services that are documented in applicant's reports that offers the protection." 

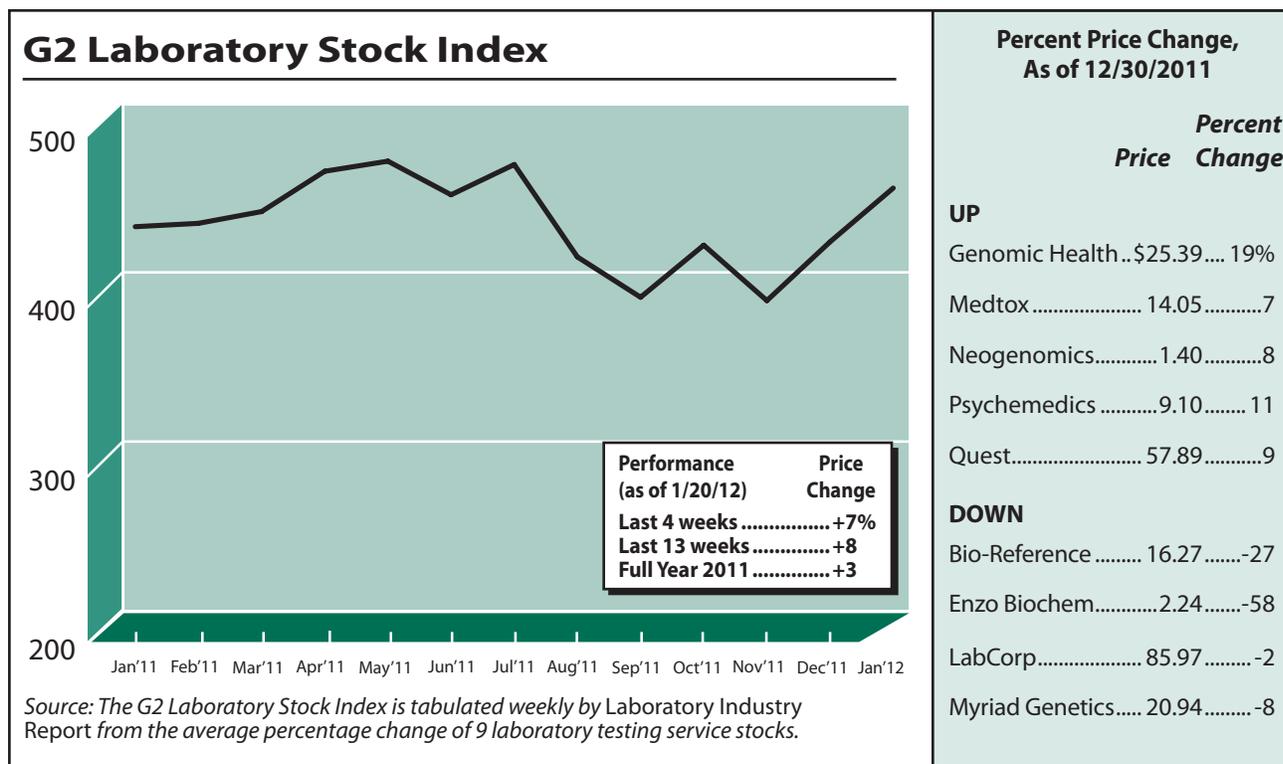
Lab Index Rises 3% in 2011, Performs Better Than Overall Market

The G2 Intelligence Laboratory Stock Index rose 3 percent in 2011, with five stocks gaining in price and four stocks falling. In comparison, the Nasdaq composite lost almost 2 percent during 2011, and the S&P was unchanged.

The top-performing stock for the year was **Genomic Health** (Redwood City, Calif.), which gained 19 percent to end the year at \$25.39. The company's stock price climbed steadily during 2011, reaching its highest level in six years on Dec. 7 after a study showed its Oncotype Dx breast cancer test can help predict which women with small tumors will see their disease worsen. The product, already sold to evaluate more advanced tumors, became available for women with ductal carcinoma in situ (DCIS) on Dec. 28.

Enzo Biochem (New York) was the worst performer during the year, with its stock dropping 58 percent to \$2.24, due in part to the life sciences industry experiencing significant softness in the academic market segment arising from reduced government funding grants and general tightness in the global economy. Even so, the company is looking to a stronger 2012 as evidenced by results from the first quarter ended Oct. 31, 2011. During the quarter, total revenues increased slightly but revenues at Enzo Clinical Labs increased 15 percent due to greater market penetration.

Shares of **Bio-Reference Laboratories** (Elmwood Park, N.J.) also struggled during the year, falling 27 percent to \$16.27. The stock price was battered in October as a result of an attack by owners of a blog who were shorting the stock. However, analysts generally feel that the company's key financial metrics are reasonable for a rapid growth company. Analysts at William Blair & Co., for example, note that Bio-Reference continues to expand its test menu and geographic presence and has signed more than 65 new agreements with payers in the last 18 months. 





INDUSTRY BUZZ

Genetic and Genomic Lab Testing Credited With \$16.5 Billion in Economic Output

The clinical laboratory industry now has new data to help it demonstrate the value of lab testing to lawmakers: a just-released report from Battelle Memorial Institute concludes that genetic and genomic laboratory testing generates 116,000 jobs and contributes \$16.5 billion annually to the U.S. economy. Because this industry sector is still in the early stages of development, much future growth is expected to occur. The report, sponsored by the American Clinical Laboratory Association (ACLA), said that the industry sector's ability to innovate and produce cutting-edge and genetic testing services and products supports about 44,000 direct jobs and generates about another 73,000 jobs in key supplier industries, such as real estate, food services, and wholesale trade businesses, as well as a result of consumer spending by laboratory employees.

Together, the genetic and genomic laboratory testing sector-related workforce received nearly \$6 billion in wages and benefits in 2009, according to the report. It also generated \$657 million in estimated state and local tax revenue and nearly \$1.2 billion in federal taxes in 2009. "The fact that genetic and genomic testing has created 116,000 jobs and \$6 billion in personal income for U.S. workers in the middle of one of the country's worst recessions should be noted by U.S. policy leaders," said Alan Mertz, ACLA president. 

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- Enzo Biochem 800-522-5052
- GE Healthcare 800-682-5327
- Genomic Health 650-556-9300
- Genoptix 760-268-6200
- Insight Genetics 615-255-8880
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