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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

Spotlight on DTC Testing Continues as FDA Warns of Tougher Oversight

The Food and Drug Administration (FDA) is planning to increase its oversight of companies that sell direct-to-consumer (DTC) genetic tests, an agency official testified July 22 during a congressional hearing.

At a House hearing to examine the accuracy of DTC genetic tests, Jeffrey E. Shuren, director of the FDA's Center for Devices and Radiological Health, testified that the FDA did not take action earlier to regulate the tests because the agency did not define the tests as "medical devices" used to diagnose or prevent diseases. However, as more of the tests have claimed to "assess high-risk but relatively common diseases and conditions," Shuren said that FDA oversight is essential to ensuring a consumer's safety.

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LabCorp, Quest Hit by Weaker Volumes in Second Quarter; Revenue Projections for the Full Year Mixed

Second-quarter results are in, and it appears that LabCorp is beating Quest in a couple of key areas. While both companies experienced weak volumes due to a decline in physician visits, LabCorp (Burlington, N.C.) actually reported better-than-expected results for the quarter and subsequently boosted its outlook for the entire year. Quest, meanwhile, reported a decline in revenues and lowered guidance for the year.

Quest's reported second-quarter revenues were $1.9 billion, 1.4 percent below the prior year's level. Clinical testing revenues decreased 1.6 percent compared to the previous year, revenue per requisition decreased 0.3 percent, and clinical testing volume decreased 1.3 percent.

Continued weakness in physician office visits, resulting in lower lab test utilization, led Quest to lower its revenue guidance for the year. The company now expects a revenue decline of 1 percent versus its prior guidance of 1 percent to 2 percent growth. Management also reduced and narrowed its 2010 earnings per share estimates to $3.90 to $4.

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LABCORP, QUEST HIT BY WEAKER VOLUMES, *from page 1*

Operating margin for the second quarter improved to 19.5 percent, with an operating income of $365.9 million compared to 18.9 percent in the same period last year when operating income was $359.3 million. The primary reason for the improvement in margin was a 6.5 percent decline in selling, general, and administrative expenses, which brought down operating expenses.

A surprise in the quarter was lower revenue per requisition growth, which was driven in part by the company's efforts to renew some managed care contracts early, as well as continued weakness in anatomic pathology.

LabCorp Beats Estimates

LabCorp reported adjusted second-quarter earnings of $1.46 per share, which beat analysts' estimates of $1.42 per share and the year-ago earnings of $1.30.

Quest, LabCorp at a Glance ($MM)

Three Months Ended June 30, 2010

	Quest	LabCorp
Net revenues	$1,874.7	1,238.4
Pretax income	329.8	260.0
Net income	194.7	153.7
Earnings per share	1.07	1.46

Revenues for the quarter rose 4.2 percent to $1.2 billion when compared to the same period last year. Testing volume dipped 2 percent, but revenue per requisition increased 6.3 percent. The continued impact of two large government contracts terminated during 2009 contributed to the volume decline.

The increase in revenue per requisition is likely due in part to the company's acquisition of Monogram Biosciences and its more favorable test mix. In addition, the drugs-of-abuse testing business, which is roughly 5 percent of volumes, increased 15.4 percent over the previous year.

LabCorp generated operating cash flow of $448.2 million (up 14.5 percent) in the first half of 2010, including $216.2 million in the second quarter. Operating cash flow for the quarter excludes a transition payment of $2.1 million to UnitedHealthcare. Free cash flow for the first half improved 15.5 percent year over year to $389.2 million.

LabCorp Continues Buying Spree With DCL Acquisition

Just a couple of months after announcing that it was buying Westcliff Medical Laboratories (Santa Ana, Calif.) and Diamond Reference Laboratory (Diamond Bar, Calif.), LabCorp acquired DCL Medical Labs (Indianapolis) for an undisclosed amount.

Specializing in women's health, DCL provides diagnostic and clinical trial testing services to physicians, hospitals, and pharmaceutical and medical device compa-

nies. In 1999, DCL became one of the first labs to offer HPV testing directly from the ThinPrep vial. In 2003, DCL became the first lab in the United States to successfully offer a DNA-based Group B Strep prenatal test. In 2009, the lab became the first in the Midwest to offer FDA-approved HPV 16/18 genotyping.

The lab was acquired in October 2007 by Thompson Street Capital Partners along with lab industry veterans Jack Bergstrom and Jay Tyler. Annual revenues are estimated at $40 million to $50 million.

Although the DCL acquisition is relatively small, the deal, along with the Westcliff acquisition, could add 10 cents to 15 cents in LabCorp's earnings per share in the first year, estimates Amanda Murphy, an analyst with William Blair & Co., an investment research firm.

The Federal Trade Commission is currently reviewing the Westcliff acquisition.

Merck Grants License to LabCorp for Hepatitis Therapy Test

Merck (Whitehouse Station, N.J.) has announcd a nonexclusive license agreement with LabCorp for the commercialization of a genetic test that may help predict the response of patients with Hepatitis C virus (HCV) infection to peginterferon alpha-based therapy.

LabCorp has developed an in vitro genetic test designed to identify the presence of the IL-28B polymorphism in patients, which studies suggest may be associated with successful response to peginterferon alphase-based therapy, the current standard of care in HCV treatment.

Under terms of the agreement, LabCorp will pay a Merck affiliate a one-time payment and royalties for tests covered under the agreement in exchange for a license to the Merck affiliate's patent rights covering the detection and use of the IL-28B polymorphism.

Increased M&A Activity

These deals, along with Genzyme's announcement that it wants to sell its genetics business, point to increased merger and acquisition opportunities in the lab space. In general, there appears to be more available for sale in the lab industry (an estimated $1 billion) than has been the case in the past two years, says Murphy. This could be driven by continued softness in lab test volumes during the economic downturn and concerns about health care reform implications and future Medicare reimbursement.

Empire BlueCross BlueShield Expands Reference Laboratory Network

Empire BlueCross BlueShield, New York's largest insurer by medical membership, will significantly expand its reference laboratory network effective Aug. 1.

Empire is expanding its HMO reference laboratory network to include LabCorp, DIANON Systems, and Centrex Clinical Labs. In addition, for the areas of Brooklyn and Queens, Shiel Medical Laboratory also will be added.

The insurer's PPO/EPO and indemnity reference laboratory network will be expanded to include LabCorp, DIANON, Centrex, BioReference Laboratories, Enzo Clinical Laboratories, and Sunrise Medical Laboratories.

Performance of Hospital-Based Outreach Programs vs. National Labs: Just How Are Outreach Labs Beating Their Competition?

Since the publication of the article, "Hospital Outreach Programs Holding Their Own Against National Labs, but Lack of Data Plagues Many Programs, Finds Survey" in last month's *Laboratory Industry Report*, readers have asked for more information about the performance of hospital-based outreach programs compared to Quest Diagnostics and LabCorp, particularly with regard to revenue per requisition and profitability.

Outreach Program Performance vs. National Laboratories

	Outreach Programs	Quest Diagnostics	LabCorp
Revenue Per Requisition*	$68.08	$44.96	$39.28
Volume Growth**	10.8%	-0.7%	1.5%
Revenue Growth**	12.2%	2.8%	4.1%
Profitability***	15%-24%	9.8%	11.6%
Bad Debt	4.0%	4.3%	5.3%
DSO	41 days	41 days	44 days

**Revenue per requisition for outreach programs based on 3.5 tests per requisition.*
***Year-over-year increase including acquisitions; outreach numbers reported as median.*
****Measured as contribution margin or after-tax profit.*
Quest and LabCorp data from Laboratory Economics, *March 2010.*

The median revenue per requisition for outreach programs ($66.08) is 51 percent higher than Quest ($44.96) and 73 percent higher than LabCorp ($39.28). How is this possible? This number is calculated based on an assumption of 3.5 tests per requisition and a per test revenue of $19.45. Outreach programs that bill under the hospital's provider number have a distinct advantage over independent laboratories. They have a higher fee schedule, and some payers reimburse on a percentage of charges basis rather than a predetermined fee schedule. This gives hospital-based programs a significant economic advantage.

Profitability for the independent laboratories is reported as after-tax profit while the figure for outreach programs represents contribution margin (or gross profit).

Secondly, profitability for the independent laboratories is reported as after-tax profit while the figure for outreach programs represents contribution margin (or gross profit). Hospital laboratories already have existing facilities, staff, and equipment to support hospital inpatients and outpatient services. This infrastructure is leveraged to produce additional testing and revenue. The costs associated with the outreach program include only the new incremental costs associated with provision of outreach services. Therefore, outreach programs appear more profitable because overhead and taxes are excluded.

Source: This clarification was provided by Chi Solutions Inc. (Ann Arbor, Mich.), which conducted the Lab Outreach Survey.

FDA Seeks Input on Regulation of Lab-Developed Tests

The U.S. Food and Drug Administration (FDA) clearly has decided it's time to step up regulation of laboratory-developed tests (LDTs). What's not so clear is just what approach the agency will take in its oversight.

As the line between LDTs and medical devices subject to premarket regulatory review has grown ever blurrier, the FDA last month announced its intention to move to a risk-based application of LDT oversight. How that goal will be accomplished remains to be seen, but the agency heard a variety of suggestions, concerns, and frustrations at a two-day public meeting it convened July 19-20 in Hyattsville, Md.

"We see LDTs being used more and more as a loophole. Preliminary medical data is being packaged as medical information."
— Elizabeth Mansfield, FDA

Approximately 600 stakeholders, including laboratory professionals, clinicians, and industry representatives, packed the auditorium of the Marriott Inn and Conference Center at University of Maryland University College for a series of public presentations and panel discussions on patient and clinical considerations concerning LDT oversight, clinical laboratory challenges, direct-to-consumer testing, and education and outreach.

"Although FDA has decided to exercise its authority over laboratory-developed tests, we have not made any decisions about how to exercise that authority," said Jeffrey E. Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health, in his opening statement. "That's what this two-day meeting is about."

LDTs and diagnostic test kits are subject to different standards and uneven enforcement, the FDA has acknowledged. Courtney Harper, Ph.D., of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), described the current regulatory strategy as bifurcated, with commercially distributed tests and LDTs taking divergent paths to market. The proportion of tests taking the LDT route, which does not require FDA submission, has climbed in the past 10 to 15 years, she said, and the volume and variety of LDTs has grown exponentially. The self-determined nature of LDT status is also problematic, noted Harper. "An LDT is not always lab-developed."

Commercially offering LDTs through a CLIA-certified laboratory created specifically for that purpose is now frequently used as a mechanism for market entry, allowing novel tests to reach the national market without going through the FDA. "We see LDTs being used more and more as a loophole," said Elizabeth Mansfield, Ph.D., director for personalized medicine at FDA OIVD. "Preliminary medical data is being packaged as medical information."

Risk vs. Benefit

The FDA's move to actively regulate this class of in vitro diagnostics (IVDs), which are manufactured and offered within a single clinical laboratory, is a response to public health risks created by LDTs that may not provide a rea-

sonable assurance of safety and effectiveness. "The goal of regulation is to maximize value and minimize risk," said Principal Deputy FDA Commissioner Joshua M. Sharfstein, M.D. "We really do want to foster innovation in testing while ensuring high quality."

"Market forces are very efficient at determining use of LDTs. Underutilization, not overutilization, is the norm. Clinicians and payers are traditionally slow adopters until there is consensus in the medical community on clinical utility."
— Benjamin Salisbury, Clinical Data

The assembled stakeholders were also focused on risks, including those of stifling innovation among test developers, depriving patients and clinicians of critical diagnostic information, burdening the small clinical laboratories for whom the LDT designation was originally designed, and overtaxing the limited resources of the FDA.

"Market forces are very efficient at determining use of LDTs," said Benjamin Salisbury, Ph.D., vice president of clinical genetics of the PGxHealth division of Clinical Data (Newton, Mass.), which offers a line of genetic tests as LDTs through its CLIA-certified lab in New Haven, Conn. "Underutilization, not overutilization, is the norm. Clinicians and payers are traditionally slow adopters until there is consensus in the medical community on clinical utility." He concluded with the example of PGxHealth's recently launched tests for inherited heart conditions. "We wouldn't have [introduced these tests] if we had to go through FDA," Salisbury said. "We want to be able to be able to react as quickly as the science will allow."

Presenters at the meeting urged FDA to undertake in-depth research on many fronts before proceeding with draft guidance. Industry consultant Mary Pendergast was one of many attendees who suggested that the agency thoroughly examine how clinicians and patients are using LDTs and how they understand the results. Pendergast agreed that a risk-based approach to regulation was needed but argued that the FDA was in danger of regulating "on opinion and anecdote," not facts.

"We have to go forward in a very measured way, identify gaps, and fully understand what's at stake," agreed Alan Mertz, president of the American Clinical Laboratory Association, who also called for a broad grandfather exception for existing, established tests. "Laboratories are laboratories, not manufacturers. We are a service provider."

Bridging Worlds

FDA representatives conceded that they have no clear idea of the scope of the LDT market they are seeking to regulate and suggested that efforts to learn who is offering what tests would be coordinated with the National Institutes of Health, which recently announced its plan to develop a genetic testing registry. "There are thousands of LDTs out there. Most have been offered safely and efficaciously for many years," said Gail Vance, M.D., representing the College of American Pathologists (CAP). "If I were

the FDA, I would start by gathering data. Get to know the universe—CAP, CLIA. It's going to take a considerable amount of effort to bridge the CLIA and FDA worlds."

Possible roles for third-party organizatins in LDT regulation figured prominently in the two-day discussion, with presenters and panelists referring to regulatory schemes proposed by groups including CAP and AdvaMed. In highlighting CAP's 2009 proposal to clarify oversight of LDTs, Vance emphasized the potential value of a risk-based approach that would be realized through "a partnership between [the Centers for Medicare and Medicaid Services], FDA, and third-party accreditors."

A collaborative solution was also favored by Judy Yost, director of laboratory services at CMS and head of the CLIA program. "A public-private partnership is probably a good way to go," she said. "We clearly offer the resources of CMS and CLIA to assist in this process." FDA's Mansfield said that the agency was considering using CLIA inspectors for the LDT inspection process.

Other commenters expressed concern at stepping up LDT oversight without first reassessing the system for reimbursement of laboratory tests. While acknowledging that reimbursement is outside FDA jurisdiction, Michael Stocum, managing director of the consulting firm Personalized Medicine Partners (Raleigh, N.C.), called for "a move toward value-based reimbursement that would reduce the bias toward an LDT solution." He also suggested that the FDA ease the burden of regulatory submissions by making available FDA-accepted sample repositories with clinical data and expanding the availability of test standardization programs.

"We'll get a lot out of this," said Alberto Gutierrez, Ph.D., director of FDA OIVD, in closing the meeting. He called the meeting "very rich." The FDA has said that it will review comments from the meeting, as well as those submitted to the docket by Aug. 15, and develop a draft oversight framework for public comment. Such a framework would likely be phased in over time based on the level of risk of the test.

Lab Institute to Include Discussion on LDTs, DTC Tests

The discussion about the federal government's evolving role in regulating lab-developed tests and direct-to-consumer tests continues at G-2 Reports' 28th Annual Lab Institute, which will be held Oct. 13-15, 2010, in Arlington, Va.

You won't want to miss this lively discussion with Alberto Gutierrez, director of the Office of In Vitro Diagnostics at the Food and Drug Administration; Sharon Terry, president and CEO of Genetic Alliance; and Ronald Weiss, M.D., professor of pathology at ARUP Laboratories/University of Utah.

More details about Lab Institute are available at *www.labinstitute.com*. Please note that early bird registration rates expire Sept. 3.

SPOTLIGHT ON DTC TESTING, *from page 1*

Marketing genetic tests directly to consumers can increase the risk of a test because a patient may make a decision that adversely affects his or her health, Shuren said. "The risk points up the importance of ensuring that consumers are also provided accurate, complete, and understandable information about the limitations of test results they are obtaining."

The House Energy and Commerce Subcommittee on Oversight and Investigations hearing was held nearly three months after the FDA notified DTC testing company Pathway Genomics Corp. that its genetic tests , which claimed to report the presence or risk of more than 70 health conditions, met the definition of a "medical device" and were not approved by the FDA.

FDA sent similar letters to four other DTC test firms on June 10, and on July 19 sent letters to an additional 15 companies that market DTC tests.

Shuren stated that most of the DTC genetic tests on the market were not subject to premarket review and approval from the FDA. When DTC genetic tests began coming on the market a few years ago, FDA met with some of the companies starting in 2007 to get a better understanding of what the companies were doing or planning to do.

According to GAO's report, the tests' results are "misleading and of little or no practical use" to consumers. The report showed that tests produced severely different results for identical sets of DNA, and the results sometimes conflicted with the DNA donor's actual medical conditions.

"Initially, their business models were not clear and the tests were being marketed for such purposes as 'antiquity determinations,'" Shuren testified. "However, since then we have seen changes in the number and types of claims being made." For example, he said, one company provided test reports for 17 diseases, condition, or traits in 2008 but provided over 100 types of results by 2010. In addition, some companies are making claims about high-risk medical indications, such as determining the risk for cancer or the likelihood of responding to a specific drug.

Partly in response to this evolution, the FDA is now "engaging in a public dialogue on how it should develop a consistent, reasonable, and fair approach to all genetic tests" to protect consumers, Shuren said. In July, the agency held a two-day public meeting on oversight of laboratory-developed tests and DTC testing (*see article, pp. 5-7*).

GAO's Negative Review of Tests

Prior to Shuren's hearing testimony, Gregory Kutz, managing director for forensic audits and special investigations at GAO, presented findings from its investigation of companies selling DTC genetic tests.

GAO purchased 10 tests from four testing companies and sent DNA samples from undercover donors to the companies' labs. The companies in GAO's investigation include 23andMe Inc., Navigenics Inc., Pathway Genomics, and deCODE Genetics. GAO's report submitted to the House panel does not name the companies, which were identified during the hearing.

According to GAO's report, the tests' results are "misleading and of little or no practical use" to consumers. The report showed that tests produced severely different results for identical sets of DNA, and the results sometimes conflicted with the DNA donor's actual medical conditions. GAO said its test subjects or donors "often received disease risk predictions that varied across the four companies, indicating that identical DNA samples yield contradictory results."

GAO also discovered 10 incidents of deceptive marketing, including false endorsements and scientifically invalid claims. In its investigation, GAO recorded representatives from Navigenics telling an undercover donor that she was "in the high risk category of pretty much getting [breast cancer]." GAO also recorded Navigenics representatives claiming the tests can be used to diagnose diseases.

Representatives from Navigenics and Pathway Genomics also told GAO's undercover donors that they could secretly test their fiance's DNA as a "surprise" gift, a practice which is currently restricted in 33 states, Kutz said.

With the number of discrepancies in the test results and reported efforts to deceive consumers, Kutz said that "these tests are not ready for prime time" and need regulation.

Companies Split on Regulation

Ashley Gould, the general counsel for 23andMe, said 23andMe's tests are very accurate, despite the inconsistencies that GAO found between the other tests. Gould said that one cause for the varying results could be that each company uses different predictive markers and has its own standards for testing the DNA samples for risks.

Gould said that there should be industrywide standards for analyzing DNA for disease risks. She added that 23andMe is not opposed to finding a new way for FDA to regulate DTC genetic tests.

However, Navigenics Chief Executive Officer Vance Vanier cautioned against extreme FDA oversight, saying, "Abrupt or overbroad regulation can chill genomic discoveries and applications in this country, driving innovation and investment to other countries and attracting with it thousands of high-value jobs in this key growth industry." Navigenics is based in Foster City, Calif.

David Becker, chief scientific officer at San Diego-based Pathway Genomics, agreed, saying new regulations also should not limit consumer access to health information or stifle scientific progress in the genetics industry.

James Evans, editor in chief of *Genetics in Medicine*, the official journal of the American College of Medical Genetics, and professor at the University of North Carolina at Chapel Hill, said it is possible for the FDA to develop a risk-calibrated regulation method by applying standards based on the risks of different DTC genetics tests. The model would not limit genetic innovation, he said. By developing these standards, the "gap between claims and reality" in DTC genetic testing will shrink and deceptive practices will decrease. In addition, tests will become more accurate and useful, Evans said.

Eye ON IMAGING

CMS Seeks 'Conveners' to Recruit Docs for Imaging Demo

Interested parties have 60 days to apply to participate in a Medicare demonstration project to determine the appropriateness of advanced diagnostic imaging services furnished to program beneficiaries, according to a July 23 *Federal Register* notice.

Demo Advanced Imaging Procedures

	Computed Tomography	Magnetic Resonance Imaging	Nuclear Imaging (SPECT-MPI)
Brain	70450; 70460; 70470	70551; 70552; 70553	
Sinus	70486; 70487; 70488		
Thorax	71250; 71260; 71270		
Heart			78464; 78465
Abdomen	74150; 74160; 74170		
Lumbar Spine	72131; 72132; 72133	72148; 72149; 72158	
Pelvis	72192; 72193; 72194		
Shoulder		73221; 73222; 73223	
Knee		73721; 73722; 73723	

According to the Centers for Medicare and Medicaid Services (CMS), the goal of the demo "is to collect data regarding physician compliance with appropriateness criteria selected by the [health and human services secretary] under the terms of the statute in order to determine the appropriateness of advanced diagnostic imaging services furnished to Medicare beneficiaries."

Advanced diagnostic imaging services are defined as magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine. The demo excludes X-ray, ultrasound, and fluoroscopy. The demonstration will focus on 11 targeted advanced imaging procedures that were selected based on high expenditures and utilization in the Medicare fee-for-service population and the availability of relevant medical specialty appropriateness guidelines: Spect MPI, MRI lumbar spine, CT lumbar spine, MRI brain, CT brain, CT sinus, CT thorax, CT abdomen, CT pelvis, MRI knee, and MRI shoulder.

In the agency notice, CMS said it is seeking "conveners" that can recruit physician practices that agree to use an advanced diagnostic imaging DSS for the purposes of the demo. CMS said it anticipates selecting up to six conveners and is seeking participation of some 2,500 to 3,000 physicians from at least 500 practices. The demonstration is scheduled to start Jan. 1, 2011, and operate for two years.

More information on the demonstration project is at *www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/Medicare_Imaging_Demonstration.pdf*. An application form is available at *www.cms.gov/cmsforms/downloads/cms10069.pdf*.

Lab Index Looking Stronger, Up 10% in July

The G-2 Reports Laboratory Stock Index showed signs of recovery in July, with the index climbing 10 percent in the five weeks ended July 30, 2010. For the year, the index is down 5 percent. In comparison, the Nasdaq composite and the S&P 500 are each down about 1 percent.

Five of the 13 publicly traded lab companies tracked by the index posted gains during the period while eight saw their share prices decline. For the second month in a row, **Genzyme** (Cambridge, Mass.) posted the biggest gain on reports that Sanofi-Aventis was attempting to buy the company (*see related item on pg. 12*). The stock climbed 30 percent to $69.56 giving the company a market cap of $18.45 billion.

Shares of **Psychemedics** (Acton, Mass.) climbed 13 percent to $9.01 for a market cap of $46.83 million while shares of Genoptix recovered some of the previous month's loss, rising 9 percent to $17.28 for a market cap of $303.17 million.

Genoptix reported second-quarter revenues of $50.9 million, a 12 percent increase over revenues for the same period in 2009. Net income was $5.6 million or 31 cents per diluted share.

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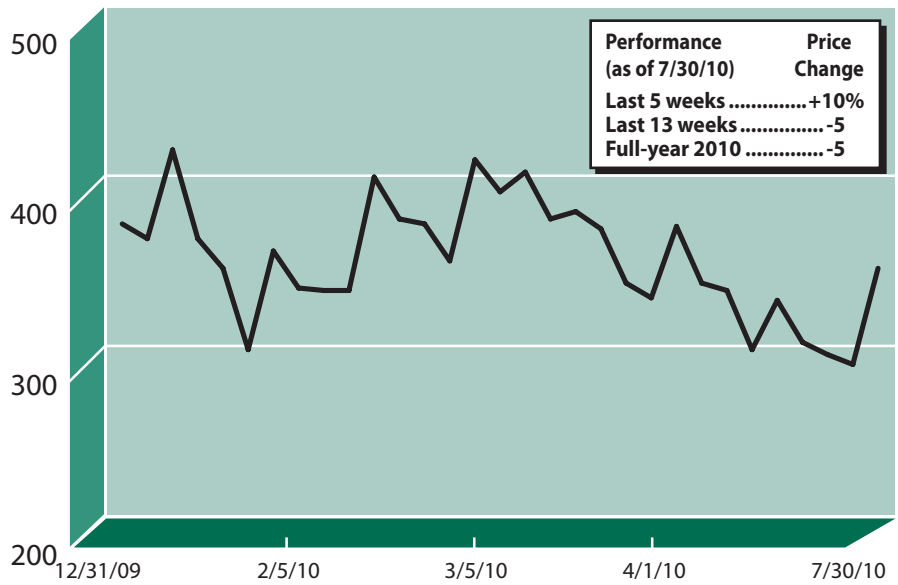
Genomic Health (Redwood City, Calif.) posted the biggest loss during the period, with shares dropping 13 percent to $12.89, giving it a market cap of $370.97 million. Also experiencing declines during the period were **Bio-Reference Laboratories** (Elmwood Park, N.J.), whose shares dropped 8 percent to $20.97 (market cap of $582.84 million), and **Myriad Genetics** (Salt Lake City), whose shares dropped 8 percent to $14.51 (market cap of $1.41 billion).

G-2 Laboratory Stock Index



Source: The G-2 Laboratory Stock Index is tabulated weekly by Laboratory Industry Report *from the average percentage change of 13 laboratory testing service stocks.*

Percent Price Change, Five weeks ended 7/30/10

	Price	Percent Change
UP		
Enzo Biochem	$4.60	+5%
Psychemedics	9.01	+13
Orchid Cellmark	1.64	+5
Genzyme	69.56	+30
Genoptix	17.28	+9
DOWN		
Bio-Reference	20.97	-8
Clarient	3.22	-1
Genomic Health	12.89	-13
LabCorp	72.98	-5
Medtox	11.53	-5
Myriad Genetics	14.51	-8
Quest	46.99	-7
Neogenomics	1.15	-11

INDUSTRY buzz

Sanofi-Adventis Bids for Genzyme

French pharmaceutical giant Sanofi-Adventis may have to up its bid of $18.4 billion for biotech firm Genzyme if it wants to convince the company to sell. Sanofi bid $69 per share for the company in early August, but sources say the Massachusetts-based firm probably won't sell unless a bid hits $80 per share.

Genzyme's shares hit a high of $83 in 2008, and the stock has surged more than 30 percent since reports of a takeover interest emerged in late July. The stock was trading at $70.22 on Aug. 3.

The *Wall Street Journal* notes that Sanofi may be taking on some risk since it's not clear whether Genzyme's manufacturing problems have been resolved. The company had to close its main production facility because of a viral contamination. Sanofi CEO Chris Viehbacher says the company will be disciplined in its acquisition approach and will not overpay. GlaxoSmithKline, Johnson & Johnson, and Pfizer have all made casual approaches to Genzyme, telling the firm to keep them in mind if they think about selling. Genzyme is keeping those potential suitors in its back pocket just in case talks with Sanofi fall apart.

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Genzyme 617-252-7500
LabCorp 800-334-5161
Myriad Genetics 801-584-3600
Navigenics 866-522-1585
Pathway Genomics 877-505-7374
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