

LABORATORY INDUSTRY REPORT®



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Outreach Labs Shows Improvement in Bad Debt, DSO

Hospital outreach laboratories showed significant improvement in their bad debt rates and days sales outstanding (DSO) in 2009 when compared to previous year, according to a survey of outreach programs conducted by Chi Solutions (Ann Arbor, Mich.)

Average bad debt declined from 10 percent in 2008 to 5 percent in 2009 while the average DSO dropped from 58 to 45 days. This was a pleasant surprise and indicates that lab outreach programs are performing well when compared to the large national labs, said Chi President Kathleen Murphy, Ph.D., who presented the results at Washington G-2 Reports' Lab Outreach 2010 on June 3.

For more on how lab outreach programs are performing, see *Inside the Lab Industry* on pp. 5-7. 🏛️

Struggling Economy Fuels Trends in Lab Space, Especially in Anatomic Pathology Market

While volume trends are relatively stable, the economic downturn appears to have escalated existing trends in the lab space, particularly in the anatomic pathology market, according to equity research firm William Blair & Co. (Chicago).

Five major labs covered by William Blair—Quest Diagnostics, Myriad Genetics, LabCorp, Genoptix, and Bio-Reference—presented at the company's 30th annual Growth Stock Conference in mid-June. "In general, volume trends appear to be stable (although still down from historical levels), the private payer pricing environment appears to be in decent shape (given large payer contracts have been signed for a number of years and include price escalators), and we believe the labs are positioned to benefit from health care reform via expanded coverage and lower bad-debt expense offset to some degree by reimbursement risk," says analyst Amanda Murphy.

The most important point that Murphy took away from the conference, she says, is that the economic downturn appears to have escalated existing trends in the lab space, particularly in the anatomic pathology market, including (1) physician in-sourcing of lab testing,

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■ STRUGGLING ECONOMY FUELS TRENDS, *from page 1*

(2) purchase of physician practices by hospitals, (3) increased competition, and (4) more aggressive tactics on the part of health plans to control leakage of tests to out-of-network labs.

“Therefore, larger labs that are less exposed to anatomic pathology (i.e., LabCorp) and smaller labs that are in-network with most payers (i.e., Bio-Reference Labs) are best positioned in our view,” writes Murphy, who highlighted presentations by the five companies.

Quest Diagnostics

Quest (Madison, N.J.) is focused on innovation in an effort to become a key provider of testing across the health care continuum, said Chairman and CEO Surya Mohapatra. The company is particularly interested in the genomics/molecular space and seems less focused on buying additional routine labs. As a result, Murphy believes Quest is more likely to pursue Genzyme Genetics versus other available merger and acquisition opportunities.

The company continues to focus on investing in point of care (or near patient) testing and international expansion (with a goal for international to be 10 percent of revenues). Mohapatra suggested that health care reform could ultimately be a net positive for the diagnostic space with an additional 32 million people to be tested annually although it may take a while for the incremental volume to flow through the system.

Despite the fact that labs continue to face a challenging environment, William Blair rates the stock outperform given its view that Quest is poised to benefit from health care reform and that the company generates strong free cash flow.

Myriad Genetics

Management of Myriad (Salt Lake City) reaffirmed revenue guidance of \$360 million to \$365 million for fiscal 2010 ending in June. Expanding use of Myriad’s BRACAnalysis test into the ob-gyn market continues to be the company’s greatest near-term opportunity, believes Murphy.

PARP inhibitors are an interesting longer-term opportunity. PARP inhibitors only work in patients with a BRCA1 and BRCA2 mutation, so Myriad’s test could be a companion diagnostic for therapeutics, thereby significantly expanding the BRACAnalysis market in oncology. There are a number of PARP inhibitors in the pipeline, with four reasonably far along in clinical trials. Murphy believes the ability to penetrate the ob-gyn (asymptomatic) market could be a significant growth driver and notes that the company has built a strong personalized medicine franchise. But given Myriad’s recent challenges and perceived intellectual property risk, WB continues to rate the shares market perform.

LabCorp

Underlying volume trends at LabCorp (Burlington, N.C.) appear to be flat, although stable, but should improve through the year as two lost government contracts reach the anniversary date. The private payer pricing environment appears



to be relatively strong, driven by price escalators embedded in long-term private payer contracts. Murphy expects continued pricing growth to be fueled by a shift to esoteric testing and, to a lesser extent, real price increases (somewhat offset by Medicare price reductions).

The company continues to focus on developing high-margin esoteric testing, particularly in the genetics and genomics space. Murphy believes that acquisition of Genzyme Genetics would be a key strategic asset. LabCorp may see an acceleration in underlying earnings growth over the next three to four years driven by expanded coverage, demographics, potentially increased focus on shifting lab testing to lower-cost providers, and cash deployment via acquisitions and share buy backs. WB rates the stock outperform.

Genoptix

Genoptix (San Diego) management substantially reduced guidance in mid-June. Full-year revenue is now expected to be \$210 million (down \$25 million to \$30 million from previous guidance), and earnings per share is now expected to be \$1.20 (down 60 cents to 65 cents).

Company officials cited a number of negative business trends that have been affecting its ability to grow volumes including (1) the impact of increased competition, (2) efforts of the part of health plans to control leakage to out-of-network labs, (3) physician in-sourcing of lab testing, and (4) acquisition of physician practices by hospitals.

Despite weaker-than-expected volumes, the company continues to invest, resulting in lower-than-expected profit margins (operating margin is now expected to be in the high teens versus prior guidance of low to mid-20s). Lab capacity expansion is expected to reduce second-half earnings per share by 15 cents and sales and marketing expansion by 19 cents. William Blair rates the shares market perform.

Bio-Reference Laboratories

Bio-Reference Labs' (Elmwood Park, N.J.) women's health franchise continues to be a key growth driver. Future growth opportunities include geographic expansion, opportunity to gain more share of the ob-gyn office, and New York state validation (which could be as much as a \$25 million revenue opportunity, according to Murphy).

With its acquisition of Lenetix, which offered a key piece of prenatal genetic testing, Bio-Reference will be able to offer a full ob-gyn tests menu by the end of 2010, which positions the company to gain share of the higher-revenue, higher-margin prenatal genetic testing. Management also plans to add 20 more ob-gyn sales reps this year.

Management suggested that physician practice sales to hospitals and in-sourcing of lab testing by physicians are two ongoing trends that may be escalating. Given Bio-References is in an aggressive market share-gaining phase, these issues are not affecting the business to a noticeable degree. Murphy rates the shares outperform. 🏠



Narrow Ruling in *Bilski* Leaves Questions Regarding Patentability of Complex Technologies

The recent U.S. Supreme Court ruling in a key patent case may be incrementally positive for Myriad Genetics (Salt Lake City), which currently is appealing a district court ruling that its patents on BRCA genes are invalid, though it still leaves questions regarding the patentability of complex technologies.

The high court June 28 affirmed the lower court judgment in *Bilski v. Kappos*, holding that the specific invention in this case, a method of predicting business or economic cycles, was ineligible for a patent. But perhaps most significant is that the court determined that the machine or transformation (MOT) test is not the sole test for process patent eligibility and indicated that Section 101 of the Patent Act (defining patent-eligible subject matter) does not categorically exclude business method patents.

In rejecting *Bilski's* patent application on the grounds that abstract ideas are unpatentable, wrote Justice Anthony Kennedy, the court "need not define further what constitutes a patentable 'process,'" beyond pointing to the statutory definition and looking to guiding precedents.

The court's highly anticipated ruling in the case, which was argued before the court on Nov. 9, 2009, was viewed as a potential bellwether for patent law. However, the decision did little to address broader questions surrounding the patentability of complex technologies and the information generated by those technologies, including sequencing technology used to identify human genes.

The Biotechnology Industry Organization (BIO) applauded the decision. The organization last year had filed a brief with the court urging it to overturn the decision of the U.S. Court of Appeals for the Federal Circuit, which created a new test under which a method or process is only patent-eligible if it is tied to a specific machine or if it transforms a particular article or substance to a different state or thing.

"The court was clearly conscious of the potential negative and unforeseeable consequences of a broad and sweeping decision," said BIO President and CEO Jim Greenwood. "This ruling specifically states that the 'machine-or-transformation test is not the sole test for patent eligibility' and recognized that the lower court's ruling could have created uncertainty in fields such as advanced diagnostic medicine techniques."

The decision may be incrementally positive for Myriad Genetics since it weakens the judge's ruling in *Association for Molecular Pathology, et al v. U.S. Patent and Trademark Office*. Judge Thomas Sweet of the U.S. District Court for the Southern District of New York in March issued a ruling that invalidated some of the patents on BRCA1 and BRCA2 genes granted to Myriad and the University of Utah Research Foundation. Myriad is now appealing that ruling. In that case, Sweet depended on *Bilski* in invalidating Myriad's method claims on isolated DNA sequences. The Supreme Court ruling could open the door to declaring such claims patentable subject matter using a test other than machine or transformation. 🏠

Hospital Outreach Programs Holding Their Own Against National Labs, But Lack of Data Plagues Many Programs, Finds Survey

Hospital outreach labs are outperforming both Quest Diagnostics (Madison, N.J.) and LabCorp (Burlington, N.C.) in several key areas, including revenue per requisition, volume growth, and revenue growth, according to the 9th Annual National Outreach Survey conducted by Chi Solutions (Ann Arbor, Mich.). Chi President Kathleen Murphy, Ph.D., presented the results June 3 at Washington G-2 Reports' Lab Outreach 2010, held in Baltimore.

Outreach labs responding to the Chi survey reported average revenue per requisition of \$68.08, significantly more than Quest's average of \$44.96 and LabCorp's average of \$39.28. Outreach volume growth of 10.8 percent and revenue growth of 12.2 percent also handily outpaced the national labs' single-digit growth (see chart).

Analysis of data from more than 100 respondents to the survey showed that these labs boast an average profitability, as measured by contribution margin or after-tax profit, of between 15 percent and 24 percent. In comparison, Quest reported profitability of 9.8 percent in 2009 while LabCorp's profitability was 11.6 percent.

Bad debt has improved considerably from last year's survey at just 4 percent compared with 10 percent last year. This compares favorably with Quest's bad-debt rate of 4.3 percent and LabCorp's rate of 5.3 percent. Days sales outstanding (DSO) also improved to 41 days, down from 58 days in last year's survey. Both Quest and LabCorp also saw improvements in their DSO rate.

"This was one of the big surprises in this year's survey," said Murphy. "Lab outreach programs are doing a stellar job in bringing these numbers down."

Outreach Labs vs. National Competitors

	Outreach Programs	Quest	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

Source: 9th Annual National Outreach Survey, Chi Solutions, www.chisolutionsinc.com

Five Key Trends

Based on the survey analysis, Murphy identified five key trends in the lab outreach market (listed in reverse order).

Trend 5: Competitive Landscape Is Changing

After coming in second to LabCorp in 2007, the year LabCorp inked its exclusive agreement with United Healthcare, Quest Diagnostics once again is considered the top competi-

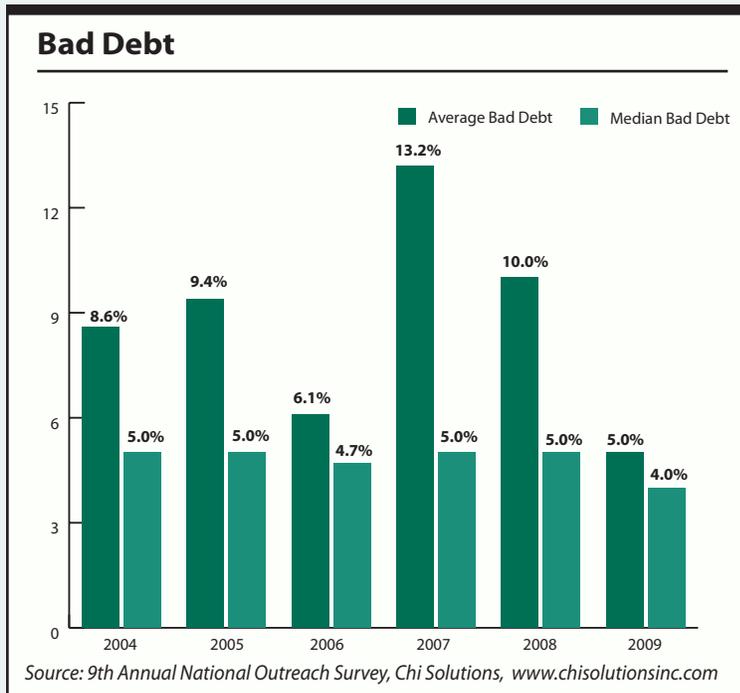
tor to outreach programs, with 39.7 percent of respondents citing Quest and 33.3 percent citing LabCorp. Regional independent laboratories are in third (13.8 percent), followed by regional hospital outreach programs and physician group laboratories (both less than 1 percent).

Most lab outreach programs responding to the survey indicated that they were either holding their own or gaining against the national laboratories based on benchmarking data and metrics. "There is a lot of evidence to show that the competitive landscape is favoring hospital labs," said Murphy.

Trend 4: Mergers and Acquisitions on the Rise

M&A activity in the lab area has picked up in the past year and is likely to continue to rise, says Murphy. Hospital lab outreach programs are part of this trend, with almost 17 percent of survey respondents saying that their hospital had been approached about selling the lab outreach program to a national or regional competitor. More than 14 percent of respondents said they are contemplating growth of their outreach program via acquisition of a lab or lab outreach program.

"Lab values are up and hospitals are strapped for cash, so it makes sense that outreach labs would make attractive acquisition targets," noted Murphy. "Many hospitals are looking to cash out of the lab business. This is consistent with other phenomena that we are seeing in health care overall."



Trend 3: Improvements in Billing

The survey revealed both good and bad news in this area, said Murphy. The good news is that both bad debt and DSO have improved over the past six years (see chart). The bad news is that only 30 percent of respondents actually know their bad-debt rate and DSO.

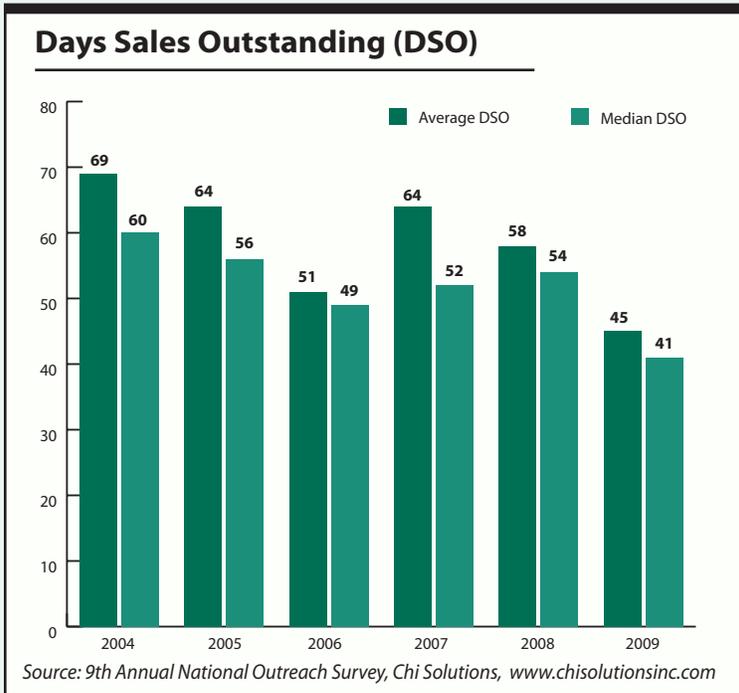
How can 70 percent of labs not know this information? "Less than 10 percent of labs outsource their billing," explained Murphy. "The vast majority of outreach labs use their hospital billing system, and most of the time they don't use line item posting.

That is a huge disadvantage if

you are in that situation because you can never track any billing-specific metrics. So billing is getting better but only for a small subset of the industry. It's still a big challenge for the rest of us."

Trend 2: Move Toward Diagnostics

Hospitals are continuing to move toward integration of diagnostic services, at least in terms of marketing. More than 38 percent of respondents



said they marketed other services along with laboratory services (up from 28 percent last year). The most common service to be comarketed is imaging (53.2 percent), followed by cardiology (21 percent), physical therapy (14.5 percent), occupational therapy (9.7 percent), and pharmacy (1.6 percent).

“The margins are much higher in these other areas, particularly imaging,” noted Murphy. “So the margins in a combined lab and imaging program are over two times that of lab alone. Moving toward a blended diagnostic model really makes sense from an economic point of view.”

Trend 1: Management by Braille

Despite improvements in key performance indicators cited by many respondents to the survey, far too many hospitals don’t really know how their lab outreach programs are performing, explained Murphy. Almost 68 percent of respondents say they don’t have the information, management reports, and key performance indicators to manage their business.

‘Typical’ Outreach Program

Net Revenue	\$5.6 million
Revenue Per Test	\$19.45
Revenue Per Requisition	\$68.08
Revenue Growth	12.2%
Profitability	15%-24%
Competitive Problems	IT, managed care, pricing
Billing	7.5% outsourced
Bad Debt	4%
DSO	41 days

Source: 9th Annual National Outreach Survey, Chi Solutions, www.chisolutionsinc.com

Almost 72 percent say they are not confident that they are collecting everything they can, and only 27 percent say they are benchmarked against other organizations with comparable outreach volume.

“Hospital labs are managing multimillion-dollar business by feeling their way,” said Murphy. “While outreach labs are competing well against

the national labs, they really need to do a better job of collecting data and benchmarking themselves against others. Imagine the potential that could be unleashed if outreach programs had the same systems in place to manage their programs as the national labs do.” 🏛️



Obama Signs Bill for Medicare Physician Fee Fix, Measure Cancels 21% Cut – For Now

President Obama June 25 signed into law legislation that provides a 2.2 percent update to fees paid under the Medicare Part B physician fee schedule retroactive from June 1 through Nov. 30, 2010.

The bill, the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010, passed the House June 24 following Senate approval of the measure June 18. The measure cancels the 21 percent cut in Medicare physician fees that took effect June 1 when the congressionally mandated freeze keeping fees at their 2009 levels expired May 31.

The Centers for Medicare and Medicaid Services (CMS) had directed contractors to hold physician claims with a date of service on or after June 1 through June 17, anticipating congressional action by then. But on June 18, with no legislative reprieve, CMS began processing the claims with the cut required under the Sustainable Growth Rate (SGR) formula used to update fees each year.

The short-term fix does not repeal the SGR formula that has triggered negative updates to Medicare physician fees for most of the past decade. An SGR cut is scheduled to return Dec. 1, 2010, when the current fix expires, unless Congress intervenes.

The agency now has directed Medicare contractors to discontinue processing claims at the negative update rates and to temporarily hold all claims for services rendered June 1, 2010, and later, until the new 2.2 percent update rates are tested and loaded into the contractors' claims processing systems. "Effective testing of the new 2.2 percent update will ensure that claims are correctly paid at the new rates. We expect to begin processing claims at the new rates no later than July 1, 2010," the agency said in a statement.

Claims containing June 2010 dates of service that have been paid at the negative update rates will be reprocessed as soon as possible, CMS said. Physician payments under the Part B fee schedule are based on the lesser of the submitted charge on the claim or the fee schedule amount. Claims containing June dates of service that were submitted with charges greater than or equal to the new 2.2 percent update will be automatically reprocessed.

Physicians who submitted claims containing June dates of service with charges less than the 2.2 percent update will need to contact their local Medicare contractor to request an adjustment. Physicians should not resubmit claims already submitted to their Medicare contractor.

The short-term fix does not repeal the SGR formula that has triggered negative updates to Medicare physician fees for most of the past decade. An SGR cut is scheduled to return Dec. 1, 2010, when the current fix expires, unless Congress intervenes. 



Medicare Proposes 6.1 Percent Cut in 2011

The Centers for Medicare and Medicaid Services (CMS) June 25 proposed a 6.1 percent cut for physician services that would take effect Jan. 1, 2011, and other changes to the Medicare Part B fee schedule, including enactment of provisions in the health care reform law.

The proposed cut was announced the same day that President Obama signed the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 (H.R. 3962). The measure replaced the 21.3 percent reduction in physician

payment rates required by the sustainable growth rate formula for 2010 with a 2.2 percent increase in effect through Nov. 30 (see item above). It makes the conversion factor \$36.8729.

The Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act (HCERA) made a number of changes affecting physicians that are expected to be included in the final *Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011*, to be published by Nov. 1.

The proposed rule would waive the Part B deductible and the 20 percent coinsurance that have been applied to most preventive services and would offer incentive payments equal to 10 percent of a primary care practitioner's allowed charges for primary care services under Part B.

The rule also would institute changes in the Physician Quality Reporting Initiative that offers an incentive payment to doctors and other professionals covered by the fee

schedule and would extend the payments through 2014.

Beginning in 2011, 20 more PQRI measures would be added, including those for reporting through registries and electronic health records. It would also add a group practice reporting option that would allow those with fewer than 200 professionals to participate. Four years later—in 2015—professionals who do not satisfactorily report would be subject to a 1.5 percent penalty.

Under the "E-Prescribing Incentive Program," professionals who perform successfully under program rules in 2011 would be able to earn an incentive payment of 10 percent of their estimated total allowed charges for fee schedule services during the reporting period. 🏠

FDA to Hold Meeting on Laboratory-Developed Tests

The Food and Drug Administration plans to hold a public meeting in July to solicit comments on how the agency can effectively regulate laboratory-developed tests (LDTs). The meeting will take place July 19-20 in Rockville, Md. The comment period for the public meeting closes on Aug. 15.

In a June 17 Federal Register notice, FDA says that initially the agency viewed LDTs as relatively simple, well-understood tests that diagnosed rare diseases and conditions and were intended to be used by physicians and pathologists in a single institution where they were actively involved in patient care. The tests were ordinarily well-characterized, low-risk diagnostic tools.

Yet in the past 15 years, FDA says, the nature of LDTs has changed dramatically. Today, the tests are becoming more complex and high risk and are playing an increasingly important role in clinical decisionmaking. "As a result, LDTs that have not been properly validated put patients at risk, such as for missed diagnosis, wrong diagnosis, and failure to receive appropriate treatment," the agency said. "Therefore, FDA believes that a risk-based application of oversight for LDTs is appropriate and seeks public input on issues and concerns related to LDT oversight."

More information about the meeting is available at www.federalregister.gov or www.fda.gov.

CMS to Allow Contractor Discretion in MRA Coverage

The Centers for Medicare and Medicaid Services (CMS) June 3 issued a final decision memo merging the coverage of magnetic resonance angiography (MRA) with magnetic resonance imaging (MRI).

CMS said its change would permit local Medicare contractors to cover (or not cover) all indications of MRA that are not specifically nationally covered or nationally noncovered. The decision, which took effect when the memo was released, affirms an earlier proposed decision memo which stated that coverage for MRA should be merged with the same national coverage as MRI.

The agency said MRA is a noninvasive diagnostic test that is an application of MRI. Since MRA is a specific application of MRI, CMS said it believes that the continued existence of separate national coverage decisions is unnecessary. 🏛️

Medical Device Firms Ask Regulators to Reduce Delays

Representatives of the medical devices industry June 22 sharply criticized the federal agency that regulates them, complaining of increased delays in product clearance for marketing, shifts in agency interpretation of guidance, and more burdensome requests for data.

Speaking at a “town hall meeting” sponsored by the Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH)—held in Woburn, Mass.—speakers also expressed reservations about the agency’s plans to tinker with its 510(k) premarket notification process.

Pam Weagraff, representing the Massachusetts Medical Device Industry Council (MassMEDIC), said that device companies “see an emerging pattern” of an increase in the scope and types of information requested, reduced predictability and transparency, and more delays. There is also an “increasing reluctance” by the agency to engage in talks with the industry to discuss alternative solutions, and CDRH has failed to readily communicate its shifts in the interpretation of guidance, Weagraff said.

Increasing regulatory uncertainty and inconsistency are “bankrupting emerging companies,” according to Paul LaViolette of SV Life Sciences. LaViolette urged the agency to consider a “special pathway for breakthrough technology,” suggesting that investors would not object to additional fees for such a process. “Innovative devices should be evaluated on the actual level of risk they present,” he said, adding that the current de novo system is burdensome. 🏛️



Lab Index Continues to Fall, Down 6% in June

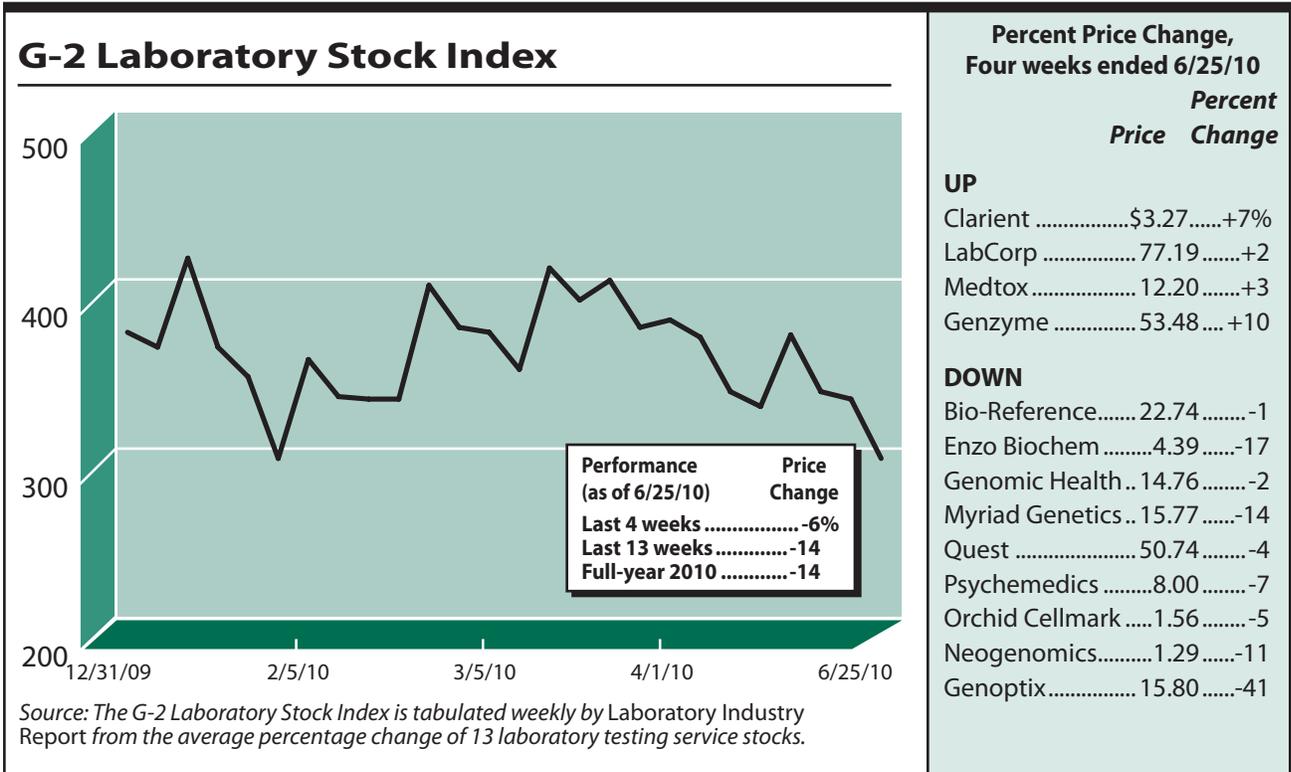
The G-2 Reports' Laboratory Stock Index continued its decline in June, with the index falling 6 percent in the four weeks ended June 25, 2010. For the year, the index is down 14 percent. In comparison, the Nasdaq composite is down 2 percent, and the S&P 500 is down about 3 percent.

Only four of the publicly traded lab companies tracked by the index posted gains during the period while nine saw their share prices decline. **Genzyme** (Cambridge, Mass.) posted the biggest gain during the period with shares climbing 10 percent to \$53.48 for a market cap of \$14.27 billion.

Shares of **Clariant** (Aliso Viejo, Calif.) rose 7 percent to \$3.27 for a market cap of \$277.96 million. The company said June 8 that it had received a U.K. patent on the company's TLE3 biomarker, which may be used to predict which cancer patients will respond favorably to taxane therapy. In addition, the company received a notice of allowance from the U.S. Patent and Trademark Office for a U.S. patent on the TLE3 biomarker.

For the second month in a row, **Genoptix** posted the biggest loss during the period, with its shares falling 41 percent to \$15.80, giving it a market cap of \$276.77 million. Shares of **Enzo Biochem** (New York City) fell 17 percent to \$4.39 for a market cap of \$167.48. Company officials June 9 reported that the company's third-quarter loss grew as it spent more in the period this year than last year. Though Enzo's revenue rose to \$23.8 million from \$23.1 million in the quarter, the company lost \$4.6 million, or 12 cents per share, compared to \$4.2 million, or 11 cents per share, a year ago. 🏰

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



First Lab Earns Global Accreditation

Spectra Laboratories (Rockleigh, N.J.) has become the first U.S.-based medical testing laboratory to earn accreditation in accordance with the international requirements of ISO 15189:2007, according to the American Association for Laboratory Accreditation (A2LA). Spectra is a unit of Fresenius Medical Care North America.

A2LA's ISO 15189:2007 accreditation is recognized by all 65 of the signatories to the International Laboratory Accreditation Cooperation mutual recognition agreement and 32 signatories to the Asia-Pacific Laboratory Accreditation Cooperation mutual recognition agreement. This means that Spectra Laboratories' accreditation will be recognized in all of the signatories' economies.

A2LA is a nonprofit, nongovernmental, public service, membership society whose stated mission is "to provide comprehensive accreditation services for laboratories, inspection bodies, proficiency testing providers, and reference material producers." Services are available to any type of laboratory or inspection body, product certification body, reference material provider, and proficiency testing provider, whether governmental or private. It is the largest multidiscipline accreditation body in the United States. 🏛️

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Quest Diagnostics 800-222-0446

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