

LABORATORY INDUSTRY REPORT®

Kimberly Scott, Senior Editor, kscott@ioma.com

Issue 10-05/May 2010

HIGHLIGHTS

TOP OF THE NEWS

G-2 Reports estimates MDx market to climb 12% in 2010 to over \$6 billion 1

Medicare physician fee cuts blocked through May 1

EARNINGS UPDATE

Winter weather hurts Quest, LabCorp first-quarter 2

INDUSTRY NEWS

Impact on innovation, access now center of gene patent debate 3

Health care reform's productivity adjustment, 5-year fee schedule cut key provisions for labs 4

CMS resumes payment for pathology TC claims 7

INSIDE THE LAB INDUSTRY

Top 5 molecular diagnostic trends 5

NEWSMAKERS

Hawaii's Diagnostic Laboratory Services to pursue MDx 8

Genomic Health signs deal to distribute Oncotype DX in Spain, Portugal 8

Lab index continues to rise, up 5% in last 5 weeks 11

INDUSTRY BUZZ

Duke teams with LabCorp on biomarkers, personalized medicine .. 12

Have You Registered?

Laboratory Outreach 2010:

Building the Value Equation

For Your Program

June 2-4, 2010

Hyatt Regency, Baltimore, MD



WASHINGTON
G-2 REPORTS

www.g2reports.com

G-2 Reports Estimates Mol Dx Market to Climb 12% in 2010 to Over \$6 Billion

Washington G-2 Reports is estimating that the molecular diagnostic testing market will grow 12 percent in 2010 to \$6.2 billion. This is over double the expected growth of 5 percent in most other areas of laboratory testing services, explained Managing Editor Stephanie Murg at the recent G-2 Reports' conference, Molecular Diagnostics 2010: Putting MDx to the Test: How Your Lab Can Capitalize on Molecular Diagnostics, held April 14-16 at the Hyatt Regency in Cambridge, Mass.

Looking ahead, this testing market is expected to grow to \$8 billion by 2012. However, molecular diagnostic testing is only offered at a small fraction of the clinical labs under CLIA. Of the over 200,000 CLIA labs, only an estimated 3 percent conducted molecular diagnostic testing in 2008, Murg explained. "Two huge roadblocks in bringing this testing into a lab are lack of standardization and clinical utility, which is the need for an accepted process to establish clinical utility," she added.

For more highlights of the conference, including the top five trends currently driving molecular diagnostic testing, please read "Inside the Industry," on pp. 5-6. 🏛️

Medicare Physician Fee Cut Blocked Through May

On April 15, President Barack Obama extended the Medicare physician fee cut freeze through May 31, 2010, by signing into law the Continuing Extension Act of 2010. This freeze had been in effect for claims with dates of service from Jan. 1 through March 31 and is now retroactive to April 1. Without the freeze, the physician fee schedule is slated to be cut by 21 percent.

In response, the Centers for Medicare and Medicaid Services announced that claims with dates of service April 1 and later that were being held by Medicare contractors are being released for processing and payment. The statutory payment floors still apply and, therefore, clean electronic claims cannot be paid before 14 calendar days after the date they are received by contractors (29 calendar days for clean paper claims).

Continued on page 2



■ **MEDICARE PHYSICIAN FEE CUT BLOCKED THROUGH MAY**, *from page 1*

The extension law also contains a provision that permits certain hospital-based physicians to be eligible for health information technology incentives for “meaningful use,” as authorized by the American Recovery and Reinvestment Act (Pub. L. 111-5).

It also extends eligibility for a 65 percent subsidy for health care coverage under the Consolidated Omnibus Budget Reconciliation Act. 🏠

Winter Weather Hurts Quest, LabCorp First-Quarter Results

Severe weather in the first few months of the year hurt first-quarter results for both Quest Diagnostics (Madison, N.J.) and LabCorp (Burlington, N.C.), leading Quest to cut its full-year revenue forecast.

Quest posted a nearly 3 percent decline in quarterly net income April 21 while profit was basically flat at LabCorp. Both companies cited the impact from winter storms, which kept people from getting lab exams.

Quest’s first-quarter revenues were \$1.8 billion, unchanged from the 2009 level. Clinical testing revenues decreased 0.4 percent compared to the prior year. Revenue per requisition increased 2.3 percent and clinical testing volume decreased 2.6 percent. Severe weather is estimated to have reduced growth in clinical testing revenues and volume by 1 percent.

For the first quarter, Quest’s operating income was \$299 million, or 16.5 percent of revenues, compared to \$321 million, or 17.8 percent of revenues, for the same period in 2009. The charge associated with workforce reductions and the estimated impact of severe weather reduced the year-over-year change in operating income as a percentage of revenues by 1.6 percent.

Quest’s bad-debt expense as a percentage of revenues improved to 4.2 percent from 4.5 percent in the prior year. Days sales outstanding improved to 41 days, compared to 43 days a year ago. Cash flow from operations was \$239 million, compared to \$273 million in the first quarter of 2009. During the quarter, the company repurchased \$251 million of its common shares and made capital expenditures of \$40 million.

LabCorp Results

LabCorp reported net earnings of \$132.7 million, compared to \$132.8 million in the first quarter of 2009. Earnings per diluted share (EPS) were \$1.25 compared to \$1.22 in 2009. Excluding restructuring and other special charges recorded in 2010, adjusted EPS were \$1.30 compared to \$1.22 in 2009.

Revenues for the quarter were about \$1.2 billion, an increase of 3.3 percent over the same period last year. Testing volume decreased 3 percent, and revenue per requisition increased 6.4 percent. Excluding the consolidation of the company’s Ontario, Canada, joint venture, revenue increased 2.2 percent, testing volume decreased by 3.3 percent, and revenue per requisition increased 5.7 percent.

LabCorp estimates that inclement weather during the quarter reduced volumes by an estimated 1.3 percent, revenue by about \$23 million, and earnings by about 8 cents. The continuing impact of two large government contracts terminated during 2009 reduced volume by an additional 2.4 percent. Excluding the impact from weather and lost contracts, volume increased 0.4 percent in the quarter.

Earnings Outlook

For full-year 2010, Quest is modifying its previously projected revenue growth of 3 percent to 4 percent downward to 1 percent to 2 percent. Full-year earnings per diluted share from continuing operations, adjusted for the impact of special charges and weather in the first quarter, are unchanged at between \$4.10 and \$4.30.

LabCorp reaffirmed its 2010 guidance, expecting revenue growth of 2.5 percent to 4.5 percent. Adjusted earnings per share is projected at \$5.35 to \$5.55, excluding the impact of any share repurchase activity after March 31, 2010. 🏠

Impact on Innovation, Access Now Center of Gene Patent Debate

When Judge Robert Sweet of the U.S. District Court for the Southern District of New York recently ruled that patents held by Myriad Genetics (Salt Lake City) on BRCA genes were invalid, the decision was hailed by supporters as a victory for the free exchanges of scientific research. The ruling was in response to a lawsuit filed in May 2009 by the American Civil Liberties Union (ACLU) on behalf of patients, women's health groups, pathology groups, other medical organizations, and research centers (*Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*).

The ACLU hailed the decision, stating that it marked the first time a court had found human gene patents unlawful. The decision also calls into question the validity of the patents currently held on approximately 2,000 human genes, including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, and asthma.

"The human genome, like the structure of blood, air, or water, was discovered, not created. There is an endless amount of information on genes that begs for further discovery, and gene patents put up unacceptable barriers to the free exchange of ideas," said Chris Hansen, a staff attorney with the ACLU First Amendment Working Group. "Today's ruling is a victory for the free flow of ideas in scientific research."

In addition, access was also an issue, as Myriad is the only testing provider offering the BRCAAnalysis predictive tests for ovarian and breast cancer. The ACLU said Myriad's monopoly on the BRCA genes makes it impossible for women to access alternate tests or get a comprehensive second opinion about their results. The monopoly also allows Myriad to charge a high rate for their tests (approximately \$3,200 per test), the plaintiffs said.

Continued on page 9



Health Care Reform's Productivity Adjustment, 5-Year Fee Schedule Cut Key for Labs

The full productivity adjustment and the five-year, 1.75 percent cut in the clinical lab fee schedule contained in the health care reform legislation will save the government a total of \$10 billion over 10 years and were necessary concessions for the government to expand coverage to an estimated 31 million Americans, explained Alan Mertz, president of one of the lab industry's primary lobbying organizations, the American Clinical Laboratory Association, during a conference call in early April.

"We believe that this will allow millions of more Americans to get access to valuable diagnostic laboratory services, which we believe are the foundation to good health care and outcomes for people," he said. "All providers had to make a contribution to this, and we were willing to do our proportional part to provide savings to the government so they could expand coverage."

The two initiatives that directly impact labs are, of course, the two reimbursement cuts—the productivity adjustment and the five-year cut to the lab fee schedule that will begin in 2011. The productivity adjustment replaces the 0.5 percent payment reduction that was initially put in place in 2008 and set to continue for five years until 2013. This reduction was agreed to by the government and the lab groups in exchange for the repeal of competitive bidding in 2008. This payment reduction will be replaced with a permanent full productivity adjustment beginning in 2011.

"For labs, the critical issue is that we are the only provider for which the productivity adjustment could have cut below zero, resulting in a negative update," said Mertz, who added that there are protections in the reform legislation protecting against a zero update. The Congressional Budget Office (CBO) estimates that the resulting savings will be \$5 billion over 10 years.

The deal that ACLA and most all of the rest of lab industry groups made in September 2009 was that a 1.75 percent cut for five years on the clinical lab fee schedule was far preferable to a permanent 2 to 3 percent tax on all lab revenue.

Lab Fee Schedule Cut

The second adjustment is the 1.75 percent annual cut to the clinical lab fee schedules from 2011 to 2015. "This adjustment could drive us below zero if the consumer price index (CPI) update is less than 1.75, but it does end after 2015," said Mertz.

CBO estimates this cut will also result in \$5 billion in savings over 10 years, even though the cut is for five years. This savings occurs

in the outlying years because the cut reduces the baseline spending by between 9 percent and 10 percent, he added.

"This is assuming that CBO's estimate of the annual consumer price index ranges from 1.3 percent to about 1.9 percent," said Mertz, adding that this was one of the issues that ACLA factored in when deciding whether to

Continued on page 7

G-2's Top 5 Mol Dx Trends: Demand for Faster Pharmacogenomic Results and Data Driving Growth of Market

The molecular diagnostic testing market continues to grow at a vigorous rate, with growth estimated to be 12 percent in 2010 to reach \$6.2 billion, according to market projections revealed at G-2 Reports' Fifth Annual Molecular Diagnostics Conference, held April 14-16, in Cambridge, Mass. Far greater than the 5 percent growth rate for most areas of the lab industry, molecular diagnostic testing market is expected to reach \$8 billion by 2012.

To assess what's driving this market, G-2 Managing Editor Stephanie Murg outlined the following top five trends in molecular diagnostic testing during her conference presentation.

Trend 1: Seizing relevant opportunities in health care reform

The recently passed health care legislation requires insurers to offer preventive testing services rated "A" or "B" by the U.S. Preventive Services Task Force (www.ahrq.gov/clinic/prevenix.htm). These tests will be provided at no additional out-of-pocket costs. In addition, beginning next year, all Medicare enrollees will be entitled to free screenings as part of an annual checkup.

However, this era of reform is also accompanied by a shift to increased regulation, especially to demonstrate cost-effectiveness and clinical utility.

Top MDx Tests Offered by Labs

- CT/NG
- HPV
- HCV
- HIVTop MDx

Tests Labs Are Planning to Add

- HSV
- CF
- HCV quantitative
- CYP450

Source: G-2 Reports' *Mol Dx Testing Survey, 2009*
(over 100 labs surveyed)

Trend 2: Accelerated adoption of pharmacogenomics

There are currently approximately 1,500 gene-based tests currently available, many of which play a vital role in drug selection, dosing, monitoring, as well as avoiding therapy-related adverse reactions or ineffectiveness. Warfarin sensitivity testing, Roche's CYP450 AmpliChip, and Third Wave/Hologic's UGT1A1 assays have driven adoption of personalized medicine and have helped to carve out a path for pharmacogenomic tests to get to market faster.

Trend 3: Increased focus on filling the data/measurement void

Everyone is desperate for more data regarding the effectiveness of molecular diagnostic testing—from payers and government regulators to clinicians.

Managed care companies are demanding this data, which will have implications for coverage policies, as well as coding utilization management and claims systems. There's also a push for the data for cost-benefit analysis and linking test results to outcomes.

Trend 4: Personal genomics gets serious

No doubt, there are more consumer-directed testing services, backed by expansive marketing efforts. These consumer-directed tests range from pa-

ternity testing to more comprehensive genome analysis, now that DNA sequencing is stepping more into the consumer market. While personal genome sequencing is still on the pricey side—about \$3,000—prices are falling fast. However, there are interpretation challenges—what do the results of a genome sequence actually mean, and how will these results be applied, if at all?

There are also regulatory questions about how the Food and Drug Administration will regulate the sequencing technology, as well as different state licensing requirements regarding this type of testing. Quality assurance is another issue, as well as questions concerning the correlations of medical evidence with genomic data. All of this impacts the willingness of medical professionals and insurers to reimburse for these tests.

Trend 5: Increased demand for faster and cheaper tests

Now that molecular diagnostics has moved beyond polymerase chain reaction (PCR) processing, there is a broader commercialization of extant assays, which will decrease costs. Tests are performed at a faster turn-around time, with higher sensitivity at small concentrations. In addition, there are more tests that can be performed on a smaller platform.

In addition, there also appears to be a move to develop technologies that can be easily adapted to low-complexity settings—maybe even in the direction of developing point-of-care molecular diagnostic tests. Given the pace and direction at which this field of testing is moving—it's no longer out of the realm of possibility. 🏠

Perkin-Elmer Buys Signature Genomic Laboratories for Estimated \$90 Million

In an effort to bolster its presence in the molecular diagnostic testing market, Waltham, Mass.-based PerkinElmer has announced that it will acquire Spokane, Wash.-based Signature Genomic Laboratories. The deal is expected to strengthen PerkinElmer's genetic testing and early disease detection capabilities. Financial details were not officially disclosed, but the transaction price is rumored to be \$90 million.

Signature was founded in 2003 by Lisa G. Shaffer, Ph.D., and Bassem A. Bejjani, M.D. The testing provider is focused on microarray-based cytogenetic testing of chromosome abnormalities in individuals with unexplained physical and developmental disabilities.

Signature's microarray diagnostic technology is available for both prenatal and post-natal identification of DNA alterations associated with genetic disease. This is in sync with PerkinElmer's neonatal and newborn testing capabilities, which has been expanding since its February 2008 acquisition of the newborn metabolic screening business of the Pediatrix Medical Group. 🏠



■ HEALTH CARE REFORM, from page 4

accept this cut in exchange for the repeal of the \$7.5 billion annual tax, which was proposed by the Senate Finance Committee last summer.

“The deal that ACLA and most all of the rest of lab industry groups made in September 2009 was that a 1.75 percent cut for five years on the clinical lab fee schedule was far preferable to a permanent 2 to 3 percent tax on all lab revenue,” he explained. “We figured out that in any year where inflation is 3 percent or more, we will actually not be cut at all. If the inflation is over 3 percent, then we will actually get an increase.”

CMS Resumes Payment for Pathology TC Claims

CMS is now accepting claims from independent clinical labs that bill for the technical component (TC) for pathology services under the “grandfather” protection. They may now submit claims for these services furnished on and after Jan. 1 of this year and be paid, the agency announced March 30.

The “grandfather” protection allows independent clinical laboratories to bill Medicare Part B separately for the TC of pathology services to inpatients and outpatients. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology.

CMS acted in response to the extension of the “grandfather” protection granted in the new health care reform law. The protection lapsed at the end of 2009 and was not restored until the president signed the Patient Protection and Affordable Care Act on March 23. It applies to claims with dates of service on and after Jan. 1, 2010, through Dec. 31, 2010.

The agency had previously advised qualified labs to hold these claims pending legislative action and said that until Congress acted, it would not pay any that were submitted, according to G-2 Reports’ *National Intelligence Report*.

The agency is now advising labs to contact their Medicare contractor if they previously submitted a claim for services covered by the “grandfather” protection that was denied.

Positive Provisions

Apart from the reimbursement cuts, ACLA is applauding a number of the reform legislation’s provisions. Notably, the legislation contains incentives for prevention and wellness testing. “Under the insurance plans in the new network exchange, there are some helpful provisions that provide testing coverage related to prevention and wellness that would eliminate or sharply limit the copays, deductibles, and out-of-pocket costs for these services,” said Mertz.

To be included in these service provisions, the testing had to receive an “A” or “B” rating from the U.S. Preventive Services Task Force (USPSTF). Mertz said that there was concern that certain testing services would be excluded following USPSTF’s November 2009 mammography guidelines that recommended against routine mammography screening for women in their 40s, as well as a reduction in frequency for screening older women at average risk of developing breast cancer.

ACLA was also pleased that the health care reform legislation included an extension of the grandfather clause allowing independent labs to receive payment for the technical component of certain pathology interpretation services. The extension is through the end of this year (see box).

“We would like a permanent extension of the TC, but when we saw what was happening with the rural extenders provision, as well as the SGR [sustainable growth formula-related 21 percent physician fee cut], which are now falling outside of health care reform, had we not had this extension in the Senate bill, I think we would still be in a situation where the TC had not been extended, but it is now,” said Mertz. 🏛️



Hawaii's Diagnostic Laboratory Services to Pursue Mol Dx Growth

Hawaii's largest locally owned testing provider, Diagnostic Laboratory Services (DLS; Honolulu), is doubling in size with plans to move into an 84,000-square-foot, \$20 million facility by the end of 2010. The expansion is a key part of the company's strategy to grow its molecular testing business lines, particularly infectious disease testing. DLS has an annual estimated revenue of \$80 million.

"Our growth strategy has been in place for the past 10 years and now we're putting it into action," explained Jonn Ragle, DLS's vice president of business development. "This expansion is giving us some room to grow as the opportunities present themselves. We need to be able to meet the growing needs of our physicians here, and one of the areas that we are focused on is in infectious disease and molecular testing.

DLS already jump-started the effort, Ragle says, by bringing on noted expert in infectious disease and clinical and molecular biology, Matthew J. Bankowski, Ph.D., in 2007. Bankowski was formerly with the ViroMed Laboratories in Minnetonka, Minn., which is owned by LabCorp.

DLS has two contracts with the Centers for Disease Control and Prevention involving tuberculosis testing in the Pacific Rim region, which will require additional capacity. DLS currently has 600 employees located in 44 locations throughout Hawaii, as well as Guam and Saipan. In addition, DLS is looking to expand its reach to the U.S. mainland, capitalizing on its expertise in setting up labs.

Ragle says DLS hasn't been significantly impacted by the purchase of its main competitor, Clinical Labs of Hawaii, by Sydney, Australia-based lab testing leader Sonic Healthcare in June 2008. DLS focuses on the physician market on the island of Oahu, where 90 percent of the population resides. DLS believes that they have captured the majority of the private physician office business. 🏢

Genomic Health Signs Deal to Distribute Oncotype DX in Spain, Portugal

Redwood City, Calif.-based Genomic Health has signed a deal with Palex Medical S.A. to distribute its Oncotype DX breast cancer test in Spain and Portugal.

The test already has widespread adoption, even outside the United States. According to the company, more than 135,000 Oncotype DX breast cancer tests—which assess the benefit of chemotherapy treatment as well as the likelihood of recurrence—have been ordered by over 8,000 physicians in 55 countries.

The deal with Palex Medical comes months after the January 2010 launch of the Oncotype DX colon cancer test, which is the first multigene expression test commercially available that has been clinically validated to predict risk of recurrence in patients with stage II colon cancer. In its 2010 financial guidance, Genomic Health officials announced that they expected test results delivered of 58,000 to 61,000, which includes both Oncotype DX breast and colon cancer tests. 🏢



■ GENE PATENT DEBATE, from page 3

Controversial Decision

Sweet's decision is "a stretch," given contrary court rulings, Royal Craig, a patent law expert with Ober/Kaler in Baltimore told Washington G-2 Reports' *National Intelligence Report*. One he cited in particular arose in 1911 from the same New York court now headed by Sweet. That decision upheld the patentability of purified adrenaline. In *Parke-Davis & Co. v. H.K. Mulford Co.*, the court said the purified naturally occurring substance was "a new thing commercially and therapeutically."

But the ACLU lawsuit against Myriad is the first case that has touched a highly personal nerve by raising the issue of who owns your DNA, Craig told NIR, because of the wide publicity given to women plaintiffs who said the patents prevented them from getting a second opinion from any other source.

With Myriad set to appeal Sweet's ruling, the question for the appellate court is whether he committed legal error by ignoring Myriad's arguments based on previous legal rulings.

It is likely, he added, that the furor surrounding the BRCA gene patents might induce Myriad to attempt to accommodate some of the concerns raised over patients' access to critical testing and restrictions on basic and applied research. Myriad obviously is not in business to hurt patients, he pointed out.

SACGHS Recommends Legislative Solution

The HHS Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) weighed in earlier this year on the gene patenting issue and its implications for personalized medicine. The panel on Feb. 5 recommended that the secretary of Health and Human Services (HHS), Kathleen Sebelius, limit the ability of gene patent holders to keep others from using those genes for diagnostic and research purposes. The report included a statement of dissent from three committee members.

The committee approved six formal recommendations, beginning with statutory changes that would exempt from liability for gene patent infringement "anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes" and those who use patent-protected genes in research.

Subsequent recommendations, which could be accomplished more quickly, include promoting adherence to norms (such as nonexclusive licensing) that are designed to ensure access. SACGHS also called for more transparency in licensing, an advisory body on the health impact of gene patenting and licensing practices, and close work with the U.S. Patent and Trademark Office to provide expertise on genetic testing issues.

Effect on Innovation

Sweet's ruling "goes to the balance given in the patent system to limited monopolies that spur innovations," according to Craig, who added that patents provide companies with market security and the ability to profit from risking their investment of time and money in bringing tests and drugs to market.

Another patent attorney interviewed by LIR agreed with Craig on the value of patents and believes that not patenting genes could actually slow down innovation. "Innovation happens, but the question is how quickly does it get translated into something commercially viable?" said Kevin Noonan, Ph.D., a molecular biologist who is also a patent attorney and partner at McDonnell Boehnen Hulbert & Berghoff LLP in Chicago. "By commercially viable, I mean something that has enough profit potential to interest early-stage investors so that it has a chance to be a successful



product that people can rely on. There's a lot of work and money that goes into this development."

In fact, Noonan believes that without the ability to patent a gene, there will be no incentive for a diagnostic or other biotechnology company to disclose information related to research and discovery of genes and genetic mutations. "The risk is that if you push the patent protection underground, then people will figure it out, but they will figure it out much less efficiently and slowly and in ways that they won't have to disclose it," he explained. "In fact, the disclosure that you need in the patent system is a lot greater than in a research paper. But there is now a premium on nondisclosure, where previously, the patent put the premium on disclosure." 🏛️

Reimbursement Protection Tops ACLA Priorities in Coming Year

Concerned about continued reimbursement pressure on labs, the American Clinical Laboratory Association (ACLA) has made protecting lab payment one of its top priorities for the coming year, says ACLA President Alan Mertz.

Reimbursement issues dominated the discussion at the ACLA annual meeting, held April 22-23 in Washington, D.C. More than 120 representatives from clinical laboratories participated in the meeting.

One of the group's top concerns is implementation of the recently passed health care reform bill, which imposed a 1.75 percent cut in the clinical lab fee schedule over five years beginning in 2011 and repealed the 0.5 percent productivity adjustment for labs, which was scheduled to continue until 2013 (*see related article on pg. 4*).

ACLA also plans to continue discussions with Congress and the Centers for Medicare and Medicaid Services (CMS) over billing, reimbursement, and coverage issues, including carrier local coverage determinations (LCDs), medically unlikely edits (MUEs), payment bundling, Medicare's date-of-service demonstration, and setting appropriate codes for molecular diagnostic tests.

The association also plans to seek a permanent extension to the so-called "grandfather" protection that allows independent clinical labs to bill Medicare for the technical component of pathology services provided to hospital inpatients and outpatients. The extension is currently in place through Dec. 31, 2010.

Finally, ACLA intends to continue its focus on how lab-developed tests (LDTs) are regulated. Currently, the Food and Drug Administration (FDA) has enforcement discretion over LDTs but appears to be moving toward increased oversight of the tests. The FDA in 2007 issued proposed guidance on in-vitro diagnostic multivariate index assays (IVDMIA) but has yet to finalize the guidance document. However, Alberto Gutierrez, Ph.D., director of FDA's Office of In-Vitro Diagnostics, said during the ACLA meeting that the agency has begun to see some adverse events related to LDTs and has developed a tracking system for these tests. 🏛️



Lab Index Continues to Rise, Up 5% in Last Five Weeks

The G-2 Reports' Laboratory Stock Index continued its rebound in late March and early April, with the index up an unweighted average of 5 percent in the five weeks ended April 23, 2010. For the year, the index is up 7 percent. In comparison, the Nasdaq is up 9 percent, and the S&P 500 is up 6 percent.

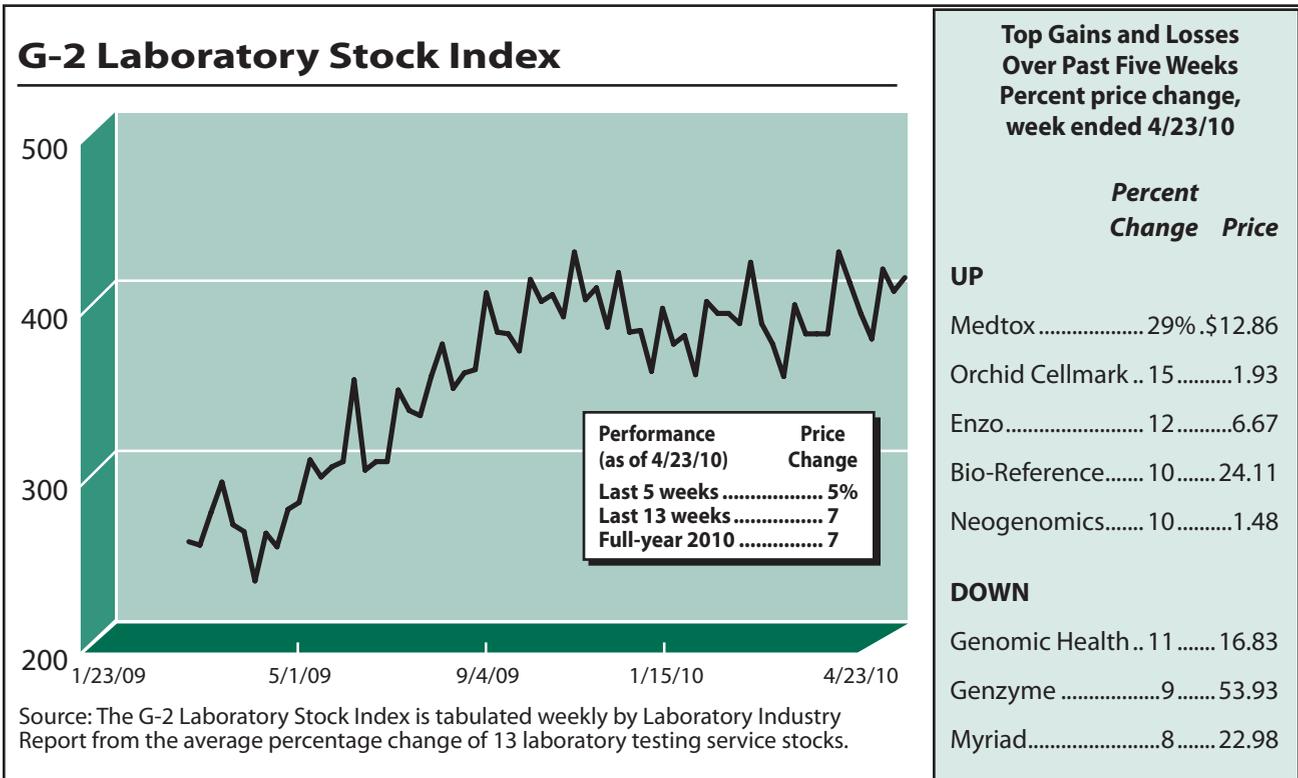
Nine of the publicly traded lab companies tracked by the index posted gains during the period while four saw their share price fall. The biggest gainer was **Medtox Scientific** (St. Paul, Minn.), whose share price increased 29 percent to \$12.86 for a market cap of \$110.98 million. Shares of **Orchid Cellmark** (Princeton, N.J.) increased 15 percent to \$1.93 for a market cap of \$57.84 million.

Other gainers were **Enzo Biochem** (New York City), whose shares increased 12 percent to \$6.67; **Bio-Reference Laboratories** (Elmwood Park, N.J.), whose shares increased 10 percent to \$24.11; and **Neogenomics** (Fort Myers, Fla.), whose shares increased 10 percent to \$1.48.

Also gaining were **Clariant**, whose shares increased 8 percent to \$2.79; **Genoptix**, whose shares increased 7 percent to \$38.32; **LabCorp**, whose shares increased 6 percent to \$79.99; and **Quest**, whose shares increased 1 percent to \$57.83.

Genomic Health (Redwood City, Calif.) saw its share prices fall 11 percent to \$16.83 for a market cap of \$483.53 million. Shares of **Genzyme** dropped 9 percent to \$53.93 for a market cap of \$14.36 billion. Also falling were **Myriad Genetics** (Salt Lake City), down 8 percent to \$22.98, and **Psychemedics** (Acton, Mass.), down 1 percent to \$7.71. 🏛️

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





Duke Teams with LabCorp on Biomarkers, Personalized Medicine

Diagnostic testing partnerships continue to bloom in North Carolina. Burlington-based LabCorp and Duke University, which is based in Durham, have announced the formation of a joint venture named the Biomarker Factor, whose focus is to commercialize new biomarkers. The new entity is designed to speed the translation of newly

discovered biomarkers into widely available clinical tools that can measure individual therapeutic responses and predict disease progression.

In related news, Duke also announced that it will partner with CancerGuide Diagnostics, which also recently announced a partnership with LabCorp. Also based in Durham, CancerGuide's CEO is Myla Lai-Goldman, the former chief science officer and chief medical officer at LabCorp. Under terms of the agreement Duke will provide CancerGuide with exclusive commercial rights to molecular tools shown to predict response for targeted therapeutics as well as collaborative access to clinical research and new molecular discoveries from Duke. CancerGuide will then use these technologies to develop and commercialize novel clinical diagnostics through its existing agreement with LabCorp. 🏰

References

American Civil Liberties Union
212-549-2500

American Clinical Laboratory
Association 202-637-9466

Bio-References Labs
201-791-3600

CancerGuide Diagnostics
919-474-2439

Enzo Biochem 212-583-0100

Diagnostic Laboratory Services
808-589-5100

Genomic Health 650-556-9300

Genzyme 617-252-7500

LabCorp 800-334-5161

Medtox Scientific 800-832-3244

Myriad Genetics 801-584-3600

Neogenomics 239-768-0600

Orchid Cellmark 800-362-8378

Psychemedics 800-628-8073

Quest Diagnostics 800-222-0446

LIR Subscription Order or Renewal Form

- YES**, enter my one-year subscription to the *Laboratory Industry Report (LIR)* at the rate of \$449/yr. Subscription includes the *LIR* newsletter and electronic access to the current and all back issues at www.ioma.com/g2reports/issues/LIR. Subscribers outside the U.S. add \$100 postal.*
 - AAB & NILA members qualify for special discount of 25% off — or \$336.75 (Offer code LIR11)
 - I would like to save \$269 with a 2-year subscription to *LIR* for \$629*
 - YES**, I would also like to order the *Lab Industry Strategic Outlook: Market Trends & Analysis 2009* for \$1495 (\$1195 for Washington G-2 Reports subscribers). (Report #3308C)
 - Check enclosed (payable to Washington G-2 Reports)
 - American Express VISA Mastercard
- Card # _____ Exp. Date _____
- Cardholder's Signature _____
- Name As Appears On Card _____
- Name/Title _____
- Company/Institution _____
- Address _____
- City _____ State _____ ZIP _____
- Phone _____ Fax _____
- e-mail address _____

*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere.

MAIL TO: Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Or call 973-718-4700 and order via above credit cards or fax order to 973-622-0595. **LIR 5/10**

© 2010 Washington G-2 Reports, a division of the Institute of Management and Administration Inc., Newark, NJ. All rights reserved. Copyright and licensing information: It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to \$150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. To ensure compliance with all copyright regulations or to acquire a license for multi-subscriber distribution within a company or for permission to republish, please contact IOMA's corporate licensing department at 973-718-4703, or e-mail jping@ioma.com. Reporting on commercial products herein is to inform readers only and does not constitute an endorsement. *Laboratory Industry Report* (ISSN 1060-5118) is published by Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Tel: 973-718-4700. Fax: 973-622-0595. Web site: www.g2reports.com.

Kimberly Scott, Senior Editor; Dennis Weissman, Executive Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, CMO; Doug Anderson, VP & Publisher; Joe Bremner, President
Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 973-718-4700.