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# LABORATORY INDUSTRY REPORT®

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## Upcoming Conferences

### MDx NEXT: Reimbursement Realities, Payment Priorities, and the Future of Genomic Medicine

Sept. 13-14, 2012

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Chicago

[www.mdxconference.com](http://www.mdxconference.com)

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## Life Technologies Buys Navigenics, Plans Further Molecular Diagnostics Moves

**L**ife Technologies (Carlsbad, Calif.) is getting serious about the clinical market. The life sciences leader announced this week that it has acquired consumer genomics player Navigenics (Foster City, Calif.) as the first step in a multistage move into molecular diagnostics. Internal development, partnerships, and additional acquisitions are planned. Financial terms of the Navigenics deal were not disclosed. The move gives the testing equipment giant an inroad to process lab tests for doctors.

"Life Technologies' entry into the clinical diagnostics market, coupled with the scope of their clinical vision, signals that personalized medicine is no longer a distant future promise, but today's reality," said Navigenics' CEO Vance Vanier in a statement. *Continued on page 2*

## Lab Groups Urge Cross-Walking for New Molecular Pathology Codes

**W**hile it remains unclear whether more than 100 new molecular pathology codes will be priced on the clinical laboratory fee schedule (CLFS) or the physician fee schedule (PFS) in 2013, industry groups are urging the Centers for Medicare and Medicaid Services (CMS) to determine payment through the cross-walking method and by referring to historical reimbursement levels.

Industry representatives testified July 16 on new and revised codes to the CLFS during CMS's annual clinical laboratory public forum. While CMS had requested that comments on whether the new molecular pathology codes should be placed on the CLFS or the PFS be provided in response to the proposed PFS rule issued July 6, many speakers took the opportunity during the meeting to address the issue of how the molecular pathology codes should be priced.

The American Medical Association (AMA) approved 101 new codes specifically for molecular pathology tests. The new code set consists of 92 codes in Tier 1, which includes the most commonly performed tests, and nine in Tier 2, which includes the more complex tests.

The current system of using stacking codes is supposed to be eliminated in favor of the new molecular codes effective Jan. 1, 2013.

*Continued on page 8*

### ■ LIFE TECHNOLOGIES BUYS NAVIGENICS, *from page 1*

"Navigenics has pioneered the synthesis and communication of complex genomic information," said Ronnie Andrews, the Clarent veteran who joined Life Technologies in February as president of medical sciences, in a statement announcing the acquisition. "And we will now pivot the company's effort to date and focus on becoming a comprehensive provider of technology and informatics to pathologists and oncologists worldwide."

The 6-year-old consumer genomics player will provide Life Technologies with a CLIA-certified laboratory in which to design and validate new tests. Formerly the Affymetrix Clinical Services Laboratory, Navigenics bought the 10,000-square-foot Sacramento facility from the microarray company in 2009.

Life Technologies plans to develop and offer lab-developed tests as well as Food and Drug Administration-approved assays and build partnerships with pharmaceutical companies for companion diagnostic development, which may include clinical trial work. Last year, the company inked a deal to develop a companion diagnostic for GlaxoSmithKline's MAGE-A3 cancer immunotherapy. It has also partnered with Gen-Probe on test development. ■

## Quest, LabCorp Lower Revenue Guidance on Weak Volumes

**W**eak volume growth during the second quarter of the fiscal year has led both Quest Diagnostics (Madison, N.J.) and LabCorp (Burlington, N.C.) to lower their revenue guidance for the year. Quest has lowered projected growth from 2 percent-2.5 percent to 1 percent-2 percent while LabCorp is now expecting growth of 2 percent-3 percent, down from 2 percent-3.5 percent.

"Weaker-than expected volumes point to a difficult utilization environment as the labor market stagnates," writes Amanda Murphy, an analyst with William Blair, in a research note. "The impact of acquisitions (Athena, Celera, Clearstone Labs, and Orchid) suggest that the organic volume growth picture is even worse."

Quest Diagnostics reported an increase of 0.7 percent in volume (in line with consensus estimates) while LabCorp reported flat volumes at -0.1 percent (versus consensus estimates of 1.3 percent). For LabCorp, revenue per accession fared somewhat better, up 1.5 percent versus the consensus of 1.8 percent. Revenue per acquisition was flat for Quest, versus Wall Street expectations of 1.2 percent.

"Given the impact of Celera and Athena on revenue per requisition, the two labs seem to be meaningfully diverging in revenue per requisition trends, with Quest reporting lower organic revenue per requisition growth over the past few quarters," said Murphy.

Quest in 2011 purchased Celera for \$657 million and Athena Diagnostics for \$740 million. LabCorp in 2011 purchased Clearstone Central Laboratories for an undisclosed amount and Orchid Cellmark for \$85 million.

### Quest Results

For the second quarter 2012, revenues were \$1.9 billion, essentially unchanged compared to 2011. Adjusted income from continuing operations was \$187 million, or \$1.17 per diluted share, compared to \$179 million, or \$1.12 per diluted

share, in 2011. Adjusted operating income was \$350 million, or 18.4 percent of revenues, compared to \$337 million, or 17.7 percent of revenues, for 2011.

For the first half of the year, revenues increased 3.2 percent from 2011, to \$3.8 billion. Adjusted operating income was \$670 million, or 17.4 percent of revenues, compared to \$638 million, or 17 percent of revenues, for 2011. Cash provided by operations was \$412 million in the first half of 2012. In 2011, cash provided by operations was \$220 million and was reduced by the Medi-Cal settlement payment.

For the full year, the company expects slightly lower revenue growth than previously expected, although earnings per diluted share of \$4.45 to \$4.60 remains unchanged from the prior outlook.

Quest at a Glance (\$MM)			
	Second Quarter 2012	Second Quarter 2011	Change
Total revenues	\$1,906.8	\$1,903.2	0.2%
Gross profit	796.3	798.8	-0.3
Net income	177.0	163.0	+8.6

### LabCorp Results

Revenues for the quarter were \$1.4 billion, an increase of 1.4 percent over the second quarter of 2011. Adjusted operating income was \$280 million, almost the same as in the same period last year. Operating cash flow for the quarter was \$186.3 million. The balance of cash at the end of the quarter was \$124.4 million.

For the first half of the year, revenues were \$2.8 billion, an increase of 2.7 percent compared to 2011. Compared to the first six months of the previous year, testing volume increased 1.3 percent and revenue per requisition increased 1.4 percent.

Operating cash flow for the first six months of 2012 was \$383.4 million, compared to \$400.2 million in 2011.

For the full year, LabCorp is expecting slightly lower revenue growth. The company also narrowed earnings per share guidance from \$6.75-\$7.05 to \$6.80-\$7.

LabCorp at a Glance (\$MM)			
	Second Quarter 2012	Second Quarter 2011	Change
Total revenues	\$1,423.4	\$1,403.3	1.4%
Gross profit	579.5	588.2	-1.5
Net income	173.6	169.0	2.8

### Investment Firms React

A number of investment analysts have reacted in recent weeks to volume weakness in the lab industry. An analyst at Raymond James in June downgraded stocks of both LabCorp and Quest to "underperform," saying he believes profit growth will be slow due to cuts in government reimbursement and investor fear about general macroeconomic conditions.

Piper Jaffray on July 17 downgraded LabCorp from an “overweight” rating to a “neutral” rating. However, analysts at Canaccord Genuity reiterated a “buy” rating on share of LabCorp on July 12, and Goldman Sachs upgraded share of LabCorp’s stock from a “sell” rating to a “neutral” rating on July 2. Analysts at Mizuho raised their price target on shares of LabCorp from \$91 to \$95; they now have a “neutral” rating on the stock. Goldman Sachs also upgraded Quest from “sell” to “neutral” on July 2, while Canaccord Genuity reiterated its “hold” positions. 

## New Test Development Pays Off for Neogenomics; Company Reports Huge Growth in Volume, Revenues, and Profit

**N**eogenomics (Fort Myers, Fla.), a cancer-focused genetic testing company, reported significant increases in volume, revenues, and profit in the second quarter of 2012, which the company’s chief executive officer attributed to development of new tests.

Revenue for the second quarter was \$15.6 million, a 49 percent increase over second-quarter 2011 revenue. Test volume increased by 57 percent. Average cost of goods sold per test improved by 10 percent from last year and resulted in gross margin improvement to 47.2 percent as compared to 44.5 percent in the second quarter of last year. As a result, gross profit increased by 58 percent to \$7.4 million.

For the first six months of 2012, revenue was \$30.8 million, a 60 percent increase over revenue in the first half of 2011. Test volume increased by 65 percent. Gross profit increased by 70 percent to \$14.5 million, and operating expenses increased by 37 percent to \$12.8 million.

Douglas VanOort, the company’s chairman and CEO, said the growth rates were accomplished despite the fact that the company had to redirect the focus of its sales force over the last four months to prepare clients for the expiration of the technical component (TC) grandfather clause on July 1.

“We also have made huge strides in increasing the productivity and efficiency of our lab operations,” he said. “The average number of tests completed per lab employee has increased 16 percent, and the average cost per test has decreased 9 percent since the end of last year.”

VanOort also noted that Neogenomics’s significant investments in new test development are starting to pay off. The company has launched 20 new molecular assays thus far in 2012 and expects to launch another 15 to 20 assays, including its new NeoTYPE Cancer Profiles, by year-end. 

Neogenomics at a Glance (\$MM)			
	Second Quarter 2012	Second Quarter 2011	Change
Total revenues	15.6	10.5	48%
Gross profit	7.4	4.7	58
Net income	551	(293)	P

# Inside The Lab Industry



## EMR Utilization and Its Effect on Laboratory Testing

**W**hile physician adoption of electronic medical records (EMRs) began slowly, new evidence shows uptake is quickening, driven largely by financial incentives defined under meaningful use provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act.

According to the Office of the National Coordinator for Health Information Technology (ONC), in 2011 about 34 percent of non-hospital-based physicians had adopted a “basic” EMR, doubling the adoption rate of 2008. The trend is expected to continue based on results of a survey conducted by the U.S. Centers for Disease Control and Prevention, which found 52 percent of office-based physicians in the United States intend to take advantage of the financial enticements available through the Medicare and Medicaid EHR Incentive Programs. EMR incentive payments for eligible health care professionals can total as much as \$44,000 under the Medicare program and \$63,750 under the Medicaid program.

Stage 1 of meaningful use had limited impact on laboratories, but stage 2, which will begin attestation in 2014, calls for greater data exchange and includes several core laboratory-related proposed requirements including using computer physician order entry for laboratory testing, incorporating laboratory test results into EMRs as structured data, and compliance with Logical Observation Identifiers Names and Codes.

### Changes in Test Utilization

With greater adoption of EMRs combined with payment reform efforts, like accountable care organizations aimed at improving care coordination, laboratories are looking for clues as to how these changes in clinical practice will manifest themselves in future laboratory test utilization. Early indications, though, point to a mixed bag with potential reductions in test volume driven by “intelligent ordering” but potential increases in volumes as ease of ordering becomes simplified with improved integrations between laboratory information systems (LISs) and EMRs.

***“There are counterinfluences that will change utilization a little bit.”***  
—Pat Wolfman, Ignis Systems

“There are counterinfluences that will change utilization a little bit,” explains Pat Wolfram, vice president of marketing for middleware vendor Ignis Systems (Portland, Ore.). “Using paper, doctors don’t do a good job of managing disease states. My mechanic and my vet are better able to tell me when to bring in my car or my dog. So this will be a positive influence on utilization when there is awareness that a test is needed. On the other hand, a little further down the road when EMRs are utilized well and there is confidence in the data, there will be a decrease in testing, as doctors see when test orders are redundant to those ordered by other care providers.”

A 2011 study published in the *American Journal of Managed Care* confirms this mixed forecast. Physicians who use EMRs provided 7.1 percent fewer laboratory tests on average across all visits, but the study found that EMR users provided, on average, 8.7 percent more total diagnostic/screening services, particularly

among office visits by chronic disease sufferers. Surprisingly, though, EMR use had little to no association with utilization during visits for preventive care. "EMR use had a mixed association with utilization, and the relationships varied by type of service and by major reason for visit," concluded author Michael F. Furukawa, Ph.D., who is now serving as acting director of the Office of Economic Analysis, Evaluation, and Modeling within the ONC.

### Lab-EMR Integration Challenges

Laboratory integration and electronic ordering, in particular, have not been a priority for EMR vendors. While they are expected to pay more attention to such integration efforts as stage 2 of meaningful use approaches, many laboratories and physicians have turned to middleware vendors to sync EMRs with LISs and improve the rates of clean, reimbursable electronic orders placed.

"A doctor might not realize that Margaret went to Dr. Jones down the street, who ordered the same tests," explains Michelle Del Guercio, director of marketing at Atlas Development (Calabasas, Calif.). "The lab won't be reimbursed and once that patient is out of the office they are out of luck as it will be tough to get an advance beneficiary notice signed."

But middleware systems can aid in verifying medical necessity and even an individual laboratory's test requirements. While generally the interoperability of EMRs in the United States has been described as "piecemeal,"

experts point to the Veterans Affairs (VA) and U.S. Department of Defense (DOD) systems as a positive example of the potential for integrating laboratory data into clinical decisionmaking.

The DOD and VA departments announced a milestone in their effort to combine their health records in what will become the world's largest electronic system by 2017. In May, the Capt. James A. Lovell Federal Health Care Center (North Chicago, Ill.) became the nation's first fully integrated DOD-VA medical facility, and by 2014 sites in San Antonio and Hampton Roads, Va.,

will also be able to access an integrated electronic health record (iEHR) for any service member or veteran seen in any DOD or VA medical facility throughout their lifetime. The iEHR will unify the departments' now-separate legacy EMR systems. Beth McGrath, a DOD deputy chief management officer, says that "the clinical capabilities [being deployed] first are focused on laboratory and immunizations."

In an effort to spur the integration of laboratory capabilities into the iEHR, in mid-June the DOD solicited a request for information from vendors to advise on the deployment of commercial LISs that can integrate iEHRs and clinical laboratory and anatomic pathology business processes for DOD/VA. The goal is a system that will provide access to the patient's full EMR for clinical decision support to include receiving the specimen and/or test order, analyzing it, validating the results, and notifying providers.

Integration of private health system LIS-EMRs is occurring in a much more isolated fashion.

***Many laboratories and physicians have turned to middleware vendors to sync EMRs with LISs and improve the rates of clean, reimbursable electronic orders placed.***

"People are trivializing lab integration because they have seen a simpler way to integrate medications and think labs should follow suit," says Wolfram. "We are waiting for when there is sharing of good, structured data that all can access. It will take time to get a lot of data into that repository, and agreement on coding could take awhile, but we see it coming. It will be an incremental process with no 'aha' moment in the transition to a better state."

### A Move to Decision Support

Integrating evidence generated from aggregated data sources to inform clinical decision support tools adds another layer of complexity to the integration equation. Some are already looking to the future where genetic test data will need to be stored in EMRs.

"It is difficult from a technological point of view to get test data used in EMRs for decisionmaking," says Joyce Mitchell, Ph.D., a professor of biomedical informatics at University of Utah (Salt Lake City). "Most genetic testing is done outside of the lab. The test report might come back as a fax. Even if you scan it in or elect to enter it as a text note it is not in a fielded report format."

Mitchell says that in order for genetic test results to truly be integrated into clinical care, decision support is needed. But for that to happen, there must be a stronger evidence base.

"Decision support is still embryonic as the knowledge base is changing so rapidly," Mitchell says. "There are few cases, but that is not enough to be the standard of care, and they aren't doing it because of the lack of evidence. It becomes a chicken-and-egg problem."

In the short term there is a major movement toward cooperation, she says, citing the National Human Genome Research Institute's efforts to coordinate national clinical variant databases.

"In five years it will be a whole different situation with one place to access a definitive source. From there decision support in EMRs will develop rather quickly," says Mitchell. "We will have a better idea of the health significance and frequency of these variances. It will change a lot in people's comfort level of knowing what to do."

In time, experts say, pooled data on genetic variants will be used to inform decisionmaking for prevention, prognosis, and treatment of individuals.

"The discipline of pharmacogenomics is identifying an increasing number of variants associated with drug responses; however, the very success of these efforts represents a barrier to implementation because no human can be expected to keep track of this increasing data set and its implications for drug prescribing," writes Dan Roden, M.D., a professor of medicine and pharmacology at Vanderbilt University (Nashville, Tenn.) in an April 25 article published in *Clinical Pharmacology & Therapeutics*. "The capability of advanced EMR systems to archive large amounts of individual data and deliver advice to providers at the point of care seems to offer an obvious solution to this problem." 

***Mitchell says that in order for genetic test results to truly be integrated into clinical care, decision support is needed. But for that to happen, there must be a stronger evidence base.***

### ■ LAB GROUPS URGE CROSS-WALKING FOR NEW MOLECULAR PATHOLOGY CODES, from page 1

Speaking on behalf of the American Clinical Laboratory Association, Peter Kazon, Esq., of Alston & Bird, said CMS “should not engage in a wholesale re-examination of the pricing of the existing MDx tests being issued new codes. . . . Therefore, the well-defined principles used in cross-walking should be applied here.” Several other presenters also agreed that cross-walking would be the best approach to pricing the codes.

Eric Zimmerman, Esq., of McDermott Will & Emery, presented recommendations on behalf of the Coalition for 21st Century Medicine, representing a number of diagnostic technology companies, clinical laboratories, researchers, physicians, and venture capitalists. The coalition believes that CMS should

cross-walk new analyte-specific Tier 1 tests to the relevant combination of molecular pathology codes by which the same tests were appropriately reported prior to 2012. If there is no established set of molecular methods codes describing the test, CMS should then resort to gap-filling, said Zimmerman.

“Laboratories offering tests that are described by new Tier 1 codes can provide CMS with information about the appropriate cross-walk between the new Tier 1 codes and the previous molecular

pathology method code combination and can identify the tests that are appropriate for gap-filling,” he said.

The Tier 2 molecular pathology codes describe tests that are intended to involve comparable levels of resource intensity yet are considered to be low-volume, though there is no clear frequency-based delineation between Tier 1 and Tier 2 tests, said Zimmerman.

The assignment of codes to a specific level by the current procedural terminology (CPT) editorial panel does not necessarily reflect a comprehensive assessment of the range of resources required for the specific tests described, he testified. “Because of the lack of granularity, Tier 2 codes may be a hindrance to providers and payers seeking to identify test-specific coverage and payment policies,” he said. “We encourage CMS and AMA to look at additional options for Tier 2 that would adequately identify tests billed to payers, e.g., Palmetto’s MolDx program, which uses unique test identifiers.”

### Multi-Analyte Assays With Algorithmic Analyses

Industry representatives also commented on Multi-Analyte Assays with Algorithmic Analyses (MAAA), a new group of tests assigned CPT codes effective for 2013. MAAAs are procedures that utilize multiple results derived from assays of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid-based assays. Algorithmic analysis, using the results of these assays as well as other patient information, is then performed and reported typically as a numeric score or as a probability.

While presenters gave pricing recommendations on individual MAAA tests, in general they urged CMS to reimburse for the algorithm component of the test and to examine each MAAA test individually to decide whether to apply cross-walking or gap-filling. According to Zimmerman, for most MAAAs, there are no comparable tests, so gap-filling is indicated.

***“Because of the lack of granularity, Tier 2 codes may be a hindrance to providers and payers seeking to identify test-specific coverage and payment policies.”***

—Eric Zimmerman, Esq.,  
McDermott Will & Emery

"With the field of molecular diagnostics rapidly evolving, CMS should leverage the expertise of the [Medicare administrative contractors]," he said, noting that there are MAAs for which a single MAC processes nearly all of the claims, giving that MAC considerable familiarity with the clinical features and resources involved with the test.

Zimmerman recommends that MAAA pricing should be set by local MACs or set by gap-fill based on the weighted median of claims to reflect the critical contribution of a single MAC to the overall claims for the MAAA.

CMS staff said they intend to announce preliminary determinations for codes on the CLFS by the end of August, with final determinations by early November. If the new molecular pathology codes are not included in the 2013 CLFS determination, it is presumed they will be priced through the PFS for 2013. The final PFS rule is also expected to be published by early November. 

### Which Is the Right Fee Schedule?

Lab and pathology groups remain largely split on whether the new molecular pathology codes should be priced on the clinical laboratory fee schedule (CLFS) or the physician fee schedule (PFS).

The College of American Pathologists and the Association for Molecular Pathology support placing the codes on the PFS, arguing that physician interpretation is required for the majority of these tests and that the PFS allows for frequent updating in light of changing technology and greater efficiencies.

The American Clinical Laboratory Association and the American Association for Clinical Chemistry (AACC) believe that each code should be assessed individually and placed on the appropriate fee schedule based on how the interpretive function is most commonly performed.

In the proposed PFS rule issued July 9, the Centers for Medicare and Medicaid Services solicited input on where the codes should be placed. The agency also stated that it believes all molecular pathology codes should be placed on one fee schedule.

In comments submitted to the agency, AACC strongly opposes this approach, recommending that "CMS review and assign the molecular pathology codes based on the level of professional interpretation required, not simplicity of implementation and oversight."

Bruce Quinn, M.D., Ph.D., a senior health policy adviser at Foley Hoag (Boston) and former regional Medicare medical director for the California Part B program, analyzed

the debate in a recent white paper published on the Foley Hoag Web site ([www.foleyhoag.com](http://www.foleyhoag.com)), "The Tempest Continues, Fee Schedules in Collision: Medicare and Genomics Tests Prepare for 2013." Quinn writes that "[T]aken at face value, current regulations seem to strongly favor placement of genetic tests on the clinical laboratory fee schedule, since they do not 'require' a physician.

"However, CMS could alter its current regulations to allow genetic tests to be physician laboratory services, measured and paid in RVUs [relative value units]," he continues. "As CMS states, it would need to revise its current regulations to do so. It seems highly unlikely that CMS would do so abruptly in the [PFS] final rule alone, without allowing public comment on the form and implications of any particular formula for new regulatory language."

The RVU framework release by CMS in the PFS proposed rule, notes Quinn, "seems a poor match for the actual economics of laboratory testing."

At a public forum held July 16, CMS officials did not indicate one way or the other where the molecular pathology codes would be placed or how they would be priced. However, Glenn McGuirk of the hospital and ambulatory policy group, said stakeholders should have an answer by the end of August when preliminary determinations are released for new codes on the CLFS. In discussions with G2 Intelligence, McGuirk said that if the molecular pathology codes were not on that list, it would be safe to assume they would be placed on the PFS.

## Genova Diagnostics Acquires Metametrix

**G**enova Diagnostics Inc. (Asheville, N.C.) has acquired Metametrix Inc. (Duluth, Ga.), although the two companies will continue to operate under both brands at this time. Financial terms of the transaction were not disclosed.

Established in 1984, Metametrix specializes in the measurement of nutritional deficiencies, metabolic dysfunction, microbial imbalances, and toxic influences on health. Genova, established in 1986, focuses on the diagnosis, treatment, and prevention of complex chronic disease. The combined entity will provide a broader range of testing services, as well as increase the breadth of support and resources dedicated to physicians and their patients.

"Consolidating our companies significantly increases our global presence," said Ted Hull, chairman and CEO of Genova Diagnostics. "Together, we were over 9,000 health care practitioners annually throughout the United States and internationally in 45 countries with our 400 employees and three locations in Asheville, N.C., Duluth, Ga., and London, England. Our combined resources will allow us to expand investments in research and development, clinical trials, medical education, and market expansion." 

## Lab Index Gains 22 Percent in First Half of Year

**T**he G2 Intelligence Laboratory Stock Index rose 22 percent in the first six months of 2012, driven largely by substantial gains in the share prices of Bio-Reference Laboratories and Medtox. Of the nine stocks tracked by the index, eight rose in price while only one, Medtox, lost value. In comparison, the Nasdaq composite climbed 11 percent, and the S&P 500 rose 7 percent.

Shares of **Medtox** (St. Paul, Minn.) soared 83 percent to \$26.96 since the beginning of the year (as of June 29, 2012). LabCorp in June said that it planned to buy the toxicology testing company for \$27 per share. The deal is expected to close later this year.

**Bio-Reference Laboratories** (Elmwood Park, N.J.) climbed 62 percent to \$26.28 since the beginning of the year. The company June 7 reported record revenues of \$163.4 million for the second quarter, the highest in corporate history. Officials also recently announced a multimillion-dollar investment in a private molecular diagnostics startup company and launched a new test used to determine the risk of developing cervical cancer.

Shares of **Genomic Health** (Redwood City, Calif.) climbed 29 percent to \$33.40. The stock continues to trade close to its 52-week high as demand for its tests continues to increase. Genomic Health's Oncotype breast cancer test, launched in 2004, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. In 2010 the company launched a test for colon cancer and is currently in the process of developing tests for prostate and renal cell cancers.

**NeoGenomics** (Fort Myers, Fla.) shares rose 20 percent to \$1.70. In the first quarter, the company reported a 75 percent increase in test volume, a 72 percent increase in revenue, and an 85 percent increase in gross profit. The company achieved profitability in the fourth quarter of 2011, and analysts expect that new initiatives taken by NeoGenomics will continue to increase the top line dramatically in coming quarters.

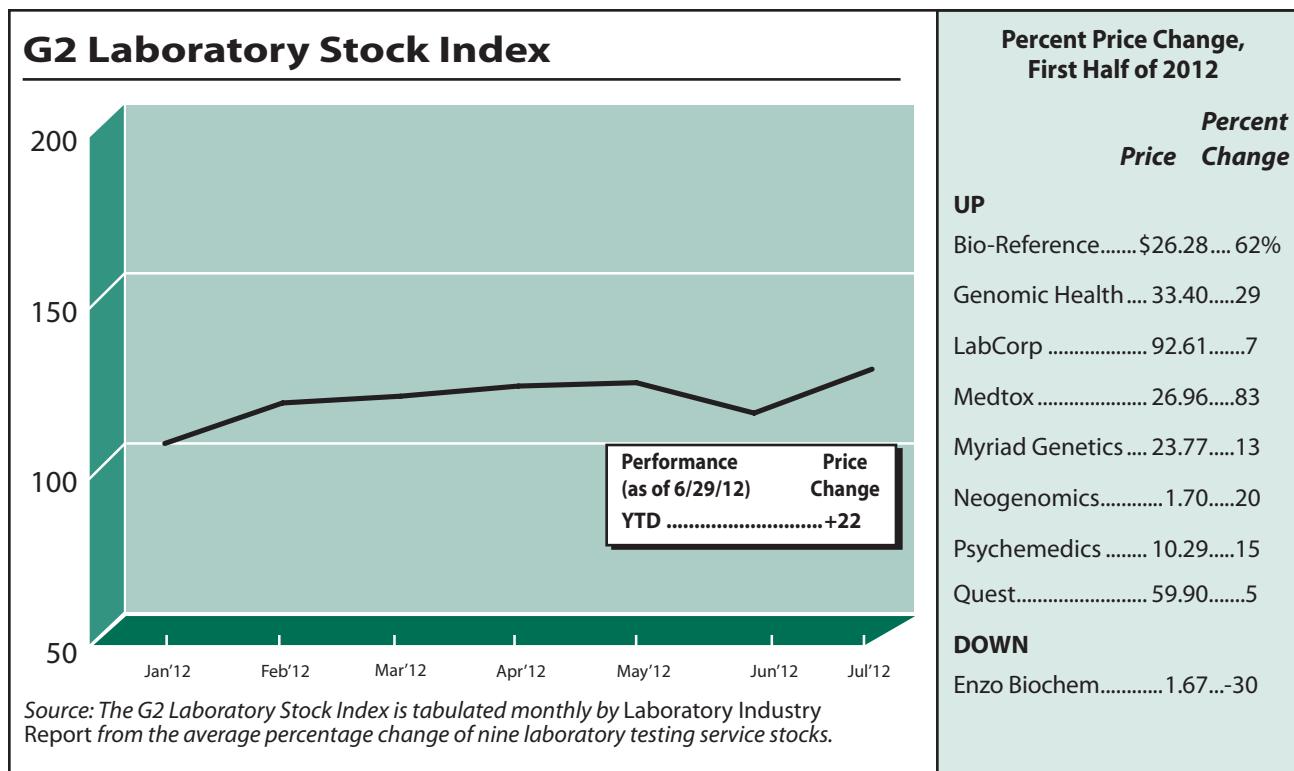
Shares of **Psychemedics** (Acton, Mass.) climbed 15 percent to \$10.29. The company in May reported record first-quarter revenues and declared its 63rd consecutive quarterly dividend. In June, it received Food and Drug Administration approval for five new, additional assays to test for the detection of cocaine, opiates, PCP, methamphetamine, and marijuana using enzyme immunoassay analysis of head and body hair.

**Myriad Genetics** (Salt Lake City) shares rose 13 percent to \$23.77. The company in May beat analysts' expectations on earnings and revenues, with its BracAnalysis product representing 81 percent of total revenues. Revenues attributable to the test increased 17 percent to \$105.9 million during the first quarter.

Shares of **LabCorp** (Burlington, N.C.) increased 7 percent to \$92.61. LabCorp has seen modest growth in testing volume and revenue per acquisition, and increased net income by about 7 percent in the first quarter. Analysts generally remain bullish on the company despite the stock's lackluster performance.

**Quest Diagnostics** (Madison, N.J.) shares rose 5 percent to \$59.90. Like LabCorp, the company has experienced modest gains in testing volume and revenues, though gross profit increased 12 percent in the first quarter of the year compared to the same time last year. The company is hoping that its new CEO, Steve Rusckowski, will help define a strategic vision to boost the company's performance.

Shares of **Enzo Biochem** (New York) fell 30 percent to \$1.67. While the company's revenues have remained relatively flat since last year, they are improving slightly quarter over quarter. While Enzo is not profitable currently, it should be cash flow breakeven in 2013 and is hoping that a recent successful launch of the ColonSentry test for providing an assessment of a patient's risk of having colorectal cancer will contribute to revenue growth. **G2**



## CMS Proposes Physician Fee Cut for 2013

**A**mong the many payment policy changes proposed in the Medicare physician fee schedule (PFS) for calendar year 2013 are two of immediate import for pathologists and clinical laboratories.

In the proposed rule released July 6, the Centers for Medicare and Medicaid Services (CMS) estimates a cut of 27 percent in the PFS update and proposes to price newly created molecular pathology codes via a single fee schedule, although the agency did not specify which fee schedule they would go on.

The 27 percent cut is required under the current statutory PFS update, which includes the sustainable growth rate factor and a budget-neutrality adjustment. The conversion factor used to translate the relative value units for services on the PFS would fall to \$24.8441 in 2013 compared with \$34.0376 this year.

These are preliminary estimates only, CMS cautions. The final fee update and the actual values used to compute physician payments for 2013 will be based on later data and will be published by Nov. 1 as part of the PFS final rule. Congress is expected to block the looming fee cut, but how to pay for it is an open question. It is also unclear whether lawmakers will impose an update freeze or grant a modest increase.

The proposed PFS rule for 2013 will appear in the July 30 *Federal Register* and be open for comment until Sept. 4. **G2**

### References

- Atlas Development 818-340-7080
- Bio-Reference 201-791-3600
- Enzo Biochem 800-522-5052
- Genomic Health 650-556-9300
- Genova Diagnostics 800-522-4762
- Ignis Systems 888-806-0309
- LabCorp 336-436-5274
- Life Technologies 800-955-6288
- Medtox 800-832-3244
- Metametrics 770-446-5483
- Myriad Genetics 801-584-3600
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- Psychmedics 800-628-8073
- Quest Diagnostics 800-222-0446

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