Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Quest Retests Thousands in Vitamin D Test Debacle

Erroneous results from a laboratory-developed test performed by the nation's largest clinical laboratory may fuel calls for regulation and increased oversight of this area of the in vitro diagnostics and clinical laboratory industries. Last year, after discovering inaccuracies in some of its vitamin D test results, Quest Diagnostics (Madison, N.J.) notified physicians and insurers of the questionable results along with the free, voluntary retesting program it was implementing for affected patients. Approximately 7 percent of all vitamin D tests performed by Quest in 2007 and 2008 were flagged for retesting.

Since late 2006, Quest has performed vitamin D testing using liquid chromatography tandem mass spectrometry, (LC-MS/MS), or tandem mass spec, which is able to quantify specific forms of vitamin D, including D2 and D3. The lab-developed test is not approved by the United States Food and Drug Administration. At the root of the inaccurate results were problems with reagent preparation "and, in some cases, with less than strict adherence to our rigorous operating procedure for the test," said Quest representative Wendy H. Bost. For more on this story, turn to *Inside the Diagnostics Industry*, p. 5

Clarient Launches Four-Gene Test for Prostate Cancer

On January 13, cancer diagnostic testing company Clarient (Aliso Viejo, Calif.) introduced a novel gene expression test for prostate cancer. Developed in conjunction with Health Discovery Corporation (HDC; Savannah, Ga.), the Prostate Gene Expression Profile (PGEP) test is based on a patented combination of four genes that have been shown to accurately identify the presence of clinically significant prostate cancer cells in prostate tissue.

The test uses real-time polymerase chain reaction to detect the presence of grade 3 or 4 cancer cells in formalin-fixed, paraffin-embedded prostate tissue. Clarient estimates the market size for the test at approximately $150 million and reimbursement for the test to range between $250 and $350.

More than one million prostate cancer biopsies are performed annually in the United States, and they can be difficult to interpret. "There are many mimickers of prostate cancer under the microscope, and people not as familiar with prostate biopsies as specialists in urologic pathology can diagnose cancer when it's not actually present," said Stephen D. Barnhill, M.D., chairman and CEO of HDC.

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▲ **Clarient Launches Prostate Cancer Test,** *from page 1*

"The high sensitivity and specificity demonstrated in the validation results of our new prostate cancer test suggest that this new molecular diagnostic could assist physicians in more accurately identifying the presence of prostate cancer in patients with both positive and negative biopsies," noted Barnhill. In the clinical validation study, the PGEP test achieved a sensitivity of 90 percent for correctly identifying the presence of Grade 3 or higher prostate cancer and a specificity of 97 percent for correctly identifying noncancer tissue.

According to Clarient CEO Ron Andrews, the companies have submitted a scientific paper documenting the validation of the PGEP test for peer-reviewed publication in an international medical journal. The publication "will be paramount to our marketing efforts," added Andrews.

Under the original agreement between Clarient and HDC, the PGEP test was to be offered exclusively by Clarient, but the two companies have recently decided to transition to a nonexclusive deal that allows for licensing of the test to additional laboratories. Under the amended agreement, Clarient retains the exclusive rights to a prognostic test that may be developed in the future with HDC.

FDA Clears BD's Rapid Molecular Test for *C. difficile*

BD Diagnostics, a segment of Becton, Dickinson and Company (San Diego, Calif.), has received clearance from the U.S. Food and Drug Administration to market its qualitative in vitro diagnostic test for the rapid detection of the toxin B gene found in toxigenic *Clostridium difficile*. Toxigenic *Clostridium difficile* is the most common cause of nosocomial and antibiotic-associated diarrhea and pseudomembranous colitis.

Using real-time polymerase chain reaction (PCR), the BD GeneOhm Cdiff assay allows same-day identification of toxigenic *Clostridium difficile*. Test results are available in less than two hours.

"This test should improve patient care because it gives labs the option of a single assay that will markedly reduce or even eliminate the need for multiple screening and confirmatory tests," said Thomas Davis, M.D., Ph.D., professor of pathology and laboratory medicine at the Indiana University School of Medicine (Indianapolis). "This would speed up reporting and help avoid unnecessary antibiotic use."

In the United States, an estimated 500,000 people are infected annually, and more than 28,000 die from *Clostridium difficile* infection (CDI). A recent national survey conducted by the Association for Professionals in Infection Control and Epidemiology suggests that 13 out of every 1,000 hospitalized patients are suffering from CDI, and more than 7,000 patients in U.S. hospitals have CDI on any given day. CDI is estimated to lead to $1 billion in excess health care costs annually in the United States. A new epidemic strain of CDI, BI/NAP1/027, has been detected in at least 38 states, Canada, and 14 European countries.

Cleared for the identification of toxigenic *Clostridium difficile* directly from stool

specimens, the BD GeneOhm Cdiff assay targets the Toxin B gene, found in virtually all toxigenic *Clostridium difficile* strains, including the BI/NAP1/027 epidemic strain.

Real-time PCR-based testing is more sensitive than tissue culture cytotoxicity methods and can be performed in the same time frame as an immunoassay, which are less sensitive than molecular methods. Use of real-time PCR-based tests may help avoid repeat testing, multi-method algorithms, and complicated results reporting.

Oncotype DX Colon Cancer Assay Enters Clinical Study

Genomic Health (Redwood City, Calif.) has begun a clinical validation study for its 18-gene Oncotype DX colon cancer assay. Using more than 1,200 patient samples, the validation study will assess the clinical utility of the Oncotype DX colon cancer assay to predict likelihood of recurrence for stage II colon cancer patients treated with surgery alone and the magnitude of treatment benefit with chemotherapy following surgery. Results from the study are expected to be reported in the second half of the year.

Stage II colon cancer affects approximately 30,000 to 40,000 people each year in the United States. About a third of patients receive adjuvant chemotherapy, usually 5-fluorouracil/leucovorin (5FU/LV) or combinations that include 5FU/LV. However, research indicates that only 2 percent to 4 percent benefit from this treatment, which has significant associated toxicity. Genomic Health's new assay aims to predict the likelihood of recurrence or magnitude of chemotherapy benefit for individual patients.

The company has already completed four development studies to identify and select the 18 genes for the Oncotype DX colon cancer assay. The validation study is utilizing samples from QUASAR, the international, multi-center trial that examined the benefit associated with adjuvant 5FU/LV for patients with stage II colon cancer.

Unlike Genomic Health's Oncotype DX breast cancer assay, which combines both recurrence and treatment benefit in a single recurrence score, the prognostic and predictive genes in the colon cancer assay do not overlap. Therefore, the colon cancer assay generates both a prognostic recurrence score and predictive treatment score.

Researchers will evaluate the association of the recurrence score with recurrence in stage II colon cancer patients treated with surgery alone. They will also evaluate the association of the treatment score with the magnitude of chemotherapy benefit in patients treated with adjuvant 5FU/LV chemotherapy.

Gene Mutations Predict Childhood Leukemia Prognosis

Newly discovered gene mutations can predict a high likelihood of relapse in children with acute lymphoblastic leukemia (ALL), the most common childhood cancer. The findings may lead to the development of molecular diagnostic tests to assess the risk of treatment failure. The findings of the study are slated for publication in the January 29 issue of the *New England Journal of Medicine*.

ALL, a cancer of the white blood cells, affects about one in 29,000 children annually. Cure rates for ALL are now upward of 80 percent, but currently available therapies have substantial side effects, and even with treatment, only 30 percent of children who experience a relapse of ALL will survive five years. Determining the risk of relapse faced by an individual patient would help physicians to tailor treatment.

In the study, researchers analyzed leukemia cells obtained at diagnosis from two different groups of children who were treated for leukemia and whose disease had a high risk of relapse. Using microarrays and DNA sequencing, they identified genetic abnormalities in leukemia cells, examined the DNA of the cells at the time of diagnosis, and then determined if any of the identified genetic changes predicted relapse.

The most significant association was with changes in IKZF1, a gene that encodes the lymphoid transcription factor IKAROS. Mutations of the gene were shown to identify a subgroup of patients that had a very poor prognosis, despite different treatment regimes. The researchers concluded that identifying IKZF1 alterations may be clinically useful and will complement existing diagnostic tests and measurement of minimal residual disease levels, another measure of treatment response in ALL.

A clinical test for alterations of IKZF1 could prove valuable for predicting poor outcomes in children with ALL. However, because the genetic alterations in ALL are not uniform or limited to a single mutation or deletion, it may be necessary to develop a panel of tests to detect various IKZF1 alterations and identify which patients are at the highest risk for relapse.

CMS to Expand Coverage of Prothrombin Time Testing

The Centers for Medicare and Medicaid Services (CMS) will add "secondary malignant neoplasm of the liver" to the list of Medicare-covered conditions for prothrombin time (PT) testing. CMS said it has accepted a request to do so from the Ingham Regional Medical Center (Lansing, Mich.).

PT testing (CPT 85610) was third in volume among the top 100 pathology and laboratory codes ranked by Medicare-allowed services in 2006, according to CMS data, totaling nearly $117 million in allowed payments.

In a recent memo, CMS said it will add the ICD-9-CM diagnosis code for this condition to the list of ICD-9 codes covered under Medicare's national coverage decision (NCD) for PT testing, one of the 23 NCDs established under the lab negotiated rulemaking process. The effective date of the revision has yet to be announced.

PT testing is frequently used to assess patients with signs of abnormal bleeding or thrombosis, a history of a condition known to be associated with the risk of bleeding or thrombosis that is related to the extrinsic coagulation pathway, and other conditions.

Quest Acknowledges Flawed Vitamin D Test Results

In recent years, Quest Diagnostics (Madison, N.J.) has trumpeted its steady, double-digit volume growth in vitamin D testing, but last year, the nation's largest clinical laboratory discovered inaccuracies in some of its vitamin D test results and implemented a free, voluntary retesting program for affected patients. Approximately 7 percent of all vitamin D tests performed by Quest in 2007 and 2008 were flagged for retesting.

"We implemented this [retesting] program in 2008 after we determined, based on a comprehensive quality review, that some of our laboratories, at times, produced questionable vitamin D test results, primarily in 2007 through early 2008," explained Quest representative Wendy H. Bost. "We defined as questionable any result that had the potential for error in a run of tests if there was any question about the overall run."

In the fall of 2008, thousands of physicians nationwide received letters informing them of the questionable results along with materials about the retesting program that they could use to inform patients about the problem. All physicians that could have been affected by the erroneous results have been notified.

"We defined as questionable any result that had the potential for error in a run of tests if there was any question about the overall run."
—Quest Diagnostics

Vitamin D testing volumes have soared in recent years as medical studies have called widespread attention to vitamin D deficiency and linked it to some infectious diseases, cancers, cardiovascular disease, and autoimmune disorders. The Mayo Clinic (Rochester, Minn.), for example, performed approximately 424,582 vitamin D tests in 2007, up 74 percent from 2006.

Quest performs vitamin D testing using liquid chromatography tandem mass spectrometry, (LC-MS/MS), or tandem mass spec, which is able to quantify specific forms of vitamin D, including D2 and D3.

At the root of the inaccurate results were problems with reagent preparation "and, in some cases, with less than strict adherence to our rigorous operating procedure for the test," said Bost. "However, it is important to emphasize that these issues were limited to specific time periods and only affected some of our laboratories that run the test. The issues were corrected last year, and we are confident that our test is producing reliable results."

Quest would not disclose the exact number of vitamin D tests performed, the number of results affected, or the cost to the company of providing free retesting. The price of Quest's LC-MS/MS-based vitamin D test with Medicare reimbursement is approximately $40, which is about the same as the Medicare-reimbursed price for an immunoassay-based vitamin D test.

Sequenom Seeks to Acquire Exact Sciences

Growing genomic analysis company Sequenom (San Diego, Calif.) has set its sights on Exact Sciences (Marlborough, Mass.), a developer of stool-based DNA screening technologies for colorectal cancer. On January 9, Sequenom submitted a proposal to Exact's board of directors to acquire all outstanding shares of common stock in the company in an all-stock deal valued at $41 million, or $1.50 per share. The offer represented a 69 percent premium to Exact's January 8 closing price of $.89 a share.

In discussing the offer, Harry Stylli, Ph.D., president and CEO of Sequenom, noted that it would "address the uncertainties currently challenging Exact Sciences, including the decline in its stock price, the risk of delisting from [Nasdaq], uncertain prospects for continued financing and significant execution risk."

The Exact board voted unanimously to reject Sequenom's bid, noting that the company is "actively pursuing a strategic alternative" that would be of greater value to investors.

Undeterred by the board decision, Sequenom reaffirmed its $41 million offer. "We have decided to move forward with this acquisition because Exact Sciences is essentially a shell with intellectual property assets," said Stylli in a statement issued on January 14.

Sequenom, which last year acquired the Center for Molecular Medicine, is looking to expand its oncology offerings. Its MassARRAY technology and quantitative DNA methylation analysis application are used by many of the nation's top cancer centers, and its recently launched OncoCarta research panel allows for molecular-based characterization of tumors.

"Exact Sciences' novel cancer screening technology and hypermethylated DNA markers are highly synergistic with Sequenom's platform and complement our noninvasive diagnostics platform," said Stylli. "Coupled with our Sequenom Center for Molecular Medicine laboratory, we are strongly positioned to maximize Exact Sciences' oncology assets for colorectal cancer screening and potentially expand into noninvasive diagnosis of aerodigestive cancers."

Medicare Lab Fees Get 4.5 Percent Increase for 2009

For the first time in five years, clinical laboratories will see an increase in their payment rates under the Medicare Part B lab fee schedule. The update, effective January 1, is 4.5 percent. Congress had blocked an annual update since 2004. In allowing the update, however, Congress required that it be 0.5 percent less than the full Consumer Price Index update in 2009 through 2013.

The 4.5 percent increase affects both local fees and national limitation amounts (fee caps). Payment for a clinical lab test is the lesser of the actual charge billed, the local fee, or the national fee cap. The Part B deductible and coinsurance do not apply for services paid under the clinical lab fee schedule. The 2009 update for payments made on a reasonable charge basis for all other laboratory services, including blood product and transfusion medicine codes, is 5 percent.

ACLA Responds to Genentech's FDA Petition on Lab-Developed Tests

The American Clinical Laboratory Association (ACLA; Washington, DC) has responded to Genentech's citizen petition, urging the United States Food and Drug Administration (FDA) to hold in vitro diagnostic tests developed by clinical laboratories for in-house testing to the same standards as those tests developed and sold as test kits (see *DTTR*, January, p. 1). FDA currently regulates tests sold in kit form but not laboratory-developed tests (LDTs).

In the 32-page petition filed on December 5, Genentech (South San Francisco, Calif.) asked the FDA to "initiate rulemaking to exercise regulatory jurisdiction over all LDTs and use its current risk-based classification system to determine the level of regulatory oversight and review that is necessary and appropriate for these tests."

The biopharmaceutical company also wants the FDA to simultaneously initiate enforcement action against "any clinical laboratory or any other company that is selling an LDT or making claims about its potential indication for use, effectiveness or value, or that otherwise impacts patient safety without having sufficient analytical and clinical evidence to support such claims."

ACLA, which represents national and regional labs as well as test manufacturers, assailed Genentech's move as posing a "chilling effect on innovation in patient care while stifling the promise of personalized medicine," which tailors a particular treatment and therapy to an individual's genetic profile. LDTs including commonly used tests for breast and colon cancer and HIV have a history of being safe and effective, ACLA said in a statement issued in late December.

"All health care-related lab tests are already either cleared by the FDA or are performed in a lab regulated by the Centers for Medicare and Medicaid Services under CLIA, or both," noted ACLA. "Also, labs that perform genetic tests must meet the most stringent level of CLIA complexity oversight, often are also regulated by states, and most have further oversight via lab accrediting bodies."

More FDA regulation would threaten rare and low-volume tests for genetic diseases, such as spinal muscular atrophy, Gaucher disease, Tay Sachs disease, and Canavan disease, among others, ACLA warned. "Because of small populations for clinical trials, [these tests] would not be able to meet FDA requirements and, with limited markets, could disappear."

The FDA currently regulates analyte-specific reagents used in LDTs and a category of LDTs known as in vitro diagnostic multivariate index assays that use a proprietary algorithm to produce a patient-specific result. Legislation to require premarket review of all LDTs was introduced in the previous Congress by Sen. Edward Kennedy; hearings were held, but no action was taken.

Abbott Molecular Launches HPV Test in Europe

Abbott Molecular (Des Plains, Ill.) has introduced its real-time polymerase chain reaction (PCR)-based test for human papillomavirus (HPV) to the European market. By combining screening for high-risk HPV types with viral genotyping,

the CE-marked assay detects the 14 highest risk HPV genotypes and, in the same procedure, can identify women infected with the HPV 16 and HPV 18 genotypes, which account for more than 70 percent of cervical cancer cases.

In a statement issued on January 13, Abbott Molecular reported that in evaluations at clinical sites throughout Europe, the Abbott RealTime high-risk HPV assay had demonstrated specificity of 99.4 percent and sensitivity of 97.5 percent for qualitative detection of the 14 high-risk HPV genotypes.

The assay uses liquid-based cytology specimens and runs on Abbott's m-Systems instruments: the m2000 for large-volume laboratories and the m24sp or manual for labs with small to midsize test volumes. In the United States, only tests for HIV-1 viral load and Chlamydia/gonorrhea (CT/NG) are available on the m2000 platform, while in Europe, Abbott also offers tests for hepatitis B viral load, hepatitis C viral load, HCV genotyping, cytomegalovirus, and Epstein-Barr virus.

Breast Cancer Gene Linked to Disease Spread

A team of researchers at Princeton University (Princeton, N.J.) and the Cancer Institute of New Jersey (New Brunswick, N.J.) has identified a gene that is overexpressed in approximately 40 percent of all breast cancer patients, spreading the disease, resisting traditional chemotherapies, and eventually leading to death. The work is described in the January 6 issue of *Cancer Cell*.

The gene, Metadherin (MTDH), is located in a small region of human chromosome 8 and is important for cancer's metastasis. The gene also makes tumors more resistant to widely used chemotherapeutic agents.

In recent years, researchers have tried to identify genetic profiles of the so-called "poor-prognosis" tumors that are likely to return after the initial treatment and are most likely to spread beyond the breast. Though useful in predicting outcomes, such studies have found differing genetic "signatures," making it difficult to identify overlapping, functionally relevant genes.

To address this problem, the researchers used a computational approach to reanalyze massive clinical breast cancer databases. They found that a small region of chromosome 8 was repeated in the genomes of poor-prognosis breast tumors. Then, by studying breast tumor samples, they confirmed that the genetic sequence identified in the database was overproduced in the DNA of the poor-prognosis tumor samples.

The researchers went on to pinpoint MTDH as responsible for the aggressive behavior of poor-prognosis tumors. In subsequent work in laboratory mice, they found that MTDH-overexpressing tumors were more likely to metastasize to the lungs, other vital organs, and bones. These tumors were also found to be more resistant to a wide range of chemotherapeutic agents. When researchers genetically altered the cancer cells to reduce the expression of MTDH, these tumor cells become less able to metastasize and more likely to be eliminated by chemotherapy agents.

The team also found that MTDH may be involved in the progression of other types of cancers, including prostate cancer.

LabCorp Teams With Denver's National Jewish Health on Molecular Diagnostics

Burlington, N.C.-based LabCorp has announced plans to partner with National Jewish Health (NJH; Denver) hospital system to develop and market molecular diagnostic tests. This is not a testing service joint-venture partnership, but rather focused on bringing companion diagnostics to market, most likely in the area of cardiology-, respiratory-, and immune-related diseases that NJH calls its "core clinical areas of excellence."

The announcement comes only months after a former LabCorp executive, Gary Smith, Ph.D., was named executive director of National Jewish Health's outreach businesses, known collectively as Advanced Diagnostics Laboratories (ADx). Smith was with LabCorp for 14 years, most recently as senior vice president of managed care, Western operations, and senior vice president of operations, Midwest division.

In addition to this deal with LabCorp, ADx has recently announced a strategic development partnership with international diagnostics companies Phadia (Uppsala, Sweden) and Roche Diagnostics (Basel, Switzerland). Both of these partnerships deal with allergy-related diagnostic development.

The recent agreement is in line with LabCorp's much-touted focus on strategic growth in personalized medicine and esoteric testing. In fact, during the company's third quarter, esoteric testing utilization was up 8.4 percent, versus core testing growth of 1.5 percent during the same period. Nevertheless, the testing provider is facing significant regulatory obstacles in this business line. In October, the company voluntarily took its OvaSure cancer test off the market in response to a warning letter from the FDA questioning the test's clinical validity.

Esoteric testing is also a focus at NJH's ADx, as is contract research organization (CRO) testing. "Advanced Diagnostic Laboratories really has two main revenue drivers—one of which is the esoteric testing market, and the other is the CRO for the pharma segment," said Smith. "We are going to be expanding both rapidly."

Smith estimates that ADx's revenue is split 50/50 between CRO and diagnostic testing services. Within the esoteric testing business, molecular diagnostic testing is a growth area for the hospital. ADL opened up a 3,000-foot molecular diagnostic testing lab early in 2008 and expects the lab's annual volume to top 10,000 in its first full fiscal year (June 2008 through July 2009), according to Smith.

The molecular diagnostic lab, which has a projected annual growth rate of 35 percent, is a vital component of NJH's strategy to expand its testing services across the country. "Our marketplace is the continental United States, and we are making these relationships to get away from being a Denver or Colorado regional lab," said Smith. "Molecular diagnostics is the vehicle by which we are going out into the marketplace."

The growth of the molecular diagnostics lab is well-defined, with the testing direction determined by two questions—what's the market potential, and does the testing support the institution's core clinical area of mycobateria, immunology, and cardiology? "For example, we would likely not offer a cervical cancer assay because that's not a core clinical area at our hospital, but if someone approaches us about offering a lung cancer test, we would be interested," said Smith.

NJH's Core Clinical Areas

Core Clinical Area	*Estimated Market in United States Based on Morbidity*
Asthma	22.9 million (2006)
Chronic lower respiratory disease*	13.6 million (2006)
Heart disease	24.1 million (2006)
HIV	1 million (2006)
Autoimmune diseases	14 million (2006)
Lung cancer	2.7 million (2004)

*Excludes asthma
Source: National Center for Health Statistics, Washington G-2 Reports

Test pricing is also part of the growth strategy, with the lab offering higher-priced tests to maximize revenue. "Strategically, in order for us to grow rapidly on the top line, we are going to focus on tests that allow us to focus on that, which means that we probably won't be offering $25 tests, but higher-priced tests," added Smith.

U.S. Health Care Spending Rises at Slowest Rate in 10 Years

According to newly released data from the Centers for Medicare and Medicaid Services (CMS), health care spending in 2007 accounted for 16.2 percent of the gross domestic product, up from 16 percent in 2006. The CMS report was published in the January issue of Health Affairs.

Medicare spending rose 7.2 percent in 2007, down from 18.5 percent in 2006, while Medicaid spending increased 6.4 percent. Medicare managed care grew 23.3 percent, accounting for nearly 60 percent of the total change in Medicare spending.

Consumers paid more out-of-pocket in deductibles and copays, $269 billion, or 5.3 percent more than in 2006 when these costs rose 3.3 percent. Health care premiums for private coverage grew 6 percent, the same rate as in 2006, but down from a high of 10.2 percent in 2002.

Hospital and physician care sectors, which accounted for 52 percent of total health care spending, showed substantial increases: Hospital spending was up 7.3 percent to $697 billion, and physician and clinical services increased by 6.5 percent to $479 billion.

Medicare managed care enrollment grew 16.3 percent versus 28.8 percent in 2006, while fee-for-service enrollment fell 0.8 percent, from 2.3 percent in 2006. Private insurance covered 35 percent of health care costs in 2007, followed by Medicare (19 percent) and Medicaid and the State Children's Health Insurance Program (15 percent).

IVD Stocks Rebound by 7%; Immucor Gains 18%

After four consecutive months of losses, the 17 stocks in the G-2 Diagnostic Stock Index gained an average of 7 percent in the five weeks ended January 9, with 10 stocks up in price, six down, and one unchanged. Both the G-2 index and the Nasdaq have plummeted 40 percent since the same time last year, while the S&P 500 is down 38 percent.

Gaining ground in recent weeks was **Immucor** (Norcross, Ga.), which climbed 18 percent on quarterly results. Shares in the maker of blood testing equipment reached a January 9 closing price of $26.46 for a market capitalization of $1.9 billion. The company reported fiscal second quarter revenue of $73 million, up 18 percent from $61.9 million in the same period last year. Company executives attributed the increase in revenue to higher prices and increased sales outside the United States.

"We continue to experience very good demand for our Echo instrument, which contributed to our solid second quarter performance and our ability to raise our guidance for fiscal 2009," said Edward Gallup, former chairman of Immucor, in a conference call with analysts. The company still expects fiscal year 2009 revenue in the range of $292 million to $300 million, but it has raised estimates for gross margin and for fully diluted earnings per share, which are now estimated at between $0.97 and $1.02, compared with the company's previous estimate of $0.94 to $0.98.

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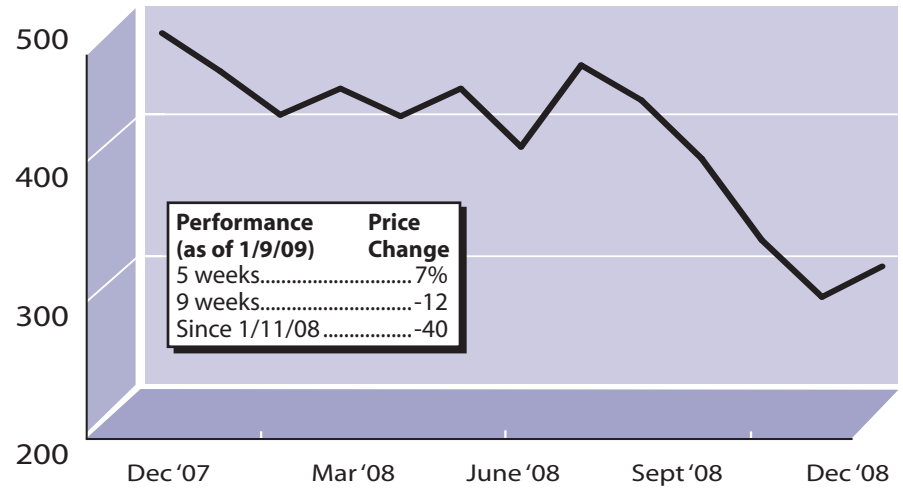
Also rebounding slightly from recent losses was **Affymetrix** (Santa Clara, Calif.), which gained 44 percent to close at $3.84 per share and a market capitalization of $257 million. The company's GeneChip microarray technology was recently used by the Cincinnati Children's Hospital Medical Center to develop a novel molecular diagnostic test to help diagnose the genetic defects in patients with inherited forms of jaundice, the most common symptom of liver disease in young children.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 17 IVD companies.

Up	Price	% Chg
Affymetrix	$3.84	44%
Abaxis	14.71	2
Beckman Coulter	42.91	6
Becton Dickinson	71.28	10
Immucor	26.46	18
Inverness Medical	20.90	27
Johnson & Johnson	59.05	1
Meridian	23.25	1
Nanogen	0.27	50
Nanosphere	5.12	24
Unchanged		
Gen-Probe	40.55	0
Down		
Abbott Labs	50.80	-4
Bio-Rad	65.17	-11
Clinical Data	8.01	-14
Luminex	18.15	-15
OraSure	3.20	-7
Quidel	12.34	-9

G-2 Insider

Biomarkers May Improve Stroke Risk Prediction

Two common biomarkers have been shown to improve the ability to predict who will suffer from a stroke. Results from a prospective study that compared the risk of stroke associated with the biomarkers to that of traditional stroke risk factors were published online on December 18 in the journal *Stroke*.

The multi-center study found that adding two biomarkers associated with inflammation, lipoprotein-associated phospholipase A2 (Lp-PLA2) and high-sensitivity C-reactive protein (hs-CRP), to traditional risk-factor assessment for stroke changed the risk category in which some patients were placed.

The third leading cause of death in the United States, stroke is preventable with medical therapy and lifestyle changes. "If we can identify increased risk for stroke, we can recommend exercise, smoking cessation, and cholesterol and blood pressure medication to reduce a person's risk for stroke by more than 30 percent," said Vijay Nambi, M.D., lead author of the study and cardiologist at the Methodist DeBakey Heart & Vascular Center and Baylor College of Medicine (Houston). "Adding these two biomarkers to traditional risk-assessment tools improves our ability to do that."

The biomarkers proved to be most useful for individuals classified as at intermediate risk for stroke by traditional risk factors, which include high blood pressure, smoking, high cholesterol, diabetes, obesity, and other hereditary factors. "With the addition of the biomarkers, Lp-PLA2 and CRP testing, 39 percent of those patients were reclassified into a lower or higher risk group," said Christie Ballantyne, M.D., senior investigator of the study.

References

Abbott Molecular 800-553-7042
ACLA 202-637-9466
Affymetrix 650-812-8700
Becton, Dickinson 201-847-6800
Clarient 949-425-5700
Exact Sciences 508-683-1200
FDA OIVD 240-276-0450
Genentech 650-225-1000
Genomic Health 650-556-9300
Health Discovery Corporation 912-443-1987
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