# Diagnostic Testing and Technology Report

**Competitive Intelligence & Analysis for an Expanding Global Market**



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CONTENTS




WASHINGTON G-2 REPORTS

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## Aetna Funds Study of Costs, Benefits of Genetic Testing

As advanced testing methods continue to move into mainstream clinical practice, in vitro diagnostics companies are under greater pressure to justify the prices of their tests. Addressing the still vast data gap, once the turf of researchers and developers, is now being taken up by payers themselves. In September, Aetna (Hartford, Conn.) announced that it is funding a national study on the use of genetic tests for cancer risk.

To be conducted by researchers from the University of South Florida and Georgetown University, the two-year study will explore patterns of how and for what groups of women the available genetic tests for BRCA1 and BRCA2 mutations are being used in community health care settings and whether significant disparities exist in the use of these tests among women of different socioeconomic, racial, and ethnic groups. The study also will examine the use of risk-reduction and screening services by patients following testing. For more on the efforts to gather data related to how testing is affecting patient outcomes, see *Inside the Diagnostics Industry*, p 5.

## GE Healthcare to Acquire Clarient in $587 Million Deal

GE Healthcare (Chalfont St. Giles, United Kingdom), a unit of General Electric, has agreed to acquire cancer testing laboratory Clarient (Aliso Viejo, Calif.) in a deal valued at approximately $587 million. GE will acquire all outstanding common and preferred shares of Clarient at $5 per common share and $20 per preferred share, in each case payable in cash. Shares in the pathology service provider closed yesterday at $3.74.

In announcing the deal, GE Healthcare emphasized Clarient's leading position in molecular diagnostics. The rapidly growing area is widely viewed as

the optimal point to integrate diagnostic testing with diagnostic imaging, in which GE Healthcare is a leading player. The combined company would initially focus on developing novel integrated tools for the diagnosis and characterization of cancer.

Clarient is focused on developing novel, proprietary diagnostic markers and tests for the profiling of breast, prostate, lung, colon, and blood-based cancers to help clinicians make informed decisions on how best to treat their patients.


*Continued on p. 2*

▲ **GE Healthcare to Acquire Clarient,** *from page 1*

The company reported $91.6 million in net revenue for 2009. Since 2005, revenues have grown at a 68 percent compounded annual growth rate.

"Adding Clarient's leading technology to our portfolio will accelerate our expansion into cancer diagnostics and therapy selection tools, while strongly enhancing our current diagnostic and life sciences offerings," said John Dineen, president and CEO of GE Healthcare, in a statement announcing the deal. "We believe we can build a $1 billion-plus business by developing integrated diagnostic solutions for cancer and other diseases."

The deal values Clarient at just under six times revenue. "This valuation is a significant premium to other recent transactions, likely reflecting the underlying value of Clarient's technology portfolio," wrote Kemp Dolliver, an equity research analyst who covers the laboratory market for Avondale Partners (Boston), in a research note. In September, LabCorp agreed to pay $925 million, or 2.5 times revenue, for Genzyme Genetics, which performs reproductive and oncology testing in the United States.

"Some in the lab industry had expected GE to make a move into the industry for some time," noted Dolliver. In January 2007, GE agreed to pay $8.13 billion for Abbott Laboratories' primary in vitro diagnostics and point-of-care diagnostics businesses. However, the companies called off the deal six months later when they were unable to agree on final terms and conditions.

## HHS Disbands Secretary's Advisory Committee on Genetics

Eight years after being established to provide a forum for expert discussion and deliberation on issues related to developments in human genetics, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is no more.

The Department of Health and Human Services (HHS) recently announced that the Oct. 5-6 meeting of SACGHS would be its last one, saying that the committee has addressed all of the major topics delineated in its charter, including the integration of genetic and genomic technologies into health care and public health; the clinical, public health, ethical, economic, legal, and societal implications of these technologies; and the impact of patent policy and licensing practices on their accessibility and availability.

Over the past eight years, SACGHS has tackled all of these issues, along with many others. Some of the committee's most significant undertakings have included repeated efforts to encourage passage of the Genetic Information Nondiscrimination Act (GINA), a 2008 report on the *U.S. System of Oversight of Genetic Testing*, a 2010 report on *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, and a 2010 report on *Direct-to-Consumer Genetic Testing* (links to all of these reports are available at *http://oba.od.nih.gov/SACGHS/sacghs_home.html*).

Despite its considerable research efforts and output, the issues SACGHS investigated have not been resolved with any meaningful degree of finality. GINA, while finally law, is still being implemented by regulatory agencies, and significant enforcement has yet to occur. Regulatory agencies have only recently begun to implement new policies designed to close the gaps in genetic testing oversight identified by SACGHS more than two years ago.

In addition, the issues identified in the committee's two most recent reports—on gene patents and DTC genetic testing—have yet to be meaningfully addressed by federal agencies and represent some of the most contentious issues in genetics law and policy today.

"As we head into a second decade of increasingly personal genomic science and services, there is every reason to expect that as our technological capabilities expand, so too will the number and complexity of issues we are forced to address," noted Dan Vorhaus, an attorney with Robinson Bradshaw & Hinson, on the blog *Genomics Law Report*.

"Our challenge is to continue to develop legal and policy strategies that are reflective and not reactionary—strategies that ensure the safety of individuals while encouraging the innovation necessary to realize the promise of personalized medicine," added Vorhaus. "We hope that the announced disbanding of this experienced and distinguished committee does not signal a declining commitment on the part of [HHS] Secretary Sebelius or [National Institutes of Health] Director Collins to this challenge."

## Novartis to Fund Commercialization of Cepheid's BCR-ABL Test

Pharmaceutical giant Novartis (Basel, Switzerland) is partnering with Cepheid (Sunnyvale, Calif.) to bring a molecular test for BCR-ABL to the U.S. market. The test, which has been available outside of the United States since 2006 and carries the CE mark, can be used to monitor the BCR-ABL gene transcript in peripheral blood specimens from patients diagnosed with Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML).

The goal of the collaboration is to gain FDA clearance and approval for a BCR-ABL test that reports results linked to the International Scale, an internationally accepted standard. Results of the test can assist clinicians in making treatment decisions for Ph+ CML patients. Novartis markets Gleevec (imatinib), a drug that targets the BCR-ABL protein in CML cells.

The agreement calls for Novartis to fund the clinical studies and other development expenses for Xpert BCR-ABL, which runs on Cepheid's Gene Xpert system. Cepheid will also receive an up-front fee of $5 million from Novartis with an additional $3 million in milestone payments over the next 12 months. Upon commercial release of the test in the United States, Novartis will have exclusive global distribution rights to the Xpert BCR-ABL test under a Cepheid/Novartis label.

## HHS Awards Grants to Help Support Lab Technology and Training

On Sept. 24, Department of Health and Human Services (HHS) Secretary Kathleen Sebelius announced that nearly $100 million in grants has been awarded to support a variety of public health programs in states and local communities, including health information technology and training at public health laboratories.

According to HHS, the grants came primarily from the Patient Protection and Affordable Care Act's (PPACA) Prevention and Public Health Fund.

More than $75 million worth of the grants will go to fund key state and local public health programs supported through the Centers for Disease Control and Prevention (CDC), HHS said. Another $26.2 million worth of grants will go to state and community substance abuse and mental health programs from the Substance Abuse and Mental Health Services Administration (SAMHSA).

HHS said that of the money being granted to CDC, approximately $26.4 million will be used to increase epidemiology, laboratory, and health information systems capacity at health departments in all 50 states, two territories, and the six largest local jurisdictions.

HHS said the awards will support hiring and training of epidemiologists, laboratory scientists, and health information specialists who can work on multiple infectious diseases; increasing the number of modern, well-equipped public health laboratories using electronic laboratory information systems to manage and exchange information effectively between labs and public health departments; and developing capacity for public health departments to participate in meaningful use of electronic health records, such as through implementation of electronic laboratory-based reporting according to national standards.

## Novel Genetic Variants Found to Modify Disease Risk in BRCA1 Mutation Carriers

Mayo Clinic researchers have demonstrated that some carriers of BRCA1 gene mutations, which substantially increase the likelihood of developing breast cancer, may possess additional genetic variants that modify their risk. The study appears in the October issue of *Nature Genetics*.

Through genomewide association studies (GWAS), the researchers analyzed 550,000 genetic alterations from across the human genome in carriers of BRCA1 mutations under age 40 who had invasive breast cancer and compared the alterations to those in BRCA1 carriers of similar age without breast cancer. They found five single nucleotide polymorphism (SNP) associated with breast cancer risk in a region of chromosome 19p13.

Further studies of those SNPs in breast cancer patients without BRCA1 mutations showed associations with estrogen-receptor-negative disease. In another GWAS, the five SNPs also were associated with triple-negative breast cancer, an aggressive form of the disease that accounts for approximately 12 percent of all breast cancer. Triple-negative tumors do not express genes for estrogen or progesterone receptors or HER2/neu. The researchers also found that these SNPs were not related to risk for ovarian cancer in BRCA1 mutations carriers.

"These findings should be useful in helping determine individual risk for breast cancer in BRCA1 carriers," said senior author Fergus Couch, Ph.D. When combined with other risk-modifying SNPs that ongoing studies by the Mayo group are seeking to identify, it may be possible to identify certain BRCA1 carriers who are at lower risk of cancer and, also, carriers at particularly elevated risk of cancer who may decide to change their approach to cancer prevention.

# Developers, Payers Move to Fill Data Gap for Advanced Testing

Genetic testing has made inroads into clinical practice, particularly in assessing a patient's predisposition to certain cancers and in determining the effectiveness and dosing of therapies like warfarin. However, insufficient clinician knowledge and inconsistent reimbursement policies are slowing the adoption of even recognized testing strategies— exposing the information gap that exists in the appropriate use of advanced genetic tests.

A host of recent studies linking genetic testing to definitive outcomes data is beginning to fill this information gap and demonstrate the real value that advanced molecular testing can bring to personalized medicine in terms of improved patient outcomes and more efficient use of health care dollars.

"What we can identify in a tumor is ahead of how we can apply it in clinics," said Cheryl Saenz, M.D, clinical professor of reproductive medicine at Moores UCSD Cancer Center. "It is conceivable in the next five years to start tailoring treatment plans based on gene expression profiles. We will start to move towards personalized medicine rather than seeing all tumors as nails and chemotherapy as a hammer."

***"There is a human value and an economic value and we must demonstrate value from multiple perspectives—the individual, payer, provider, and society as a whole."***
***-Eric Stanek,***
***Medco Health Solutions***

Until custom tailored treatments and personalized medicine become a reality, screening and prevention is the best hope for women identified as having a hereditarily high risk for gynecological cancers. A study released in September by researchers collaborating at 22 medical centers across the United States and Europe revealed that for women identified as carriers of the BRCA1 or BRCA2 gene mutations, preventive surgery—mastectomy or salpingo-oophorectomy—was associated with both a decreased risk of developing breast and ovarian cancer and a decreased risk of death. Having a BRCA mutation can increase a woman's risk of breast cancer by 85 percent. The study, published in the *Journal of the American Medical Association*, involved 2,500 women and provides important clinical data definitively linking the BRCA genetic test to improved patient outcomes.

BRCA1 and BRCA2 are among just a handful of single-gene mutations that have become clinically relevant. Researchers identified many other mutations that are not yet medically meaningful.

"We have identified tons of low penetrance genes that increase the risk [of cancer] but not by as much [as BRCA]," explains Virginia Kaklamani, M.D., of Northwestern University's Feinberg School of Medicine. "Other gene mutations are way more frequent, occurring in 10 to 15 percent of the population . . . but increase risk maybe 1.2-fold."

Kaklamani, an associate professor of hematology and oncology, believes that unless the

identifiable risk of disease is significantly elevated and clinicians can do something to alleviate that risk, too much genetic information may cloud clinical decisioning. "If the risk is 1.1 times higher, why would I want to know that? If we recommend a double mastectomy, in my experience, it has to be a greater than a 50 percent increased risk, otherwise patients won't go for it and I don't blame them."

While clinicians await additional guidance and as in vitro diagnostics developers rush to provide evidence of clinical utility, the United States Food and Drug Administration (FDA) recently announced plans to revamp how it regulates product development including the use of biomarkers for personalized medicine. In recognition of the need to accelerate the translation of laboratory innovation into clinically relevant applications, the FDA released a white paper titled "Advancing Regulatory Science for Public Health" on Oct. 6 in which the agency states it must modernize its dated evaluation and approval processes to reduce the cost of bringing products to market and to ensure that innovative products expeditiously reach the patients who need them.

While experts anticipate these revamped regulations will lead to an increase in the number of novel drugs paired with companion diagnostics, the greatest near-term expansion of pharmacogenomics testing will likely apply to existing drugs and common conditions.

A study conducted by Medco (Franklin Lakes, N.J.) and the Mayo Clinic revealed that incorporating genetic testing information into the management of patients taking the blood thinner warfarin led to a 30 percent reduction in hospitalization rates for bleeding incidents as compared to a matched group that didn't receive genetic testing. The study validates that testing for an individual's genetic sensitivity to the drug can significantly improve warfarin's safety and effectiveness.

"Here is an example of a commonly used drug used in a constellation of common clinical circumstances that clearly has a personalized medicine application," says Eric Stanek, Pharm.D., of Medco Health Solutions Inc., the nation's largest pharmacy-benefits management company. But, "Of patients new to warfarin therapy, less than 2 percent received any type of testing that could be considered pharmacogenomics testing. It just hasn't filtered into practice yet."

Fueled by the need to demonstrate both clinical efficacy and value, recent studies are still trying to justify the cost of genetic testing.

"Is there value there? Yes," says Stanek, senior director of research and personalized medicine. "It doesn't take a great deal of imagination. If a test is available for $200 or less and hospitalizations cost $10,000 to $15,000, it is not that difficult to come to a reasonable assessment that testing will create value."

"It is not just about simple economics. It is about value," cautions Stanek. "There is a human value and an economic value and we must demonstrate value from multiple perspectives—the individual, payer, provider, and society as a whole. We at Medco are working hard to develop that—what is the clinical utility and is there value from the different perspectives?"

# Cancer Screening Tests Still Utilized in Terminal Patients

Patients with advanced cancer and resulting limited life expectancy continue to undergo routine cancer screening, according to a study published in the Oct. 13 issue of the *Journal of the American Medical Association* (*JAMA*). The findings could have implications across medical specialties as payers search for savings through the elimination of unnecessary care.

The study shows that fee-for-service Medicare beneficiaries with advanced cancer continue to receive common cancer screening tests at a rate of 35 percent to 55 percent of the utilization rates observed in cancer-free controls.

The study identified 88,000 patients from the Surveillance, Epidemiology, and End Results (SEER) cancer registry diagnosed between 1998 and 2005 with stage IIIB-IV lung; stage IV colorectal, breast, or gastroesophageal; and advanced-stage pancreatic cancers. Median survival was less than two years.

The data from the SEER registry was linked with Medicare claims data using ICD-9 and HCPCS diagnosis and procedural codes for mammography, Papanicolaou test, prostate-specific antigen (PSA), colonoscopy, and flexible sigmoidoscopy. Analysis was restricted to codes specifically identified as screening and excluded claims billed during the first two months subsequent to diagnosis to ensure the procedures were not ordered as part of diagnosis or staging workup.

Rates of cancer screening were compared to a cohort of fee-for-service Medicare enrollees without cancer residing in the SEER areas matched by year of birth, sex, and race.

Among the women with advanced cancer, nearly 9 percent received at least one screening mammogram and 6 percent received at least one Papanicolaou test compared with 22 percent and 13 percent of controls. Among men with advanced cancer, 15 percent received PSA testing compared with 27 percent of controls. Lower gastrointestinal (GI) endoscopy was performed in 1.7 percent of all cancer patients versus 4.7 percent of the controls. Utilization of screening tests was higher among patients who had a previous history of regularly receiving the screening tests.

"Patients and their health care practitioners accustomed to obtaining screening tests at regular intervals continue to do so even when the benefits have been rendered futile in the face of competing risk from advanced cancer," wrote lead author, Camelia Sima, M.D., assistant attending biostatistician in the department of epidemiology and biostatistics at Memorial Sloan-Kettering Cancer Center (New York), while acknowledging there is no way to determine if test use was patient- or physician-driven. "We hypothesize that neither primary care physicians nor oncologists routinely engage in the difficult discussions that require explanation of why continuation of procedures to which patients have become accustomed to is no longer necessary."

Half of the patients who received mammographies, Papanicolaou tests, or PSA tests did so within 10 months of the cancer diagnosis, and half of those receiving GI endoscopy screening did so within 18 months of diagnosis.

The authors say their results are "conservative," with screening rates presumed to be higher among younger, commercially insured patients.

"We have identified a very specific circumstance in which the case for wasteful care is clear," explain the authors. "Curbing cancer screening for patients with advanced cancer would have a small impact on Medicare as a whole. . . . However, iteration of this paradigm across other diseases and conditions could systematically improve the value of each Medicare dollar spent."

Current guidelines do not specifically address appropriate testing for individuals diagnosed with a terminal illness.

## Beckman Coulter's Modified Assay Kits Lead to Shareholder Lawsuit

Shareholders filed a class-action lawsuit against Beckman Coulter Inc. (Brea, Calif.) on Sept. 3 for financial damages resulting from the company's modifications of its troponin assay kits.

Filed in the U.S. District Court for the Central District of California, the suit alleges that the board of directors and other company executives violated the Securities Exchange Act of 1934 by making "materially false and misleading statements regarding Beckman's business and financial results" and by failing to disclose quality and compliance issues related to the company's troponin test kits.

Beckman's AccuTnI is an immunoassay that tests for cardiac troponin I (cTnI) levels for the diagnosis and treatment of myocardial infarction and cardiac muscle damage.

The U.S. Food and Drug Administration (FDA) said in a June 21 letter to the company that Beckman was in violation of the law for marketing AccuTnI on its Access immunoassay system without agency clearance or approval. The FDA determined "significant modifications" were made to the test kits, calling them "adulterated" and "misbranded."

The kit was ultimately recalled on July 12 because the assays might produce lower than expected results.

On July 22, the company announced it had missed earnings estimates for the second quarter and lowered annual revenue and earnings expectations for 2010 in part because of "recent compliance and quality challenges in the U.S." The next day Beckman stock (NYSE: BEC) tumbled 21 percent from the previous days' closing price of $59.90 per share to $47.26.

The plaintiffs in the class-action suit include those who held Beckman common stock shares between July 31, 2009, and July 22, 2010. A spokesperson for the company said they do not comment on pending litigation.

The company is working to reconcile the regulatory issues at the center of the case. In an Securities and Exchange Commission filing the company stated they are pursuing 510(k) clearances for their troponin tests. "Based on our discussions with FDA, we are

planning to conduct a prospective clinical study and to submit two separate 510(k) submissions for our troponin test in the first half of 2011—one for Access instruments and one for DxI instruments."

Scott Garrett, Beckman's CEO, resigned on Sept. 7 and was replaced by J. Robert Hurley as interim CEO.

## New CLSI Guideline Addresses Testing Errors at Point of Care

A new guideline published by the Clinical and Laboratory Standards Institute (CLSI; Wayne, Pa.) details approaches to reducing errors at the point of care. The document describes a core infrastructure for a standardized error-tracking system targeted to reduce risk and increase quality of point-of-care testing (POCT), while accumulating standardized data for benchmarking use.

"The goal of [the guideline] is to improve the performance of POCT by using different indicators, many listed in the document, that are applicable to different aspects of pre-examination, examination, and post-examination phases of testing," said Lou Ann Wyer of Sentara Laboratory Services, who served as chairperson of the CLSI subcommittee that developed the guideline. "Also, it highlights critical components of a quality-management program and how a central laboratory can play into the coordination of the POCT quality program."

The document, "Quality Management: Approaches to Reducing Errors at the Point of Care (POCT07-A)," includes information about potential sources of error, analytes that may be affected, as well as practical suggestions to mitigate the potential error; appendices with templates and examples that can be easily modified and interpreted; and a case study that spans the process of error identification, documentation, and corrective action.

"The aim of POCT07-A is to raise awareness of all the steps in the testing process where things can go wrong," said Valerie Ng, M.D., Ph.D., an adviser to the subcommittee that developed the guideline. "The reader will hopefully use this document to assess his or her own practice, identify areas of weakness, and put in place corrective systems. In doing so, he or she will ensure test results will truly be accurate."

The guideline is intended for use by laboratory directors, managers, supervisors, quality managers, point-of-care coordinators, and other testing personnel responsible for implementing the policies, processes, procedures, activities, and records that support the quality-management activities.

## NCI Awards Grant to Develop Nanotechnology for Pancreatic Cancer

A team of researchers at the University of North Carolina (UNC) has received a five-year $2.3 million grant from the National Cancer Institute's Cancer Nanotechnology Platform Partnerships to address the need for early diagnosis of and more effective treatments for pancreatic cancer.

Using targeted nano-particle technology, based on nano-materials developed in the laboratory of Wenbin Lin, Ph.D., researchers at UNC's Lineberger Comprehensive Can-

cer Center will design nanoscale metal-organic frameworks capable of carrying both imaging and therapeutic cargoes or multiple drugs to increase therapeutic effect.

"Pancreatic cancer is difficult to detect early and to treat," says Lin. "By developing a more targeted delivery system for imaging, we hope to be able to detect tumors earlier. And by using the hybrid nano-materials to deliver drugs directly to the tumor, we could lessen side effects for patients."

## Study Finds Delayed Breast Cancer Diagnosis Linked to Race/Ethnicity

Race and ethnicity appeared to affect diagnostic delay more than insurance status for women with breast abnormalities, according to findings presented at the American Association for Cancer Research Conference on the Science of Cancer Health Disparities, held Sept. 30-Oct. 3, 2010 in Miami.

Heather J. Hoffman, Ph.D., assistant professor of epidemiology and biostatistics at George Washington University School of Public Health and Health Services, and colleagues at the George Washington Cancer Institute, conducted a retrospective cohort study of 983 women examined for breast cancer between 1998 to 2009 at six hospitals and clinics in Washington, D.C.

Study results revealed that non-Hispanic black and Hispanic women with government or private insurance waited more than twice as long for a definitive diagnosis than non-Hispanic white women with government or private insurance.

Diagnostic delay time, or the amount of time between when abnormalities were found until a diagnosis was reached, for uninsured black women was more than twice as long as that of black women with private insurance. Although having private insurance reduced time to diagnosis for black women, they still waited significantly longer for a diagnosis than white women with private insurance.

"We were surprised by the fact that non-Hispanic black and Hispanic women with health insurance experienced greater delays than non-Hispanic white women with health insurance," Hoffman said. "We thought having health insurance would even the field among all women. Insured women should have had the same rapid evaluation regardless of race and ethnicity."

Among those with private insurance, diagnostic delay time, or the number of days from abnormal screening to definitive diagnosis, was 15.9 days for white women, 27.1 days for black women, and 51.4 days for Hispanic women. Diagnostic delay times among those with government insurance were 11.9 days for white women, 39.4 days for black women, and 70.8 days for Hispanic women. Finally, among those without insurance, diagnostic delay times were reported as 44.5 days for white women, 59.7 days for black women, and 66.5 days for Hispanic women.

"Non-Hispanic black and Hispanic women should be the focus of breast cancer screening outreach and follow-up since they experience greater delays in diagnosis than non-Hispanic white women, regardless of type of insurance," Hoffman said. "In particular, we need to investigate the barriers to rapid workup in insured non-Hispanic black and Hispanic women first and then investigate barriers in all uninsured women."

# IVD Stocks Climb 9%; Nanosphere Soars 53%

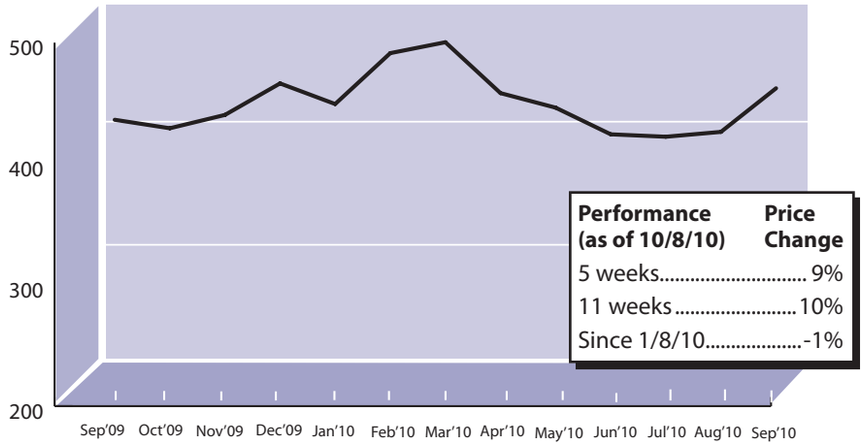
The G-2 Diagnostic Stock Index gained 9 percent in the five weeks that ended Oct. 8, with 14 stocks up in price, three down, and one unchanged. The G-2 index is down by 1 percent since January, while the S&P 500 is up 2 percent, and the Nasdaq is up 4 percent over the same period.

Gaining the most ground in recent weeks was **Nanosphere** (Northbrook, Ill.), which climbed 53 percent to close at $4.88 per share with a market capitalization of $134 million. Shares rose after the company reported positive results for the prostate-specific antigen (PSA) assay it is developing for clinical use. Nanosphere is collaborating with AnalizaDx (Cleveland), which has developed a platform to screen for protein biomarkers in serum and other biological fluids, on next-generation PSA tests for prostate cancer.

At the annual meeting of the North-Central American Urological Association, researchers presented data combining the AnalizaDx technology with the Nanosphere PSA assay. Data for blood serum showed that at a sensitivity of 100 percent, the specificity was 76 percent, with a negative predictive value of 100 percent and a positive predictive value of 84 percent.

One of the few stocks to lose value in recent weeks was **Immucor** (Norcross, Ga.). Shares in the in vitro diagnostics company dropped 12 percent to close at $16.52 per share with a market capitalization of $1.26 billion. At $86.3 million, total revenues for the most recent quarter were up 1 percent over the same period last year, but Immucor saw sales of traditional reagents fall by 9 percent and revised down its outlook for the 2011 fiscal year. "While our financial results were not significantly impacted in the beginning of the economic downturn, it is now evident that an overall weakness in industry demand, particularly in the U.S. market, is negatively impacting both our reagent volumes and our instrument orders," said Immucor President and CEO Gioacchino De Chirico.

## 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 18 IVD companies.

| Up | Price | % Chg |
|---|---|---|
| Abaxis | $23.87 | 23% |
| Abbott Labs | 52.38 | 3 |
| Beckman Coulter | 47.78 | 3 |
| Becton Dickinson | 74.25 | 6 |
| Bio-Rad | 91.46 | 7 |
| Cepheid | 19.83 | 14 |
| Clinical Data | 18.16 | 10 |
| Gen-Probe | 47.93 | 3 |
| Johnson & Johnson | 63.23 | 7 |
| Luminex | 16.27 | 7 |
| Meridian | 21.83 | 11 |
| Nanosphere | 4.88 | 53 |
| OraSure | 4.44 | 20 |
| Sequenom | 7.08 | 14 |
| **Unchanged** | | |
| Quidel | 30.29 | 0 |
| **Down** | | |
| Affymetrix | 4.42 | -1 |
| Immucor | 16.52 | -12 |
| Quidel | 11.59 | -3 |

**A novel approach to PSA testing . . .** Researchers at Memorial Sloan-Kettering Cancer Center (New York) and Lund University (Lund, Sweden) have found that a PSA test at the age of 60 can accurately predict the risk that a man will die from prostate cancer within the next 25 years. The findings, published Sept. 14 online in the *British Medical Journal*, suggest that a baseline PSA could determine who should and should not continue to be screened for prostate cancer.

The study analyzed blood samples from 1,167 men born in 1921 that were collected as part of a Swedish study. All men were followed until they had reached age 85 or had died. After studying various biomarkers, the researchers found that the PSA level was a highly accurate predictor of long-term risk. According to the study, 126 men were diagnosed with prostate cancer, and of those, 90 percent of deaths occurred in men in the top 25 percent of PSA levels at age 60. The researchers concluded that men with a PSA level above 2 ng/ml at age 60 should be considered at increased risk of aggressive prostate cancer and should continue to be screened regularly.

Men with a PSA level below 1 ng/ml had a 0.2 percent chance of death from prostate cancer. The researchers concluded that men with PSA levels in this range should be considered at low risk of prostate cancer death and may not need to be screened in the future. The study also indicated that some men found to be at low risk may actually have prostate cancer; however it is not likely to cause symptoms or shorten their life by the age of 85.

## Company References

Aetna 860-273-0123
AnalizaDx 216-432-9050
Beckman Coulter 714-993-5321
Cepheid 408-541-4191
Clarient 949-425-5700
CLSI 610-688-0100
CMS 410-786-3000
FDA OIVD 301-796-5450
GE Healthcare 870-606-1921
Genzyme 617-252-7500
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Nanosphere 847-400-9000
Novartis 41-61-324-11-11

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