Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Pathway Genomics Draws Government Scrutiny

Most of the so-called consumer genomics firms that have appeared on the scene in recent years have kept relatively low profiles. Pioneers in this nascent market, such as 23andMe and Navigenics, have tried to avoid making claims that would raise the ire of regulators and have framed their businesses as providing information for "recreational" rather than diagnostic purposes. They have also kept their operations fairly discreet and conducted business almost entirely online. Pathway Genomics (San Diego) decided to buck the trend, blanketing consumer media with news that it would be offering its saliva collection kit through thousands of drugstores nationwide beginning in mid-May.

Pathway's marketing blitz quickly drew the attention of the U.S. Food and Drug Administration (FDA), which promptly issued a warning letter to Pathway Genomics CEO James Plante notifying him that the test required FDA clearance. Walgreens and CVS soon decided not to offer the test in their stores. Then lawmakers escalated the issue, embarking on a broad-based investigation of personal genetic testing services. On May 19, leaders of the House Energy and Commerce Committee asked Pathway Genomics, 23andMe, and Navigenics to respond to concerns by the scientific community about the accuracy and proper consumer use of the test results. For more on DTC genetic testing, see *Inside the Diagnostics Industry*, p. 5.

Health Care Reform Law Expected to Boost Preventive Testing

When the dust settled on the health care reform legislation, diagnostic testing providers had managed to avert the restoration of a 20 percent copay for Medicare-covered clinical laboratory services and a proposed $750 million annual levy on labs but were left with a 2.3 percent excise tax on medical devices, including reagents, kits, and equipment purchased by laboratories. With 32 million more Americans set to become insured by 2019, many in the industry are crossing their fingers that expanded coverage will generate increased utilization of lab services covered by Medicare and private payers, softening the blow of the law's estimated $10 million in Medicare Part B reimbursement cuts.

Continued on p. 2

▲ Health Care Reform Law Expected to Boost Preventive Testing , *from page 1*

However, much will depend on the implementation of key measures outlined in the massive law. Among the reform initiatives that providers, developers, and manufacturers of diagnostic tests will be monitoring most closely are those that promise an increased focus on prevention and wellness.

The health care reform law puts a premium on services recommended by the U.S. Preventive Services Task Force (USPSTF). Medicare may decide to cover additional screening tests with an A or B rating, while group and individual health plans will be required to cover services rated A or B, along with other recommended preventive services and immunizations.

The task force is an independent panel of private-sector experts charged with assessing the scientific evidence for the effectiveness of a broad range of clinical preventive services, including screening, counseling, immunizations, and medications, which may vary by age, gender, and risk factors for disease.

The task force grades the strength of the evidence as A (strongly recommends), B (recommends), C (no recommendation for or against), D (recommends against), or I (insufficient evidence to recommend for or against).

The current panel has 12 members drawn from primary care and prevention fields and has numerous partners in medical specialty organizations and federal agencies.

The reform law requires broader representation of clinical specialties on the task force. It also requires the panel to update previous recommendations by considering best practices from government agencies, professional medical societies, patient groups, and scientific societies. The Clinical Laboratory Coalition was among those that lobbied for this wider input in the USPSTF decisionmaking process.

The USPSTF is administered by the Agency for Healthcare Research and Quality (AHRQ) within the Department of Health and Human Services (HHS). It is supported by an Evidence-based Practice Center, which, under contract to AHRQ, conducts systematic reviews of the scientific evidence for the task force recommendations.

Other prevention and wellness initiatives included in the health care reform law include the creation of a program that provides grants to small employers that establish wellness programs. Additionally, in 2013, employers can offer employees rewards up to 50 percent of the cost of coverage for participating in a wellness program and meeting certain health-related standards.

The law also provides for the establishment of the National Prevention, Health Promotion, and Public Health Council. Among the responsibilities of this body is to develop a national strategy for the implementation of a national public-private partnership to conduct an outreach and education campaign to raise awareness of health improvement across the life span. HHS is also required to convene a public meeting on how to determine payment levels for new lab tests under Medicare, including a discussion of payment reform for such tests. HHS will submit a report to Congress summarizing the meeting, including recommendations for legislative or regulatory action.

FDA Clears Quest's Test for H1N1 Flu

The U.S. Food and Drug Administration (FDA) has issued 510(k) clearance for the 2009 H1N1 influenza test developed by Focus Diagnostics, a subsidiary of Quest Diagnostics (Madison, N.J.). The laboratory-developed test, which is marketed under the Simplexa brand, is the first test to be cleared by the FDA for use as an aid in the detection and differentiation of influenza A and 2009 H1N1 influenza viral RNA.

The Simplexa influenza A H1N1 (2009) test uses real-time reverse transcription PCR (rRT-PCR) to qualitatively detect 2009 H1N1 influenza viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, and nasal aspirates from patients with signs and symptoms of respiratory infection. The test is cleared for use on the on the 3M Integrated Cycler. Focus has performed the test in its Cypress, Calif., laboratory since May 2009.

"When 2009 H1N1 surfaced about a year ago, limitations in traditional flu tests made them unsuitable for dealing with a virus infecting large swaths of the population. These limitations included the sensitivity of rapid tests and the need to ship samples to reference labs with reliable PCR methods," said John G. Hurrell, Ph.D., vice president and general manager of Focus Diagnostics. "We designed our Simplexa 2009 H1N1 test to overcome these problems by bridging highly reliable PCR with testing technologies that many hospital labs can perform in-house."

The test was among the first to receive emergency use authorization (EUA) from the FDA following the April 26, 2009, declaration of a public health emergency involving H1N1. In an EUA issued on July 24, 2009, the FDA authorized Focus to distribute the test to laboratories certified under CLIA to perform high-complexity tests. Use of the handful of tests that received EUAs is authorized only for the duration of the declaration of emergency, which is currently set to expire on June 23, 2010.

Molecular Diagnostics Startups Raise Venture Funding

Venture capital continues to flow into startup companies focused on developing molecular diagnostic tests and technology. CardioDx (Palo Alto, Calif.) and Exosome Diagnostics (New York City) are two such firms that have recently announced substantial investments and partnerships.

CardioDx has inked a deal with GE Healthcare (Fairfield, Conn.) to advance and co-develop diagnostic technologies to improve the care and management of patients with cardiovascular disease. Additionally, a new GE equity fund focused on promising health care technology companies has invested $5 million in CardioDx as part of a Series D round that the fund is leading. This marks the first investment for the $250 million Healthymagination Fund, part of a GE initiative to reduce cost, increase access, and improve quality in health care. Other financial terms were not disclosed.

Founded in 2004, CardioDx develops genomic tests to aid in the assessment and tailoring of care of individuals with cardiovascular diseases such as coronary artery disease (CAD), cardiac arrhythmias, and heart failure. The company's initial product, Corus CAD, is a molecular test that integrates the expression levels of 23 genes and other

patient characteristics that have been demonstrated to indicate obstructive CAD—a narrowing or blockage of the coronary arteries that can lead to heart attack or death. The test is performed exclusively by CardioDx's CLIA-licensed laboratory.

Another developer of molecular diagnostic tests, Exosome Diagnostics, recently announced that it has raised $20 million, coled by NGN Capital (New York City) and Forbion Capital Partners (Naarden, the Netherlands), to further develop and commercialize a series of body fluid-based oncology diagnostics through its proprietary, exosome-based technology platform. The company is establishing research and development and service operations in New York and Munich.

Exosome Diagnostics was formed in May 2008 following completion of an exclusive license from Massachusetts General Hospital to commercialize exosome technology. Exosomes are shed by solid tumors into bodily fluids, such as blood and urine. Tumor exosomes contain nucleic acid sequences of a cancer's genetic material.

"We believe our exosome-based technology offers a new medium for reproducible, high-quality extraction of RNA from blood," said James McCullough, CEO of Exosome Diagnostics. "This financing round provides us with the strong global network necessary to accelerate product development and provide a comprehensive molecular companion diagnostic program to pharmaceutical partners."

EHRs Lack Usability Standards, Study Finds

Usability is vital for driving the appropriate utilization of electronic health record (EHR) systems, but this important factor remains poorly defined by vendors. A new report published by the Agency for Healthcare Research and Quality (AHRQ) presents key findings from a recent EHR vendor survey on usability as well as recommendations based on the findings.

The report, "Electronic Health Record Usability Vendor Practices and Perspectives," is based on a series of interviews with vendors of ambulatory EHR products. Interviews focused on the existence and use of standards and "best practices" in designing, developing, and deploying EHR products; how usability is tested and evaluated; and supporting post-deployment monitoring to ensure patient safety and effective use.

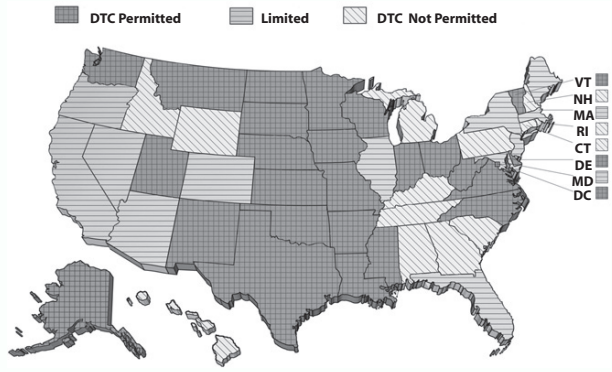
All vendors interviewed expressed their commitment to the development and provision of usable EHR products, but specific best practices and standards of design, testing, and monitoring of the usability of EHR products are not readily available, the report finds. Moreover, because nearly all vendors surveyed viewed usability as their chief competitive differentiator, collaboration among vendors with regard to usability is almost nonexistent.

Among the recommendations offered by AHRQ are to encourage EHR vendors to address key shortcomings that exist in current processes and practices related to usability of their products, particularly lack of adherence to formal user-design processes. AHRQ also supports the formation of an independent body for vendor collaboration and standards development as well as the development of standards and best practices in the use of customization during EHR deployment.

Pathway Genomics Test Prompts Broader Investigation

Personal genomics companies such as 23andMe (Mountain View, Calif.) learned early on to avoid making brash claims about how the information provided by their genotyping tests was intended to be used. "What we do not and will not do is provide medical advice to our customers," the company has said, a statement that was echoed by deCODE Genetics (Reykjavik, Iceland), which has described its direct-to-consumer (DTC) offerings as "not a clinical service to be used as the basis for making medical decisions." Pathway Genomics didn't take the hint.

State DTC Testing Statutes and Regulations



Source: Genetics and Public Policy Center

In May, the startup company trumpeted news that its Insight Saliva Collection Kit would soon be available in thousands of Walgreens drugstores. "We're revolutionizing the way people access information about their genetics," said CEO Jim Plante, who founded Pathway Genomics in July 2009. "The value of knowing how genes play a role in our personal lives, and potentially the lives of our children, is critical for making well-informed health and wellness decisions."

Slated to retail at between $20 and $30, the product includes a saliva collection kit, instructions, and a postage-paid envelope to send the swab to Pathway for analysis. Customers who have purchased the kit can activate an online account and choose to order a variety of results reports, including those that analyze single nucleotide polymorphisms (SNPs) related to drug metabolism (which costs an additional $79) and predispositions to common health conditions such as heart disease, cancer, and diabetes ($179).

Genotyping is performed in a CLIA-certified laboratory. Because Pathway's facility has not been licensed by the New York State Department of Health, the company cannot accept samples from New York state. Pathway's services are also currently unavailable to residents of Maryland, according to the company. However, Pathway has not addressed the variety of state statutes and regulations that limit or prohibit consumers from ordering and/or receiving results for laboratory tests.

The Insight kit has yet to make it on store shelves. In a May 10 warning letter, the U.S. Food and Drug Administration (FDA) said that Pathway's DTC product "appears to meet the definition of a medical device" in federal law and gave the company until May 25 to explain why it believes the product does not require FDA clearance or approval. Walgreens and CVS, which had also planned to stock the product, announced that they would not sell it.

As scrutiny of DTC genetic testing intensified, Congress broadened the inquiry to other firms. On May 19, leaders of the House Energy and Commerce Committee gave Pathway Genomics, 23andMe, and Navigenics (Foster City, Calif.) until June 4 to respond to concerns by the scientific community about the accuracy and proper consumer use of the test results. According to the House panel, the investigation was motivated by Pathway's attempt to market its kits in retail stores "despite concern from the scientific community regarding the accuracy of test results."

Routine Kidney Function Tests Can Predict Mortality Risk

Common tests of kidney function and damage predict the risk of death from cardiovascular diseases and other causes, according to a study published in the May 18 online edition of *The Lancet*. Undertaken by the Chronic Kidney Disease Prognosis Consortium, the analysis of 21 studies from 14 countries found that tests of estimated glomerular filtration rate (eGFR) and urine albumin-to-creatinine ratio (ACR) were strongly related to mortality risk.

A meta-analysis sheds new light on the usefulness of GFR and albuminuria to define and assign stages to chronic kidney disease.

Clinical and laboratory guidelines recommend ACR as the preferred measure of albuminuria for the definition of chronic kidney disease and for assignment of disease stages. The urine dipstick test is often used for initial screening because it is less expensive and can be done at the point of care.

"People with high levels of albumin in their urine were at markedly higher risk of mortality than people with low levels of albumin in the urine," said Kunihiro Matsushita, M.D., Ph.D., lead author of the study and a postdoctoral fellow at the Johns Hopkins Bloomberg School of Public Health.

"The risk of mortality was elevated by nearly 50 percent at 30 mg/g albumin to creatinine ratio, which is the threshold for defining chronic kidney disease," explained Matsushita. "In addition, mortality risk increased more than fourfold at high levels of albuminuria compared to an optimal level of 5 mg/g." The data presented in the analysis confirm that current thresholds are indicative of increased mortality risk, with both kidney filtration function and urine protein contributing to risk.

The new findings are part of a larger effort to use data to refine the definition and staging of chronic kidney disease. Current guidelines from the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative define chronic kidney disease based on the presence (for greater than three months) of either estimated kidney filtration function below 60 ml or kidney damage most commonly detected by protein in the urine.

"This study conclusively confirms earlier suggestions for including both of these kidney measures in risk evaluation and provides a quantitative basis for chronic kidney disease definition and staging," said co-author Josef Coresh, M.D., Ph.D., professor in the Bloomberg School's Department of Epidemiology and director of the George W. Comstock Center for Public Health Research and Prevention.

Gene Mutation Is Promising Target for Pharmacogenomics

A novel single nucleotide polymorphism (SNP) alters the level of a protein in the liver responsible for processing between 45 percent and 60 percent of medications used to treat a wide range of conditions. The discovery, reported in a study published online in *The Pharmacogenomics Journal*, could result in a genotyping test that improves dosing for approximately half of the clinically used drugs on the market.

The novel SNP affects the gene's protein-producing process, in turn lowering the level of an enzyme known as CYP3A4. Levels of this enzyme can vary widely. When this enzyme level is lowered by the presence of this SNP, people are likely to require smaller doses of medicines that the enzyme metabolizes. Higher doses of these same drugs can be dangerous to people with the mutation.

The researchers suggest that this mutation could serve as a molecular biomarker to aid doctors in clinical practice, affecting dosing requirements, patients' response to medications, and toxicity levels of numerous drugs, particularly anti-cancer medications.

Among the drugs metabolized by the CYP3A4 enzyme are three specific types of cholesterol-lowering drugs known as statins: atorvastatin (Lipitor), lovastatin (Mevacor), and simvastatin (Zocor). The researchers tested for the presence of the newly identified SNP as a biomarker in patients taking statins to control their cholesterol.

Among a group of 273 patients taking the three relevant statins, 22 were carriers of the mutation. The doses that these patients took were significantly lower than the doses taken by patients without the mutations. Cholesterol levels among all the patients were similar. Further testing demonstrated that carriers of the mutation were less likely to be taking a higher statin dose based on lower levels of the CYP3A4 enzyme present in their livers.

Using this SNP as a biomarker could reduce the guesswork associated with prescribing drugs. "Right now, because there are no biomarkers available to predict CYP3A4 activity, trial and error determines whether cholesterol goes down with the prescribed dose," said Danxin Wang, a research scientist and adjunct assistant professor of pharmacology at Ohio State University and lead author of the study. "You never know who has what enzyme level, so you never really know what dose to give an individual if you don't have a biomarker."

The biomarker also could be applied to early clinical trials of new drugs, Wang said, by identifying research participants ahead of time who will not respond well to new formulations.

Aurora Diagnostics Files $150 Million IPO

Aurora Diagnostics, a diagnostic lab and anatomic pathology company based in Palm Beach Gardens, Fla., has filed for a $150 million initial public offering of stock. The company plans to trade on Nasdaq under the symbol "ARDX."

Aurora was founded in 2006 as a platform for the acquisition and integration of anatomic pathology and other diagnostic laboratory businesses. It is owned in part by Summit Partners (51 percent), KRG Capital Partners (34 percent), and company management (15 percent). Pricing and additional terms of the IPO have not been disclosed.

The majority of Aurora's revenues in 2009 were derived from physicians providing diagnostic services in the nonhospital outpatient channel of the anatomic pathology market. The company maintains 36 exclusive contracts with hospitals under which it provides outpatient professional anatomic pathology services. It also provides medical

director services and, for some hospitals, technical slide preparation services.

"The success of our business model and the value of our specialized diagnostic service offerings are reflected in our significant growth allowing us to reach $171.6 million in annual revenues in 2009," notes the company in a filing with the Securities and Exchange Commission. "Through a combination of organic growth and strategic acquisitions, we have achieved a scale allowing us to provide diagnostic services to the patients of our approximately 10,000 referring physicians, generating approximately 1.6 million accessions in 2009. With 19 primary locations across the United States, we have achieved a national footprint and a leading presence in our local markets upon which we are continuing to build a more integrated and larger-scale diagnostics company."

Through March 31, 2010, Aurora has acquired 17 diagnostic services companies throughout the United States. The most recent acquisition, in November 2009, was a pathology practice for $15.3 million.

According to a company filing, Aurora's net revenues reached $171.6 million in 2009, an increase of 8.7 percent from $157.9 million in 2008. Organic revenues increased 7.7 percent from $150.2 million to $161.8 million, with the remaining increase of $2.2 million reflecting the impact of the 2008 and 2009 acquisitions.

Aurora attributes the organic revenue growth to a 4.5 percent increase in the volume of accessions and a 3 percent increase in the average revenue per accession. Average revenue per accession increased 3 percent from about $106 to $109 resulting from a combination of an increase in reimbursement and the ordering of additional tests for accession related to cervical screenings.

While Aurora anticipates continued organic growth in annual accession volumes of 5 percent to 10 percent, it also expects the average revenue per accession to decline as the result of a number of factors, including a trend toward referring physicians performing technical and/or professional components of their diagnostic services in their offices, which results in a lower average revenue per accession.

Reform Law Includes Tax Credits, Grants for Biomedical Research

The Internal Revenue Service has released guidance concerning the application process for the new Therapeutic Discovery Project Program created by the health care reform law. The program will provide up to $1 billion in tax credits and grants to small companies that show significant potential to produce new therapies, address unmet medical needs, reduce the long-term growth of health care costs, and advance the goal of curing cancer within the next 30 years.

The credit's allocation will also take into consideration which projects show the greatest potential "to create and sustain high-quality, high-paying jobs in the United States and to advance our competitiveness in the fields of life, biological, and medical sciences," according to a statement issued by the U.S. Department of the Treasury on May 21. The program is open to companies that have 250 or

fewer employees at the time the application is submitted.

The credit covers up to 50 percent of the cost of qualifying biomedical research, up to a maximum credit of $5 million per firm and $1 billion overall. To provide an immediate boost to biomedical research, the credit is effective for investments made in 2009 and 2010. Companies may submit applications beginning June 1, 2010, and applications must be postmarked by July 21, 2010.

The Department of Health and Human Services (HHS) will evaluate each project for its potential to produce new therapies or reduce health care costs. Only projects that show a reasonable potential to meet these goals will be certified as eligible for the credit. Credits and grants will be announced by the end of October based on the decisions made by HHS.

Reimbursement Protection Tops ACLA Priorities in Coming Year

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

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

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

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

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

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

Hawaii's Diagnostic Lab Services Expands Molecular Testing

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

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

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

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

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

CLSI Publishes Guideline on Point-of-Care Tests

The Clinical and Laboratory Standards Institute (CLSI; Wayne, Pa.) has published a guidance document on selecting point-of-care testing (POCT) devices. The approved guideline discusses best practices for selecting POCT devices based on the patient care setting and clinical needs.

CLSI's 68-page document is designed to help clinical laboratory managers simplify and facilitate the POCT selection process by providing a more thorough understanding of the implications, limitations, and overall components involved in POCT device selection. The guideline also allows evaluation of devices to identify those that are optimal to the patient care setting and population served.

"This document really gets to the critical issue behind implementing a point-of-care test," says Marcia L. Zucker, Ph.D., director of clinical support at Response Biomedical Corp. and chairperson of the committee that developed the guideline. "They will understand the pitfalls, understand how to make implementation of the system as smooth as possible, and have evidence that implementation will likely improve patient care."

IVD Stocks Dip 3% as Spring Slump Continues

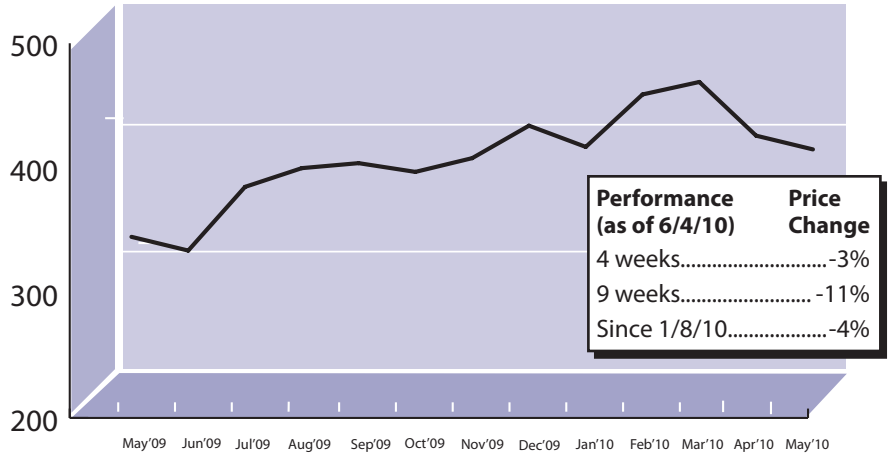
The G-2 Diagnostic Stock Index fell an average of 3 percent in the four weeks ended June 4, with 13 stocks down in price, four up, and one unchanged. The G-2 index is down 4 percent so far this year, as is the Nasdaq, while the S&P has fallen 7 percent.

Among the many stocks losing ground was **Abbott Labs** (Abbott Park, Ill.), which fell 4 percent to close at $46.53 per share with a market capitalization of $70.8 billion. Market reaction was muted to news that the U.S. Food and Drug Administration (FDA) cleared Abbott's test for monitoring ovarian cancer. The Architect HE4 (human epididymis protein 4) assay, which measures levels of the HE4 biomarker in blood, was developed in partnership with Fujirebio Diagnostics (Malvern, Pa.). The automated immunoassay is designed to be used as an aid in monitoring recurrence or progressive disease in patients with epithelial ovarian cancer.

Also slipping 4 percent was **Immucor** (Norcross, Ga.), which closed at $19.32 per share with a market capitalization of $1.3 billion. While share prices have stagnated in recent months, the in vitro diagnostics company is forecasting growth for its 2011 fiscal year, which began June 1. Revenue is expected to increase by $10 million to $15 million to between $345 million and $355 million. Immucor management attributed the growth to projected increases in sales of reagents from instrument placements as well as higher prices, which are expected to add $8 million to $12 million.

An outlier in the index over recent weeks has been **Sequenom** (San Diego), which jumped 30 percent to close at $6.15 per share with a market capitalization of $360 million. The molecular diagnostics company recently allayed investor concerns about funding with the announcement that it has raised $51.6 million in a private placement. Sequenom intends to use the net proceeds from the financing to advance its research, development, and commercialization of various diagnostic tests. The company is slated to launch its test for trisomy 21 (Down syndrome) late next year.

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
Affymetrix	$6.40	4%
Gen-Probe	44.97	2
Luminex	17.20	5
Sequenom	6.15	30
Unchanged		
Cepheid	17.03	0
Down		
Abaxis	21.73	-9
Abbott Labs	46.53	-4
Beckman Coulter	56.29	-6
Becton Dickinson	69.71	-5
Bio-Rad	90.00	-8
Clinical Data	15.81	-2
Immucor	19.32	-4
Inverness Medical	34.61	-6
Johnson & Johnson	58.01	-8
Meridian	17.18	-6
Nanosphere	5.01	-7
OraSure	4.61	-14
Quidel	11.39	-12

G-2 Insider

NIH announces plans for a genetic testing registry . . . The National Institutes of Health (NIH) is creating a public database that researchers, consumers, health care providers, and others can search for information submitted voluntarily by genetic test providers, including clinical laboratories, test manufacturers, and entities that report and interpret tests performed elsewhere. With the oversight of the NIH director's office, the Genetic Testing Registry (GTR) is to be developed this year by the National Center for Biotechnology Information and is expected to be available in 2011.

In compiling the database, NIH defines a genetic test as "a test that involves an analysis of human chromosomes, DNA, RNA, genes and/or gene products (e.g., enzymes and other types of proteins), which is predominantly used to detect heritable or somatic mutations, genotypes, or phenotypes related to disease and health." More than 1,600 genetic tests are available to patients and consumers, but there is no single public resource that provides detailed information about them, NIH said. The new registry is intended to fill that gap.

Information that can be submitted for inclusion in the GTR includes what tests are available, indications for testing, and who offers the tests, as well as details on test quality. Test providers will be encouraged to provide "explicit molecular information" about the test they perform and to cite published support for their assertions to help the public evaluate the data. The registry will also help identify health care professionals who can assist with the testing process and other resources such as referral information for community support groups and disease information.

Company References

Abbott Labs 847-937-6100

ACLA 202-637-9466

AHRQ 301-427-1364

Aurora Diagnostics 561-626-5512

23andMe 650-938-6300

CardioDX 650-475-2788

Cepheid 408-541-4191

CLSI 610-688-0100

deCODE Genetics 354-570-1900

Diagnostic Laboratory Services 808-589-5100

Exosome Diagnostics 646-843-4930

FDA OIVD 301-796-5450

Immucor 770-441-2051

Navigenics 650-585-7743

Pathway Genomics 877-505-7374

Quest Diagnostics 973-520-2700

Sequenom 858-202-9000

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