Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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SACGHS Report Calls for Expanded FDA Oversight

In its final report on gaps in the oversight of genetic testing, the Department of Health and Human Services (HHS) Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) has urged the Centers for Medicare & Medicaid Services (CMS) to increase proficiency testing in this rapidly expanding market. The panel also said, in the report released April 30, that the Food & Drug Administration should expand its regulation to all lab tests, including lab-developed tests (LDTs).

In its main FDA recommendation related to clinical validity, SACGHS said the agency should "address all laboratory tests in a manner that takes advantage of its current experience in evaluating lab tests." In comments on the previous draft, lab and pathology groups argued that the CMS CLIA program should have the lead oversight role for genetic testing, in particular over LDTs, while the FDA should have a consultative role. For more on the final SACGHS report, see *Inside the Diagnostics Industry*, pp. 5-6.

Myriad Genetics to Expand Direct-to-Consumer Marketing Efforts

Myriad Genetics (Salt Lake City) announced on May 6 that it will expand its direct-to-consumer (DTC) marketing campaign for BRACAnalysis, its flagship genetic test for hereditary breast and ovarian cancer. The first campaign debuted last September in the northeastern United States at an estimated cost to Myriad of $8 million and concluded in March of 2008. A second campaign of approximately the same size and cost will be held in the southern region of the country, primarily Texas and Florida, which Myriad says represents 18 percent of the U.S. market for BRACAnalysis, compared with 12 percent for the northeast region.

At Washington G-2 Reports's molecular diagnostics conference on May 2, Greg Critchfield, M.D., president of Myriad Genetics Laboratories, called the initial campaign a success in raising awareness about BRACAnalysis among physicians—particularly obstetricians and gynecologists—as well as consumers. He noted that the company saw a 79 percent increase in third-quarter revenue in the campaign territory as compared with revenues from the previous year. Critchfield also noted other factors that have boosted revenue at Myriad, including the company's recent expansion of its sales force into the OB/GYN market segments and practice guidelines that emphasize the importance of identifying individuals at risk for hereditary cancer. *Continued on p. 2*

▲ **Myriad Genetics,** *from page 1*

As with the initial campaign, the new campaign begins with a direct-to-physician component that precedes the DTC advertising. According to Myriad, the physician-directed phase of the new campaign is already underway, while the southern DTC campaign is expected to run from September 2008 until March 2009.

On May 6, Myriad also announced its results for the third quarter of fiscal year 2008. Total revenues for the quarter were $62 million, compared to $41 million in the same period last year. The company's molecular diagnostics revenue for the third quarter of fiscal 2008 was a record $59 million, compared with $38 million in the third quarter of fiscal 2007, an increase of 55 percent. For the nine months ended March 31, 2008, molecular diagnostics revenue rose to $158 million, from $103 million in the same period in fiscal 2007.

"The DTC campaign has clearly had a significant impact on our revenues over the past two quarters."

The company believes that its increased sales, marketing, and educational efforts, including its DTC advertising campaign in the northeast region, have resulted in increased demand for its molecular diagnostic products, all five of which saw double-digit quarter-to-quarter growth. "We continue to see strong growth in the northeast region as a result of our direct-to-consumer marketing campaign," said Pete Meldrum, president and CEO of Myriad, on the company's May 6 conference call. "The DTC campaign has clearly had a significant impact on our revenues over the past two quarters, and our sample volume has remained strong." According to Meldrum, the company will assess "the staying power" of the DTC campaign by calculating a return on investment in late June and again at the end of the calendar year.

FDA Clears Third Warfarin Genotyping Test

Less than a year after approving a change in the labeling of warfarin to provide information about how people with certain genetic variations may respond to the popular blood thinner, the United States Food and Drug Administration (FDA) has cleared for marketing a third genotyping test to detect the presence of variations in the CYP2C9 and VKORC1 genes. Information about CYP2C9 and VKORC1 genotypes may be used as an aid in the identification of patients at greater risk for warfarin sensitivity. The FDA previously cleared similar tests manufactured by Nanosphere (Northbrook, Ill.) and AutoGenomics (Carlsbad, Calif.).

On April 28, ParagonDX (Research Triangle Park, N.C.) received 510(k) marketing clearance from the FDA for its rapid genotyping assay for CYP2C9 and VKORC1 for use on Cepheid's SmartCycler Dx platform. ParagonDX plans to seize upon its test's speed—results are available in less than one hour—to differentiate itself in an increasingly crowded market. The company also plans to compete on price. It will sell its warfarin testing kits for approximately $350 each, at the low end of the $300 to $500 range for currently marketed gene-based warfarin tests.

Funded by Stratagene founder Joseph A. Sorge, M.D., ParagonDX was formed

in 2007 as a spin-off of Gentris (Morrisville, N.C.). Stratagene was sold to Agilent Technologies for $246 million in June of 2007.

In September, the FDA cleared Nanosphere's warfarin sensitivity test for use on the company's Verigene system, a random access, molecular diagnostics workstation for nucleic acid and protein diagnostics. According to Nanosphere, the Verigene system produces results in 45 to 90 minutes. In January of this year, the FDA cleared the Infiniti Warfarin XP dose-response assay manufactured by AutoGenomics for use on the company's Infiniti platform.

Among the companies that market lab-developed tests for warfarin sensitivity are Clinical Data, LabCorp, Nanogen, and Genelex. In January, Osmetech (London) submitted its eSensor 2C9/VKOR test to the FDA for 510(k) pre-marketing clearance. Third Wave Technologies (Madison, Wis.) has said that it plans to submit its warfarin sensitivity test for FDA clearance in the near future.

Congress Passes Ban on Genetic Discrimination, Measure Ready for Signing

The Senate and the House of Representatives have passed the Genetic Information Non-Discrimination Act (GINA) bill, which bars employers from using genetic information in decisions on hiring, firing, job placement, or promotion. It also prohibits group health plans and other health insurers in the group and individual market from using genetic information to deny coverage or set premium rates and from requiring individuals to undergo genetic testing.

The House has already passed a similar bill twice in the last two years with broad bipartisan support: first in early 2007 as a stand-alone measure, then in March of this year as part of a broader mental health parity bill. The White House has given assurances that President Bush will sign the GINA bill, congressional supporters say.

Critics of the bill say that it defines genetic information too broadly and could prompt frivolous lawsuits. Some groups also point to the fact that if passed, GINA would not preempt the laws of individual states. Meanwhile, advocates hail the legislation as a landmark advance for personalized medicine by establishing federal safeguards to assuage fears by individuals that the results of potentially beneficial genetic testing could be used against them. They point out that with GINA's federal baseline protections, states could enact stronger protections on an individual basis.

Genzyme Genetics Launches Testing for Spinal Muscular Atrophy

Genzyme Genetics, the national laboratory owned by Genzyme (Cambridge, Mass.), has launched population carrier and prenatal diagnostic testing for spinal muscular atrophy (SMA), the most common inherited cause of infant mortality.

An autosomal recessive disease, SMA is characterized by progressive muscle degeneration of motor neurons, resulting in severe muscle weakness. In 60 percent to 70 percent of cases, children with SMA die from respiratory failure by age two. After cystic fibrosis, SMA is the second most common lethal autosomal recessive disease in the United States.

To test for SMA, Genzyme licensed from Athena Diagnostics (owned by Thermo Fischer) a quantitative polymerase chain reaction (PCR)-based assay that can determine the number of SMN1 genes. An individual with one SMN1 gene is a carrier of SMA; a fetus with no SMN1 genes will be affected with SMA. SMA is caused when both parents have only one SMN1 gene. Approximately one in 41 people is a carrier of the SMA-causing gene, resulting in an incidence rate of one in 6,000 to 10,000 births. If both parents are found to be carriers, prenatal diagnosis by chorionic villus sampling or amniocentesis is available.

"Carriers of SMA have no symptoms of the disease and rarely have a family history of SMA," says Stirling M. Puck, M.D., of Genzyme Genetics. "Advancements in technology have led to the ability to detect approximately 94 percent of carriers and then to offer prenatal testing to at-risk parents; these advancements will help couples planning a pregnancy make informed decisions." Greater than 94 percent of SMA carriers have a deletion of one SMN1 gene.

For the first quarter of 2008, the Genzyme Corporation's Genetics business is up 12 percent to $74 million compared to the last year's first quarter. The company attributes the growth to a higher volume of reproductive diagnostic testing, as well as improvement in operating efficiencies and adding information technology infrastructure. Genetic testing contributes 7 percent to the company's total revenues, which grew 25 percent to $1.1 billion, compared to the same time period a year ago.

Inverness Completes Acquisition of Matria Healthcare

Inverness Medical Innovations (Waltham, Mass.) has completed its acquisition of health management company Matria Healthcare (Marietta, Ga.), the company announced on May 9. The final purchase price consisted of approximately $143.9 million and approximately 1.8 million shares of Inverness stock.

Announced in January, the Matria deal is another sign of Inverness's faith in the home health care market for diagnostics. The company plans to consolidate Matria with its three other recently acquired health management businesses—QAS, Alere, and ParadigmHealth—to capitalize on what the company sees as a "general convergence of diagnostics with traditional health management."

In a quarterly conference call on April 24, Inverness CEO Ron Zwanziger noted that Inverness will draw upon its experience following the 2007 acquisition of Biosite to ensure "a successful combination" with Matria. Meanwhile, revenues from Inverness's health management segment reached $45.2 million in the first quarter of 2008, representing 12 percent of total quarterly revenues of $372.2 million.

SACGHS Calls for Expanded Regulation, Resources for Genetic Testing

Charged in March of 2007 with investigating specific questions related to the adequacy and transparency of the current oversight system for genetic testing, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) submitted on April 30 its final report to Michael O. Leavitt, secretary of the Department of Health and Human Services (HHS). Among the committee's key recommendations are calls for expanded federal oversight of laboratory tests in general, with genetic tests given highest priority and for increased proficiency testing (PT) in this rapidly expanding field.

The committee's recommendations are based on the gaps it identified in five areas: regulations governing laboratory quality; oversight of clinical validity of genetic tests; transparency of genetic testing; current knowledge about the clinical usefulness of genetic tests; and meeting the educational needs of health professionals, the public health community, patients, and consumers, along with providing tools to assist these groups in interpreting and communicating genetic test results.

In its 276-page report, the committee noted that it "used a broad interpretation of oversight" that encompassed not only federal and state governments

SACGHS Critical Action Steps for CMS, FDA, and HHS

Clinical Laboratory Quality

- ❑ Require proficiency testing (PT) for all nonwaived laboratory tests for which PT products are available (CMS)
- ❑ Ensure funding for development of platform validation, quality control, and standardization methods (HHS)

Oversight of Clinical Validity of Genetic Tests

- ❑ Oversee *all* laboratory tests, regardless of whether they are produced as commercial tests kits or laboratory-developed tests (FDA)

Transparency of Genetic Testing

- ❑ Support development of mandatory, publicly-available online registry for laboratory tests (HHS)

Knowledge of Clinical Usefulness of Genetic Tests

- ❑ Create and fund a public-private partnership to evaluate the clinical utility of genetic tests (HHS)

Educational Needs for Test Use and Interpretation

- ❑ Support efforts to identify education and training deficiencies relevant to such groups as health professionals, public health workers, and patients (HHS)
- ❑ Support development of clinical decision support systems (HHS)
- ❑ Prepare guidance document articulating the scope of its regulation of clinical decision support systems (FDA)

Source: *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services*, SACGHS, April 2008.

and agencies but also public and private sector health care payers, professional societies, health care providers, and patients. SACGHS's primary recommendations for action are addressed to HHS as well as the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA). Given the complexity of the oversight system, the committee urged "enhanced interagency coordination of activities associated with the oversight of genetic testing."

In its main recommendation related to clinical validity, SACGHS said that the FDA should "address all laboratory tests in a manner that takes advantage of its current experience in evaluating laboratory tests." Here, the committee referred to laboratory-developed tests (LDTs), as well as those produced as commercial test kits. In comments on the previous draft, lab and pathology groups argued that the CMS CLIA program should have the lead oversight role for genetic testing, in particular over LDTs, while the FDA should have a consultative role.

But SACGHS said the FDA should exercise this expanded role by consulting "with a multi-stakeholder public and private sector group to determine the criteria for risk stratification and for systematically applying them." The effort should involve, the committee said, a look at various regulatory models and data sources (for example, New York State, which has the most stringent genetic testing requirements among the states).

The committee's recommendations with regard to FDA oversight encompass genetic tests, as well as all other laboratory tests. "Although SACGHS was tasked to look at the oversight of genetic tests specifically, we concluded that the concerns associated with genetic testing generally do not differ from other complex laboratory tests," the committee noted, adding that genetic tests should be given highest priority in what is expected to be the incremental expansion of FDA oversight.

For CMS, the advisory committee recommended requiring PT for an expanded list of regulated analyses. For tests without PT products, labs should use alternative assessment methods, as required under current CLIA rules. The agency also was advised to develop training for inspectors of genetic testing labs. To pay for these initiatives, the CLIA program should be exempt from hiring constraints imposed by or on HHS, the panel noted.

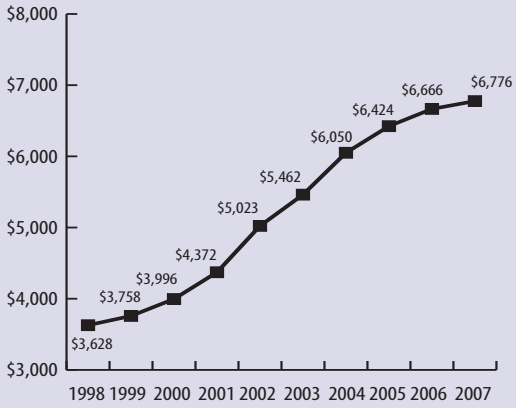
Other committee recommendations were based on enhancing the knowledge of the usefulness of genetic testing and educating various stakeholders about interpreting and communicating test results in the context of clinical decisionmaking. SACGHS recommended that HHS create and fund a public-private partnership to evaluate the clinical utility of genetic tests. In addition to recommending HHS support for development of clinical decision support systems, SACGHS recommended that the FDA prepare a guidance document articulating the scope of its regulation of clinical decision support systems.

Part B Lab Spending Climbs to $6.8 Billion in 2007

Medicare Part B spending for clinical laboratory services increased to $6.8 billion in 2007, up 1.6 percent from 2006, according to the latest data from the 2008 Medicare Trustees Report. The increase, however, is less than in 2006, when the spending rose 3.7 percent over the total for 2005. Medicare Part B lab spending for 2008 is estimated to grow 3.1 percent to just under $7 billion.

The Medicare program covered 44.1 million enrollees in 2007. From 2002 to 2007, Part B lab spending increased an average 8 percent per year. Over the same period, total Part B spending rose 9.6 percent per year to reach $169.7 billion, or 1.3 percent of the gross domestic product (GDP). It is expected to reach $183.9 billion this year and to grow to about 4.1 percent of GDP by 2082. Meanwhile, total Medicare program expenditures increased 5.9 percent to reach $432 billion in 2007, compared with $408 billion in 2006.

Medicare Part B Lab Spending (1998-2007)
($ in millions)



Source: 2008 Medicare Trustees Report

Although the report projects an average annual growth rate of 6.2 percent in Part B costs over the next 10 years, the trustees note that this rate is unrealistically constrained by factoring in multiple years of physician fee reductions that would occur under current law (the SGR formula), including a cut of 10.6 percent that CMS projects for the second half of 2008. If Congress continues to override these reductions, as it has from 2003 through the first half of 2008, the Part B growth rate would average approximately 8 percent.

"Actual future Part B costs will depend on the steps Congress takes to address the situation but could exceed the current-law projections by 7 percent to 8 percent in 2010 and by roughly 10 percent to 20 percent for 2030 and later," the report stated.

LabCorp Expands Companion Diagnostic Development Focus

LabCorp (Burlington, N.C.) and Siemens Healthcare (Deerfield, Ill.) have entered into a nonexclusive agreement to pursue co-development of diagnostics tests relating to companion diagnostics, metabolic syndrome, oncology, and diabetes, both companies announced on May 8. Developing companion diagnostics is increasingly a strategic focus for LabCorp, according to company officials.

"Alliances, such as this between developers and providers of new tests, are critical in translating emerging biomarkers from research into clinical practice," said Myla Lai-Goldman, M.D., executive vice president, chief scientific officer, and medical director for LabCorp.

Earlier this year, the company acquired Tandem Labs Inc. (Salt Lake City), a bioanalytical contract research organization working with pharmaceutical and biotechnology companies on discovery, preclinical, and clinical drug development programs. At the time, LabCorp spokesman Erik Lindblom indicated that the acquisition was more of a strategic move to develop and bring companion diagnostics to market rather than expanding the clinical trials business.

Beckman Coulter Licenses HCV Test from Siemens

Beckman Coulter (Orange County, Calif.) has licensed testing rights for the hepatitis C virus (HCV) from Siemens Healthcare Diagnostics (Deerfield, Ill.) for $12 million. Under the agreement, Beckman Coulter can develop, manufacture, and sell a quantitative viral load HCV blood test for use on the company's molecular diagnostic instrument, which is slated to launch in 2010.

An estimated 180 million people are chronically infected with the hepatitis virus, with which 3 million to 4 million people are newly infected each year. HCV infection can cause acute hepatitis and chronic liver disease, including cirrhosis and liver cancer.

HCV viral load tests measure HCV ribonucleic acid (RNA) in blood to assess whether the virus is actively replicating. Usually performed after a patient has tested positive for exposure to HCV based on an antibody test, viral load testing can confirm HCV infection.

Critical to managing HCV patients, viral load testing is also used to monitor therapy for the duration of the infection. In February, the United States Food and Drug Administration approved for marketing Siemens Healthcare's Versant 440 molecular system for use with the company's Versant HCV RNA 3 assay for management of HCV-infected patients undergoing antiviral therapy.

Group B Strep Increases Among Adults

According to a study in the May 7 issue of the *Journal of the American Medical Association*, the incidence of group B streptococcus (GBS) increased nearly 50 percent among adults between 1999 and 2005. Despite the increase in people aged 15 to 64 years, GBS was found to have declined approximately 25 percent among infants younger than seven days in the same period. Revised in 2002, the Centers for Disease Control and Prevention (CDC) guidelines recommend the screening of all pregnant women for GBS at 35-37 weeks of pregnancy.

A leading cause of sepsis and meningitis in the first weeks of life, GBS can also cause invasive disease in older infants, pregnant women, children and young adults with underlying medical conditions, and older adults. In 2005, GBS caused an estimated 21,500 cases of invasive disease and 1,700 deaths in the United States.

Researchers at the CDC evaluated trends and characteristics among cases of laboratory-confirmed invasive GBS disease identified by population-based surveillance in 10 states. From 1999 through 2005, surveillance identified 14,573 cases of invasive GBS disease, of which 1,232 were early-onset disease. Disease incidence decreased 27 percent after the 2002 release of revised early-onset disease prevention guidelines, from 0.47 per 1,000 live births in 1999-2001 to 0.34 per 1,000 live births in 2003-2005.

GBS incidence increased 48 percent for those age 15 years to 64 years, while those 65 years or older experienced a 20 percent increase. The study found an overall increase of 32 percent in the incidence of adult disease, which reached 7.9 per 100,000 in 2005.

NEJM Study Finds Genetic Links to Neuroblastoma

Neuroblastoma accounts for 7 percent of all childhood cancers, but due to its aggressive nature, it causes 15 percent of all childhood cancer deaths.

An international team of researchers has identified a chromosomal region that is the source of genetic events that give rise to neuroblastoma, an often fatal childhood cancer of the peripheral nervous system that usually appears as a solid tumor in the chest or abdomen. In a study published May 7 in the *New England Journal of Medicine* online, the investigators found that the presence of common DNA variations in the 6p22 region of chromosome 6 raises the risk that a child will develop a particularly aggressive form of neuroblastoma.

"Until now we had very few clues as to what causes neuroblastoma," said pediatric oncologist John M. Maris, M.D., who led the study at the Children's Hospital of Philadelphia, where he is the director of the Center for Childhood Cancer Research. "Understanding this cancer's origin provides a starting point for developing novel treatments."

In the *NEJM* study, researchers analyzed blood samples from approximately 1,000 neuroblastoma patients and 2,000 healthy children. DNA chip analysis identified three single nucleotide polymorphisms (SNPs) that out of over 550,000 SNPs studied were much more common in patients with neuroblastoma, compared to the controls. The three SNPs occurred together on a band of chromosome 6 designated 6p22. This region contains two genes, but their functions are largely unknown.

Patients with these at-risk SNPs on chromosome 6 were more likely to develop aggressive neuroblastoma. The initial changes on chromosome 6 in all their body cells eventually led to the genetic abnormalities seen in tumor cells in high-risk forms of the disease.

The researchers confirmed their findings in additional studies of patients and controls from the United States and the United Kingdom. Further studies are underway to examine how the relatively common genetic changes identified translate to increased cancer risk. "Ultimately, they probably cause subtle changes in gene expression during early development, interacting with other genes yet to be discovered," said Maris. "This suggests that neuroblastoma has complex causes, in which a series of genetic changes may occur at different sites to combine into a 'perfect storm' that results in this cancer."

Saliva-Based Method Shows Promise for Early Diagnosis of Heart Attack

A team led by University of Texas researchers has developed a nano-bio-chip-based assay that could enable rapid, early diagnosis of heart attack, using saliva. Presented at the 2008 annual meeting of the American Association for Dental Research in April, the assay could ultimately be used to analyze a patient's saliva at the point of care, in such settings as an ambulance or a dentist's office.

"Many heart attack victims, especially women, experience nonspecific symptoms and secure medical help too late after permanent damage to the cardiac tissue has occurred," says John T. McDevitt, Ph.D., principal investigator and designer

of the nano-bio-chip. "Our tests promise to dramatically improve the accuracy and speed of cardiac diagnosis."

McDevitt and his collaborators developed a series of compact nano-bio-chip sensor devices that can detect blood serum proteins that are significant contributors to, and thus indicators of, both cardiac disease and risk of future heart attack. Among the biomarkers assessed in both saliva and serum samples were brain-natriuretic peptide, troponin I, creatine kinase-MB, and myoglobin.

Researchers from the University of Kentucky tested saliva from 56 people who had a heart attack and 59 healthy subjects for 32 proteins associated with atherosclerosis, thrombosis, and acute coronary syndrome. They found these proteins were in higher concentrations in saliva of heart attack victims and that specific salivary proteins were as accurate in the diagnosis of heart attack as those found in blood serum using standard methods.

The new diagnostic test uses a saliva sample that is transferred to a credit card-sized card that holds the nano-bio-chip. The loaded card is inserted into an analyzer that manipulates the sample and analyzes the patient's cardiac status on the spot. The system can produce results in as little as 15 minutes.

"What's novel here is our ability to measure all such proteins in one setting and to use a noninvasive saliva sample, where low protein levels make such tests difficult even with large and expensive lab instruments," McDevitt says.

Now in the clinical testing phase, the cardiac diagnostic technology will likely be developed commercially through LabNow (Austin, Texas), a startup venture that licensed the lab-on-a-chip technologies from the University of Texas at Austin. LabNow's first lab-on-a-chip product, the CD4Now BioChip and analyzer device, is for point-of-care HIV immune function testing and can be used in resource-poor settings.

Enzo Biochem Buys Biomol to Boost Life Sciences Business

Life sciences and biotechnology company Enzo Biochem (Farmingdale, N.Y.) has paid $18 million in cash and stock to acquire privately held Biomol International (Plymouth Meeting, Pa., and Exeter, England). With annual revenues of approximately $12 million and 50 employees in its United States and United Kingdom facilities, Biomol produces specialty life science products in the areas of signal transduction, lipid research, apoptosis, neuroscience, and drug discovery, with a research focus in functional proteomics.

The deal should bolster Enzo Life Sciences, one of Enzo's three wholly owned subsidiaries. According to Enzo Biochem President Barry Weiner, the company will combine Biomol with Axxora Life Sciences, which it acquired in 2007, to "transform Enzo Life Sciences into a global manufacturer and marketer of reagents and systems spanning a wide spectrum of scientific applications." In 2007, revenues for Enzo's life sciences division totaled $12.5 million as compared to $7.9 million in the prior year, inclusive of $3.3 million in revenue from Axxora. Meanwhile, 2007 revenue for the company's clinical lab division increased 27 percent to $40.4 million as compared to $31.9 million in 2006.

IVD Stocks Lose 4%; Affymetrix Drops 34%

The 18 stocks in the G-2 Diagnostic Stock Index fell an average of 4 percent in the five weeks ended May 2, with 11 stocks down in price, six up, and one unchanged. The G-2 index is down 13 percent so far this year, while the S&P 500 has fallen 2 percent and the Nasdaq is down 5 percent.

Shares in **Affymetrix** (Santa Clara, Calif.) dropped 34 percent to $11.23 a share for a market capitalization of $788 million. On April 14, the gene chip maker lowered its financial guidance for 2008, announcing that it now expects full-year revenue between $490 million and $510 million, compared with a prior range of $505 million and $525 million.

Affymetrix attributed the guidance cut of approximately 3 percent to pharmaceutical companies's decreased use of Affy chips for gene expression research. The company says that it is now "reviewing ways to further reduce operating expenses to offset the impact of this revenue reduction." Despite the decrease in pharmaceutical research clients, demand for Affymetrix's newer genotyping chips is growing rapidly, with first quarter sales up 24 percent compared with the same period of 2007.

Also falling in recent weeks was **Meridian Biosciences** (Cincinnati). Shares of the diagnostic company were down 19 percent to $28.01 a share for a market capitalization of $1.12 billion. Meridian's second-quarter results, including record sales of $36.2 million, narrowly missed market expectations due to weak sales in its life sciences business.

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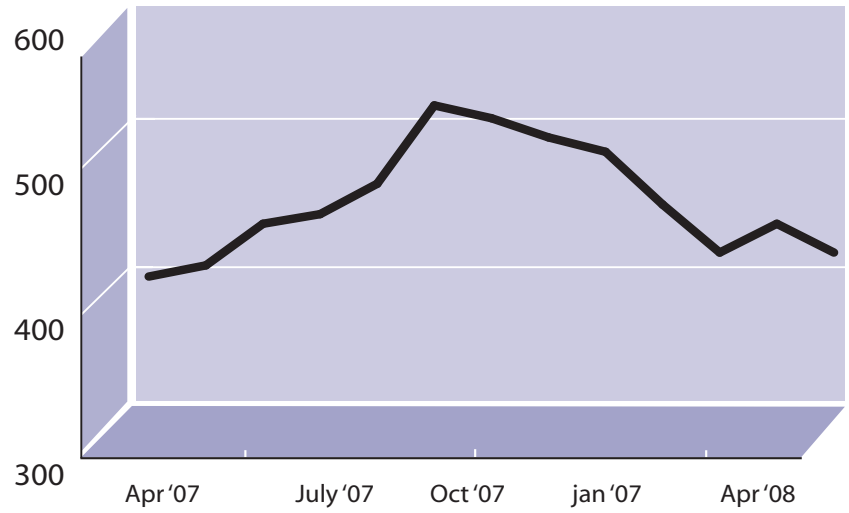
However, Meridian's diagnostics business units continue their strong growth, led by tests for influenza and other upper respiratory infections as well as its tests for *Helicobacter pylori* and the toxin-producing strains of *E. coli*. In April, the company launched two rapid tests for Epstein-Barr Virus (EBV) under its TRU brand.

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	$25.56	3%
Becton Dickinson	89.17	4
Gen-Probe	56.56	9
Immucor	27.92	4
Inverness Medical	36.94	15
Johnson & Johnson	68.26	4
Unchanged		
Beckman Coulter	66.97	0
Down		
Abbott Labs	53.17	-3
Affymetrix	11.23	-34
Bio-Rad	84.15	-5
Clinical Data	16.10	-11
Luminex	19.93	-1
Meridian	28.01	-19
Nanogen	0.40	-5
Nanosphere	6.73	-19
OraSure	6.72	-11
Quidel	16.37	-1
Third Wave	8.94	-6

G-2 Insider

Laboratory Outreach Testing by the Numbers . . . Learn from industry leaders at Washington G-2 Reports's seventh annual laboratory outreach conference, which will take place June 18-20 at the Bellagio Hotel in Las Vegas. The premier business event dedicated to improving the performance, profitability, and management of hospital and health system laboratory outreach programs will provide expert advice and practical strategies on such topics as outreach billing and collections, developing outreach sales and marketing plans, building strategic alliances, and using outreach as a strategy for hospital and health system growth, including the following confirmed speakers and sessions:

- ❑ **Priscilla Cherry**, president of laboratory services at Fairview Health Services, will give a keynote presentation on reconstructing an outreach program.
- ❑ Navigant Consulting's **Linda Flynn** and **Bill Evans** will discuss how to determine market potential and market share for your outreach program.
- ❑ **Scott Liff**, vice president of laboratory services and imaging development at John Muir Health System, will address how outreach testing can succeed in a competitive market and contribute to the success of a hospital.
- ❑ Piedmont Medical Labs CEO **Joe Skrisson** and **Gene Heidt** of Central DuPage Hospital will offer advice on how to build outreach connectivity, including the systems available and related costs.

For a full list of sessions or to secure your place at this event, visit *www.g2reports.com* or call 800-401-5937, ext. 3892.

Company References

Affymetrix 408-731-5000
AutoGenomics 760-804-7378
Beckman Coulter 800-742-2345
CMS 877-267-2323
Enzo Biochem 212-583-0100
FDA OIVD 240-276-0450
Genzyme 617-252-7500
Inverness Medical Innovations 800-257-9525
LabCorp 800-526-3593
LabNow 512-329-9998
Matria Healthcare 800-456-4060
Meridian Biosciences 513-271-3700
Nanogen 858-587-1121
Nanosphere 847-400-9000
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