Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Stephanie Murg, Managing Editor

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WASHINGTON G-2 REPORTS

Established 1979

New NIH Pilot Program Aims To Move Genetic Tests For Rare Diseases Into Clinical Labs

According to the National Institutes of Health (NIH), there are about 6,000 rare diseases affecting 25 million Americans. Although a great deal of research is conducted on the genetics of rare diseases, some of the tests for these disorders never make it out of research facilities and into CLIA-certified labs. At the request of the United States Congress, the NIH's Office of Rare Diseases (ORD) has established the Collaboration, Education, and Test Translation (CETT) Program for Rare Genetic Diseases. This pilot program is intended to promote new genetic test development and better understanding of rare diseases. With input from the Trans-NIH Rare Diseases Working Group, federal agencies, professional associations, patient advocacy groups, and others, the CETT Program will develop models to facilitate the translation of genetic tests from research laboratories to clinical practice.

Under the CETT Program, a collaborative group consisting of a research laboratory, a clinician involved in the study of the disease, a clinical laboratory, and a patient advocacy group may apply to ORD for funds to develop a new clinical test for a rare genetic disease. "We really felt that for quality testing to be performed, all parties had to be involved," says Andrew Faucett, the coordinator of the CETT Program. "Any of the parties can take the lead." The program accepted its first applications in March of this year.

For more about the CETT Program, see *Inside the Diagnostics Industry*, pp. 5-7.

Medicare Will Cover Cambridge Heart's Cardiac Screening Test

After a nine-month process that included two separate public comment periods, CMS has announced that Medicare will cover the Microvolt T-Wave Alternans (MTWA) test developed and manufactured by Cambridge Heart (Bedford, MA). The test was cleared by the FDA in 2002.

The MTWA test measures extremely subtle beat-to-beat fluctuations in a person's heartbeat called T-wave alternans. Clinical research has shown that patients with symptoms of life threatening arrhythmias who test positive for T-wave alternans are at significant risk for subsequent sudden cardiac events including sudden death, while those who test negative are at

➥ *p. 2*

▲ **Medicare Will Cover Cambridge Heart's Cardiac Screening Test,** *from page 1*

minimal risk. The MTWA test is useful for screening out those patients who are not likely to benefit from implantable cardioverter defibrillator (ICD) therapy.

The noninvasive test, which costs about $400 and takes less than 30 minutes, is performed by placing electrodes on a patient's chest prior to a period of controlled exercise. The tiny voltage changes detected by the electrodes are calculated by spectral analysis and then analyzed by software. The final National Coverage Determination by the Centers for Medicare and Medicaid stated that "MTWA diagnostic testing is covered for the evaluation of patients at risk of sudden cardiac death, only when the analytic spectral method is used." Cambridge Health has sold about 500 machines for conducting the test. The machines are priced at $30,000.

Cambridge Heart President and CEO David Chazanovitz said that Medicare coverage of the test "allows caregivers to incorporate MTWA testing into their diagnosis algorithm. The decision represents the clinical validation of MTWA testing. We will continue to work with physicians and providers to establish MTWA as a standard of care in cardiology."

Meridian Bioscience Receives FDA Clearance For Stomach Ulcer Test

H. pylori is believed to infect approximately two-thirds of the world's population and approximately one-third of the population of the United States.

Meridian Bioscience (Cincinnati, OH) has received clearance from the FDA to market its improved stool antigen test to diagnose Helicobacter pylori (H. pylori) infection. The test has been cleared for use on both children and adults.

Able to live in the stomach and duodenum, H. pylori bacteria cause the majority of stomach and duodenal ulcers and are also linked to late-onset stomach cancer. The American Gastroenterological Association's recently issued guidelines for evaluating dyspepsia recommend the use of direct H. pylori tests prior to prescribing symptom-relieving drugs.

Conditions Associated With Helicobacter pylori

- ❏ Duodenal ulcers
- ❏ Gastric (stomach) ulcers
- ❏ Stomach cancer
- ❏ Non-ulcer dyspepsia

Meridian's noninvasive Premier Platinum HpSA (H. pylori Stool Antigen) Plus test detects H. pylori antigen directly from a fresh or frozen stool specimen. The sensitivity and specificity of the test exceed 90%. The list price for the test is $1,584, a company representative tells *DTTR*.

The test is as simple as a blood test, but has the advantage of being able to detect active H. pylori infection. Blood tests only detect antibodies to the organism, so they cannot distinguish between active infection and infection that has been resolved or cured. The test also has less potential for false-negative results due to medications than another noninvasive test known as the urea breath test. John Kraeutler, Meridian's president and chief operating officer, believes that the test's improved accuracy and ease of use make it "ideally suited for high-volume labs."

★ New Editor for *LIR* and *DTTR* ★

Washington G-2 Reports is pleased to announce that Stephanie Murg is taking over editorial responsibilities for *Laboratory Industry Report* and *Diagnostic Testing & Technology Report*. In addition, Stephanie will contribute regularly to the *Lab & Diagnostic eAlert*, work on a variety of G-2's research reports, and participate in a number of our audioconferences and conferences. Most recently, Stephanie has written G-2's soon-to-be-published study on building a molecular diagnostics laboratory.

Stephanie's background fits perfectly with G-2's future and the needs of our readers, including a bachelor's degree in neurobiology from Harvard and experience as a research associate at Harvard, JPMorganChase, and the National Bureau of Economic Research. She will be working out of the New York office and can be reached at *smurg@ioma.com*.

Fisher Scientific Expands Presence In Molecular Diagnostics

Fisher Scientific (Hampton, NH), a leading supplier to scientific, research, and healthcare markets, has agreed to acquire Athena Diagnostics (Worcester, MA) from Behrman Capital (New York, NY) for $283 million in cash. The transaction is expected to close in the second quarter of this year. Fisher simultaneously agreed to purchase 9% of publicly traded biotechnology firm Nanogen (San Diego, CA) for $15 million in cash. The acquisitions will significantly strengthen Fisher's presence in molecular diagnostics.

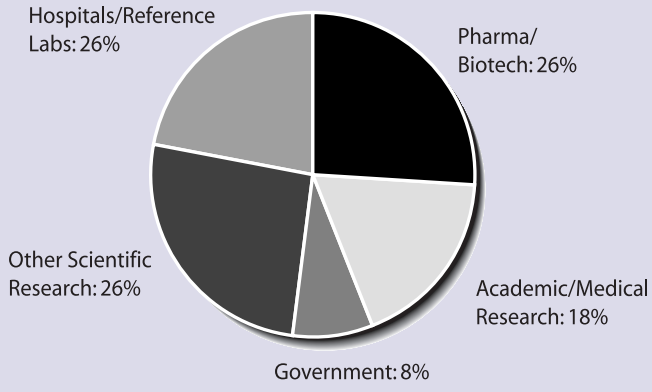
Fisher Scientific at a Glance

Founded: 1902
Headquarters: Hampton, NH
Chairman and CEO: Paul M. Montrone
Revenue (2005): $5.6 billion
Products: 600,000
Employees: 19,500
Sales Force: 3,900, including 800 application specialists
Source: Fisher Scientific

Founded in 1989 as Genica Pharmaceuticals, Athena Diagnostics develops and commercializes diagnostic tests for neurological, nephrological, and endocrine disorders. In 2002, the company was purchased by the private equity firm Behrman Capital from Elan Pharmaceuticals. Athena's portfolio of proprietary tests includes assays for about 80 conditions, including neurogenetic and neuromuscular disorders, Alzheimer's disease, multiple sclerosis, and diabetes. The company's net revenue in 2005 was $55 million.

To expand the use of Athena's proprietary markers and tests, Fisher will collaborate with Nanogen, a provider of advanced molecular diagnostic equipment, microarrays, and reagents for molecular diagnostic applications. Nanogen CEO Howard C. Birndorf sees Fisher's agreement to buy a 9% stake in the company as "another indication that molecular diagnostics for personalized healthcare is gaining momentum and being adopted by mainstream diagnostic laboratories."

Fisher's Customer Base



Source: Fisher Scientific

The Athena acquisition and the Nanogen purchase will help to add high-margin products and services to Fisher's life sciences and scientific product offerings. Since its IPO in 1991, Fischer has acquired all or part of 42 companies. According to Vice Chairman Paul Meister, Fisher expects revenues of about $5.9 billion in 2006, making for a 15% compound annual growth rate (CAGR) since 2001, roughly half of which is attributable to acquisitions and the other half to internal growth. "Fundamentally, we are assembling a much broader portfolio," Meister told attendees at the Lehman Brothers Global Healthcare Conference in March, adding, "Acquisitions have fueled our growth, but we are not relying on them to drive the growth."

JAMA Study Finds Flaws In Myriad Genetics Breast Cancer Test

A study in the March 22/29 issue of the *Journal of the American Medical Association* found that about 12% of breast cancer patients from high-risk families who tested negative for mutations in the BRCA1 and BRCA2 genes carried previously undetected cancer-associated mutations.

The study calls for the use of alternative approaches to the commercial blood test, manufactured by Myriad Genetics (Salt Lake City, UT), for evaluating women with a high probability of carrying a mutation in BRCA1, BRCA2, or other breast cancer-associated genes but who test negative with the Myriad test.

Myriad has a U.S. patent on both the test, known as BRACAnalysis, and the gene sequences of BRCA1 and BRCA2. It charges as much as $3,000 for the test. Accusations that the company's monopoly has hampered the development of more thorough breast cancer assays are likely to increase in the wake of the *JAMA* study. On the day the study was published, shares of Myriad Genetics traded at seven times their average volume, falling $1.46, or 5.4%, to $25.79 in afternoon trading on the Nasdaq, after dropping as low as $23.88 earlier in the day.

UCLA Researchers Develop Saliva-Based Test For Oral Cancer

According to the National Institute of Dental and Craniofacial Research, oral cancer will be diagnosed in approximately 30,000 Americans this year and will cause more than 8,000 deaths. It is the sixth most common cancer in men and the fourteenth most common in women.

Researchers at UCLA's School of Dentistry have developed the first standardized, saliva-based test for oral cancer. The test detects the presence of RNA biomarkers for oral cancer. In a study of 100 people with and without oral cancer, the saliva RNA test proved 82% accurate in detecting oral cancer based on four RNA markers.

According to David Wong, D.M.D., director of the UCLA Dental Research Institute, "Our motivation in investigating the saliva signature for oral cancer was to create a simple yet accurate way to detect this disease early enough in its progression" to avoid fatal outcomes as well as the facial disfigurement and speech impairment that oral cancer can cause when not fatal.

Most oral cancers are diagnosed in late stages, with only half of those diagnosed surviving for more than five years. However, early detection increases survival rates to between 80% and 90%. The new test could greatly reduce oral cancer mortality and morbidity as well as improve the quality of life for oral cancer patients.

Unlike traditional cancer assays that use blood serum, the saliva-based test does not require needles and is simple to perform using polymerase chain reaction (PCR) technology. Results are available within 24 hours. "The test meets the pressing need for a quick, inexpensive, noninvasive, and convenient diagnostic tool," Wong says.

Although the researchers collaborated with Qiagen, a leading provider of molecular biology tools and reagents, to identify the ideal preservative with which to stabilize RNA in saliva, there is not yet a commercial partner producing the test itself. The next step will be to initiate a multi-center study in association with the National Cancer Institute to validate the test for clinical use. Wong tells *DTTR* that he expects that the test will be commercially available within two years at a cost of approximately $10 per test.

NIH Pilot Program Aims To Speed Genetic Tests For Rare Diseases Into Clinical Labs

Currently the knowledge of the genetic basis for disease is outpacing the development of genetic tests, particularly tests for rare genetic diseases. Though individually rare, these diseases and conditions collectively affect a significant portion of the population. The majority of the 6,000 to 7,000 rare diseases known today are considered genetic conditions, and this makes genetic testing an essential part of the diagnosis and management of patients. A new NIH-funded program aims to improve the availability, quality, and accessibility of genetic testing for rare diseases and to promote development of processes and models to enhance the translation of genetic tests from research to clinical practice.

Background and Objectives

Sponsored by the NIH's Office of Rare Diseases (ORD), the Collaboration, Education, and Test Translation (CETT) Program is a pilot program to promote new genetic test development and better understanding of each rare disease. CETT will last about two to three years in this initial phase, according to program coordinator Andrew Faucett, who outlined the program in a recent presentation to members of the Genetic Alliance, a coalition of genetic advocacy organizations, health professionals, clinics, hospitals, and companies.

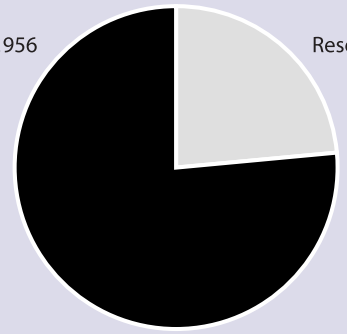
CETT Program Objectives

- ❑ New genetic test development (for diseases that currently have no tests available)
- ❑ Test translation from research to clinical practice
- ❑ Education about each rare genetic disease, research opportunities, and clinical impact

The program was established at the request of the U.S. Congressional House Appropriations Committee and was developed in part through a series of three conferences that took place in 2004 and 2005 and focused on laboratory testing for rare diseases and how to ensure quality in genetic testing. The program was started by the Centers for Disease Control, the ORD, and Emory University.

As of April 2006, the GeneTests database, which is funded by the NIH, listed 1,250 genetic diseases for which there were tests. Of those genetic tests, 294 were available only in research laboratories, most of which

Genetic Disease Tests Indexed in GeneTests



Source: GeneTests (April 2006)

are not certified by the Clinical Laboratory Improvement Amendments (CLIA). Moreover, the number of "research only" tests is likely an underestimate due to lack of reporting by research labs. Additionally, of the 956 tests in clinical usage, approximately 25% of them are only available outside of the United States, and most international laboratories are not CLIA certified (although two Canadian labs are). A primary goal of the CETT Program aims is to move tests into CLIA-certified labs.

CMS regulates all laboratory testing performed on humans in the United States for non-research purposes through CLIA, which covers approximately 189,000 laboratory entities. CLIA regulations, which became effective in 1992, state that any facility performing laboratory testing on "specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health" must become CLIA certified.

Applying to the Program

The CETT Program promotes collaboration among clinical laboratories, researchers, clinicians, and patient advocacy groups. In order to apply, applicants must assemble collaborative groups focused on a particular disease or disorder. Each group must include a clinical (CLIA-certified) laboratory, a researcher (laboratory and/or clinician), and a patient advocacy group. Any of the parties may take the lead in the process. "We really felt that for quality testing to be performed, all parties had to be involved," says Faucett.

The program has facilitated the application process by minimizing the paperwork required and rapidly responding to applicant feedback. Applications are accepted on a monthly basis and reviewed in cycles lasting six to eight weeks. The first applications, accepted in March, are currently under review.

Applicants are required to provide:

- ❏ Information on the scientific evidence linking the test and the disease
- ❏ Information on the qualifications of the laboratory
- ❏ Description of testing approach and clinical uses of the test
- ❏ Information on interpretation of test results for clinical care providers and for patients and their families
- ❏ Projected cost of test setup and charge for individual test
- ❏ Information on clinical utility regarding payor reimbursement
- ❏ Educational materials for clinical care providers and patients/families regarding the test itself, clinical uses of the test, and how test results can be used in patient care
- ❏ Methods to collect and store clinical information on each sample in publicly accessible databases while respecting patient confidentiality
- ❏ Methods to collect and store test result information in publicly accessible databases

Applicants are required to provide scientific evidence, laboratory qualifications, evidence of collaboration among the applying group, and educational materi-

als aimed at three audiences: medical geneticists, non-geneticist clinicians, and patients. The educational materials must discuss how to interpret test results for negative, positive, or indeterminate results. This is an important concern, says Faucett, because "many [genetic test] reports are difficult to interpret, and one of the goals of the program is to improve test reporting."

In addition, applicants must detail their proposed testing methodology, the impact of the test on healthcare, and how data will be collected. CETT has partnered with the National Center for Biotechnology Information (NCBI) to develop a useful data collection scheme, which will include capturing mutation data in a graphical format. According to program staff, NCBI's contribution will help to put the test, phenotype, and mutation data in a broader biomedical context to advance knowledge about the disorder.

Review Process

Applications are reviewed in a two-stage process—first by program staff and then by CETT's review board. Each application will be evaluated by a five-member board comprised of a clinical geneticist certified by the American Board of Medical Genetics (ABMG), a laboratory geneticist certified by either the ABMG or the American Board of Pathology in either clinical molecular genetics or molecular genetic pathology, a patient advocate experienced in genetic disorders, a research scientist whose focus is genetic diseases, and a healthcare provider whose primary focus is not genetics. The review board will set the guidelines by which applications are evaluated, assess the quality of each application, and provide feedback for each application.

Program funding "is not meant to cover research costs. It's primarily meant to pay for translation," says Faucett. "This is when you have a test that is ready to move to a clinical setting." The potential outcomes for the CETT Program are considerable and significant, including an improved understanding of CLIA and quality standards for laboratory testing and an enhanced dialogue between the research, clinical, and lab communities, stakeholders in genetic testing that according to Faucett, "don't really know each other."

Potential Outcomes of CETT Program

- ❏ Improve understanding of CLIA and quality standards
- ❏ Improve dialogue between stakeholders: clinical laboratories, reference laboratories, researchers, clinicians, patient advocates, oversight bodies, payers
- ❏ Improve genotype-phenotype correlations
- ❏ Provide backup laboratories (especially prenatal testing)
- ❏ Replace lost tests and learn how to prevent needed genetic tests from disappearing from use
- ❏ Separate test translation costs from research costs
- ❏ Provide model for genetic test development

St. Jude Develops Simpler, More Affordable ALL Follow-Up Test

"The cost for the reagents required for the new test is approximately $20 per patient. A traditional MRD test by flow cytometry or PCR would require reagents costing at least $120 per patient. Moreover, traditional MRD tests require more sophisticated equipment and considerably more expertise and training to be performed correctly," says Dario Campana, M.D., Ph.D.

Researchers at St. Jude Children's Research Hospital (Memphis, TN) have developed a simpler, more affordable way to identify children with acute lymphoblastic leukemia (ALL) who have a superior clinical outcome. A study evaluating the method is slated to appear in the July 1 issue of *Blood*, the journal of the American Society of Hematology, and is now available as a "First Edition Paper" on the journal's Web site. The new test could provide laboratories with minimal resources an affordable way to improve the outcome of ALL treatment for many children by reducing the side effects of chemotherapy, which can be serious and life-threatening.

The test measures the small number of leukemic cells that survive after remission therapy induction. Known as minimal residual disease (MRD), this measurement helps clinicians to pinpoint differences in initial treatment responsiveness and identify patients predicted to have superior outcomes who might be cured with milder treatment. According to Raul Ribeiro, M.D., a co-author of the study, "Clinicians have known since the 1970s that about 40 percent of children with ALL can be cured with less intense treatment. The problem is identifying those children."

Despite the clinical utility of traditional MRD assays, which use molecular and flow cytometric methods, their complexity, high costs, and technical skill requirements are obstacles to widespread use. The new test is a simplified flow cytometry assay based on the expression of CD19, CD10, and CD34 antigens by bone marrow cells. "The cost for the reagents required for the new test is approximately $20 per patient," the study's senior author, Dario Campana, M.D., Ph.D., tells *DTTR*. "A traditional MRD test by flow cytometry or PCR would require reagents costing at least $120 per patient." The novel assay method is detailed in the paper and can be easily performed using commercially available reagents and a basic single-laser flow cytometer. "Of course, the new test is applicable only during initial therapy whereas traditional tests can be used at any point during therapy and off therapy," adds Campana.

In the study, the new test was used to examine bone marrow samples from 380 children with B-lineage ALL (the subtype that accounts for nearly 85% of pediatric ALL cases) taken 19 days after the beginning of remission induction therapy. In 211 patients (55.5%), the test determined that leukemic cells made up 0.01% or more of the cells in the sample. This result closely agreed with the results from the traditional and more expensive tests. Additionally, the results obtained from the simplified test more accurately predicted whose disease would relapse and whose would respond well to chemotherapy than did standard risk factors such as age and presence of certain mutations in the cancer cells.

The study also evaluated the "exportability" of the assay to resource-poor settings by piloting it in a laboratory in Recife, Brazil, that lacked experience in MRD assays. Sample processing, antibody staining, and the initial flow cytometric analysis were performed as specified by the St. Jude protocol. Although based on limited sampling, the results indicate that the test was successfully transferred to the Recife laboratory, which supports a leukemia treatment program with improving results. The St. Jude International Outreach Program is now implementing a new treatment strategy in the Recife lab using the simplified assay.

Inverness Acquires CLONDIAG Chip Technologies For Rapid POC Tests

Inverness Medical Innovations (Waltham, MA), a manufacturer and marketer of consumer and professional medical diagnostic products for women's health and chronic disease management, has signed an agreement to acquire privately held CLONDIAG Chip Technologies (Jena, Germany), a manufacturer of in vitro diagnostic platforms. The agreement calls for Inverness to acquire 67.45% of CLONDIAG stock for approximately $3.1 million and approximately $10 million worth of debts. Inverness will acquire the remaining stock in August of this year for an additional $4.9 million (based on current exchange rates).

CLONDIAG's AssayProcessor (shown here with hand-held reading and processing instrument) integrates multiple steps of a molecular assay, such as target amplification, hybridization, and signal detection, into a single device that can be used at the point-of-care.

Established in 1998, CLONDIAG develops and manufactures novel integrated analysis systems that enable the setup of rapid, relatively low-cost multiplex assays in nucleic acid and serological diagnostics. The systems' core units are miniaturized probe arrays (also known as "chips") that allow for parallel analysis of multiple-test parameters in a single assay.

According to Inverness CEO Ron Zwanziger, CLONDIAG's technology offers the company "a significant new opportunity to develop easy-to-use, rapid tests with far higher performance characteristics than are available using today's lateral flow platforms." He added that Inverness plans to build "a significant patent portfolio" in chip-based point-of-care diagnostics.

Quest Launches Less Invasive Leukemia And Lymphoma Tests

According to the Leukemia & Lymphoma Society, an estimated 747,465 Americans are living with leukemia, Hodgkin and non-Hodgkin lymphoma, and myeloma.

Quest Diagnostics (Lyndhurst, NJ) launched the first seven of its Leumeta cancer assays on March 28. The new family of tests tracks genetic components of leukemia and lymphoma tumors in blood plasma, allowing for detection of specific proteins, DNA, RNA, or other molecular targets expressed on or within tumor cells without painful bone marrow extraction.

The Leumeta tests are designed to measure tumor load, detect certain blood cancer markers, and help clinicians monitor treatment. "Using these tests, doctors can get a more frequent indication of a patient's disease status and decide whether to alter their treatment," says Frances Giles, M.D., chief of developmental therapeutics at M.D. Anderson Cancer Center in Houston. "The ability to sequentially obtain so much data from blood plasma specimens is a major help in optimally using the available therapies and in assessing the efficacy of novel agents. To obtain this data without the need for bone marrow tissue is a major advance."

Clinical Uses of Available Leumeta Tests

- Detect drug-resistant mutations to Gleevec (Imatinib) in patients with chronic myeloid leukemia and identify candidates for alternative therapy
- Diagnose and monitor minimal residual disease in patients with mantle cell lymphoma
- Diagnose and monitor follicular lymphoma
- Diagnose chronic myelogenous leukemia
- Diagnose Philadelphia-chromosome-positive acute lymphocytic leukemia, determine prognosis and response to therapy, and detect minimal residue disease
- Determine prognosis of patients with B-cell chronic lymphocytic leukemia
- Diagnose or confirm the diagnosis of myeloproliferative disease and monitor therapy
- Diagnose mastocytosis and other hematopoietic malignancies and predict response to therapy

Source: Quest Diagnostics

The seven tests launched in late March analyze gene mutations (of ABL kinase, IgVH, or JAK2), quantify BCR/ABL protein, or use real-time PCR to analyze various bcl gene products. Five other Leumeta tests, which use quantitative or qualitative PCR to analyze gene rearrangements linked to specific types of leukemia and lymphoma, will launch later this year.

Developed by Quest researchers using licensed technology discovered by one of the researchers while previously at M.D. Anderson Cancer Center, the tests are sold through Quest for approximately $170 each. Ultimately, the tests may provide an alternative to bone marrow biopsies, which can be both painful and stressful for cancer patients.

Bayer Chooses Stratagene QPCR For New Molecular Diagnostic Platform

Quantitative PCR is the most widely used technology in the approximately $1.5 billion molecular diagnostic testing market.

Stratagene (San Diego, CA) recently announced that the Diagnostics Division of Bayer Healthcare, a member of the Bayer Group (Leverkusen, Germany), will purchase customized Mx3005P instrument systems for use in a new platform that Bayer is developing to perform molecular diagnostic tests worldwide. Bayer will use the Stratagene instruments as components of its modular quantitative polymerase chain reaction (QPCR) systems.

"We believe that this agreement provides confirmation of our capability of building instrument platforms for molecular diagnostics companies for the hospital and clinical markets," said Stratagene President and CEO Joseph A. Sorge, M.D. Stratagene's QPCR instruments and related biological products grew 20.6% in 2005 compared with 2004. "We believe our innovative Mx instrument offering, newly improved MxPro software, and wide menu of unique reagent chemistry should allow us to sustain our double-digit growth rate for QPCR products into 2006," Sorge added.

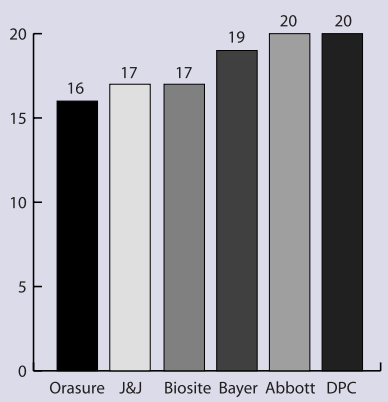
In December of last year, Stratagene entered into an agreement with Focus Diagnostics (Herndon, VA) to address the growing molecular diagnostics market for infectious diseases. Focus, which specializes in infectious disease tests and is a leading reference laboratory for infectious and immunological diseases, was granted a nonexclusive license to Stratagene's proprietary FullVelocity technology. Stratagene will also help Focus to develop and manufacture selected molecular diagnostic testing kits. Additionally, Stratagene will manufacture and sell reagents to Focus for laboratory-developed tests to be used in Focus's national reference laboratory. According to Sorge, Stratagene's recent agreements with Bayer and Focus Diagnostics represent "significant milestones toward executing our molecular diagnostics strategy," which is to create a full suite of products for the molecular diagnostics marketplace.

IVD Stocks Up 4%; Meridian And Abaxis Jump

The 22 stocks in the G-2 Diagnostic Stock Index rose by 4% in the five weeks ended April 7, 2006, with 13 stocks up in price and 9 down. Year to date, the G-2 Index is up 12%, compared with a 6% gain for the Nasdaq and a 4% gain for the S&P 500 Index.

Meridian Bioscience (Cincinnati, OH) jumped 24% to $26.97 per share for a market cap of $681 million. On March 16, the company announced that the FDA granted marketing clearance to its Premier Platinum HpSA Plus test for the presence of a bacteria associated with stomach ulcers and certain types of late-onset stomach cancers (*see pg. 2*). The test was cleared to be used both in adults and in children.

IVD Company P/E Ratios

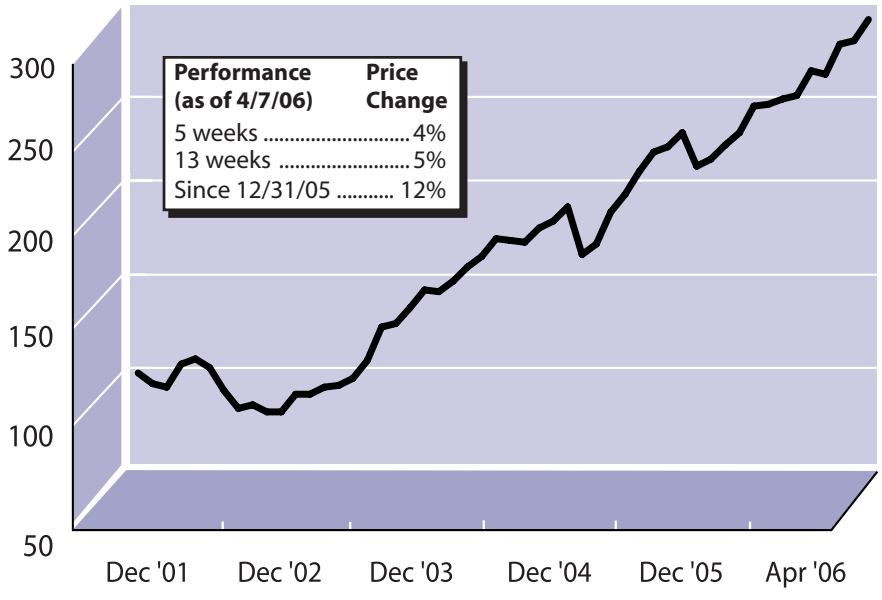


Source: *DTTR*

Abaxis (Union City, CA) was up 14% to $23.88 per share for a market cap of $508 million. The manufacturer of point-of-care blood analysis systems announced in late March that it will license its Orbos lyophilization technology to bioMerieux SA. According to Kenneth Aron, vice president of R&D, Abaxis sees "significant opportunities for further licensing in the fields of molecular diagnostics and environmental monitoring."

Meanwhile, an analysis of the P/E ratios of IVD companies shows that **OraSure Technologies**—with a P/E ratio of 16—is currently the least expensive stock. Other IVD companies with a P/E ratio of 20 or less include: **Johnson & Johnson** and **Biosite**, each at 17; **Bayer** at 19; and **Abbott Labs** and **Diagnostic Products Corp. (DPC)**, each at 20.

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 22 IVD companies.

Avg. % Price Change, 5 weeks ended 4/7/06

UP	Price	% Chg
Abaxis	$23.88	14%
Affymetrix	32.46	7
Bayer	40.51	4
Becton Dickinson	63.56	1
Bio-Rad	63.20	7
Cholestech	12.98	12
Diagnostic Products	46.18	2
Gen-Probe	54.21	4
Immucor	30.20	4
Inverness Medical	27.11	8
Meridian	26.97	24
Quidel	12.51	12
Ventana	42.11	13
DOWN		
Abbott Labs	42.09	-4
Beckman Coulter	52.85	-1
Biosite	50.75	-1
Cytyc	27.83	-6
Dade	33.50	-6
Digene	37.39	-10
Johnson & Johnson	57.83	-2
OraSure	9.41	-6
Third Wave	2.91	-12

G-2 Insider

Affy's PERL of wisdom? Biopharmaceutical company Perlegen Sciences (Mountain View, CA), which was spun off from Affymetrix in 2001, announced on April 7 that it has filed for an initial public offering of as much as $115 million in common stock. At press time, the company had not decided on the number of shares it would sell or when it would make them available. Perlegen is seeking a Nasdaq listing under the symbol "PERL."

Perlegen (derived from the Latin word, "perlego," meaning "to scan, to examine all over, to survey thoroughly, or to read through") is developing a pipeline of late-stage genetically targeted therapeutics and diagnostics. Two of its drug candidates are now in Phase II trials. The company also collaborates with a variety of organizations on pharmacogenomics research. In January, it announced its collaboration with Genentech to study cancer genetics using Affymetrix GeneChip technology. Other Perlegen collaborators include AstraZeneca, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, and many government agencies and foundations.

Perlegen at a Glance

Headquarters: Mountain View, CA
Chief Executive Officer (co-founder): Brad A. Margus
Chief Scientific Officer (co-founder): David R. Cox, M.D., Ph.D.
2005 Revenue: $40.5 million

Affymetrix still owns a 25.4% stake in Perlegen. Pfizer owns 13.3%, and hedge fund Maverick Capital holds 8.1%.

Using their own cost-effective whole genome association approach, Perlegen can genotype millions of unique single nucleotide polymorphisms (SNPs) in thousands of cases and controls within months rather than years. Has the much-touted "era of personalized medicine" finally arrived? With Perlegen's focus on personalized medicine, its IPO will be one to watch for indications on how pharmacogenomics will play out in the diagnostic industry, big pharma, and clinical practice.

Company References

Abaxis 510-675-6500

Bayer Diagnostics 914-631-8000

Cambridge Heart 781-271-1200

CETT Program 404-727-4510

Fisher Scientific 603-926-5911

Inverness Medical Innovations 781-647-3900

Meridian Bioscience 513-271-1720

Myriad Genetics 801-584-3600

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