# Diagnostic Testing and Technology Report

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


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WASHINGTON G-2 REPORTS

**Established 1979**

## SACGHS Releases Final Report On State Of Genetic Testing and Reimbursement

On March 27, the Department of Health and Human Services (HHS) Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) released its final report on changes needed in coverage and reimbursement for genetic tests and services. The report discusses problems with current policy and offers recommendations for improvement. In addition, it proposes nine steps that would improve access to and utilization of genetic tests. The steps include more consistent coverage decisions by Medicare and other third-party payers, addition of more screening services to Medicare's preventative services benefit, and higher fees to align genetic test prices with actual costs. For more on the SACGHS report, see *Inside the Diagnostics Industry*, pp. 5-6.

## Siemens Enters IVD Market With Diagnostic Products Corp. Acquisition

Industrial conglomerate Siemens (Erlangen, Germany) has entered into an agreement to acquire Diagnostic Products Corporation (DPC; Los Angeles, CA), a leading provider of immunodiagnostic systems and reagents, for approximately $1.86 billion in cash. The merger, which is expected to close in mid-2006 and is subject to regulatory approval, is intended to strengthen Siemens's healthcare unit, Medical, which was the company's most profitable business unit in the quarter that ended March 31, accounting for 12.6% of sales. In 2005, Siemens reported worldwide sales of $88.2 billion.

Siemens's healthcare portfolio currently includes diagnostic imaging, healthcare information technology, and molecular biology and biochemistry. Adding DPC will provide the company with expertise and products in the area of early diagnosis, an expansion beyond its strengths in electronic diagnosis and medical technology. Siemens's entrance into the IVD market is indicative of the broader trend for industrial conglomerates to seek out acquisitions in medical diagnostics to round out their healthcare businesses. In 2003, General Electric acquired British diagnostics company Amersham for $9.5 billion.

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▲ **Siemens Enters IVD Market,** *from page 1*

The acquisition of DPC comes just over a year after Siemens purchased Knoxville, Tennessee-based CTI Molecular Imaging in a transaction valued at $1 billion. CTI has since been merged with the existing activities of Siemens Medical Solutions to form its Molecular Imaging Division.

Founded in 1971, DPC reported sales of $481 million last year. The company has a presence in 155 countries and offers more than 75 tests, including its popular IMMULITE chemiluminescent assay system and tests for such conditions as allergies, anemia, cardiovascular disease, and diabetes.

# AACR Meeting Focuses On Early Detection, Molecular Diagnostics

Early detection and molecular diagnostics were the prevailing themes of this year's Annual Meeting of the American Association of Cancer Research (AACR), held this spring in Washington, D.C. Below, *DTTR* highlights two novel molecular tests for cancer, based upon research presented at the meeting.

### RT-PCR Detection of Blood-Borne Cancer

A Purdue University research team used reverse transcription-PCR (RT-PCR) to detect a messenger RNA variant responsible for the expression of a cancer-specific protein known as tNOX. Using an assay they developed to test the blood of 32 cancer patients and 22 controls, the researchers found that 100% of patients with cancer were positive for the tNOX variant mRNA, while the controls tested negative.

According to the study's lead author James Morre, Ph.D., "The test detects circulating cancer cells, and it does have the potential to become a standard screening assay, especially for post-operative breast cancer patients to monitor the potential for metastatic spread." Future studies will use larger cohorts to define the effectiveness of the technology in detecting splice variant-tNOX mRNA in blood-borne cells and its utility in cancer management.

### Gene Expression Profiling Improves On Bronchoscopy for Lung Cancer Detection

A team of researchers led by Avrum Spira, M.D., dramatically improved the sensitivity of diagnosing lung cancer by combining a gene expression assay with bronchoscopy, the best available procedure to detect lung cancer. They found that the RNA expression signature from normal epithelial cells of the upper airways in smokers identified three times as many early stage cancers as did conventional bronchoscopy.

The gene expression profile of the epithelial cells complemented the clinical bronchoscopy results to identify 95% of patients with early or late stage lung cancer. By itself, the gene data identified 80% of 60 patients who developed lung cancer, while bronchoscopy diagnosed only 53% of those patients. "We are adding value to the bronchoscopy exam," said Spira. "In the event where the bronchoscopy misses the diagnosis, our test often detects the cancer."

# Chembio's Rapid HIV Tests Closer To FDA Approval

Chembio Diagnostics (Medford, NY) has received an "approvable" letter from the FDA for its Sure Check HIV and HIV 1/2 Stat-Pak test Premarket Applications (PMAs). PMA approval, a process initiated by Chembio in February of 2005, is subject to final FDA review of the products' package inserts and other conditions related to all PMAs. The FDA conducted a preapproval inspection of Chembio facilities in September of last year.

Sure Check HIV and HIV 1/2 Stat-Pak are rapid tests that detect HIV-1 and HIV-2 antibodies in fingerstick whole blood, venous whole blood, serum, and plasma. The qualitative test enables visual detection of HIV antibodies on a strip and requires no electricity, additional equipment, or skilled personnel for test interpretation. The self-contained format also minimizes handling of potentially infected specimens. Results are available within 10 to 15 minutes from sample application. Internal IgG controls are built-in to both products, and the tests have an 18-month shelf life without refrigeration. The specificity and sensitivity of the tests exceeds 99.6% (when compared to a Western blot).

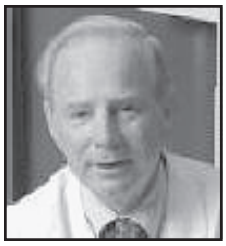
In accordance with FDA export regulations, Chembio has been manufacturing and selling these products in foreign jurisdictions, including Brazil, Mexico, and India, since 2001. "We believe PMA approval, when granted, will provide further impetus to our marketing efforts, including opening markets not currently available," said Chembio President and CEO Lawrence Siebert. Chembio received an FDA Investigational Device Exemption (IDE) to conduct clinical trials for both tests in the United States.

According to Chembio Vice President Avi Pelossof, the company has not yet finalized its pricing strategy for the U.S. market. "Internationally, we generally offer our rapid HIV tests in the $1.00 to $2.00 per test range, depending on the test format," Pelossof tells *DTTR*. The company is in discussions with a potential U.S. marketing partner.

Formed in 1985, Chembio Diagnostic Systems merged with Trading Solutions.com in May 2004, and the combined company became known as Chembio Diagnostics. In 2005, Chembio's revenues were $3.94 million, up 19% from 2004. Rapid HIV test revenue for the year increased about 93% to $2.40 million as compared to $1.24 million in 2004. In addition to its HIV products, Chembio is developing rapid tests for tuberculosis and working with partners in the areas of BSE (Bovine Spongiform Encephalopathy, also known as "mad cow disease") and dental bacteria.

# JAMA Metanalyis Urges Dual Test Approach For Diabetes Monitoring

A metanalysis published in the April 12 issue of the *Journal of the American Medical Association* urges physicians and patients to combine self-monitoring of blood glucose (SMBG) with more precise physician-ordered testing of hemoglobin A1c ($HbA_{1c}$) to best manage diabetes and prevent complications of the disease.


Christopher Saudek, M.D.

"The message is we have tools that are very accurate, but they don't work at all if they are not used properly," says Christopher Saudek, M.D., head of the Johns Hopkins Diabetes Center and lead author of the article. "We need to do a better job of monitoring our patients, as well as advising them."

Saudek and colleagues analyzed data from studies published from 1975 through 2005 that were relevant to SMBG and $HbA_{1c}$. They concluded that patient-conducted SMBG gives an accurate reflection of immediate blood glucose levels. However, $HbA_{1c}$ performed in a doctor's office or clinic is a better measure of long-term blood glucose control. The article recommends that diabetics get tested for HbA1c every three to six months.

***According to the American Diabetes Association, about 14.6 million people in the United States have been diagnosed with diabetes. One out of every 10 U.S. healthcare dollars is spent on diabetes and its complications.***

Changes are ongoing for both tests. Intermittent SMBG is moving toward continuous glucose monitoring, which can use alarms to alert patients to fluctuations and dangerous spikes in blood glucose concentrations. Meanwhile, a newly developed International Federation of Clinical Chemistry method provides more specific measurement of $HbA_{1c}$, using mass spectroscopy and capillary electrophoresis. Saudek expects that the new method "will become the anchor for glycated hemoglobin assays worldwide, but debate is ongoing as to how the new results will be reported, and even what the new test will be called."

## Primagen Gets U.S. Patent For Mitox Mitochondrial DNA Biomarker

Primagen (Amsterdam, Netherlands), a molecular diagnostics company that specializes in infectious disease and oncology, has been awarded a U.S. patent for its use of mitochondrial DNA quantification as a biomarker for treatment efficacy and adverse drug reactions. The technology, known as Mitox, may be used to monitor patients undergoing antiviral treatments for such conditions as HIV-1 and Hepatitis C.

"This patent is an important milestone in our efforts to bring the Mitox diagnostic test to market, ultimately giving physicians a new tool for improved patient management," said Jos Rijntjes, Primagen's Chief Commercial Officer. The test, which measures mitochondrial DNA and RNA in clinical samples, is currently used for early assessment of drug toxicity in the development of nucleoside analogues, which are known for their mitochondrial toxicity.

Primagen also plans to expand the use of its Mitox technology into the field of oncology, where the test could be used to monitor and predict adverse effects of cancer treatment. The company presented some initial clinical data on differential gene expression in cancer at the meeting of the American Association for Cancer Research in April of this year.

# SACGHS Releases Final Report On Genetic Testing, Reimbursement

Established in 2002, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) provides policy advice to the Department of Health and Human Services on the broad array of complex medical, ethical, legal, and social issues raised by genetic testing. The committee's recently released report, *Coverage and Reimbursement of Genetic Tests and Services*, is the product of more than a year of deliberation, research, and public comment. The 114-page report offers nine recommendations on how current coverage and reimbursement mechanisms might be improved.

### Evidence-Based Coverage Decisions

The report calls for a greater emphasis on evidence-based coverage decision making and cites the lack of available evidence to make informed coverage decisions about many genetic tests and services. Among the unique challenges of genetic testing is the difficulty in establishing a causal link between genetic tests and services and improved health outcomes. Additionally, many genetic tests lack therapeutic and preventative options. Moreover, costs associated with these tests and services may not be recouped in a short enough time frame.

To address this issue, the report recommends the creation of a group that would develop a set of principles to guide coverage decision making for genetic tests and services. This group would also determine whether the evidence for genetic tests and services is adequate to establish their analytical validity, clinical validity, and clinical utility.

### Influence Of Medicare In Private Plans

Although Medicare's decisions are monitored closely by private health insurers, the report notes that Medicare may not be an appropriate model for coverage of genetic tests and services. Recognizing that Medicare's coverage of preventative services is limited and that most hereditary diseases manifest before age 65, the report recommends that private payers be encouraged and provided with information to make their own coverage determinations relative to the populations they serve.

### National Versus Local Medicare Coverage Policies

Given that Medicare coverage decisions are made at both the national and local levels and that variation in local decisions can lead to inconsistencies in coverage from one region to another, the report recommends that CMS develop a plan for evaluating local coverage decisions to determine which ones should be adopted nationally and to what extent greater consistency can be achieved. The report also suggests that CMS consider a mechanism that would automatically initiate a national coverage review process for any test or service that is approved for coverage by a certain number of local Medicare contractors.

### Medicare Screening Exclusion

A federal statute prevents Medicare from covering preventative services unless explicitly authorized by Congress. Since predictive and predispositional genetic

### SACGHS Report Recommendations

- ❑ Evidence-based coverage decisions
- ❑ Influence of Medicare in private plans
- ❑ National vs. local Medicare coverage policies
- ❑ Medicare screening exclusion
- ❑ Medicaid and SCHIP coverage
- ❑ Medicare Clinical Laboratory Fee Schedule
- ❑ Billing and reimbursement of genetic counseling services
- ❑ Provider education and training in genetics
- ❑ Public awareness

tests are considered screening tests, they are not covered by Medicare. Medicare's coverage for genetic counseling is also limited by this screening exclusion. The report recommends that HHS urge Congress to add a benefit category for preventative services.

**Medicaid And SCHIP Coverage**

With the exception of newborn screening, genetic tests and services are optional Medicaid benefits. Changes in state Medicaid funding, as well as variation in Medicaid coverage across states, can result in unstable and disparate access to genetic tests and services. To address this issue, the report recommends that HHS share with states existing evidence on genetic tests and services to inform Medicaid coverage decisions. It further recommends that HHS continue to provide grant support to states that encourage coverage, adoption, and provision of genetic services that have a sound evidence base.

**SACGHS Study Priorities**

- ❑ Genetic Discrimination
- ❑ Coverage and reimbursement
- ❑ Pharmacogenomics
- ❑ Large population studies
- ❑ Direct-to-consumer marketing
- ❑ Patents and licensing
- ❑ Oversight
- ❑ Genetics education and training
- ❑ Access
- ❑ Public awareness
- ❑ Genetic exceptionalism
- ❑ Vision statement

**Medicare Clinical Laboratory Fee Schedule**

Given the contention by many providers that Medicare's payment rates for genetic tests do not reflect their true cost and that Congress has mandated a freeze on payment rates for clinical laboratory tests until 2009, the report recommends that HHS address variations in payment rates for genetic test CPT codes through its inherent reasonableness authority. This authority allows HHS to correct payment amounts for items and services that are so grossly excessive or deficient that they threaten to reduce beneficiary access to care.

*Concurrent with the report's release, SACGHS held its ninth meeting in Bethesda, Maryland. The meeting focused on pharmacogenomics, genetic discrimination, patents and licensing, and large population studies—four of the group's study priorities. For in-depth coverage of the meeting, see the July issue of* DTTR.

**Billing And Reimbursement Of Genetic Counseling Services**

The report makes a number of recommendations relevant to billing and reimbursement. First, it recommends that HHS identify a mechanism to determine which health professions are qualified to offer genetic counseling services and which of these professions should be able to practice without physician supervision. The report suggests that those professions that can practice independently be named to the list of non-physician practitioners eligible to bill Medicare directly. The report also recommends that HHS assess the adequacy of existing CPT codes relevant to counseling services.

**Provider Education And Training In Genetics**

Citing the importance of genetics education for health payers to make informed coverage decisions, the report recommends the development of a plan for HHS agencies to work collaboratively with federal, state, and private organizations to develop, catalogue, and disseminate case studies and models that demonstrate the relevance of genetics and genomics to clinical practice. The committee also encourages HHS to provide financial support to assess the impact of genetics education and training on health outcomes.

**Public Awareness**

Finally, because public awareness of new healthcare tests can create consumer demand and given that the complexity of genetics can result in inappropriate demand for genetic tests and services, the report recommends that HHS ensure that educational resources are widely distributed to inform decisions about genetic tests and services.

# Testing of Tomorrow

***In this new section of* DTTR*, we'll review cutting-edge research developments that represent promising precursors for clinical diagnostics.***

## Study Finds Distinct Protein Profiles In Head And Neck Cancer

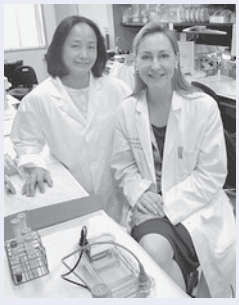
A study published in the April issue of *Archives of Otolaryngology* used proteomic analysis to distinguish patients with head and neck squamous cell carcinoma (HNSCC) from healthy controls with a high degree of sensitivity and specificity. The unique patterns of protein expression found to be associated with HNSCC could ultimately serve as a screening test for those at risk of developing the highly aggressive cancer and help clinicians to classify specific types of head and neck cancer.

*Overall survival rates for patients with head and neck squamous cell carcinoma (HNSCC) have remained unchanged over the past 30 years. There is currently no effective screening test for the disease beyond physical examination.*

Serum samples from 78 patients with HNSCC and 68 controls were analyzed with ProteinChip surface-enhanced laser desorption and ionization time-of-flight mass spectrometry (SELDI-TOF-MS). "We found scores and scores of proteins that were differentially expressed," says Christine Gourin, M.D, an otolaryngologist at Medical College of Georgia and lead author of the study. "We found at least eight proteins whose expression significantly differs between controls and people with cancer."

By analyzing the distribution of these protein expression differences, the authors were able to correct classified HNSCC patients with 82% sensitivity and 76% specificity. The study also found that protein expression may be used to classify the site of tumor origin and may be used to distinguish between pre-treatment and post-treatment samples.

Overall survival rates for HNSCC patients have remained unchanged over the past 30 years, largely because the disease's early stage is associated with few signs and symptoms. Once patients present with symptoms such as a sore throat or mouth pain, their disease has usually entered an advanced stage, which is associated with increased treatment morbidity and poorer survival rates. If caught in stage one, HNSCC patients have a 95% five-year survival rate, but once tumors have progressed to stage three or four, that rate drops to 50%.



*Bao-Ling Adam, Ph.D. and Christine Gourin, M.D.*

*Photo courtesy Medical College of Georgia*

"Right now there is no good, effective screening test for head and neck cancer short of physical examination," says Gourin. "Unfortunately it takes the development of symptoms to warrant a visit to the doctor. Sometimes the first sign is a lump in the neck, which is already a sign of an advanced tumor that has spread to the lymph nodes."

The researchers are now collecting more patient data to ensure that the patterns identified in the study are effective biomarkers for HNSCC. They are also investigating whether the protein expression patterns found in blood are expressed by the cancer cells themselves. Notes senior author Bao-Ling Adam, Ph.D., "What we see in the blood could be from the cancer cells or from the body's response to cancer."

# Gen-Probe To Develop Novel Molecular Testing Platform, Cancer Assays

Gen-Probe (San Diego, CA) will develop a novel nucleic acid testing (NAT) platform based on the FDA-approved FastPack immunoassay system developed and patented by Qualigen (Carlsbad, CA). The company also recently announced that it has licensed from the University of Michigan exclusive worldwide rights to develop diagnostic tests for newly discovered genetic translocations that have been linked to prostate cancer.

In its decision to use Qualigen technologies, Gen-Probe will exercise the exclusive 18-month option it acquired for $1 million in November 2004 to develop a point-of-use NAT platform based on the FastPack system. As part of its recent decision to exercise the option, Gen-Probe acquired a 19.5% stake in Qualigen for approximately $7 million. Qualigen may also receive up to $3 million from Gen-Probe based on development milestones. Qualigen would also receive royalties on product sales.

Gen-Probe's new FastPack-based platform, a closed unit-dose assay system, would provide a portable system for the rapid detection of genetic mutations and microorganisms that could be used in such locations as physicians' offices, outpatient clinics, and blood screening centers. FastPack, a quantitative immunoassay system, was approved by the FDA in July 2000 and received the CE Mark in April 2004. According to Qualigen, about 600 systems have been placed to date. List price for the system is $9750, with pricing plans varying based on test volume.


*Qualigen's FastPack quantitative point-of-care immunoassay system, which consists of an analyzer and a sample dispenser*

In a separate announcement, Gen-Probe said that it has licensed novel cancer biomarkers from the University of Michigan. The company purchased worldwide rights to develop assays based on the specific genetic translocations discovered by U of M researchers for an up-front license fee of $0.5 million and pledged five years of cancer research funding for the university as well as additional payments based on development milestones and royalties.

Discovery of the prostate cancer-linked translocations, fusions between the prostate-specific TMPRSS2 gene and members of the ETS gene family, was published in *Science* last October. In early-stage research, the authors found that 23 of 29 cancerous prostate samples contained the translocations. Subsequent studies with larger sample sizes have confirmed this finding, and the gene fusions have not been found in healthy prostate tissue.

These biomarkers will bolster Gen-Probe's existing portfolio of prostate cancer biomarkers and its efforts to develop prostate cancer diagnostics. "In addition to being useful as a specific prostate cancer marker, these gene fusions likely play a role in prostate cancer development," said Arul Chinnaiyan, M.D., Ph.D., senior author of the *Science* study and a professor of pathology at the University of Michigan Medical School. "Analogous gene fusions may be present in other common solid tumors."

Gen-Probe began shipping an analyte specific reagent (ASR) version of its PCA3 Aptima test for prostate detection earlier this year (see *DTTR*, February 2006, p. 1-3). Clinical trials for the test are underway, and Gen-Probe expects to submit an application for premarket approval to the FDA next year. The test is based on technology licensed from Diagnocure (Quebec City, Canada), which specializes in the development of cancer tests. Gen-Probe is expected to have a CE-marked PCA3 test on the European market later this year and an FDA-cleared test kit for the U.S. market should be released in 2008. Labs are expected to price the test at roughly $200-$300 (after discounts).

## FDA Clears Beckman Coulter's New Immunoassay Workstation

Beckman Coulter (Fullerton, CA) has received FDA clearance for its newest chemistry-immunoassay workstation, the UniCel DxC 600i Synchron Access clinical system, a second generation workcell that begins shipping later this year. The system enables clinical laboratories to perform chemistry and immunoassay testing simultaneously from a single point of sample entry. List price for the system will be $165,000, a company representative tells *DTTR*.

The UniCel DxC 600i offers a menu of more than 150 tests, including those for cardiac and tumor markers, diabetes, and renal function. "Workcells are often the first step in automating a clinical diagnostics laboratory," said Jeff McHugh, group vice president of lab systems and routine testing for Beckman Coulter's diagnostics division. The system has a throughput of up to 990 tests per hour and up to 100 immunoassay tests per hour.

## Qiagen To Acquire Sample Prep Leader Gentra Systems For $38M

Molecular diagnostics and sample preparation supplier Qiagen (Venlo, Netherlands) has agreed to purchase all outstanding shares of privately held Gentra Systems (Minneapolis, MN) for about $38 million in cash. The transaction is expected to close at the end of the second quarter and will contribute approximately $6 million in sales in the second half of this year.

Founded in 1988 by Ruth Shuman, Ph.D., Gentra develops and markets manual and automated nucleic acid purification products for clinical lab use. Among its DNA and RNA purification products are the Puregene, Purescript, Generation, and Versagene kits, as well as its Autopure LS instrument platform for high-volume DNA purification and Autotech platform for lower throughput.

The acquisition of Gentra, with its focus on nucleic acid purification from large-scale blood samples up to 10ml, will expand Qiagen's presence in the increasingly important market niches of biobanking and DNA archiving, and also in the fields of molecular diagnostics and preanalytical sample preparation. Qiagen has been aggressive in building its market share in these fields. In 2005, the company's acquisitions included the reagent business of Eppendorf, Hitachi Chemical Research's RNAture nucleic acid purification product portfolio, and molecular assay company artus.

# Asuragen Finds CF Test Marketing Partner In Digene

*Cystic Fibrosis (CF) is the most common autosomal recessive disease in the Caucasian population, with a prevalence estimate of one in 2,500 to 3,300 live births.*

Newly formed molecular diagnostics company Asuragen (Austin, TX) has entered a marketing and distribution agreement with Digene (Gaithersburg, MD), best known for its HPV DNA test. Under the agreement, Digene will have exclusive worldwide rights to market Asuragen's products for cystic fibrosis (CF) screening as the company works to attain FDA approval for the test. Financial terms of the deal were not disclosed.

In a move aimed to differentiate their HPV-dominated testing mix, Digene will market and distribute Asuragen's Signature CF 2.0 analyte specific reagent (ASR) test, which screens for mutations in the CFTR gene using Luminex xMAP technology. The Signature CF 2.0 test's primary mutation panel is based on the 2001 recommendations of the American College of Medical Genetics and the American College of Obstetricians and Gynecologists.

Asuragen will also develop the next generation of their CF test for to be sold exclusively by Digene. The test, to be known as Signature CF Expand, will add additional CFTR mutations, including ethnic-specific mutations that can be adapted for use in carrier screening and newborn testing. If approved by the FDA, Asuragen's CF screening products would compete with Tm Bioscience's Tag-It CF test kit, which was cleared by the FDA in May of last year.

"Prenatal testing is an excellent fit with Digene's focus in women's health diagnostics, and the CF market is a rapidly growing area of molecular testing," said Evan Jones, chairman and CEO of Digene. The largely untapped CF market represents a significant opportunity for Digene, which can market the Asuragen test through its existing women's health-focused sales force. The CF test will likely be offered at the same price as the HPV test: about $21 per test.

## Asuragen at a Glance

Headquarters: Austin, Texas

President and CEO: Matt Winkler, Ph.D.

Business Units: Molecular Diagnostics, Molecular Biology Services, Discovery (R&D)

Employees: 95

Facilities: 35,000 sq ft of research labs, manufacturing, and office space, and another 45,000 sq ft to be completed by July 2006

Funding: ~$35 million from sale of Ambion's research products division to Applied Biosystems

Asuragen was formed earlier this year as a spin-off of Ambion in the wake of the $273 million sale of Ambion's Research Products Division to Applied Biosystems (Foster City, CA), a division of Applera. Asuragen is comprised of Ambion's diagnostics and services divisions, along with a new discovery group to translate new research developments into clinical products. The company plans to focus around microRNAs and their potential roles as cancer diagnostics. "My vision for Asuragen is to become a fully integrated diagnostic company focused on molecular oncology," said CEO Matt Winkler.

# IVD Stocks Rise 7%; Diagnostic Products Jumps 25%

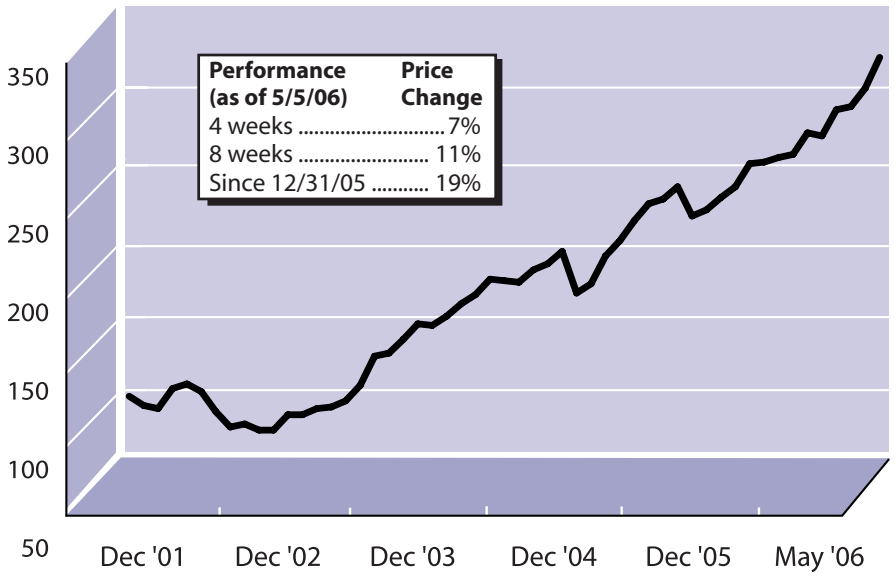
The 22 stocks in the G-2 Diagnostic Stock Index rose an average of 7% in the four weeks ended May 5, with 14 stocks up in price, seven down, and one unchanged. Year to date, the G-2 index is up 19%, while both the S&P 500 and the Nasdaq are up 6%.

**Diagnostic Products** (Los Angeles, CA) was up 25% to $57.74 for a market capitalization of $1.7 billion. The maker of tests for cancer, cardiac disease, and allergy conditions posted earnings of $18.0 million, or $0.60 per diluted share, in the three months ended March 31, compared with $16.1 million, or $0.54 per share, earned in the year-ago quarter. Revenue was $129.6 million, up 14% from last year. On April 27, industrial conglomerate Siemens agreed to buy Diagnostic Products for $1.86 billion (*see pg. 1-2*).

**Bayer** (Leverkusen, Germany) was up 16% to $45.77 per share for a market capitalization of $34.3 billion. European Union antitrust regulators have cleared the company's joint ownership with GE of the European silicone business OSi Europe. Additionally, Bayer and Onyx Pharmaceuticals recently completed patient enrollment in Phase III clinical trials of Nexavar (sorafenib) for the treatment of advanced liver and skin cancer. In February, the companies initiated a Phase III trial of the drug in non-small cell lung cancer.

**Digene** (Gaithersburg, MD) rose 15% to $42.82 per share for a market capitalization of $917.6 million. Digene markets the only FDA-approved and CE-marked test for high-risk HPV. Testing for HPV is becoming standard of care for cervical cancer screening, and the company has rolled out television and print ads for its HPV test. A recently published metanalysis of 11 clinical studies involving more than 60,000 women found that testing for high-risk types of HPV is a consistently more sensitive tool for cervical cancer screening than cytology.

## 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, 4 weeks ended 5/5/06**

| | Price | % Chg |
|---|---|---|
| **Up** | | |
| Abbott Labs | $42.77 | 2% |
| Abaxis | 24.19 | 1 |
| Bayer | 45.77 | 16 |
| Beckman Coulter | 55.89 | 6 |
| Bio-Rad | 70.75 | 12 |
| Biosite | 57.62 | 14 |
| Dade | 37.71 | 13 |
| Diagnostic Products | 57.74 | 25 |
| Digene | 42.82 | 15 |
| Gen-Probe | 56.50 | 4 |
| Inverness Medical | 30.50 | 13 |
| Johnson & Johnson | 58.70 | 2 |
| Third Wave | 3.00 | 3 |
| Ventana | 48.40 | 15 |
| **Unchanged** | | |
| OraSure | 9.40 | 0 |
| **Down** | | |
| Affymetrix | 28.82 | -11 |
| Becton Dickinson | 62.63 | -1 |
| Cholestech | 12.65 | -3 |
| Cytyc | 26.08 | -6 |
| Immucor | 29.87 | -1 |
| Meridian | 26.40 | -2 |
| Quidel | 11.22 | -10 |

# G-2 Insider

**And mark it with a "P". . .** Pharmaceutical giant Pfizer (New York, NY) announced that it will invest $25 million in Monogram Biosciences (South San Francisco, CA). The investment, made through a 3% Senior Secured Convertible Note, is expected to close by June 1 and is subject to customary closing conditions.

Pfizer has also entered into a worldwide nonexclusive collaboration to distribute Monogram's HIV Co-Receptor Tropism Assay, a test that determines the dominant co-receptor of HIV and can provide useful information at all stages of antiretroviral therapy. The assay has been used in HIV/AIDS clinical trials for maraviroc, Pfizer's investigational CCR5 inhibitor drug candidate. "With this collaboration we are working to advance global access to new diagnostics that may better assess the potential for CCR5 antagonists to fulfill an unmet clinical need," said John LaMattina, president of Global Research and Development at Pfizer. Pfizer Global Research and Development is the world's largest privately owned biomedical research organization.

Pfizer's recent investment and agreement with Monogram is part of a broader trend of collaborations between pharmaceutical firms and IVD companies, particularly in the area of pharmacogenomics. Merck, for example, recently reiterated its interest in "enhancing [their] core business" through diagnostics. "We must integrate key product enablers, such as biomarkers, to differentiate Merck's medicines in the marketplace," Merck CEO Richard Clark told analysts and investors last fall. For an in-depth analysis of recent alliances between pharmaceutical and diagnostics companies, see next month's *DTTR*.

## Company References

Asuragen 512-651-0191

Beckman Coulter 714-993-5321

Chembio 631-924-1135

Digene 301-944-7000

Gen-Probe 800-523-5001

Monogram Biosciences 650-635-1100

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