Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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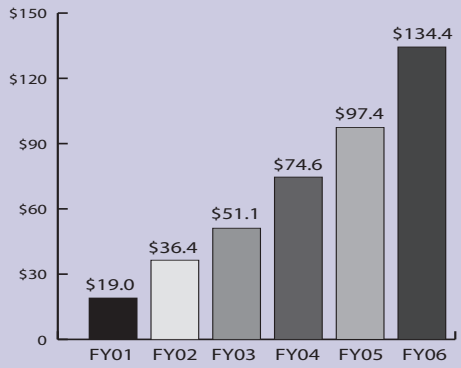
WASHINGTON G-2 REPORTS

Established 1979

Qiagen To Merge With Digene In $1.6B Transaction

A new molecular diagnostics powerhouse is in the making. Global life sciences company Qiagen (Venlo, Netherlands) recently announced its plan to merge with human papilloma virus (HPV) testing leader Digene (Gaithersburg, MD) in a transaction valued at $1.6 billion. The combined company would have approximately $350 million in molecular diagnostics revenues and more than $800 million in total 2008 revenues. The boards of directors of both companies have unanimously approved the transaction, and it is expected to close by late September.

Digene HPV Revenue *($ millions)*



Source: Digene

According to the merger agreement, Qiagen will acquire all of Digene's stock for a combination of cash and Qiagen common stock. The transaction is an exchange offer followed by a merger of Digene into a Qiagen subsidiary. Ultimately, Qiagen shareholders will own approximately 78% of the combined company on a fully diluted basis, and Digene shareholders will own approximately 22%.

Continued on p. 2

ThinPrep Maker Cytyc To Combine With Hologic For $6.2B

It's a good time to be an in vitro diagnostics company with a leading cervical cancer screening test. While Qiagen looks to close its deal with Digene (see above), breast imaging leader Hologic (Bedford, MA) is broadening its hold on women's health by merging with Cytyc (Marlborough, MA). Cytyc is best known for its ThinPrep Pap test, which is currently the only liquid-based cytology method approved by the FDA for human papilloma virus (HPV) and chlamydia/gonorrhea (CT/NG) testing. The combined company will be a $10 billion women's health giant and will be known as Hologic.

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DTTR Exclusive:

Exagen Diagnostics submits genomic biomarker-based breast cancer prognostic test for FDA clearance. See *Inside the Diagnostics Industry* (p. 5) for *DTTR's* exclusive interview with Exagen CEO James McClintic.

▲ **Cytyc To Combine With Hologic,** *from page 1*

According to the merger agreement, Cytyc shareholders will receive 0.52 Hologic shares and $16.50 in cash for each Cytyc share, which represents a value of $46.46 per share (a 33% premium) for an approximate total consideration of $2.2 billion in cash and $4 billion in stock.

The transaction is expected to close in the third quarter of 2007. Upon completion of the transaction, Hologic shareholders would own 45% of the combined company and Cytyc shareholders would own 55%.

"The combined company has nine number-one products," said Hologic Chairman and CEO Jack Cumming at the Needham & Company Biotechnology & Medical Conference on June 14. "We become a dominant force in women's health." Hologic projects approximately $1.7 billion in combined revenues for fiscal year 2008.

Hologic's core business (95% of revenues) is breast health and densitometry, and it is the market share leader in the United States for mammography and osteoporosis detection. One-third (13,000) of the mammography systems installed worldwide are made by Hologic. The company is focused on penetrating the emerging market of digital mammography, as opposed to analog or film-based methods. Hologic's digital mammography business grew by more than 50% in fiscal years 2005 and 2006.

The Cytyc merger makes for an appealing synergy story. "We are trying to leverage the OB/GYN channel. We believe that this is where it all begins. This is where the referrals come from," said Cumming. "This is the gatekeeper to women's health today. Whether it's for detection or screening or therapy, the OB/GYN is the starting point." In addition to the OB/GYN channel, Cytyc has a direct sales force into the breast surgery and radiation oncology marketplaces, sectors that appeal to Hologic because of a number of new products it has in its pipeline and because they plan to ultimately sell digital mammography and bone densitometry products into those practices.

The combined company will have about 425 salespeople and 250 service people. Hologic will maintain its headquarters in Bedford and Cytyc's offices in Marlborough. Additionally, the company will continue to use the Cytyc brand on such products as ThinPrep, the NovaSure System endometrial ablation device, the MammoSite radiation therapy system, and the FirstCyte ductal lavage-based breast cancer test.

▲ **Qiagen/Digene,** *from page 1*

Known for its sample and assay technologies, Qiagen already has a $150 million molecular diagnostics franchise, which represents a significant portion of the $535 million in (pre-transaction) revenue that the company has forecasted for this year.

Adding Digene to its product mix would give Qiagen a leadership position in HPV testing, Digene's primary product. Although companies such as Third Wave and Gen-Probe are nipping at their heels, Digene's test is currently the only FDA-approved and CE-marked HPV test. Washington G-2 Reports estimates that the worldwide HPV testing market will reach $170 million in 2007 and is growing by more than 25% per year.

OTC Fertility Screening Test Hits U.S. Market

A new two-part test enables couples to assess their fertility in the privacy of their own home in just 80 minutes. Fertell, manufactured by reproductive health company Genosis (Surrey, United Kingdom), hit the shelves of U.S. stores in June. The FDA-cleared test retails for around $100 at stores such as CVS, the nation's largest drugstore chain, and through the Genosis Web site. The company will spend around $5 million on its marketing campaign to launch the product in the United States.

Fertell consists of two devices to assess both male and female fertility. Results are available in 30 minutes and 80 minutes, respectively. The male device measures the concentration of motile sperm, and the female device measures the level of follicle stimulating hormone (FSH) in urine as an indicator of ovarian reserve, a measure of ovary age and ability to respond to FSH to produce eggs capable of fertilization. Both tests are 95% accurate, according to the company.

Genosis estimates that the potential market for the test is more than $500 million worldwide. Each year in the United States, approximately three million couples aged 25 to 40 are seeking to conceive, and about one million American women seek medical help for fertility-related issues, according to the Centers for the Disease Control.

Fertell is the first product for Genosis, which launched the test in the United Kingdom last year through an exclusive arrangement with Boots, the country's largest healthcare retailer. However, according to the company, unit sales of Fertell through Boots have been below expectations. In the United Kingdom, Genosis recently launched a female-only fertility test that measures ovarian reserve. Last year, the company earned revenue of £227,000 ($452,000), all of which came from Fertell sales. In 2005, Genosis secured £11 million ($21.7 million) in venture funding.

Inverness Triumphant In Biosite Bidding War

After a prolonged bidding war with Beckman Coulter, Inverness Medical Innovations (Waltham, MA) reached an agreement to acquire Biosite (San Diego, CA) for $92.50 per share, which values the 19-year-old diagnostics company at as much as $1.58 billion. The transaction is expected to close by the beginning of the third quarter of 2007.

Acquiring Biosite, which earned $309 million in revenue in 2006, will give Inverness a strong foothold in the point-of-care (or "near-patient") testing market, both inside and outside of hospitals. More than 70% of U.S. hospitals use Biosite's Triage products, which are heavily weighted toward cardiovascular disease diagnostics. The company also boasts a robust pipeline in the field of proteomics-based diagnostics.

deCODE Genetics Launches Type 2 Diabetes Test

Biopharmaceutical company deCODE Genetics (Reykjavik, Iceland) now offers DNA testing services through its Clinical Laboratory Improvement Amendments (CLIA)-certified reference laboratory in Woodridge, Illinois. This coincides with the launch of the company's newly developed deCODE T2 test, which tests for

The U.S. Centers for Disease Control estimates that more than 50 million American adults are prediabetic, with either impaired fasting glucose or impaired glucose tolerance.

a genetic risk factor for type 2 diabetes. The laboratory-developed test, which has not been cleared by the FDA, is also available through DNA Direct (San Francisco, CA). The test is priced at $500 and is not currently reimbursable.

The sequence variant detected by deCODE T2 is a single nucleotide polymorphism (SNP) in the TCF7L2 gene on chromosome 10. Recent studies on the SNP in peer-reviewed publications, including the *New England Journal of Medicine* and *Nature Genetics*, have found that 8% to 11% of the world's population carries two copies of the risk variant, but type 2 diabetics are almost twice as likely to carry two copies. An individual with two copies of the risk variant will receive a positive result for deCODE T2, and those with only one or no copy of the risk variant will receive a negative result for the test.

In a prospective clinical study of prediabetics (individuals with blood glucose levels that are between normal and those indicative of type 2 diabetes), about a third of them progressed to type 2 diabetes within three years. However, among prediabetics who carried two copies of the TCF7L2 gene variant, the risk was substantially greater, 1.8 fold compared to those who tested negative. The deCODE T2 test could therefore assist clinicians in deciding which prediabetics to treat more aggressively through weight loss programs and drugs, such as metformin, both of which have been shown to reduce progression rates of prediabetics to type 2 diabetes.

deCODE T2, which can only be ordered by medical practitioners, can be performed on whole blood samples or buccal swabs. Turnaround time for the test averages two to three weeks, although according to the company, it can take up to eight weeks to receive results. The $500 test price includes shipping costs and any pre- and post-testing consultations with a genetic counselor through DNA Direct.

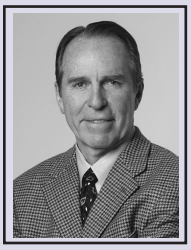
Next up in deCODE's diagnostic pipeline are tests for genetic variants that the company has linked to risk factors for atrial fibrillation and stroke, prostate cancer, heart attack, and breast cancer. The company is also working with Illumina (San Diego, CA) to develop DNA-based test kits for gene variants in diseases including type 2 diabetes, heart attack, and breast cancer, based on Illumina's clinical genotyping platform, Veracode.

Bio-Rad To Acquire Serology Company DiaMed For $389M

Life science and clinical diagnostics company Bio-Rad Laboratories (Hercules, CA) has agreed to acquire DiaMed Holding (Cressier sur Morat, Switzerland), which manufactures and markets reagents and instruments used in blood typing and screening. Bio-Rad will pay approximately $389 million (477 Swiss francs) for 77.7% of DiaMed's outstanding shares and will conduct a tender offer for an additional 12.7% of the outstanding shares after the transaction close, which is expected later this year.

Founded in 1977, DiaMed is best known for its ID Micro Typing System, a gel-based immunohematology platform that can perform such tests as Rh phenotyping, antibody screening, and reverse grouping. According to the company, over a million tests are performed using the ID System each day around the world. DiaMed has annual sales of $200 million and 800 employees worldwide, including about 300 in its Swiss headquarters.

Exagen Diagnostics Prepares To Launch First Genomic-Based Prognostic Test



Exagen CEO James McClintic

What do you get when you mix an algorithm designed to test automobile parts with genomic data that run to the billions of base pairs? A speedy, novel approach to finding genomic biomarkers for diseases such as breast cancer. Five-year-old Exagen Diagnostics (Albuquerque, NM) is leveraging unique data-mining technology to zero in on disease-related genes for which it can develop, manufacture, and distribute molecular diagnostic tests to hospitals, reference laboratories, and pharmaceutical companies. At the helm of the company is CEO James McClintic and President and COO Robert A. Mignatti, both veterans of Esoterix, the specialized clinical laboratory that was acquired by LabCorp in 2005. In the wake of Exagen's first FDA submission, *DTTR* spoke with McClintic about Exagen's origins, technology, tests, and pipeline.

Can you tell us about the history of Exagen?
It came from a "Who would have thunk it?" kind of situation. A company in Albuquerque called Quasar [International] was trying to figure out a way to find defects in automobile parts. They hired a man named Cole Harris to develop an algorithm that would read tuning fork vibrations that were indicative of the quality of automobile parts. At about the same time, the human genome was being discovered, and [Harris] thought that since he was measuring thousands of different inputs, maybe his algorithm would work in genes and finding genomic markers. So he looked around and found some available public data sets and focused on conditions such as glioma and acute myelogenous leukemia. He took the information into his algorithm, and with some adjustments, found that he could identify gene sets involved in these diseases.

In January of 2002, Cole Harris and Waneta Tuttle, Ph.D., founded Exagen. They raised venture capital, attracted larger investors, and began to refine the technology. I came along about three years later in October 2006.

What makes the technology that drives Exagen's product development unique?
Because it's an algorithm that is performed by computers using patient datasets, it doesn't have bias. Traditionally, the way that people go about determining what genes are involved in various disease states is sort of like trial and error. They look at various genomic regions, and they computer model it. What our discovery platform does is look at all 30,000 genes and just says which genes seem to be involved in this particular disease state. It doesn't have any human intervention.

Also, a traditional gene identification program usually takes two to three to four years. Our technology can do things in weeks. The gene sets for our bowel disease test were discovered in about six weeks, and those for our chromosomal aberration test were discovered in less than three weeks.

Would Exagen's tests fall within the category that the FDA calls in vitro diagnostic multivariate index assays (IVDMIAs)?
Yes. We think they will. We support what the FDA is doing and have built our business model around it. The management of Exagen is basically from the laboratory business, so we know about laboratories, and we know how to set up CLIA labs.

Setting up a CLIA lab is not a big deal. The bigger deal is taking a compound or a test and taking it through an FDA process, which means that you have to do very rigorous testing and actually prove—in a blinded method—that your test does

"Setting up a CLIA lab is not a big deal. The bigger deal is taking a compound or a test and taking it through an FDA process."

what you say it does. That's a long and laborious process, but we've figured out a way to discover the genes and develop a test from start to finish—from the day of discovery to the day that we launch it in the marketplace—in less than two years and at a total cost of less than three million dollars per test.

Exagen recently submitted the eXagenBC fluorescent in situ hybridization (FISH) assay for FDA clearance. Can you tell us about this test?

eXagenBC is a test for stage 1 breast cancer, and about 70% of all breast cancers are stage 1. The test was developed to predict cancer recurrence—if a woman has a tumor removed, what are her chances of having that cancer recur? Who is in a high-risk group and who is in a low-risk group for cancer recurrence?

How long does the eXagenBC test take to perform? How might this test fit in with existing breast cancer testing?

It takes around two days to perform the test and process the results. When a breast cancer tumor is removed, it's sent to the laboratory to determine if it's malignant or benign. Once the determination is that it's malignant, they want to determine the HER2 [human epidermal growth factor receptor-2] status, which is also a FISH test, and then they want to determine whether the tumor is ER/PR [estrogen receptor/progesterone receptor] positive or negative. So is the cancer going to respond to hormonal therapy or do you go directly to chemotherapy? And eXagenBC could be the third test that would be administered. Oncotype DX could also be administered at that particular point.

How is eXagenBC different from Genomic Health's Oncotype DX test?

The main difference between the eXagenBC test and Oncotype DX is that the Oncotype test is done in Redwood City, California, by Genomic Health, and our test will be done by local or regional laboratories who have FISH capability and who perform HER2 by FISH. There are about 40 such laboratories in the United States.

What is the estimated price for eXagenBC? Will it be reimbursable?

FISH technology has its own CPT codes, so if the laboratory performs our test, they bill by probe. We have three genes, so therefore we have three probes. The laboratory that performs eXagenBC can then bill under the existing CPT codes for FISH analysis, and the reimbursement by Medicare, while it varies from state to state and region to region, the three markers will be reimbursed at an average of about $700 for Medicare. The insurance companies will probably reimburse it at a rate 30% higher than that, so the range is going to be from around $700 for Medicare to $1000 for private insurance.

And that's another major difference between eXagenBC and Oncotype DX—the codes are covered. Genomic Health has done a great job in getting [insurance] carriers like Aetna, UnitedHealthcare, and Medicare to reimburse for Oncotype DX, but they don't have universal coverage. FISH-based testing does.

What will Exagen charge laboratories for the test?

Our list price for the test is $500. Our introductory price will be $400. And that's for every laboratory

Prognostic Gene Expression Testing for Breast Cancer

Test	*Method*	*Manufacturer*
Oncotype DX	RT-PCR	Genomic Health
MammaPrint	Microarray	Agendia
Breast Cancer Gene Expression Ratio	RT-PCR	AviaraDx
eXagenBC	FISH	Exagen
Mammostrat	Immunohistochemistry	Applied Genomics
TBA (14-gene prognostic score)	TBA	Celera*
TBA (ER/PR receptor status)	TBA	Celera*

*Development and commercialization licensed to LabCorp in April 2007

Source: *DTTR*

in the country. We're not going to offer discounts. We're not going to offer price cuts based on volume. Everybody's going to buy it at the same price.

What other tests does Exagen have in the pipeline?
We're looking across all publicly available [genetic] data sets to see if there are places where there is a testing need, an unmet medical need, and a market big enough to sustain our development and that will give us the appropriate return on investment. It just so happens that breast cancer was the first such field.

We have another test that is going to be developed for breast cancer, the ER/PR-negative variety, which we are going to call eXagenHRN. Then we'll leave cancer and go into bowel disease, where we have two tests that are under development. One determines the difference between ulcerative colitis and Crohn's disease. When we were discovering those genes, we also found that we could distinguish between irritable bowel syndrome and whether or not people just had an upset stomach. So we have two tests for inflammatory bowel disease. These are blood tests that are run a real time PCR instrument. We will sell them for $200, and reimbursement will average about $400. We expect to launch them sometime in 2008.

Then we have the Exagen chromosomal aberration test, which we expect to launch in the early part of 2009. There's about six million biopsies done in the United States every year, and in some cases—about 6% of biopsies—they are just a clump of cells, indeterminate specimens. Our test will determine the difference between malignant or benign cells in these specimens. Because it contains 12 probes, this test will probably be [reimbursed] in the $2000 range.

The last two tests in the pipeline are for hepatitis C. These are the furthest out, and we plan to launch them sometime in 2009 and 2010. The hepatitis tests really look at whether therapy is going to work. And we actually have four more tests in the discovery stage that we're not talking about.

What did you learn from your experience at Esoterix that has been most helpful to you as CEO of Exagen?
When I left Esoterix, I wanted to find a way to combine my 25 years of experience in pharmaceuticals with my 15 years of experience in laboratories. I had a brief overview from Exagen about what they were trying to do, and then I looked at the S-1 [SEC filing] for Genomic Health, which was using a pharmaceutical approach to laboratory testing. And we had done this at Esoterix. We created and launched 20 new tests when I was at Esoterix, so we knew that you could develop new tests, and we knew that you could market them. And one of the things that you had to do was go to the physician and inform and educate them about why that new test was worthwhile and why they should order it. So if the promise of Exagen held true—if the technology worked and it could identify these gene sets—we could apply pharmaceutical marketing techniques to the laboratory business.

And because there aren't just three or four genes that are involved in cancer or other disease entities, you can find more than one test that will work in any given disease category. That was our premise. With Genomic Health, Agendia's MammaPrint being cleared by FDA this year, and Celera, which has a couple of tests that they believe will be good for breast cancer recurrence, there are going to be four of five tests in the next few years that will be launched into the breast cancer testing marketplace. That pays off on my original hypothesis: It's going to be much more like pharmaceuticals than like the old days of laboratory testing.

Biomoda Validating Early Detection Lung Cancer Test

Cancer diagnostics company Biomoda (Albuquerque, NM) is partnering with the Mayo Clinic (Rochester, MN) to conduct a broad validation study of Biomoda's patented, noninvasive cytology-based lung cancer diagnostic assay. The test uses Biomoda's Tetrakis Carboy Phenyl Porphine (TCPP) technology, which was originally developed at Los Alamos National Laboratories and licensed from the University of California in 1995.

TCPP, a unique type of blood-related biological pigment known as a porphyrin, has an affinity to bind with cancer cells. When exposed to certain wavelengths of fluorescent light, the TCPP stain causes cancer cells to light up red/orange, with a degree of fluorescence proportional to the abnormality of the cell.

In early June, Biomoda filed for an additional patent for the use of its patented porphyrin molecule to detect different cell variations of lung cancer. According to Biomoda president, John Cousins, the company is trying to protect all uses of the molecule to prevent competitors from "target[ing] our patents with a so-called 'picket fence' of minor patents that could weaken our powerful market position." The new patent application details a number of ways that a mixture of porphyrin molecules uniquely binds to various types of lung cancer.

In addition to its diagnostic products, Biomoda intends to ultimately develop and market cancer treatment products with an initial focus on lung cancer. Biomoda is also developing a second generation of products that will combine TCPP with radioactive copper, in separate formulations for imaging and treating human lung cancer. The company also plans to develop an international presence through licensing agreements and possibly joint ventures with international partners.

Sorenson Genomics Buys Identigene

DNA-testing laboratory Sorenson Genomics (Salt Lake City) has acquired Identigene (Houston), which specializes in forensic and paternity DNA testing. Financial terms of the deal were not disclosed.

Founded in 1993 by Caroline Caskey, Identigene pioneered short tandem repeat analysis, a technology for human identification used in forensics and relatedness DNA testing. In addition to direct-to-consumer paternity, forensic, and ancestry testing, the company offers mouse genotyping services to researchers. The laboratory will keep its name and remain in its Houston facilities.

Sorenson Genomics, founded by James LeVoy Sorenson, also serves the forensics and relatedness testing markets. The company's 10-year-old GeneTree division offers direct-to-consumer DNA testing. List price for a home paternity test is $199, and the company's PCR-based Pink or Blue Early Gender Test detects Y chromosomal DNA in maternal blood for a cost of $249. In 2001, Sorenson opened a high-throughput DNA purification, genotyping, and sequencing facility and launched Relative Genetics, a division that serves the genetic genealogy and ancestry markets. The company has a network of over 3,000 DNA collection sites worldwide.

AHRQ Report Faults Data On Gene-Based Testing For HNPCC

A report released in late May by the Agency for Healthcare Research and Quality (AHRQ; Rockville, MD) finds that there is little published evidence on the accuracy and reliability of laboratory testing used to diagnosis hereditary nonpolyposis colorectal cancer (HNPCC), also known as Lynch syndrome, in colorectal cancer patients or their family members.

HNPCC is an autosomal dominant disorder that is associated with a substantially increased risk for several forms of malignancy, particularly colorectal and endometrial cancer. Testing for HNPCC analyzes tumor or blood cells for mutations in DNA mismatch repair (MMR) genes, but most patients with colorectal cancer do not have gene mutations.

The results of a computer model showed that identification of HNPCC in high-risk patients by evaluating for three risk factors (age less than 50, history of colon or endometrial cancer in a first degree family member, and presence of multiple cancers in the patient) and then analyzing the tumor tissue may potentially be as effective as other strategies, while reducing the number of tests.

The evidence report is the first step in the two-step process of CDC's Evaluation of Genomic Applications in Practice and Prevention (EGAPP) pilot project to evaluate and make recommendations regarding the use of gene-based tests. The EGAPP working group, an independent, non-Federal panel, will issue recommendations on the use of these tests in the diagnosis and treatment of hereditary nonpolyposis colorectal cancer based on the evidence report and other considerations, including alternative approaches for screening and diagnosis, patient access to testing, and cost.

FDA Recalls Abbott Troponin Test

The Food and Drug Administration (FDA) recently issued a Class I recall of the Architect Stat Troponin-1 immunoassay manufactured by Abbott Laboratories (Abbott Park, IL). The blood test is used to diagnose damage to the heart and/or a heart attack (myocardial infarction) in people who have had chest pain. Abbott issued a voluntary, nationwide recall of the product on May 27 and also provided laboratories with updated directions for the test. Earlier this year, the FDA issued a Class I recall of select lots of VITROS Troponin I Reagent Packs manufactured by Ortho-Clinical Diagnostics (Rochester, NY) due to problems with false-negative results.

Abbott's Architect Stat Troponin-1 test was recalled after some clinical laboratories reported inconsistent or invalid test results at very low levels of troponin-1 (i.e., less than 0.1ng/mL). Falsely low troponin results could delay treatment, while falsely high results may lead to unnecessary surgery. The FDA advised laboratories to "be cautious when reporting results at or near the lower limit of detection and to advise physicians ordering the tests about the possibility of inaccurate results at those levels." Abbott reports that it has "identified the root cause and is working on correcting the issue."

JAMA Study Probes Gastric Cancer-Linked Gene Mutations

Gastric (stomach) cancer is the second most common cause of cancer death worldwide. Those families with CDH1 mutations are estimated to have a 40% to 60% cumulative risk of gastric cancer.

Mutations in the epithelial cadherin (CDH1) gene cause hereditary diffuse gastric cancer (HDGC) and are due to both independent mutational events and common ancestry, according to a study published in the June 6 issue of the *Journal of the American Medical Association (JAMA)*.

HDGC is an autosomal-dominant cancer susceptibility syndrome that is characterized by early onset diffuse gastric cancer and lobular breast cancer. For families with HDGC, genetic testing has become popular since the disease's genetic underpinnings were discovered in 1998. Based on the results of genetic testing, many of those from affected families that carry CDH1 mutations choose to undertake cancer risk reduction strategies, such as endoscopic screening and prophylactic gastrectomy.

The *JAMA* study analyzed 38 families with diffuse gastric cancer. Twenty-six families had at least two gastric cancer cases, with one case of diffuse gastric cancer in a person younger than 50 years old; 12 families had either a single case of diffuse gastric cancer diagnosed in a person younger than 35 or multiple cases of diffuse gastric cancer diagnosed in persons older than 50. The analysis revealed 13 different CDH1 mutations in 15 of these families (40% detection rate). Eight of the mutations were classified as recurring, including two mutations that were found in more than one family.

"Our results confirm that between 30% and 40% of families with a positive family history of gastric cancer and more than 50% of families with two diffuse gastric cancer cases diagnosed prior to age 50 years will carry germline mutations in the CDH1 gene," wrote the researchers, who were led by Pardeep Kaurah, M.Sc., of the British Columbia Cancer Agency (Vancouver, Canada).

Early detection of gastric cancer is difficult, in part because early lesions are often multifocal and located underneath normal gastric mucosa. Additionally, recently recommended screening methods for at-risk individuals—positron emission tomographic scanning or chromoendoscopy-directed biopsies—appear to have low sensitivity and failed to detect early gastric cancer in six patients with HDGC in a recent study.

Severely Obese Women More Likely to Skip Cancer Screening Tests

Severely obese women tend to skip Pap smears, clinical breast exams, and mammograms more often than their nonobese peers, according to a study in the June issue of the *American Journal of Preventive Medicine*. The study found that physicians are as likely to recommend mammograms and Pap smears to obese as to nonobese women.

Lead author Jeanne Ferrante, M.D., conducted the study in 2006 and analyzed data from the 2000 National Health Interview Survey, involving nearly 8,300 women ages 40 to 74. Up-to-date status on clinical breast exams, mammograms, and Pap smears was 9% to 10% less prevalent among severely obese women, compared to women of normal weight. Severely obese women (those with a body mass index, or BMI, of at least 41) had 51% lower odds of adhering to physician recommendations for mammography and 83% lower odds of adhering to Pap test recommendations.

IVD Stocks Flat; Digene, Cytyc, and Cholestech Climb On Merger News

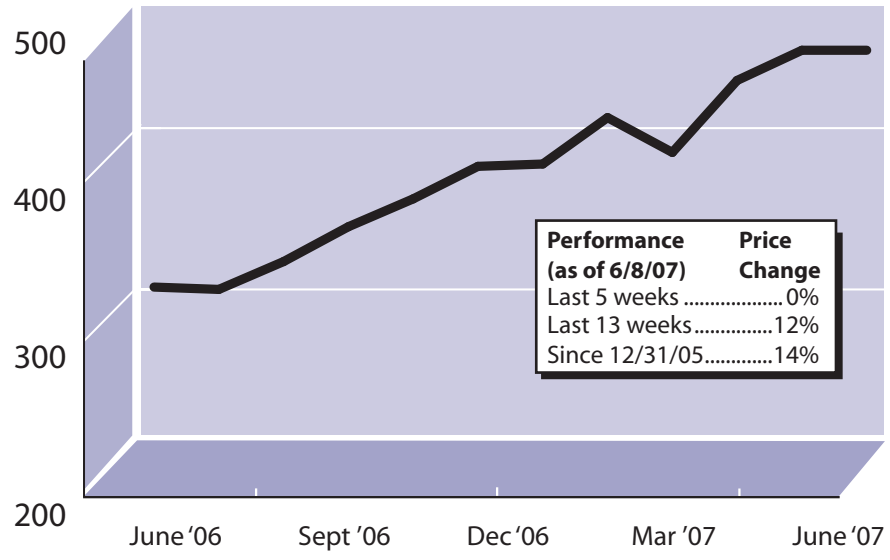
The 23 stocks in the G-2 Diagnostic Stock Index held steady in the five weeks ended June 8, with 12 stocks down in price and 11 up. Year to date, the G-2 Index is up 14%, while both the S&P 500 and the Nasdaq have gained 6% so far this year.

This month, **Stratagene** drops out of the G-2 index in the wake of Agilent's acquisition of the life sciences research and diagnostics company. Agilent paid approximately $250 million for Stratagene in a transaction that closed on June 7. As part of the deal, some of the company's assets were sold to **Decisive Diagnostics** (Jackson Hole, WY), a new molecular diagnostics company founded by former Stratagene CEO Joseph A. Sorge. Decisive Diagnostics paid Agilent $6.6 million for certain assets of Stratagene and will license from Agilent some of the company's molecular diagnostics technologies. Decisive Diagnostics is working on developing quantitative PCR-based tests kits for diagnostic applications that include pharmacogenomics, cancer, and infectious diseases.

Shares in **Cholestech** (Hayward, CA) were up 15% to $20.43 a share for a market capitalization of $336 million. On June 4, **Inverness Medical Innovations** (Waltham, MA) announced that it will acquire the company in a stock deal valued at $326 million. This would make Cholestech the eighth acquisition for Inverness this year. The company recently won a bidding war with Beckman Coulter for Biosite (see p. 3).

Things were also looking up at **OraSure Technologies** (Bethlehem, PA). Shares in the immunoassay manufacturer were up 1% to $7.60 per share for a market cap of $381 million. The company recently received European regulatory approval for its OraQuick Advance HIV-1/2 antibody test. The test detects HIV-1 and HIV-2 antibodies in samples of oral fluid, blood, or plasma in about 20 minutes. The approval gives the test CE-marked status so that it can be sold in the 27 countries of the European Union. The CLIA-waived test has already been approved by the FDA.

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 23 IVD companies.

Avg. % Price Change, 5 weeks ended 6/8/07

Up	Price	% Chg
Beckman Coulter	$66.87	6%
Bio-Rad	74.04	5
Cholestech	20.43	15
Cytyc	41.67	19
Dade	51.71	2
Digene	56.25	22
Gen-Probe	55.59	5
Inverness Medical	47.62	20
OraSure	7.60	1
Third Wave	5.60	9
Ventana	51.88	2
Down		
Abaxis	$22.61	-2%
Abbott Labs	54.29	-7
Affymetrix	25.37	-4
Becton Dickinson	75.38	-5
Biosite	92.18	-2
Clinical Data	21.88	-2
Immucor	29.23	-12
Johnson & Johnson	62.13	-4
Luminex	11.85	-15
Meridian	22.02	-28
Nanogen	1.38	-22
Quidel	13.82	-2

G-2 Insider

A kinder, gentler molecular diagnostics platform . . . AutoGenomics (Carlsbad, CA) is focused on making molecular diagnostics faster, easier, and cheaper for clinical laboratories, including the hospital market. The privately held company recently completed a $12 million Series C funding round to continue its development of Infinti, a novel molecular diagnostics platform designed specifically for the clinical laboratory market. AutoGenomics was founded in 1999 by CEO Fareed Kureshy, who previously led such companies as Sequenom, Behring Diagnostics, and PB Diagnostics.

The company's novel platform uses a polyester film-based microarray technology that is designed to be less expensive and more efficient than existing platforms, with automation from sample to result and the ability to combine genomic and proteomic analysis with multiplexing capability. The system consists of a self-contained Infiniti analyzer and BioFilmChips, microarrays that will be offered in ready-to-use formats for the laboratory and can be customized for lab-developed test and research applications.

AutoGenomics plans to partner with universities, pharmaceutical companies, and reference laboratories to develop customized microarray applications based upon genomic and proteomic signatures of disease. The Infiniti's application menu currently includes analyte-specific reagents that can be used to identify genetic mutations associated with Factor II, Factor V Leiden, and cystic fibrosis.

Company References

Abbott 847-937-6l00

AHRQ 301-427-1364.

AutoGenomics 760-804-7378

Biomoda 505-821-0875

Bio-Rad 510-724-7000

Biosite 858-805-2820

Beckman Coulter 714-871-4848

Cholestech 510-732-7200

Cytyc 508-263-2900

deCode Genetics 354-570-1900

DiaMed 41-26-674-51-11

Digene 301-944-7000

Exagen Diagnostics 505-272-7966

Genomic Health 866-662-6897

Genosis 781-444-2663

Hologic 781-999-7300

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Inverness 781-647-3900

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