# Diagnostic Testing and Technology Report

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



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CONTENTS




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## Myriad Genetics May Spin Off Pharma Business

By this time next year, Myriad Genetics (Salt Lake City) may be two separate companies: one focusing on the company's pharmaceutical business and the other on the diagnostics business. Spinning off the pharmaceutical division from the molecular diagnostics division—best known for its BRACAnalysis test for breast cancer—is one of the "strategic alternatives" now being reviewed by Myriad's board of directors, the company announced on September 11.

"The board is committed to growing both of our business opportunities in a way that seeks to maximize shareholder value," said John Henderson, board chairman. "We are continuing our deliberations and intend to announce a decision before the end of the year." According to Myriad, spinning off the pharmaceutical subsidiary from the molecular diagnostic business would result in two independent and highly focused businesses.

## FDA Clears Third IVDMIA: XDx's AlloMap

The U.S. Food and Drug Administration (FDA) has cleared for marketing the AlloMap test developed by XDx (Brisbane, Calif.). The multi-gene, multi-pathway gene expression test can be used to assist physicians in managing heart transplant patients for potential organ rejection. AlloMap is the third in vitro diagnostic multivariate index assay (IVDMIA) cleared by the FDA. IVDMIAs are medical devices that combine the values of multiple variables to yield a single, patient-specific result.

From a blood sample, the AlloMap test measures expression of 20 different genes, resulting in a score that indicates whether a heart transplant patient is unlikely to reject the new organ. "AlloMap can help contribute to an appropriate treatment plan by identifying those patients not experiencing post-operative heart transplant rejection," said Daniel G. Schultz, M.D., director of the FDA's Center for Devices and Radiological Health. "It is an example of how advancements in science and technology are leading to new medical care diagnostics."

According to XDx, AlloMap testing is intended to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment. *Continued on p. 2*

▲ **XDx's AlloMap,** *from page 1*

In 2006, there were more than 2,000 heart transplants performed in the United States, according to the American Heart Association. Following a heart transplant, physicians regularly monitor patients for transplant rejection, a significant risk to patient survival. Rejection occurs when the patient's immune system rejects the new organ and begins to attack it. Successful heart transplants depend on a balanced immune system response—one suppressed enough to accept the new organ but strong enough to protect the patient from infections.

AlllloMap provides an alternative to the heart biopsies that are routinely used to determine whether a patient is rejecting a transplanted heart. Biopsies are difficult to perform and can be risky for the patient.

According to the National Heart, Lung, and Blood Institute, half of all possible rejections happen during the first six weeks after surgery and 25 percent of patients have signs of possible rejection at least once during the first year following a transplant.

XDx developed AlloMap using blood and biopsy samples and other information collected from heart transplant recipients at nine U.S. heart transplant centers participating in the *Cardiac Allograft Rejection Gene Expression Observational Study* (CARGO). CARGO provided data from 153 patients on 300 medical visits at various times after heart transplant operations.

In July 2007, the FDA issued a draft guidance document to address premarket pathways and postmarket requirements for IVDMIAs, a novel category of medical device that combines the values of multiple variables to yield a single, patient-specific result. Since then, the FDA has cleared a total of three IVDMIAs. The first such test to receive clearance was Agendia's MammaPrint breast cancer prognostic test. In July 2008, Pathwork Diagnostics received FDA clearance for its tissue of origin test, which uses microarray technology to compare the gene expression patterns of a patient's tumor with genetic information on malignant tumor types stored in a database.

## Nanogen to Merge With French Diagnostics Company

Molecular diagnostics-focused Nanogen (San Diego, Calif.) has entered an agreement to combine with the privately held Elitech Group (Paris, France) in an all-stock deal valued at approximately $98 million. With estimated first-year revenues of $150 million, the combined company will encompass molecular and point-of-care diagnostics as well as clinical chemistry and molecular biology. Structured as a reverse acquisition of Nanogen by Elitech, the deal has been approved by the boards of both companies and is expected to close by the end of the first quarter of 2009.

"The combination with Elitech will accelerate the transition of Nanogen into a global, profitable diagnostics company with the critical mass needed to bring our leading molecular and point-of-care technologies to customers worldwide," said Howard Birndorf, Nanogen's chairman and CEO, in a statement announcing the deal.

The combined company will be headquartered in San Diego. Elitech President Pierre Debiais will serve as CEO, and Elitech Vice President Michael Saunders will become COO, focusing on European business and global commercial operations. Nanogen President and COO David Ludvigson will also serve in a COO role, with a focus on the U.S. business as well as global business and finance. Nanogen CFO Nick Venuto will continue in that role for the combined company.

Founded in 1993, Nanogen's products include molecular diagnostic kits and reagents and kits for rapid point-of-care testing. Nanogen has pioneered the development of biomarkers, molecular biology technologies, and nanotechnology.

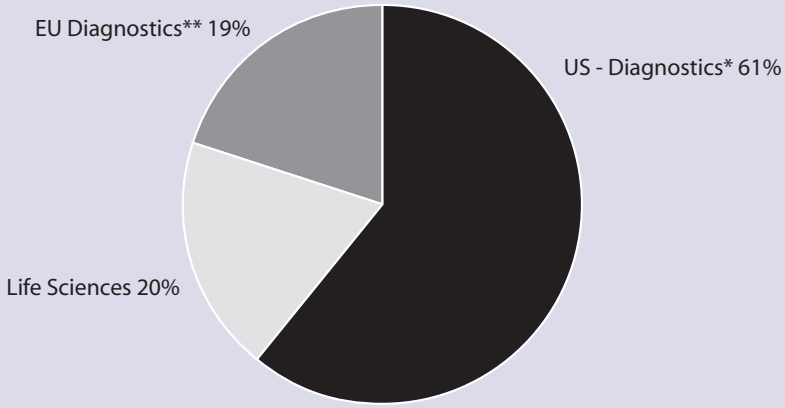
Nanogen earned 2007 revenues of $38.2 million, an increase of 43 percent over 2006. The company expects total 2008 revenues to increase by approximately 25 percent from 2007 levels to $47.8 million. The company has never been profitable. In 2007, it posted a net loss of $39.9 million versus $49.1 million in 2006.

## Meridian Bioscience Inks Canadian Distribution Deal

Meridian Bioscience (Cincinnati) is making good on its promise to expand its business outside of the United States. On September 10, the developer, manufacturer, and distributor of rapid diagnostic tests announced that it has entered into a new exclusive Canadian distribution agreement with Somagen Diagnostics (Edmonton, Alberta), a specialty distributor of clinical laboratory products.

Merdian currently operates in 60 countries worldwide through approximately 40 sales representatives and 100 distributors. The majority (61 percent) of Meridian's revenue comes from its diagnostics business in the Americas and the Pacific Rim. An additional 19 percent of revenue is derived from sales of test kits in Europe, Scandinavia, the Middle East, and Africa. The remaining 20 percent of revenue comes from Meridian's life sciences business, which includes viral proteins, antibodies, and technologies.

**Meridian Bioscience: Revenue by Region**




*Includes Americas and Pacific Rim.
**Includes Europe, Scandinavia, Middle East, and Africa.
Source: Meridian Bioscience

"The effective global distribution of our rapid tests for infectious disease is one of Meridian's key strategies," said CEO Jack Kraeutler. "Our effort to improve and expand distribution outside the U.S. is beginning with one of the world's leading health care markets."

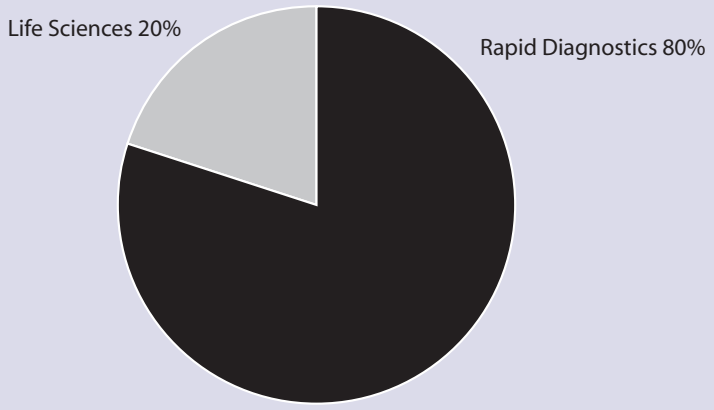
Founded as Immucor Canada in 1988, Somagen focuses on niche markets within the clinical diagnostic market. These markets include cellular pathology, point-

of-care (POC) diagnostics, electrophoresis, and immunology. The company also offers products in such areas as automated hemoglobin A1c testing, automated immunoassay systems, molecular diagnostics, and allergy testing.

Founded in 1977, Meridian developed the first rapid strep test, which was licensed to Marion Laboratories, which merged with Dow Pharmaceuticals in 1989. Meridian went public in 1986 and currently has approximately 400 employees.

Approximately 80 percent of Meridian's revenue comes from sales of rapid diagnostics. "We sell these tests into markets that appreciate the 'test and treat' philosophy. In other words, with the result, the doctor can choose the right therapy or choose no therapy," said Kraeutler at the Robert Baird Small Cap Health Care Conference in New York City on September 10. "Our market tends to be the acute care market, so hospitals, reference laboratories, and outpatient clinics, and within that [market], we are specialists in the microbiology, virology, and parasitology labs. These are labs that tend to handle rather small numbers of specimens, and the specimens are typically not blood, serum, or urine that are capable of being automated. Usually there's a real-time need for that test. "

**Meridian Bioscience: Revenue by Segment**




Source: Meridian Bioscience

Merdian avoids two other markets for point-of-care testing: the physician's office and the over-the-counter (OTC) channel. "The doctor's office today still really only does four or five diagnostics in the office: strep, pregnancy, flu, [and] glucose. Those are the big drivers for that market," said Kraeutler. "Billions of dollars have been spent trying to develop products and access that doctor's office market, and the opportunities never seem to pan out." As for the OTC market, it not only presents significant regulatory hurdles but also can lead to a brand getting "lost" in a sea of competitors, noted Kraeutler.

The remaining 20 percent of Meridian's revenue comes from its life sciences business, through which the company supplies viral proteins, antibodies, and technologies. Kraeutler described this business segment as consisting of the key biologicals for automated testing, which Meridian sells to large manufacturers of automated diagnostics worldwide, "so that every time an Abbott instrument runs a hepatitis A test, it's using Meredian's protein."

In discussing Merdian's acquisition activity, Kraeutler emphasized, "The opportunities for us will come from small life sciences businesses, from expanding our international distribution through distributors that we've known for many years, and for nonstrategic carve-outs from some of the larger diagnostic players."

# Nanogen's David Ludvigson on Mergers, Markets, and Microarrays

Nanogen (San Diego, Calif.) recently agreed to combine with the privately held Elitech Group (Paris, France) in a deal valued at approximately $98 million (*see p. 2*). The combined company will encompass the molecular, point-of-care, clinical chemistry, and microbiology diagnostics and will have estimated first-year revenues of more than $150 million. *DTTR* recently talked with David Ludvigson, president and chief operating officer of Nanogen, to get his view on what makes the companies a good match, what the deal means for Nanogen's pipeline, and on the possibly intersecting futures of Nanogen's two key markets: molecular and point-of-care diagnostics.

*David Ludvigson*

**You've been with Nanogen since 2003. What experience did you bring to your role at the company?**

I was on the board of directors at Nanogen from 1996 until I came into the company on a full-time basis. My background is really general management—financial management—in the biotech world. I was at Idec, which is now Biogen-Idec, and when I was there, I was running the financial functions and really worked on the Rituxan deal [to develop and commercialize the first FDA-approved therapeutic antibody to treat cancer] with Genentech. And then I also worked for a company called Matrix Pharmaceuticals, an oncology-oriented company with cancer-based products, which was purchased by Chiron. In addition to that, I did a number of high-tech projects with a couple of companies that are in the computer hardware and software area.

**Can you give us a little background on Nanogen's decision to merge with the Elitech Group?**

It started out almost a year ago with a discussion with the Elitech group about their need to get technology and products into their business. And so it was originally a discussion about licensing technology or using them as a channel for buying our products. The more time that we spent with them, the more we realized that there was a real good fit between the two companies. They have a business that is a very stable, successful, growing business in clinical microbiology, and so they have a good, profitable business. It's about $80 million in [annual] revenue. Pierre Debiais, who is the CEO, started the company himself. He grew it from zero up to $80 million in about 10 years time.

**What were the key factors that make Nanogen and Elitech a good match?**

The positive is that they have great distribution and sales capability, and they have this nice set of products. The negative was, from their standpoint, that they wanted to get into the faster growing portions of the in vitro diagnostics market, particularly molecular diagnostics and point-of-care [testing].

So from our standpoint, we have lots of products, lots of technology. We are really in our infancy in terms of building out our go-to-market capabilities and our distribution capabilities. You have in Elitech a company with a strong base that drives profitability, and you have in Nanogen the high-growth engine.

***"We really believe that the underserved portion of the IVD market is in the smaller laboratories and point-of-care testing areas..."***
***— David Ludvigson***

And finally, we are both very much focused on small- and medium-sized users, because we really believe that the underserved portion of the IVD market is in the smaller laboratories and point-of-care testing areas that really need products in order to be responsive to their customers and to their patients. So we just found that there was a great deal of synergy, very little overlap, and when we put the pieces together, it just looked really good. Stylistically, we're a similar company. We're entrepreneurial and very interested in delivering innovation to customers.

**How do you think that this deal will affect Nanogen's pipeline? What projects might be accelerated or expanded as a result?**

Well, I think that it helps with the cash flow and affordability portion a lot, because you've got a combined company that in its first year will be over $150 million of revenue, and it will be profitable with positive cash flow. So that allows you to make investments and to pursue more aggressive timelines that maybe we've been a little reluctant to do on our own. So I expect that we will probably accelerate first of all the development of some of the infectious disease molecular diagnostics that we have for sale in the United States as kit products, FDA-cleared products versus ASRs [analyte-specific reagents]. And their resources will allow us to do the clinical trials necessary to do that.

The second area that I think will affect us is we have a very interesting point-of-care technology that we've been developing under a contract from the Centers for Disease Control and Prevention for rapid testing of influenza and potential pandemic infectious disease. That platform is really outstanding. It has fabulous sensitivity, and the numbers that we're seeing on the influenza tests are really way beyond anything that's in the marketplace today in terms of rapid testing. That platform is being developed for this influenza test, but we really think that it has a great deal of applicability to advances in cardiovascular rapid testing and potentially the development of tests around cardiovascular health that maybe we haven't had the sensitivity to do in the past. So I expect that we will utilize this combination to be much more aggressive in developing alternative applications for this third generation point-of-care platform.

**This year we've seen a lot of acquisition activity where young molecular diagnostics companies—particularly those with platforms behind them—are concerned. Do you think that this is a trend that's going to continue?**

I do think that it's going to continue to be a trend. Small companies like Nanogen develop technologies for the newer, emerging markets that are smaller today but are growing 30 percent a year—they're where the growth is in the market. As soon as those markets get large enough, then the large players all of a sudden look around and say, "Gee, there's this big market, and we need to be able to service that for our customers." So I think that's going to continue to be a trend.

With all of the emphasis we're seeing around personalized health care and also the emphasis on cost control of health care, I think that we agree with the general predictions that more of the health care dollar is going to be spent on diagnostics and particularly on the newer diagnostics that test for some of these infectious disease conditions or even getting into predictive testing as well.

**Given Nanogen's presence in both molecular and point-of-care testing, do you see those fields ultimately coming together into a new area of molecular point-of-care diagnostics?**

Yes, absolutely, but I would emphasize that it's several years away. I don't think we have a specific time frame in mind, but we do look at many of the elements of our technologies as being able to do rapid point-of-care molecular testing, although I'm not sure we're going to get the 10 or 15 minute kind of rapid testing we see in immunoassays. But I would say that the work we've done and will do suggests that we can do pretty rapid PCR-based molecular in certainly less than a 30- or 40-minute time frame. And as the technology improves, I think that we'll be able to cut into that. So I do think that there's going to be a very significant market—again, we're talking five years or more away—for point-of-care molecular.

**Last year, Nanogen decided to exit its microarray business to focus on molecular and point-of-care. What led you to make this decision?**

The array business, for us, was an affordability issue. It's an advanced technology that's in a very early emerging market stage, and we just found that the missionary selling cycle was very long and the infrastructure requirement for a big platform like that was very significant, and we just got to a place where the cost of keeping the platform outweighed what we saw as the predictable time frame in which people would adopt multiplex molecular diagnostics testing that would come in a volume sufficient to justify the platform.

It was a very difficult decision. Most of our customers were sad to see us discontinue it because most of our customers are early adopters, with a lot of combination research and diagnostic testing and really loved the platform. But we just couldn't afford it, and if you look at the financial performance of the company a year later, it's just really significantly improved and that allowed us to really move forward with the Elitech Group. I'm not sure that somebody like the Elitech Group would have wanted to marry up with us if we had continued to have the very significant burn rate that we had associated with the microarray platform.

# New Gene Variant Linked to Prostate Cancer Risk

A novel gene variant may contribute to the risk of developing prostate cancer. Scientists have discovered a second independent site within the prostate cancer gene HNF1B, which is located on chromosome 17. The finding was reported in a study published online in *Nature Genetics* on August 31.

After conducting a "fine-mapping study" of two large groups of prostate cancer and control cases, the researchers found two separate clusters of prostate-cancer-associated single nucleotide polymorphisms (SNPs), one in a previously identified region and one in a new region. The researchers then confirmed the association by looking at the same locations in five other large studies of prostate cancer patients and found that prostate cancer risk was higher among men who had the genetic variants.

Earlier this year, the same research group reported in the *New England Journal of Medicine* that genetic variants have a strong cumulative effect. A man with four of the five previously discovered variants has a 400 percent increased risk of developing prostate cancer compared to a man with none of the variants.

"As we find more of these [genetic variants], it improves our ability to predict prostate cancer risk," said Jianfeng Xu, M.D., Ph.D., senior researcher on the study and a professor of epidemiology and cancer biology at Wake Forest University School of Medicine. At the same time, Xu predicts that prostate cancer will be found to be polygenic, "not dependent on one gene, but a group of genes."

# Protein Variant Predicts Chemotherapy Response

*"If we could find out which individuals carry this variant, it might change our decisions about treating them with cisplatin."*

Researchers at the Moores Cancer Center at the University of California, San Diego (UCSD) in La Jolla have found evidence to explain the varying responses of cancer patients to cisplatin, a common chemotherapy drug that is the first-line therapy for testicular and ovarian cancers. Findings published online on September 3 in the *Proceedings of the National Academy of Sciences* demonstrated that when a variant version of a key protein that normally causes cell death is active, patients may be resistant to the cancer-killing drug.

In a series of experiments, UCSD professors Jean Wang, Ph.D., and Richard Kolodner, Ph.D., and their colleagues found that when a specific variant form of the "mismatch repair" protein, PMS2, is active, cisplatin doesn't kill cancer cells the way it normally does. In the presence of this active variant, cancer cells are basically rendered resistant to the drug.

As a repair protein, PMS2 is crucial to fixing mistakes in DNA that may occur during replication. Defects in such mismatch repair genes and proteins have been associated with increased cancer risk, particularly for hereditary nonpolyposis colorectal cancer (HNPCC). The human PMS2 gene has at least 12 different forms. In studies on mouse cells lacking PMS2, the researchers tested several different variations of the human PMS2 protein, showing for the most part that PMS2 sensitized cells to cisplatin, causing cell suicide. They ultimately found that one variant, PMS2 (R20Q), failed to bring about cell death in response to cisplatin. The drug's toxic effects were compromised in cells with the PMS2 (R20Q).

"We don't know how many people have this PMS2 variant," explained Wang. "We would like to take these findings to human tumor samples. If we could find out which individuals carry this variant, it might change our decisions about treating them with cisplatin." If it were possible to track how fast ovarian cancer patients' tumors develop resistance to cisplatin, Wang said, correlation studies might be performed to find risk factors, such as gene variants.

## Pathwork Diagnostics Raises $20 Million

Oncology-focused molecular diagnostics company Pathwork Diagnostics (Sunnyvale, Calif.) has closed on a $20 million funding round led by Abingworth, a venture capital firm that specializes in early-stage life sciences and biomedical companies. Other investors included Prospect Venture Partners and Advent Venture Partners. This is Pathwork's second funding round.

In July, the U.S. Food and Drug Administration (FDA) cleared Pathwork's tissue of origin test for diagnosis of tumors of uncertain origin, including poorly differentiated, undifferentiated, and metastatic tumors. The test was the second in vitro diagnostic multivariate index assay (IVDMIA) to receive regulatory clearance.

Pathwork President and CEO Deborah J. Neff said that the company will use the capital infusion to fund "important commercialization programs." These include offering the tissue of origin test through an additional distribution channel. The company currently sells the test in kit form and performs the test in its CLIA-certified laboratory.

As Pathwork rolls out its kit offering of the newly cleared test, it is focused on building its customer support team and expanding the applications of its technology to other cancer diagnostics. The company's tests use proprietary analytics and a companion Pathchip microarray, which runs on Affymetrix's GeneChip system.

## Pall Corporation Acquires GeneSystems

Pall Corporation (PLL; East Hills, N.Y.), which specializes in filtration, separation, and purification for industrial and life sciences applications, has purchased privately held GeneSystems (Bruz, France), an eight-year-old biotechnology company that has developed a real-time polymerase chain reaction (PCR)-based molecular diagnostics platform. Financial terms of the deal were not disclosed.

Pall plans to use the GeneSystems's patented approach to rapid microbiological detection to expand its capabilities in the $1 billion biopharmaceuticals process monitoring market, an area that is coming under increasing regulatory scrutiny. Process monitoring includes analytical testing required during biopharmaceuticals manufacturing for environmental monitoring, in-process control testing, and finished product release testing.

After receiving patents for its core GeneDisc Cycler, GeneExtract, and GeneDisc technology in 2001, GeneSystems launched its quantitative Legionella diagnostic platform. The company has since developed real-time PCR-based systems for the rapid and precise diagnosis of a range of pathogens, including food safety testing focused on E. coli.

# Physicians Frustrated by CMS's Quality Reporting Initiative Feedback

Physicians are not satisfied with the information on improving patient care obtained from their 2007 Physician Quality Reporting Initiative (PQRI) feedback reports prepared by the Centers for Medicare & Medicaid Services (CMS), according to survey results released September 8 by the Medical Group Management Association.

Furthermore, a full 92.9 percent of respondents said they had at least moderate difficulty assessing the feedback report from the CMS Web site and 58.2 percent characterized that difficulty as extreme.

The Medical Group Management Association (MGMA; Englewood, Colo.), a professional association for medical group practice administrators, found that of the respondents able to obtain their reports, almost 70 percent reported no or low satisfaction with the feedback's effectiveness in "providing guidance about how the practice can improve patient care outcomes."

PQRI is a voluntary program enacted in 2006 under which physicians and other eligible professionals can receive bonus payments of up to 1.5 percent of their total Medicare charges, subject to a cap, by satisfactorily submitting quality information for services rendered between July and December 2007. Incentive payments will be made based on the entire year of 2008. Congress approved an increase in the incentive up to 2 percent in 2009 and 2010.

The bonus payments were sent in the middle of July, and the feedback reports became available July 15.

Respondents spent a median of five hours downloading their report from the CMS Web site, according to the MGMA survey, and 58.2 percent of respondents said they had "extreme difficulty" accessing the report. Almost 30 percent said they attempted to download the report but gave up due to difficulty.

"Members tell us that their frustrations also stem from the 18-month lag time between their initial reporting and receipt of the results," William Jessee, MGMA president and chief executive officer, said in a statement. "To truly improve patient care, programs such as PQRI must provide timely, actionable clinical information to physicians. Our data show the program has penalized practices trying to do the right thing for their patients by wrapping them in red tape."

MGMA recommended in its statement that CMS implement more efficient reporting mechanisms, like statistical sampling.

*The MGMA survey data are available at www.mgma.com/WorkArea/showcontent.aspx?id=21972.*

Despite the difficulties, 91 percent of practices that reported participating in the 2007 PQRI are still reporting for the 2008 PQRI, and almost 50 percent said the increased incentive in 2009 and 2010 will be enough for them to begin or continue participation, according to the MGMA survey.

About 65 percent of respondents reported in 2007, according to the survey. CMS paid out more than $36 million to more than 56,700 health professionals for participating in the 2007 PQRI.

# IVD Stocks Down 6%; OraSure, Luminex Only Gainers

The 17 stocks in the G-2 Diagnostic Stock Index fell an average of 6 percent in the five weeks ended September 5, with 15 stocks down in price and two up. The G-2 index is down 11 percent so far this year, while both the Nasdaq and the S&P 500 are down 14 percent.

One of only two gainers in recent weeks was **OraSure Technologies** (Bethlehem, Pa.). Shares in the company rose 20 percent to a September 5 closing price of $4.87 for a market capitalization of $232 million. In April, the company began a clinical study to seek regulatory approval for an over-the-counter version of its OraQuick rapid test for HIV. Testing has been completed for the first 1,000 subjects in the study. "[We] believe we have met the stopping criteria under our protocol," said OraSure President and CEO Douglas A. Michels. "We have also continued to make good progress in our clinical trials to support a PMA submission for our OraQuick rapid HCV test to the FDA."

In explaining the company's recently announced share repurchase program, OraSure management reported that the company will soon be able to extend the shelf life of its domestically distributed OraQuick test, a FDA-approved rapid point-of-care blood test for diagnosis of HIV-1. The company has seen strong growth in its infectious disease business and noted that it is on track with clinical programs for HIV and hepatitis C diagnostics.

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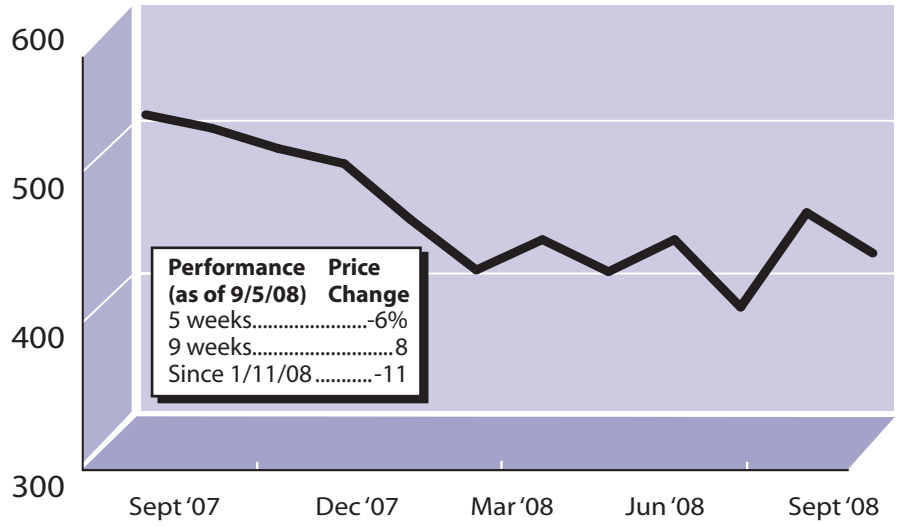
Posting a narrow loss was **Immucor** (Norcross, Ga.), a maker of automated instrument-reagent systems to the blood transfusion industry. Stock in the company fell 3 percent, ending the period with a share price of $31.08 and a market capitalization of $2.25 billion. Immucor recently announced the closing of its previously announced acquisition of molecular diagnostics company BioArray Solutions (Warren, N.J.) for $17 million. In 2005, BioArray obtained FDA clearance for an autoantibody profiling BeadChip assay on its array imaging system.

## 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 17 IVD companies.

| Up | Price | % Chg |
|---|---|---|
| Luminex | $25.85 | 11% |
| OraSure | 4.87 | 20 |
| **Down** | | |
| Abbott Labs | 57.01 | -3 |
| Affymetrix | 8.18 | -7 |
| Abaxis | 18.45 | -17 |
| Beckman Coulter | 72.25 | -4 |
| Becton Dickinson | 85.04 | -2 |
| Bio-Rad | 102.55 | -4 |
| Clinical Data | 15.94 | -16 |
| Gen-Probe | 56.35 | -6 |
| Immucor | 31.08 | -3 |
| Inverness Medical | 33.55 | -6 |
| Johnson & Johnson | 70.67 | -1 |
| Meridian | 25.47 | -4 |
| Nanogen | 0.34 | -15 |
| Nanosphere | 8.45 | -23 |
| Quidel | 17.50 | -12 |

# G-2 Insider

**New biomarker could translate to prognostic test for soft tissue sarcoma. . .** A gene linked to susceptibility for a retinal cancer (retinoblastoma) may be the first independent prognostic biomarker in cases of soft tissue sarcoma (STS), according to a study published in the August 1 issue of *Clinical Cancer Research*. Researchers found that a reduction in the expression of the tumor suppressor gene pRb2/p130 can mean a higher risk of recurrence and death from STSs. A member of the retinoblastoma family of genes, pRb2/p130 regulates a portion of the cell cycle.

STS is a rare cancer that can be highly aggressive and unpredictable. A prognostic biomarker could help physicians determine which patients have a higher risk of recurrence of the disease and who might benefit from a more aggressive adjuvant therapy.

In the study, researchers examined specimens taken from 41 patients with STS and in a subset of 31 cases of nonmetastatic cancers, they found a direct relationship between pRb2/p130 expression and the clinical outcome of patients.

"We found that pRb2/p130 expression was lost or decreased and significantly correlated with recurrence of disease and poor survival rates in the subset of patients with nonmetastatic tumors," said the study's lead author, Valeria Masciullo, M.D., Ph.D., a professor at Temple University in Philadelphia.

According to the researchers, the reliability of pRb2/p130 as a potential marker in the clinical routine assessment and management of STS patients merits further evaluation in long-term follow-up studies on a larger number of cases.

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Meridian Bioscience
513-271-3700

MGMA 303-799-1111

Myriad Genetics
801-584-3600

Nanogen 858-587-1121

OraSure 610-882-1820

Pall Corporation 800-521-1520

Pathwork Diagnostics
408-400-0828

Somagen Diagnostics
780-702-9500

XDx 415-287-2300





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