# Diagnostic Testing and Technology Report

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



Stephanie Murg, Managing Editor, smurg@ioma.com



**Vol. VIII, No. 8/April 2008**


CONTENTS




WASHINGTON G-2 REPORTS

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## *JAMA* Study Sends Chill Through IVD Market

Is universal, hospital-based screening for the so-called "superbug" methicillin-resistant *Staphylococcus aureus* (MRSA) an effective way of controlling infection rates? Not according to a new study by researchers from the University of Geneva. The Swiss team's study, which appears in the March 12 issue of the *Journal of the American Medical Association*, found that a rapid MRSA screening strategy did not reduce the rate of hospital-acquired MRSA infection in surgical patients.

The publication of the *JAMA* study sent a chill through the in vitro diagnostics industry and prompted Cepheid CEO John Bishop to post a letter to his company's Web site addressing the study and affirming Cepheid's financial guidance for 2008. Cepheid has built its business on the GeneXpert molecular diagnostics platform and its MRSA screening test. Last year, revenues for the clinical product sales segment of Cepheid's business, which accounted for 52 percent of total 2007 product sales of $116.5 million, were primarily *Cont., p. 8*

## Immucor Bets on Blood Genotyping

Pretranfusion diagnostics company Immucor (Norcross, Ga.) has agreed to acquire privately held BioArray Solutions (Warren, N.J.) for $117 million. BioArray is a molecular diagnostics company that has developed a novel BeadChip platform for nucleic acid and protein analysis. Immucor will focus on BioArray's genotyping tests for blood donors and transfusion recipients.

"With this acquisition, Immucor becomes the first traditional blood bank company to move into molecular diagnostics," said former Immucor CEO Ed Gallup on a March 12 conference call announcing the acquisition. "Our plan is to develop and launch a fully automated instrument that will greatly expand the market for transfusion genotyping."

BioArray's BeadChip system uses planar arrays of proprietary encoded microparticles to analyze nucleic acids and proteins. Its recently launched transfusion genotyping system is installed in several large donor and transfusion centers for research use only. Over the next few years, Immucor plans to make significant investments in the BioArray business to develop a fully automated, FDA-cleared system.

Gioacchino De Chirico, president and CEO of Immucor, called the deal "a landmark acquisition" that would allow the combined company to develop more precise genotyping tests. "This acquisition also opens up broader opportunities for Immucor in transplantation and transfusion-related applications," he said. *Cont., p. 2*

▲ **Immucor Bets on Blood Genotyping,** *from page 1*

De Chirico also noted how genotyping can be used to overcome some limitations of traditional blood banking reagents, including lack of reagent-grade product for rare antigen typing, weak reactivity for RhD or Jka (both responsible for hemolytic diseases in newborns), and variability of reactivity between monoclonal and polyclonal reagents.

Immucor plans to maintain BioArray in its existing 30,000-square-foot New Jersey headquarters, where it will continue to operate under the name BioArray Solutions. Meanwhile, in advance of the deal closing, BioArray's current owners intend to form a new company to commercialize BioArray technologies in fields outside of blood transfusion and transplantation. In connection with its acquisition of BioArray, Immucor will receive a 19 percent ownership interest in the new company.

## Third Wave Sees Clinical Revenue Grow 25% in '07

Molecular diagnostics company Third Wave Technologies (Madison, Wis.) reported clinical molecular diagnostic revenue of $26.3 million in 2007, an increase of 25 percent from 2006. Total 2007 revenues were up 11 percent to $31.1 million, which includes $4.6 million in research revenue. The company reported a net loss of $16.8 million in 2007, compared to last year's net loss of $18.9 million.

In a conference call on February 26, Third Wave executives discussed the 2007 results and the outlook for 2008, emphasizing the company's focus on capturing the global market opportunity for human papilloma virus (HPV) testing. In late December of 2007, Third Wave completed the enrollment phase of the clinical trial for its HPV test and expects to announce the results of that trial by the end of the first quarter. Third Wave President and CEO Kevin T. Conroy called the HPV clinical trial "a monumental undertaking that represents a significant hurdle to others entering this market."

This month, the company plans to submit two products to the FDA: its 14-type high-risk screening test and a genotyping test for types 16 and 18. The test uses Third Wave's proprietary Invader chemistry and allows users to reflex HPV-positive samples from the high-risk test to the genotyping test, providing independent results for HPV types 16 and 18. In 2007, the company achieved CE mark certification of its high-risk screening test, appointed the first EU distributors for the test, and submitted it to Health Canada for regulatory approval. Third Wave currently sells a number of analyte-specific reagents (ASRs) for HPV.

On March 11, Third Wave announced that it had achieved all primary clinical endpoints in the clinical trial for its HPV tests. The 14-type high-risk HPV test demonstrated a negative predictive value greater than the study's 99 percent goal. The company expects to publicly release the clinical trial data shortly after making its FDA submissions.

Third Wave is also focused on expanding its product menu and instrument offerings, with an emphasis on testing for methicillin-resistant *Staphylococcus aureus* (MRSA) and chlamydia/gonorrhea, as well as the development of a simple, user-friendly instrument for use in hospital laboratories.

On the call, Conroy described diagnostics for hospital-acquired infections as "the next big tests" and said that the company hopes to launch ASRs for MRSA in the second half of this year. "As MRSA testing grows, plate-based testing is the way to go," said Conroy. "We believe that we will address the higher volume labs…that are doing broad screening programs, and we think that over the long haul that will be about 70 percent of the market."

Third Wave anticipates total revenues of $36 million to 37.5 million for 2008, with clinical molecular diagnostic revenue expected to grow to $33 million to 34.5 million, an increase of at least 25 percent from 2007.

## *NEJM* Study Probes Pharmacogenomics of Warfarin Metabolism

A study published in the March 6 issue of the *New England Journal of Medicine* sheds new light on how genetic variation affects patients' initial response to the common blood thinner warfarin (Coumadin). The finding could help doctors determine the optimal dose of warfarin more quickly and precisely through genetic screening and could reduce the incidence of side effects from the drug, particularly severe bleeding.

*According to the study, genetic variation in VKORC1, but not in CYP2C9, modulates the early response to warfarin.*

An estimated 2 million people in the United States take warfarin to prevent blood clots, but warfarin therapy is challenging because patients' responses to the drug vary widely. Last year the U.S. Food and Drug Administration (FDA) approved updated labeling for warfarin to notify doctors that genetic testing could help improve their estimates for the initial dosages needed by their patients.

In this study, researchers at Vanderbilt University Medical Center (Nashville, Tenn.) explored the relative impact of polymorphisms in the genes that encode cytochrome P-450 2C9 (CYP2CP) and vitamin K epoxide reductase (VKORC1), two enzymes involved in warfarin metabolism. "Our study showed that during the first weeks of warfarin therapy, variation in the VKORC1 gene is a more important contributor to sensitivity to warfarin than variation in the CYP2C9 gene," said the study's senior author, C. Michael Stein, M.D., associate chief of clinical pharmacology at Vanderbilt.

Variants of both CYP2CP and VKORC1 were associated with warfarin dose requirements after an initial two weeks of therapy but not with the incidence of bleeding episodes. Further studies are needed to determine how CYP2CP and VKORC1 variants may interact with other genetic variations and additional factors that can affect patients' response to warfarin.

"Warfarin is probably the first example of a widely used drug where we're predicting variability in a large chunk of the population, and the variability may make a difference in outcome," said Dan Roden, M.D., vice chancellor for personalized medicine, who contributed to the study. "The ultimate goal is to have these kinds of data available at the time of prescription. Imagine a day when we can get your whole genome sequenced fast and cheap. It might even become part of neonatal testing."

# PerkinElmer Acquires Pediatrix's Newborn Screening Lab

PerkinElmer (Waltham, Mass.) has completed its acquisition of the newborn metabolic screening business of Pediatrix Medical Group (Sunrise, Fla.) for an undisclosed cash sum. The deal gives PerkinElmer Pediatrix's reference laboratory, as well as its StepOne screening test for inherited disorders and other genetic screening products. The lab provides neonatal screening and consultative services to five states and the District of Columbia and also to hospitals and medical groups.

Meanwhile, Pediatrix will focus on expanding within the physician services sector, including anesthesiology. The company continues to operate its separate newborn hearing screen program, a hospital-based service that screens for possible hearing loss. Additionally, Pediatrix expects to work with PerkinElmer to identify and conduct clinical research into possible applications for tandem mass spectrometry technology in prenatal and neonatal testing and diagnostics.

# New Bioimaging System Promises Improved HER2 Testing

A novel biomaging system may improve the detection of HER2-positive breast cancer, according to a paper published online in the *International Journal of Cancer*. Researchers at the National Institute of Standards and Technology (NIST), the National Cancer Institute (NCI), and the scientific research firm SAIC found that a chicken immunoglobulin Y (IgY) antibody created against the HER2 protein could be tagged with tiny, intense light sources known as "quantum dots" to more reliably detect the HER2 biomarker than existing diagnostic tests that use mammalian antibodies tagged with conventional fluorescent dyes. Overall, the improvement in sensitivity to the HER2 biomarker was about 40 percent to 50 percent.

About 20 percent to 25 percent of breast cancers have multiple copies of the HER2 gene. This results in the overproduction of the HER2 protein, which stimulates tumors to be particularly fast growing and difficult to treat. Patients with HER2-positive breast cancer—about 40,000 women in the United States annually—can be treated with a monoclonal antibody (trastuzumab) that targets and inhibits the growth of tumor cells with higher-than-normal levels of HER2.

Existing tests for HER2 biomarkers can yield a significant number of false positives. The increased sensitivity of the HER2 quantum dot-based quantitative bioimaging system stems from the broad genetic differences between avian and human species. The chicken IgY antibody to HER2 reacts strongly with the target protein while ignoring other human proteins that can interfere with current diagnostic tests.

Other advantages of the new system include faster and larger-scale production of the antibodies and a more reliable quantitative measure of HER2 biomarker level, in part because the quantum dot tags will stay bright and detectable, while fluorescent dyes fade over time.

Although patient numbers in this study were small, the findings demonstrate the feasibility of relative quantitation of cancer biomarkers with IgY and quantum dot fluorophores. The next step is rigorous clinical validation in large patient cohorts.

# Ikonisys Boosts Automated FISH Platform with New Reference Lab

This year will be a busy one for cell-based diagnostics company Ikonisys (New Haven, Conn.). After closing a $30 million Series E funding round led by Goldman Sachs last fall, the company started 2008 with a CLIA inspection for its new clinical laboratory and expects to receive FDA clearance for three new tests by the end of the year.

Ikonisys was founded in 1999 by Petros Tsipouras, M.D., Triantafyllos Tafas, Ph.D., and Michael Kilpatrick, Ph.D. At the core of the company is its proprietary digital microscopy platform, which automates fluorescence in situ hybridization (FISH)-based testing. In 2006, the United States Food and Drug Administration (FDA) cleared the Ikoniscope fastFISH imaging system and the fastFISH amniocyte application, which allows for the automated, FISH-based identification and enumeration of chromosomes 13, 18, 21, X, and Y in amniotic fluid cells.

In addition to prenatal testing, Ikonisys is focused on cancer diagnostics, and last year, the FDA cleared the company's oncoFISH bladder cancer test. Also run on the Ikoniscope platform, oncoFISH bladder enables automated testing of cells found in urine specimens to aid in the detection of bladder cancer. It also detects aberrations in chromosomes 3, 7, 9, and 17. Results from the test were found to correlate well with those of the UroVysion, Abbott's FISH-based bladder cancer test kit.

In the pipeline are additions to both the fastFISH (prenatal testing) and oncoFISH (cancer diagnostics) product lines. In early June, Ikonisys plans to release a FISH-based breast cancer test to assess HER2/neu gene status. A cervical cancer test is also in development. In February, the company began a clinical trial to evaluate its test for early detection of trisomy 21 (Down's syndrome) in circulating fetal cells. Ikonisys expects this to be the first in a suite of noninvasive cell-based fetal tests.

In March, Ikonisys announced its newest venture: a clinical laboratory. The CLIA-certified facility will serve as a reference lab for FISH-based testing, as well as a resource for evaluating its own products. Ikonisys Chairman and CEO Petros Tsipouras, M.D., recently talked with *DTTR* about the company, including the factors behind the decision to launch a clinical laboratory and the company's platform.

**How did the company come about?**

About 10 years ago, two colleagues and I wanted to develop a system to detect circulating fetal cells for noninvasive prenatal diagnosis, and very early on, we realized that the numbers of those cells ranged from two to five per milliliter of maternal blood. So we did not want to take the approach of overselecting for fetal cells as other groups had done because that would most likely eliminate those rare cells. We decided instead to relax selection

for those cells and use the power of automated high-throughput microscopy to interrogate a large number of cells.

**Can you tell us a little bit about CellOptics, Ikonisys's robotic microscopy platform?**
This platform is like a three-legged stool. There is a robotic microscope, which is a fully digital microscope. You can put in 175 slides and press a button, and it will process them and give you a report. The second component of the platform is the imaging software, and unlike the microscope, this is test-specific. And the third component of the platform is the reagents.

The robotic microscope can process tests for different applications, so what are test-specific are the imaging software and the reagents. The microscope was designed with the idea of having a high-throughput system, both in terms of cells or nuclei that are interrogated and also in terms of tests that can be done in a period of time. This is more or less in agreement with our original plan: to develop a system for rare cell detection.

So you can see the CellOptics platform as a convergence of a variety of disciplines: inputs like cell and microbiology because we're dealing with cells and we're dealing with signals—molecular signals—that must be generated either within the cell or on the surface of the cell. We're dealing with imaging, that is how this signal is captured and analyzed. We're dealing with IT in the broadest possible sense, and of course we're dealing with microscopy.

**And any FISH test can be run on the platform?**
Yes, this is the secondary utility of a platform like that. It offers automation, and this is a dark field microscopy system so any test which is based on FISH or immunohistochemistry that uses nonproprietary reagents can be performed in that system.

We can make the platform as open or as closed as one would like. Open meaning we have a generic system that captures signals and closed meaning we have imaging software that is specific for the type of signals that one would encounter in a specific test. To be more specific, if you do bladder cancer tests, you have different types of cells and nuclei that you are dealing with than if you do a cervical cancer test or fetal cells—the types of cells, the morphology of the cells, and the types of signals differ from tissue to tissue.

**Can those with the system use it to develop their own tests?**
The system is not open. We will have a version of the system that is going to be RUO [research use only], which will allow the user to modify or adapt it for a variety of signals of interest. However, the product that we have, we have proprietary positions in terms of reagents and imaging. So it's not like you get a box and then you run away with it. So there is protection and licensing agreements.

**What is the cost of the system and how widely has it been adopted so far?**
The list price of the instrument is $200,000. We have placed well over 20 in-

struments. We started marketing that in the middle of last year. Neogenomics was our first customer, and we have placed instruments in large labs—Quest [Diagnostics] has our system. We have placed instruments in regional labs and in urology practices such as the Michigan Institute of Urology. And we're placing instruments in smaller hospitals.

**What were the factors behind your decision to start a CLIA lab?**
There were three primary reasons. Number one was [because it would serve as a] revenue accelerator. All products will be going through FDA clearance, but before getting clearance and therefore being able to market them in the broader market, we could launch those products as laboratory-developed tests . . . and therefore demonstrate to the broader market that these tests can be utilized and you can generate information.

So, number one is [that the lab would serve as a] revenue accelerator; number two is [it would serve as a] showcase for our product; and number three, having a CLIA-registered lab, we can actually use it as a site for our clinical trials. So these are three compelling reasons for having a clinical laboratory in place.

Unlike some other companies, we don't view [having a clinical laboratory] as an opportunity to shortcut the [regulatory approval] process. Every test goes through FDA clearance. What makes us different from others is that we have the lab and we will use that both as a showcase and a revenue accelerator, but we realize that the market is not necessarily limited to what we can capture. It is a much broader market, which we would like the natural players to capture, and so we sell them our reagents and our instrument.

**What testing volume do you expect for 2008?**
I want to make clear that this lab is not meant to be a competitor to our natural customers. We're not out there to compete with our natural customers: Quest, LabCorp, Genzyme, or other labs. We use this lab to launch our own proprietary tests and to some extent, if our customers want, we can use it to offer them nonproprietary tests for which they have a need but they don't want to offer it themselves.

So in terms of forecasting how many tests we're going to perform this year, it depends on how early we're going to launch the fetal and cervical cancer [tests]. We estimate at this point to be launching them in the third quarter through the lab. So the estimate is between 5,000 to 10,000 tests for 2008.

**Your lab has a dedicated sales and marketing team in place. What potential clients will your sales and marketing team focus on?**
We're going to be targeting the obstetricians and the maternal fetal medicine specialists, who are a subspecialty of OB-GYN, because of the two products that we're going to be launching: first, the circulating fetal cells [test] and then a predictive test for cervical cancer, which is going to be a reflex to Pap and HPV.

▲ ***JAMA* Study,** *from page 1*

driven by the U.S. market launch of the Xpert MRSA test in April 2007.

Led by Stephan Harbarth, M.D., M.S., the *JAMA* study evaluated the effect of an early MRSA detection strategy on MRSA infections acquired in a hospital among 21,754 surgical patients. There were two MRSA control strategies: rapid screening on admission plus standard infection control measures versus standard infection control alone.

Over the course of two nine-month periods at a Swiss teaching hospital, patients admitted to certain surgical wards for more than 24 hours were screened before or on admission using a multiplex quantitative polymerase chain reaction (qPCR) test for MRSA that was developed at the University of Geneva. Median time from admission screening to notification of test results was 22.5 hours.

A total of 93 patients developed nosocomial (hospital-acquired) MRSA infection in the intervention periods compared with 76 patients in the control periods. The rate of MRSA surgical site infection and nosocomial MRSA acquisition did not change significantly. Fifty-three of 93 infected patients (57 percent) in the intervention wards were MRSA-free on admission and developed MRSA infection during hospitalization.

In Bishop's letter to Cepheid shareholders, he noted the already low MRSA infection rate at the institution studied and the fact that Cepheid's MRSA test offers a 72-minute turnaround time and enables a specimen collection to result in approximately two hours (compared to the study test's median screening-to-result time of 22.5 hours). "This time-to-result is critical for reducing infection rates in hospitals," wrote Bishop.

"While awaiting more and better data, what should clinicians do to control MRSA in hospitals?" asked an editorial that accompanied the *JAMA* study. "The first part of a tiered approach should include careful assessment of MRSA within the local healthcare environment," write Daniel J. Diekema, M.D., and Michael Climo, M.D., in the editorial. "Hospitals should first adhere to established infection control principles and pursue patient-safety initiatives known to reduce morbidity and mortality from all healthcare-associated infectious pathogens.

## Quidel RSV Test Gets CLIA Waiver

The U.S. Food and Drug Administration (FDA) has granted a CLIA waiver for the QuickVue respiratory syncytial virus (RSV) test manufactured by Quidel (San Diego, Calif.). The test qualitatively detects RSV, the leading cause of pneumonia and bronchiolitis among children two years of age and younger. The test is intended for use as an aid in the diagnosis of acute RSV viral infections for symptomatic pediatric patients.

QuickVue RSV is a dipstick immunoassay that detects the RSV fusion protein directly from nasopharyngeal swab or nasopharyngeal aspirate specimens. Results of the test are available in 15 minutes, and the company recommends that negative results be confirmed by cell culture. Quidel's list price for the test is $285.71 for a box of 12 20-test kits ($1.19 per test). The 2008 Medicare clinical laboratory fee schedule national limit for the test (CPT code 87807) is $16.76.

## Abbott to Co-Develop Pharmacogenomic Test for Lung Cancer Drug

The molecular diagnostics business of Abbott (Abbott Park, Ill.) has entered a collaboration with Genentech, Roche, and OSI Pharmaceuticals to develop a molecular test that will assess the clinical benefit of erlotinib (Tarceva), an orally-administered drug that is used to treat patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen.

Under the agreement, Abbott will develop a test to detect extra copies of the epidermal growth factor receptor (EGFR) gene using its proprietary fluorescence in situ hybridization (FISH) technology in NSCLC. Financial terms of the agreement were not disclosed.

While there are no nucleic acid-based tests approved by the U.S. Food and Drug Administration to identify patients who may derive greater treatment benefits from targeted lung cancer therapies, they are available as laboratory developed tests (LDTs). For example, Genzyme offers KRAS mutation analysis (see *DTTR*, January 2007), which can help identify NSCLC patients who test positive for specific mutations in the KRAS gene that have been associated with resistance to the chemotherapeutic drugs known as tyrosine kinase inhibitors, including erlotinib.

## Quest Diagnostics Signs Onto Google Health EHR

Patients who want to access their lab test results may soon be able to simply Google them. Quest Diagnostics (Madison, N.J.) has announced that it will collaborate with the Internet giant on Google Health, a pilot electronic health record (EHR) system that will allow users to manage their health information online. Google Health was launched last month at the Health Information Management Systems Society trade show. In addition to Quest, Google Health's future partners include Aetna, Wal-Mart, the University of California at San Francisco, the American Medical Association, and Cedars-Sinai Medical Center.

Under the terms of its collaboration with Google Health, Quest is developing solutions that will provide patients, through their physicians, with easy and secure electronic access to their diagnostic test results. Quest's proprietary Care360 patient-centric physician portal will serve as the platform for securely transferring patient diagnostic laboratory data into a Google Health account, at the user's request.

According to Quest, in addition to providing diagnostic laboratory data, the collaboration will allow physicians to securely send historical laboratory data to the patient's Google Health account. Physicians will also be able to comment on their patients' test results to better inform them about their health status.

Google Health will directly compete with Microsoft's HealthVault, an online EHR launched last fall. Microsoft's focus thus far has been on connecting its system to devices rather than institutions and service providers. HealthVault-compatible devices include LifeScan blood glucose monitors, Polar heart rate monitors, and Microlife monitoring devices.

## ACLA Presses SACGHS for Clarification on Genetic Testing Oversight

The American Clinical Laboratory Association (ACLA) is urging a top federal panel to clarify its explanation of the oversight of genetic tests. The industry group recently submitted its comments to the HHS Secretary's Advisory Committee on Genetics, Health, & Society (SACGHS).

SACGHS met February 12-13 to finalize its draft report and recommendations to Secretary Michael Leavitt on filling gaps in governmental and private oversight of genetic testing, including laboratory-developed tests (LDTs). The final version is slated to go to Leavitt at the end of April and could be a springboard for further action by HHS and Congress.

ACLA urged SACGHS to amend "one particularly important recommendation that, if not carefully communicated to the Secretary, could have unintended consequences." In the recommendation, SACGHS affirms its support for the Food & Drug Administration's regulation of LDTs and the flexible risk-based approach the agency is taking to prioritize review of these tests.

Concerned that this could be interpreted to mean that FDA requirements should be applied to LDTs without interagency coordination, ACLA noted: "Though there are many similarities between FDA's and CLIA's quality validation, there are clear redundancies and duplications that if not coordinated, harmonized, and streamlined will stifle innovations in this area. These include separate requirements for inspection, quality systems, reporting and labeling, and other rules for design control, corrective action, and prevention."

ACLA asked SACGHS to make clear that interagency coordination is the goal for LDT regulation. This is in line, ACLA said, with the "overarching" guidance in the SACGHS draft report to "enhance interagency coordination" and "promote public-private partnerships" to tackle knowledge gaps concerning clinical validity and utility.

The draft SACGHS report advised the FDA to take a "go slow," broader consultative approach to LDT oversight. ACLA and the College of American Pathologists contend that CMS's CLIA program should be the lead federal agency to oversee genetic testing services, while the FDA's role should be consultative.

## Beckman Coulter Launches High-Volume Testing System

Beckman Coulter (Fullerton, Calif.) has released a new workstation that combines chemistry and immunoassay testing for high-volume laboratories. The UniCel DxC 880i Synchron Access clinical system combines Beckman Coulter's chemistry system (the UniCel DxC 800) and its high-throughput immunoassay system (the UniCel DxI 800). Laboratories that have installed either of those 800-level systems can upgrade to the new 880i configuration.

The UniCel DxC 880i has an onboard menu of 120 tests, including stat testing, cardiac and tumor markers, and renal function tests. The system can process up to 1,440 chemistry tests per hour and up to 400 immunoassay tests per hour. List price for the system is $650,000. Beckman Coulter is now developing three additional work cells, designed for different testing volumes.

# IVD Stocks Fall 7%; Inverness Plummets 33%

The 18 stocks in the G-2 Diagnostic Stock Index dropped an average of 7 percent in the five weeks ended March 7, with 15 stocks down in price and three up. The S&P 500 has lost 11 percent so far this year, and the Nasdaq is down 15 percent.

Leaving the G-2 index this month was **Ventana Medical Systems** (Tucson, Ariz.). On February 19, **Roche** (Basel, Switzerland) completed its acquisition of the automated diagnostics company through a tender offer and short-form merger, after which Ventana shares ceased to trade on the Nasdaq. The deal, valued at $3.1 billion, began as a hostile takeover effort in June of 2007.

Roche is now working to integrate Ventana into its diagnostics division and plans to maintain its Arizona headquarters. Outgoing Roche Chairman and CEO Franz B. Humer said, "Ventana will enhance our position as the world's leading personalized healthcare company." Severin Schwan, formerly CEO of Roche Diagnostics, succeeded Humer as group CEO at the March 4 annual shareholders' meeting.

Shares in point-of-care testing company **Inverness Medical Innovations** (Waltham, MA) were down 33 percent to $29.49 a share for a market capitalization of $2.01 billion. The drop is related to a number of factors, including investor and analyst concerns regarding Inverness's roll-up strategy focusing on disease management and its pending $900 million acquisition of Matria Healthcare. Serving health plans, employers, and government agencies, Matria provides patient wellness programs, as well as case management of acute and catastrophic conditions.

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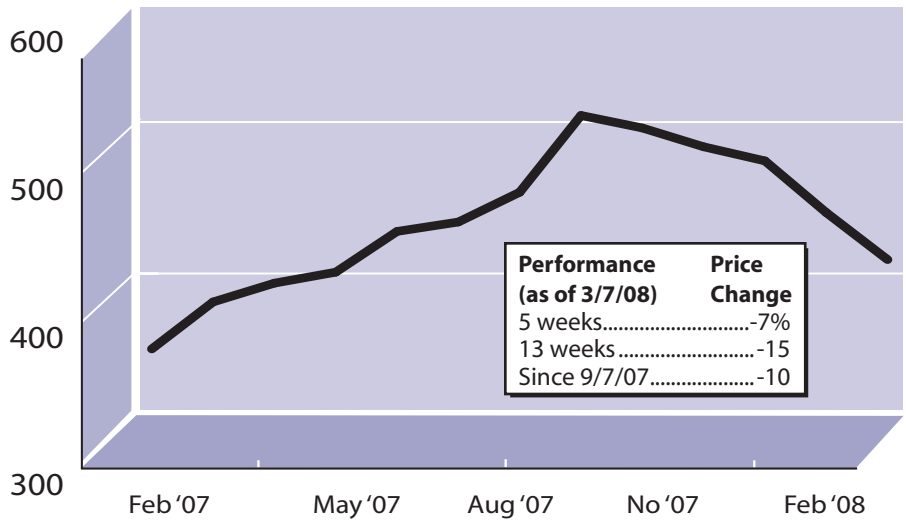
Inverness also recently announced that it will close its Unipath manufacturing facility based in Bedford, England. The company plans to transfer the plant's operations to lower-cost facilities in Asia. During the second half of 2007, Unipath manufactured approximately 53 million tests, of which approximately 46 million were supplied to Inverness's consumer diagnostics joint venture.

## G-2 Diagnostic Stock Index




Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 18 IVD companies.

| UP | Price | % Chg |
|---|---|---|
| Immucor | $27.69 | 2% |
| Meridian | 31.87 | 2 |
| Nanogen | 0.54 | 20 |
| **DOWN** | | |
| Abaxis | 26.83 | -6 |
| Abbott Labs | 51.04 | -10 |
| Affymetrix | 17.36 | -11 |
| Beckman Coulter | 65.10 | -8 |
| Becton Dickinson | 86.10 | -4 |
| Bio-Rad | 88.48 | -1 |
| Clinical Data | 19.06 | -6 |
| Gen-Probe | 47.19 | -17 |
| Inverness Medical | 29.49 | -33 |
| Johnson & Johnson | 61.51 | -1 |
| Luminex | 15.66 | -8 |
| Nanogen | 9.66 | -15 |
| OraSure | 6.70 | -12 |
| Quidel | 14.59 | -7 |
| Third Wave | 7.12 | -11 |

G-2 Insider

# Lung Cancer-Focused Allegro Diagnostics Raises $4 Million

Allegro Diagnostics (Boston) has completed a $4 million Series A financing round led by Kodiak Venture Partners and joined by Catalyst Health Ventures and Boston University. Founded in 2006, Allegro is a molecular diagnostics company focused on developing and commercializing products based on gene expression technology developed by Jerome Brody, M.D., and Avrum Spira, M.D., at the Boston University School of Medicine. Brody was recently appointed chief scientific officer of the company.

Allegro will initially focus on developing more accurate methods to diagnose early stage lung cancer. Last year, Brody was senior author of a paper published in *Nature Genetics* that detailed the validation of an 80-gene biomarker that distinguishes smokers with and without lung cancer. The biomarker is based upon gene expression in cytologically normal large-airway epithelial cells and may be linked to a cancer-specific airwaywide response to cigarette smoke. According to Dan Rippy, Allegro's president and CEO, this first round of financing will be used to commercialize this microarray-based test.

## Company References

Abbott Molecular 224-361-7800
ACLA 202-637-9466
Allegro Diagnostics 617-414-6990
Beckman Coulter 800-742-2345
BioArray 908-226-8200
Cepheid 408-541-4191
CMS 877-267-2323
FDA OIVD 240-276-0450
Genzyme 617-252-7500
Immucor 770-441-2051
Ikonisys 203-776-0791
Inverness 781-647-3900
PerkinElmer 203-925-4602
Quest Diagnostics 201-393-5000
Quidel 858-552-1100
Roche 41-61-688-1111
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Ventana Medical Systems 520-887-2155



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DTTR 4/08



*Diagnostic Testing & Technology Report* (ISSN 1531-3786) is published by Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Tel: 212-629-3679. Fax: 212-564-0465. Order line: 212-629-3679. Web site: www.g2reports.com.

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