Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Stephanie Murg, Managing Editor, smurg@ioma.com

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Quest Settles Nichols Institute Case for $302 Million

Quest Diagnostics (Madison, N.J.) has finalized its settlement of criminal and civil claims concerning diagnostic tests marketed and sold through Nichols Institute Diagnostics (NID), the test kit developer that it shuttered in 2006. The nation's largest commercial laboratory will pay a total of $302 million to resolve the allegations, the United States Department of Justice announced on April 15.

In Brooklyn Federal Court, Quest's NID subsidiary pleaded guilty to a felony misbranding charge relating to the Nichols Advantage Chemiluminescence Intact Parathyroid Hormone (PTH) Immunoassay. As part of the plea, NID will pay a criminal fine of $40 million. The $262 million civil settlement resolves False Claims Act allegations relating to five NID assays, including the PTH test, that allegedly provided inaccurate and unreliable results. Quest has also agreed to pay various state Medicaid programs approximately $6.2 million to resolve similar civil claims.

The government's civil and criminal investigation was sparked by a whistleblower suit brought by Thomas Cantor, president and founder of Scantibodies Laboratory (Santee, Calif.), which developed its own PTH assay and opened a clinical lab in 2000. Cantor will receive approximately $45 million from the False Claims Act settlement.

Clinical Data Sells Genomics Services to Beckman Coulter

Biotechnology company Clinical Data (Newton, Mass.) has sold Cogenics, its genomics service business, to Beckman Coulter (Orange County, Calif.) for $17 million. Cogenics' services include current and next generation sequencing, gene expression, clinical and nonclinical genotyping, biomanufacturing support, nucleic acid extraction, and biobanking. Clinical Data will retain its rapidly growing molecular diagnostic testing business.

At the April 14 closing, Clinical Data received $15.4 million in cash after adjustments, with $2.5 million held in escrow for 18 months. Clinical Data also retained approximately $2.2 million in cash from Cogenics immediately prior to the sale, resulting in net cash proceeds of $14.9 million. The purchase included all of Cogenics' operations in the United States, United Kingdom, Germany, and France.

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"Molecular diagnostic test revenues have been growing north of 100 percent, year over year."
— Clinical Data CEO Drew Fromkin

▲ **Clinical Data,** *from page 1*

The sale is part of Clinical Data's efforts to focus resources on advancing the company's two late-stage targeted therapeutic programs. Clinical Data expects to complete its Phase III registration trial of vilazodone, an antidepressant, in the second quarter of 2009. "We did identify markers for response to vilazodone that we have filed patents on, and we believe that there are added benefits that may come along with that, including patent extension opportunities and certainly major differentiation [among anti-depressants]," said Drew Fromkin, president and CEO of Clinical Data, at the BioCentury Future Leaders in the Biotech Industry Conference on April 2. "With a companion diagnostic, we believe that vilazodone may be well-positioned to have peak sales north of $2 billion in the U.S."

The company also expects further growth in its genetic-testing division, PGx Health. Among the tests offered are those that detect genetic variants that can cause cardiac channelopathies. "We have a growing and thriving molecular diagnostic business, where test revenues have been growing north of 100 percent, year over year, and this is driven by our specialized cardiac salesforce and our managed care organization," said Fromkin. "We've had quite a bit of traction with payors in our molecular diagnostic business, and that's driving our revenue."

Meanwhile, Cogenics is expected to complement Beckman Coulter's Agencourt Biosciences' business, which delivers genomic services and nucleic acid purification products. "We are excited about the new opportunities and confident that these combined offerings will enable us to meet the full spectrum of service requirements—sequencing, genotyping, gene expression, and DNA and RNA extraction," said Susan Evans, vice president and general manager of Agencourt.

Cogenics customers include pharmaceutical and biotechnology companies, U.S. National Institutes of Health agencies, government and academic researchers in the international life science community, and major agricultural companies and agencies.

FDA Clears Arbor Vita's Rapid Test for Bird Flu

On April 7, the United States Food and Drug Administration cleared for marketing a new, rapid test for the detection of influenza A/H5N1, a disease-causing subtype of the avian influenza A virus that can infect humans. The AVantage A/H5N1 flu test is manufactured by Arbor Vita (Sunnyvale, Calif.), an 11-year-old biopharmaceutical company that develops diagnostics and therapeutics based on targets known as PDZ proteins.

Using the company's proprietary PDZ proteomics technology, the test detects the influenza virus nonstructural protein 1 (NS1) in specimens from throat swabs or nose swabs collected from patients with flu symptoms. Results are available in less than 40 minutes, compared to previously cleared tests that can take up to 24 hours.

Influenza A infects both humans and animals. The H5N1 subtype is found mostly in birds, although infections have also occurred in humans, mostly in people who have come into contact with the virus through infected poultry. According to the

According to the CDC, of the few avian influenza viruses that have infected humans, the H5N1 subtype has caused the largest number of detected cases of serious disease and death.

Centers for Disease Control and Prevention (CDC), of the few avian influenza viruses that have infected humans, the H5N1 subtype has caused the largest number of detected cases of serious disease and death.

In clinical studies conducted in collaboration with the U.S. Navy, the AVantage test correctly identified the absence of infection in more than 700 specimens. In addition, the test correctly detected the presence of influenza A/H5N1 virus subtype in 24 cultured specimens from infected patients.

Given the highly mutable nature of influenza viruses, some experts fear that the influenza A/H5N1 virus subtype will mutate further and spread quickly to humans, causing an influenza pandemic. According to the World Health Organization, there are 412 confirmed human cases of infection from this virus, almost all in Asia and northern Africa. This virus subtype, which can cause life-threatening illness, has not been detected in the Americas.

Last June, the Centers for Disease Control and Prevention awarded $12.9 million to Nanogen (San Diego) and Meso Scale Diagnostics (Gaithersburg, Md.) for the development of low-cost influenza tests that can detect and differentiate seasonal human influenza viruses from avian influenza within three hours. The contracts provide for funding up to $10.4 million (Nanogen) and $12.1 million (Meso Scale Diagnostics) for additional development up to three years.

Arbor Vita is currently developing a test for seasonal flu (Flu A/Flu B). Using nasal and throat specimens, the test is expected to provide early detection of seasonal flu infections. The company is also collaborating with the Program of Appropriate Technology in Health (PATH; Seattle) on a cervical cancer test based on detection of the cancer-causing viral oncoprotein E6. A large-scale clinical trial of the test is slated to begin in China by the end of 2009.

AdvaMed Proposal to FDA Reignites Controversy Over Lab-Developed Tests

In a March 27 submission, the Advanced Medical Technology Association (AdvaMed; Washington, D.C.) called on the United States Food and Drug Administration (FDA) to use a risk-based approach to regulate all in vitro diagnostic tests, regardless of whether produced by medical device manufacturers or developed in-house by labs. A risk-based approach would determine the intensity of review required, though certain low-risk tests should be exempt from premarket review, AdvaMed said.

The group also said the FDA should align its "safe and effective" requirements with CLIA quality control requirements and the Medicare program should support "timely and adequate reimbursement for all new diagnostics."

The AdvaMed submission comes on the heels of a petition filed with the FDA last December by Genentech, the biotechnology giant that was acquired in March by Roche (Basel, Switzerland). The company asked the FDA to subject lab-developed tests (LDTs) to the same scientific and regulatory standards, including premarket review and post-market surveillance, that it applies to in vitro diagnostic tests developed and sold by device makers as test kits.

The clinical lab industry reacted strongly against the Genentech petition. LDTs include commonly used tests for breast and colon cancer, HIV, and other diseases that have a history of being safe and effective, said the American Clinical Laboratory Association. ACLA and the College of American Pathologists oppose expansion of the FDA's authority, saying CLIA standards assure the analytical and clinical validity of these tests.

Commenting on the AdvaMed petition, representatives of lab industry groups said they can agree with the call for a risk-based regulatory approach and better reimbursement for new diagnostic tests. But they opposed being considered as medical device makers subject to FDA oversight. Labs performing LDTs are not selling test kits, they noted, but are selling a service performed only in that lab and subject to the most stringent level of CLIA regulation.

The FDA currently regulates analyte-specific reagents used in LDTs and a category of LDTs known as IVDMIAs (in vitro diagnostic multivariate index assays) that use a proprietary algorithm to produce a patient-specific result.

Olympus Gets FDA Clearance for Cancer Immunoassays

Olympus (Center Valley, Penn.) has received 510(k) clearance from the United States Food and Drug Administration for two additional tests for its previously cleared AU3000i immunoassay system, a fully automated chemistry analyzer that quantitatively determines analytes in human serum and plasma. The carcinoembryonic antigen (CEA) test detects a group of markers indicating the presence of carcinomas including colon cancer while the alpha-fetoprotein (AFP) test can be used to aid in the detection of certain malignant cancers.

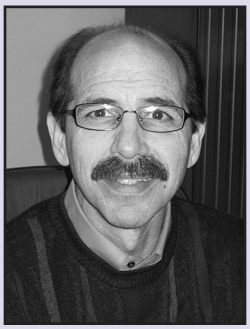
Both the CEA and AFP tests are two-step enzyme immunoassays that measure analyte concentrations in serum or plasma samples. Results are available within 28 minutes. Each test kit is sufficient to process 200 tests and contains reagents, a calibrator, and a control.

Other tumor marker tests for the AU3000i system include those for prostate-specific antigen (PSA), free PSA, carbohydrate antigen 19-9 (CA19-9), and CA15-3, but these are only available outside of the United States. Domestically available assays include thyroid and fertility tests. Olympus is developing AU3000i assays for applications including anemia, diabetes, allergies, and metabolic function.

Humana Exec Appointed CEO of Navigenics

Personal genomics testing company Navigenics (Foster City, Calif.) has appointed Jonathan "Jack" T. Lord, M.D., to serve as president and CEO. He takes office on May 1. Lord comes to Navigenics from Humana (Louisville, Ky.), where he served as chief innovation officer. Before Humana, Lord was president of Health Dialog (Boston, Mass.) and also served as chief operating officer of the American Hospital Association in (Washington, D.C.). Lord previously held executive vice president positions at Anne Arundel Medical Center (Annapolis, Md.) and Sun Health in (Charlotte, N.C.). Lord replaces Navigenics's founding CEO, Mari Baker, who departed in February to become CEO of PlayFirst, a video game company.

Veridex Sees Rapid Growth, Expanded Applications for Circulating Tumor Cell Testing



Robert McCormack, Ph.D.

In a few short years, circulating tumor cell (CTC) technology has become one of the hottest and most rapidly growing areas of cancer testing. A pioneer in this area of in vitro diagnostics has been Veridex (Raritan, N.J.). The Johnson & Johnson subsidiary received U.S. Food and Drug Administration (FDA) clearance for its CellSearch CTC test in January 2004. Originally cleared as a diagnostic tool for identifying and counting CTCs in a blood sample to predict progression-free survival and overall survival in patients with metastatic breast cancer, CellSearch was subsequently cleared as an aid in monitoring metastatic colorectal patients (November 2007) and metastatic prostate cancer patients (February 2008). Currently reimbursed under existing CPT codes, the test can be used at any time during the course of disease for serial monitoring of patients with these types of cancer.

DTTR recently talked with Robert McCormack, Ph.D., vice president of medical and scientific affairs at Veridex, about the past, present, and future of CellSearch CTC technology, as well as Veridex's GeneSearch line of molecular diagnostic tests for cancer.

First, can you tell us about the technology underlying the CellSearch test?
The technology is based on magnets and the capture of cell populations based on the expression of very specific antigens on the targeted cell population. So, in the peripheral blood, we're looking for circulating tumor cells that are epithelial in origin, so we use a monoclonal antibody against EpCAM [epithelial cell adhesion molecule], a very specific receptor on the epithelial cell, and we use that to selectively capture those cells in the peripheral blood. We can then use a magnetic field because these antibodies are covalently bound to iron particles. We can pull them out of solution, wash away all of the background red cells and white cells, and then selectively enumerate the captured tumor cells.

An increasing number of labs around the country now offer CellSearch. How would you describe the typical lab that offers the test?
That's a little bit difficult for me to do because we have the technology placed now in community hospitals, large oncology practices, university medical centers, and it also exists in several of the largest reference laboratories in the United States. Where the middle of that would be, I would say between the large oncology practice and the university-based setting, but we've completely spread it across all possible market segments, so that has worked out quite well.

Can you give us any indication of annual volumes that you're seeing or changes in test demand?
I can only tell you that the volume of testing increases substantially every year for two reasons: first, we continue to increase usage of the test in metastatic breast cancer, and second, we now have two additional indications,

metastatic colorectal and metastatic prostate cancer. Adding those to the indications allows more people to use the technology. So it's been growing substantially every year.

Additionally, we've seen a lot of uptake in the technology from drug developers, for their clinical trials, and by professional groups incorporating it into clinical trials. To that end, it's probably important to note that about a year ago, the National Institutes of Health sponsored a one-day workshop on incorporating CTCs into clinical trials, so that you would be able to standardize how they're used and understand what the data are telling you.

Veridex's CellSearch system

How are results of the CellSearch assay reported and communicated to physicians?
The test uses one tube of blood, which is 7.5 milliliters, and the cells are counted by the laboratory and reported back to the clinician as the number of CTCs per 7.5 ml of blood. In the breast and prostate settings, the metastatic settings, the cutoff is five CTCs per 7.5 ml of blood. It's a little bit lower in colorectal cancer, where it's three CTCs per 7.5 ml.

What is the potential for using CTCs as a method of early detection?
The CellSearch test is now cleared for patients with metastatic breast, metastatic colorectal, and metastatic prostate cancer. It is not cleared for early detection of cancer in patients who have not been diagnosed. So right now there are a lot of people looking at that and not much of the data has been published. Right now, the entire clinical utility is in the metastatic arena.

As the new indications have come on board, what efforts has Veridex undertaken to educate clinicians about the new indications and what the test can do?
We're doing several things. We're still very dependent on and very proactive with [published studies in peer-reviewed journals] because the important thing is having the data out there to support the intended use. We've also increased our own sales activities, both in-house and by partnering with Ortho Biotech, which is a Johnson & Johnson company in the pharmaceutical space. They are helping us reach more oncologists with the message and the indications for use.

Can you give us a summary of the findings and what you see as the implications of the study published in the March 2009 issue of the* Lancet Oncology*?
The study is actually a subanalysis of a pivotal trial that we submitted to the FDA that was published in *Clinical Cancer Research* last fall. What Dr.

[Howard] Scher and his colleagues did with this analysis was, whereas the original study was the metastatic prostate cancer patients starting any line of therapy, what they did was a subanalysis of only those patients starting first-line therapy—chemo. This was important because it allows you to focus down on the most important subpopulation within the larger study: those patients that are starting first-line chemo. You want to give them an adequate amount of attention, and you want to be able to understand how their therapy is working. Whereas the original trial was about 240 patients, this trial is about 164 patients, all starting first-line therapy. It allows you to understand more accurately the performance of the test and also understand the commonalities of all of the patients being treated.

Veridex also has the GeneSearch line, focused on molecular diagnostics for cancer. Currently we have one product on the market and that is the breast lymph node test, which determines the presence of breast cells in the sentinel lymph node of patients just diagnosed with primary breast cancer. It's a molecular test that looks for the presence of two genes: one is specific for epithelial cells and one is specific for breast cells. This is different from what is currently used right now, which is standard pathology, in which they make a smear of the tissue and try to determine if the cells are there. We take a molecular approach.

What additional GeneSearch tests do you have in development?

We have in clinical trials right now a test for methylated genes being detected in the urine of men who have been diagnosed with primary prostate cancer. We also have a series of tests being developed with signatures of genes that can give you an indication as to the prognosis of these patients at the time of diagnosis.

Finally, what is next for CellSearch? Do you envision ultimately combining the cellular and molecular approaches?

What we're doing now with CellSearch is exploring other opportunities for FDA approval or clearances, and we're working feverishly at that, looking at all of the feasibility data that we've generated. The second thing we're doing is achieving what we consider to be the perfect world setting, where we take our molecular technology and we apply it to our cellular technology. There are a lot of efforts going on by us and others where now not only are we capturing and counting the circulating tumor cells but we're actually starting to apply molecular technology to learn more about the CTCs. For example, we are learning where they might metastasize to and which drugs they might respond to. Some of these reagents will become available for research use only because we have a whole line dedicated to research around CTCs. So that's where we have our immediate activity going on right now.

*Scher HI, Jia X, de Bono JS, Fleisher M, Pienta KJ, Raghavan D, and Heller G. "Circulating tumour cells as prognostic markers in progressive, castration-resistant prostate cancer: a reanalysis of IMMC38 trial data." *The Lancet Oncology* 10.3 (March 2009): 233-39.

Novel Biomarker Shows Promise for Prostate Cancer Diagnosis

According to a study published in the April 1 issue of *Cancer Research*, a newly discovered gene variant is highly expressed in a subset of prostate cancers and may lead to more accurate tests for the disease. The biomarker, a gene fusion known as SLC45A3-ELK4, is detectable at high levels in the urine of some men at risk for prostate cancer.

"We think this is going to be a potentially important diagnostic marker in prostate cancer," said senior author Mark A. Rubin, M.D., the Homer T. Hirst professor of oncology in pathology, professor of pathology and laboratory medicine, and vice chair for experimental pathology at Weill Cornell Medical College (New York City). "PSA testing is inadequate. PSA detects men with cancer but also many men with benign conditions. As we have seen recently from two major studies on PSA screening, for every 50 men with a positive PSA screening, only one man's life is saved. We urgently need biomarkers to detect clinically significant prostate cancer."

Rubin's team is working with Gen-Probe (San Diego) to develop a urine test for prostate cancer using a chromosome-based gene fusion called TMPRSS2-ERG that the team discovered previously while working with researchers at the University of Michigan. In preliminary data presented by Gen-Probe researchers at the 2009 Genitourinary Cancers Symposium held in February, a prototype molecular assay predicted the presence of cancer at biopsy with 85 percent specificity and test results correlated with indicators of prognosis.

Rubin anticipates that the newly discovered SLC45A3-ELK4 gene fusion may be added to that urine test in the future to increase its accuracy and also to potentially help determine the level of response to certain nonsurgical systemic treatments. The TMPRSS2-ERG urine test is being evaluated in multiple early clinical trials in the United States and Europe.

"Our work has a long-term goal of achieving a test that distinguishes clinically significant prostate cancer from indolent disease that does not require additional treatment," said Rubin. "With better diagnosis, we will be able to treat cancer patients with individualized therapies."

Inverness Launches New Rapid Test for C. difficile Infection

Inverness Medical Innovations (Waltham, Mass.) has begun marketing and distributing a new rapid test to aid in the diagnosis of *Clostridium difficile*-associated disease (CDAD). Manufactured by Techlab (Blacksburg, Va.), the test has been cleared by the United States Food and Drug Administration.

The C. Diff Quik Chek Complete test is a rapid membrane immunoassay that simultaneously detects both *C. difficile* glutamate dehydrogenase and toxins A and B in fecal samples. It can be used for screening while also confirming the presence of toxigenic *C. difficile* strains. Results are available in approximately 30 minutes.

C. difficile is responsible for the most common form of hospital-acquired diarrhea and antibiotic-associated colitis. U.S. hospitals spend an estimated $40 million in testing aimed at diagnosing CDAD.

Cleveland Clinic Invests $25 Million in Reference Lab Expansion

"What we are doing is managing very tightly to the economy, while targeting those areas that are important for our future, and one of them is laboratory medicine."

Outreach testing now comprises only 10 percent of the Cleveland Clinic's annual volume of 10 million tests, but that outreach volume is set to grow in the coming years, as the world-renowned medical facility leverages both its reputation and advanced diagnostic technology to expand its reference laboratory capabilities by building a new $25 million, 10,000-square-foot facility.

Slated for completion in 2010, the new laboratory, which will be part of the clinic's Pathology and Laboratory Medicine Institute, is expected to create 500 jobs over the next five years. Currently, the Institute employs 800, including 59 pathologists.

While the current economy is forcing many hospitals to scale back on planned outreach expansion, the reference lab's CEO Dino Kasdagly said that the clinic has another perspective on pursuing growth during the recession. "With the advances of esoteric tests, along with the economic challenges that smaller hospitals have across the country, many hospitals can't make the investments in providing this kind of patient care," he explained. "Yes, the economy is bad, but if you just manage to a bad economy, then you forget about the future. What we are doing is managing very tightly to the economy, while targeting those areas that are important for our future, and one of them is laboratory medicine."

As for the new reference lab's test menu, Kandice Kottke-Marchant, M.D., Ph.D., chairperson of the Pathology and Laboratory Medicine Institute, said the focus will be on expanding molecular diagnostic offerings, as well as immunopathology, flow cytometry, and hematology. In fact, the current lab just established a molecular pathology department.

"The other focus is what I would call interpretative diagnostic testing, so the results won't be just numbers, but ways in which we can help clinicians understand the meaning of their test results," she added. "What I want to do is get to the point where we can help clinicians and hospitals order the right tests for their patients." This approach will also serve to bring more patients into the clinic, as a referral for difficult patients at other facilities that may require another level of care.

Since the Cleveland Clinic is renowned for its expertise in cardiology, molecular testing in this specialty will be another focus. In addition, the lab would like to offer more tests related to cardiac pharmacogenomics, such as warfarin testing. "We also have a strong hematopathology group and are looking at expanding our hematopathology and hematonocology molecular testing, as well as [adding] more prognostic and drug-related molecular testing in those areas," she explained.

CEO Kasdagly explained that the lab expansion will happen in two phases, with the first phase focusing on local outreach growth in northeast Ohio to ensure that the appropriate infrastructure and integration is in place. "The second phase will be to broaden nationally and expand our current hospital client base, eventually solidifying our national presence with esoteric reference testing," he said. "This could also be international. Once we have a solid foundation, it shouldn't hold

us up to go internationally." The clinic is currently developing partnerships in Vienna, Austria, and Abu Dhabi in the United Arab Emirates.

Genoptix Sees Further Growth Potential in Solid Tumor Testing

Genoptix (Carlsbad, Calif.), the hematopathology laboratory founded in 1999, continues its impressive growth. Increased volumes boosted 2008 revenues to $116.2 million, a gain of 96 percent over the previous year. With an active customer base of 1,000 by the end of 2008, the company saw a 71 percent year-over-year increase in volume, which reached 39,000 total cases with average revenue of $3,000 per case.

The company, which completed its initial public offering in November 2007, expects 47 percent revenue growth to $170 million in 2009 inclusive of all applicable changes to the Medicare Fee Schedule for this year. Genoptix has recently moved into solid tumor testing with the January launch of K-RAS mutational analysis and EGFR amplification analysis. "These new tests will serve to provide clear direction for our physician customers, helping them identify patients who are good candidates for targeted cancer therapies," said Tina Nova, Ph.D., the president, CEO, and founder of Genoptix on the company's most recent earnings call.

The company also hopes to use this new technology to increase sales to existing customers, which currently ranges between 3.5 to 5 cases per customer per month, explained executive vice president and chief operating officer Sam Riccitelli on the conference call."By moving into the solid tumor space, we open up a greater potential for the company," he explained. "Instead of 4.5 to 5, we are estimating it could be more like 15 to 20 cases per month."

Bill Introduced to Modernize Lab Fee Schedule

A new bill backed by the Clinical Laboratory Management Association (CLMA; Wayne, Penn.) and the American Society for Clinical Laboratory Science (ASCLS; Bethesda, Md.) would establish a negotiated rulemaking process to modernize the lab fee schedule and align payments with increased costs. The effort would be guided by the Institute of Medicine report in 2000 that included a recommendation to move to a national lab fee schedule adjusted for geographic cost variations.

CLMA and ASCLS argue that the current fee schedule has not undergone a fundamental review and updating since it was adopted 25 years ago. As a result, clinical labs have suffered real reductions in reimbursement, they say, noting that labs today are paid only 75 percent of the 1984 level when adjusted for inflation.

The bill, H.R. 1452, also would raise the fee for collecting lab test specimens from nursing homes and homebound beneficiaries to $6.04 in 2010 and adjust it thereafter by the annual Consumer Price Index update.

H.R. 1452 was introduced by Rep. Bart Stupak (D-Mich.), chairman of the House Energy and Commerce subcommittee on oversight and investigations, along with two Republican co-sponsors, Michael C. Young (Texas) and C.W. Bill Young (Fla.).

IVD Stocks Rise 21%; G-2 Index Up 8% Year to Date

After plummeting 21 percent last month, the G-2 Diagnostic Stock Index gained an average of 21 percent in the five weeks ended April 9, with 12 stocks up in price, two unchanged, and two down. The G-2 index is up 8 percent so far this year, while the Nasdaq is up 5 percent and the S&P has slipped 4 percent.

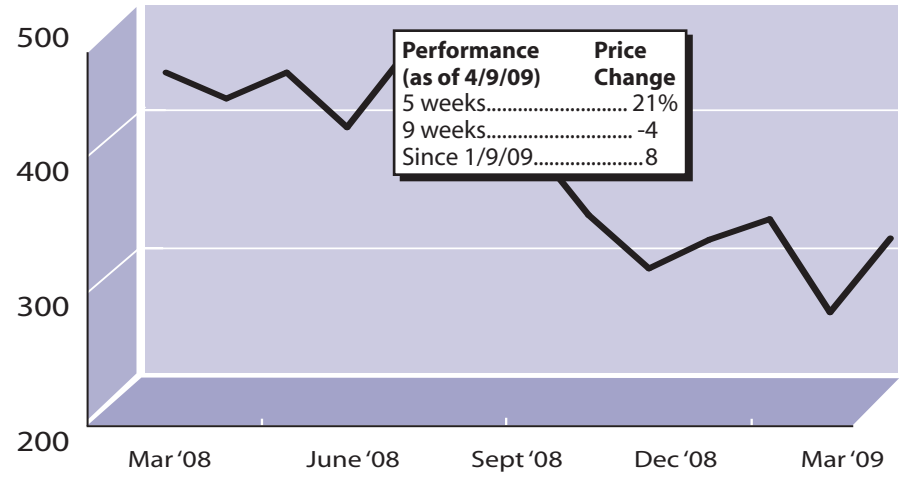
Immucor (Norcross, Ga.), a maker of automated instrument-reagent systems for the blood transfusion industry, gained 10 percent, ending the period with a share price of $23.06 and a market capitalization of $1.57 billion. The company recently reported financial results for its fiscal third quarter ended February 28. Quarterly revenue was $75.3 million, up 12 percent from $67 million in the same period last year. The company expects fiscal 2009 revenue in the range of $292 million to $300 million.

According to Immucor president and CEO Gioacchino De Chirico, demand for Immucor's reagent products, which account for nearly 90 percent of total revenue, has remained stable in recent months. Additionally, the company recently renewed an agreement with Quest Diagnostics (Madison, N.J.) that extends by five years Immucor's current status as Quest's preferred vendor for reagents and blood bank automation systems. Among the company's current priorities is developing the next generation of automated BioArray instruments to further commercialize the assets of BioArray Solutions, which Immucor acquired last August for $117 million.

For up to the minute laboratory and diagnostic firm data, financial news, and company podcasts—go to **www.g2reports.com**

Holding steady in recent weeks has been **Abaxis** (Union City, Calif.), which closed at $16.06 per share on April 9 with a market capitalization of $335 million. The maker of point-of-care blood tests recently announced a reorganization of its sales and marketing organization. Abaxis is now recruiting a successor to Christopher M. Bernard, vice president of North American medical sales and marketing, who left the company in April amid the shake-up.

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 16 IVD companies.

Up	Price	% Chg
Affymetrix	$3.68	95%
Beckman Coulter	53.80	29
Becton Dickinson	67.24	5
Bio-Rad	69.23	26
Clinical Data	11.50	48
Gen-Probe	47.00	17
Immucor	23.06	10
Inverness Medical	28.56	30
Johnson & Johnson	51.41	7
Luminex	17.66	13
Nanosphere	4.60	51
OraSure	2.93	26
Unchanged		
Abaxis	16.06	0
Meridian	17.78	0
Down		
Abbott Labs	$43.63	-6
Quidel	8.50	-11

G-2 Insider

A urine test that can predict lung cancer in smokers? It might be on the horizon, according to data presented on April 19 at the annual meeting of the American Association for Cancer Research in Denver. Jian-Min Yuan, Ph.D., M.D., an associate professor of public health at the University of Minnesota, and colleagues analyzed urinary levels of NNAL, a tobacco-specific nitrosamine metabolite, in relation to lung cancer development in two groups of cigarette smokers. NNAL has been shown to induce lung cancer in laboratory animals, but the effect has not yet been studied in humans.

To evaluate the impact of NNAL, researchers identified 246 current smokers who later developed lung cancer and 245 smokers who did not develop lung cancer over a 10-year period. Urine levels of NNAL were divided into three groups. Compared to those with the lowest levels, patients with a mid-range level of NNAL had a 43 percent increased risk of lung cancer, while those at the highest level had a more than two-fold increased risk of lung cancer after taking into account the effect of number of cigarettes per day, number of years of smoking, and urinary levels of cotinine (a nicotine metabolite) on lung cancer risk. Levels of nicotine in the urine were also calculated. Those with the highest levels of nicotine and NNAL had an 8.5-fold increase in the risk of lung cancer compared with smokers who had the lowest levels after accounting for smoking history.

"Smoking leads to lung cancer, but there are about 60 possible carcinogens in tobacco smoke, and the more accurately we can identify the culprit, the better we will become at predicting risk," said Yuan.

Company References

Abaxis 510-675-6500
AdvaMed 202-783-8700
Arbor Vita 408-585-3900
Beckman Coulter 800-742-2345
Becton, Dickinson 201-847-6800
Bio-Reference 201-791-2600
CDC 800-232-4636
Clinical Data 617-527-9933
CLMA 610-995-2640
CMS 877-267-2323
CAP 847-832-7000
FDA OIVD 240-276-0450
Genoptix 760-268-6200
Gen-Probe 858-410-8000
Immucor 770-441-2051
Inverness Medical Innovations 781-647-3900
Meso Scale Diagnostics
Navigenics 650-585-7700
Nanogen 858-410-4600
Olympus 800-645-8160
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