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Competitive Intelligence & Analysis for an Expanding Global Market

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Meridian Sees Double-Digit Growth in Diagnostics

On November 12, Meridian Bioscience (Cincinnati) announced record fourth quarter and full-year results for its 2008 fiscal year, which ended September 30. Fueling the 14 percent increase in annual sales was strong growth in Meridian's diagnostics business, which is focused on tests for respiratory, gastrointestinal, viral, and parasitic infectious diseases. Sales for fiscal 2008 were $139.6 million, up 14 percent from $123 million in fiscal 2007. Diagnostic sales in the United States and Europe accounted for 83 percent of sales and were up 18 percent over 2007 levels.

Looking to 2009, Meridian CEO John A. Kraeutler predicts continued double-digit growth in the company's core diagnostic categories as it works to improve global distribution and boost its life science business. In January, Meridian plans to enter clinical trials for a novel molecular testing platform based upon loop mediated isothermal amplification (LAMP). The first test to use the technology will be for the toxin-producing forms of *C. difficile* bacteria. "Over the next five years we will aggressively expand the menu of this new molecular testing platform," added Kraeutler.

Myriad Genetics Will Split Molecular Diagnostics, Pharma

Salt Lake City-based biopharmaceutical company Myriad Genetics is moving forward with plans to split its pharmaceutical development and molecular diagnostic testing businesses. The molecular diagnostics business will retain the name Myriad Genetics and will have 800 full-time employees (FTEs). The pharma company will be called Myriad Pharmaceuticals and will have 200 FTEs. Each will operate as an independent public company.

This decision follows an announcement in September by president and CEO Peter Meldrum, who indicated that the company had hired J.P. Morgan Chase (New York City) to help its board conduct a strategic review of the biotech company's business. "By separating these unique businesses into two highly focused companies, we believe we will be able to unlock the intrinsic value of both business opportunities and create greater value than under our current structure," said Meldrum.

Molecular diagnostics continues to be a growth engine at Myriad, where revenue was up 53 percent for the first quarter of fiscal year 2009. For the three-month period ended September 30, total revenues increased to $73.6 million from $48.3 million in the same period last year. Molecular diagnostic revenues for the quarter climbed 52 percent to reach $70 million, compared to $46.1 million in the same quarter of the prior year.

Osmetech Begins Trials for Extended Warfarin Sensitivity Test

Molecular diagnostics company Osmetech (Pasadena, Calif., and London, England) has begun clinical trials for an extended version of its eSensor test for sensitivity to warfarin. The expanded test incorporates additional biomarkers, including CYP450 4F2, which Osmetech has exclusively licensed from Marshfield Clinic (Marshfield, Wisc.).

In July, the United States Food and Drug Administration (FDA) cleared Osmetech's eSensor warfarin sensitivity test to be used as an aid in the identification of patients at risk for increased sensitivity to the widely used blood-thinner. The test was cleared along with Osmetech's second generation platform, the eSensor XT-8. In the United States, the products are being marketed together with Osmetech's genotyping test for the drug metabolism gene CYP450 2C9, which is available for research use purposes only.

Clinical trials on the extended warfarin test will be conducted at three sites, and the company plans to use the results to support its application for 510(k) clearance. Osmetech expects to submit the application before the end of 2008. CEO James White said that he believes the new test will be "the most comprehensive FDA-cleared test for warfarin sensitivity available in the marketplace."

Osmetech is planning commercial launches of a number of additional tests for its eSensor XT-8 system. In addition to the extended warfarin panel, the tests include those for cystic fibrosis, venous thrombosis (Factor II, Factor V Leiden, and MTHFR), and the RESPLEX II respiratory pathogen assay that the company recently in-licensed from Qiagen.

Invitrogen, Applied Biosystems Progress Toward Merger

Invitrogen (Carlsbad, Calif.) and Applied Biosystems (AB; Norwalk, Conn.) are nearing the close of their proposed merger. After receiving shareholder approval and all required regulatory clearances, the companies scheduled a closing date of November 21 for the cash and stock deal, which is valued at $6.7 billion.

Announced in June, the strategic merger of Invitrogen and AB will create a global biotechnology company with deep offerings in both reagents (Invitrogen) and systems (AB). The companies also note that the new company will be well-positioned in such rapidly growing markets as next generation sequencing, proteomics, and cell biology.

The combined company would generate approximately $3.5 billion in sales. After closing, the combined organization will be known as Applied Biosystems and will have its headquarters in Carlsbad.

In recent months, both companies have emphasized that they do not expect the ongoing upheaval in the capital markets to have any impact on the financing for the merger deal. On an October 21 conference call, Invitrogen management noted that the merger integration plan remains on track, with planned cost synergies for the first year estimated at $80 million.

Ikonisys Gets FDA Clearance for HER-2 Breast Cancer Test

The United States Food and Drug Administration (FDA) has cleared an automated fluorescence in situ hybridization (FISH)-based test to determine HER-2 status in human breast cancer specimens. The presence of HER-2 gene amplification indicates whether a breast cancer patient is a candidate for treatment with Herceptin (trastuzumab).

Developed by cell-based diagnostic company Ikonisys (New Haven, Conn.), the oncoFISH her2 test is a fully automated method to process breast cancer specimens with Abbott's PathVysion HER-2 DNA Probe Kit. The test runs on Ikonisys's proprietary CellOptics platform, which includes a proprietary high-throughput, digital microscope. By automating the colocalization of area of interest on H&E slides with corresponding FISH slides, FISH side scanning, and preliminary classification of cells, the test promises greater standardization in FISH-based HER-2 testing as well as faster turnaround time.

In 2006, Ikonisys obtained FDA clearance for its fastFISH amnio application to identify numerical aberrations of chromosomes associated with common birth defects. Last year, the company received FDA clearance for oncoFISH bladder, which aids in the initial diagnosis of bladder cancer.

ACLA Panel Sees Future of Genetic Testing in Multiplex, Microrray Analysis

Multiplex testing, genomic hybridization, and high-throughput sequencing are fueling the rapidly advancing field of genetic testing, said experts from various areas of genetic testing at an October 28 panel discussion sponsored by the American Clinical Laboratory Association (ACLA; Washington, D.C.).

"Technology will continue to advance, and we will have more microarray technology and more multiplex testing," said panelist Gail Vance, M.D., a professor at the Indiana University School of Medicine.

Vance sees genetic testing becoming "more and more sensitive" through genomic hybridization and analysis of single nucleotide polymorphisms (SNPs), DNA sequence variations that occur when a single nucleotide differs between paired chromosomes.

There's also a push to develop more sophisticated high-throughput sequence analysis to perform massive parallel genetic sequencing, said panelist Sherri Bale, Ph.D., president and clinical director of GeneDx (Gaithersburg, Md.), a molecular diagnostic testing company focused on developing and providing molecular diagnostic tests for over 150 rare hereditary disorders. "There is a lot of effort going in this direction," she said of advances in sequencing. "This will greatly reduce the costs of genetic tests."

But the drive for improved technology underscores the need for continued investment and higher reimbursement in the genetic testing field. "This highlights the importance of reimbursement and venture capital funding of genetic testing," said ACLA president Alan Mertz.

Indiana University's Vance agreed. "Labs continue to get squeezed and squeezed," she said, adding that there are currently only three CPT codes provided for microarray molecular tests. "Reimbursement of this testing is critical."

LabCorp Discontinues OvaSure Testing After FDA Warning

In response to a warning letter from the United States Food and Drug Administration (FDA), LabCorp (Burlington, N.C.) is no longer offering its OvaSure test for ovarian cancer. In a letter sent to LabCorp in late September, the FDA questioned the clinical validity of the laboratory developed test, which LabCorp launched in June.

"LabCorp does not agree with the assertion in the warning letter that OvaSure is a medical device subject to regulation under the Federal Food, Drug, and Cosmetic Act (FDC Act)," wrote LabCorp senior vice president and general counsel F. Samuel Eberts in an October 20 letter to the FDA. "As we have previously stated, we believe that laboratory developed assays are not medical devices within the meaning of the FDC Act and that they are not subject to regulation as medical devices."

The September warning letter was the second sent to LabCorp regarding OvaSure, a multi-protein biomarker panel test that is intended to detect ovarian cancer at its earliest stages. In both letters, the FDA's director of the Office of In Vitro Diagnostic Device Evaluation and Safety, Steven Gutman, M.D., expressed concern that the test was "high-risk" and had not been adequately validated. In the most recent letter, Gutman noted that the test appears to have been designed, developed, and validated by investigators at Yale University and not LabCorp, and that instructions for use and performance characteristics also appear to have been developed by Yale investigators.

In response, LabCorp's Eberts responded that the company's interactions with Yale do not provide the FDA with any basis for exercising jurisdiction over the test. "Yale's role in LabCorp's test is limited to licensing to LabCorp certain intellectual property," wrote Eberts in his letter. "Yale has no control, contractual or otherwise, to influence the development, methodology, validation, performance characteristics, use, distribution, or any other aspects of LabCorp's testing service.

Nevertheless, the letter goes on to say that LabCorp will voluntarily discontinue offering the test as of October 24 and requests a meeting with the FDA to discuss the issue.

Medicare Physician Fees Will Rise in 2009

Medicare physician fees will rise by 1.1 percent in 2009. Congress authorized the fee hike through 2009. Had lawmakers not intervened, physician payments were due to be cut by 15.1 percent under the statutory update formula.

Pathologists and others paid under the fee schedule can also receive an incentive payment of 2 percent of the total allowed charges for successfully participating in the 2009 Physician Quality Reporting Initiative (PQRI). The PQRI quality measures include pathology protocols for breast and colorectal cancer.

The final rule implements new financial incentives Congress authorized for physicians who adopt e-prescribing. Those who use qualified electronic prescribing systems to send prescriptions to pharmacies can earn an incentive payment of 2 percent of their total Medicare allowed charges during 2009.

As Rising Costs Threaten Future of Cancer Care, OncotypeDX Found to Influence Treatment Decisions

Two new studies highlight the significance and value of diagnostic tests that can assist clinicians in managing and predicting the benefits of costly cancer treatment. A recent National Analysts Worldwide (NAW; Philadelphia, Penn.) survey of practicing oncologists found that financial factors are increasingly influencing treatment conversations and presentation of therapy options, while a study published in the October issue of the *American Journal of Surgery* concludes that treatment of patients was significantly altered as a consequence of the Oncotype DX test.

The results of the NAW survey, *Oncologists Look at Oncology: The Prognosis of U.S. Cancer Care*, are sobering. Of the oncologists surveyed, 74 percent believed that rising costs will eventually exceed society's ability to pay for optimal oncology care. Survey participants estimated that discussions of therapy options with patients are shaped by finances 40 percent of the time and expect that figure will increase to 50 percent over the next five years. However, the rising costs are broadening the discussion: 57 percent of oncologists agreed that high out-of-pocket costs have led them to be more explicit about likely treatment outcomes so patients can fully weigh the return on their investment.

Tests such as OncotypeDX, although itself costly at approximately $3,000 per test, can aid clinicians in managing treatment decisions and targeting therapies. Developed and performed by Genomic Health (Redwood City, Calif.), OncotypeDX is a 21-gene assay that can predict the likelihood of chemotherapy benefit and risk of disease recurrence in women with estrogen-receptor-positive, lymph node-negative breast cancer. The test is recommended by both the American Society of Clinical Oncology and the National Comprehensive Cancer Network (NCCN). To date, 7,500 physicians have ordered more than 75,000 tests. Medicare and private health plans covering approximately 90 percent of insured lives provide reimbursement for the test.

The study published in the *American Journal of Surgery* sought to determine whether the results of Oncotype DX influence the decision to administer chemotherapy. Researchers retrospectively reviewed the charts of 85 consecutive patients with node-negative, estrogen receptor-positive breast cancer, who had used OncotypeDX. Patients were divided into three risk categories based on their test results, known as a recurrence score. Researchers then compared treatment recommendations made utilizing the recurrence score to recommendations made based on the 2007 NCCN guidelines before OncotypeDX was incorporated into those guidelines.

Results showed that the OncotypeDX results influenced recommendations concerning chemotherapy in 37 patients (44 percent), while 33 patients who would have received a recommendation for chemotherapy based on the 2007 NCCN guidelines received a recommendation for hormone therapy alone based on their OncotypeDX recurrence score. Conversely, and notably, four patients who would have received a recommendation against chemotherapy based on the 2007 NCCN guidelines were placed in the high-risk group based on their recurrence score and received a recommendation for chemotherapy.

Steven Shak, M.D., chief medical officer of Genomic Health, pointed to an additional seven studies conducted by independent physicians who use the test. According to Shak, this research demonstrates that "OncotypeDX optimizes the use of chemotherapy to ensure those women who need chemotherapy get it, while sparing those who are not likely to benefit from its side effects and high costs."

Sequenom's Down Syndrome Test Enters Study

In late October, Sequenom (San Diego, Calif.) announced the launch of an independent, prospective, multi-center study to document the performance of the company's prenatal test for Down syndrome. Sequenom, which recently agreed to acquire the Center for Molecular Medicine (Grand Rapids, Mich.), expects that the 16-month study will be completed after the planned mid-2009 launch of the test and will result in data for submission to a peer-reviewed journal.

The primary goal of the study is to document the clinical sensitivity and false-positive rate of Sequenom's T21 technology, which uses fetal RNA in maternal plasma to identify Down syndrome in early pregnancy. The study has a secondary goal of developing a bank of samples to help improve the technology's ability to detect other chromosomal abnormalities. Investigators will test blood samples from up to 10,000 pregnant women in high-risk pregnancies late in the first trimester (to be confirmed by chorionic villus sampling) or early in the second trimester (to be confirmed by amniocentesis).

The study is directed by Jacob Canick, Ph.D., professor of pathology and laboratory medicine at Brown University Medical School, and Glenn Palomaki, associate director of the division of medical screening at Women & Infants Hospital at Brown University Medical School. According to Canick, the procedures used in the study, from collection to shipping to testing, "will represent, as closely as possible, a methodology that can be offered as a routine clinical test in multiple laboratories."

Protein-Based Blood Test Could Predict Impending Heart Attack

Researchers at Johns Hopkins University have identified five key proteins that could be used as a more accurate early warning test for impending heart attack in people with severely reduced blood flow, or ischemia. Results of the study were presented on November 9 at the American Heart Association's annual Scientific Sessions in New Orleans.

Conducted by mass spectrometry, the massive protein analysis project was based on 76 arterial blood samples from 19 men and women taken immediately before and after a period of medically induced ischemia lasting as long as 45 minutes.

"From the start, we knew that we were looking for rare, almost unique biomarkers that bore some direct relationship with ischemia," says Jennifer Van Eyk, Ph.D, a senior investigator on the study and a professor at the Johns Hopkins University School of Medicine. The researchers found that only five of the thousands of possible proteins were present in significantly increased amounts after ischemia occurred, with at least a doubling in the blood concentration, compared with those recorded during healthy blood flow. These were lumican, semenogelin, angiogenin, extracellular matrix protein, and so-called long palate, lung, and nasal epithelium carcinoma-associated protein 1.

"Our results lay the foundation for a first-of-a-kind, early-warning system that

could save 10s of thousands of people on the brink of a heart attack," says Van Eyk. A test based on these five proteins, says Van Eyk, could provide a "more definitive answer" to the question "how serious is it?" much earlier than existing assays for heart attack, such as tests for troponin proteins I and T.

The researchers now plan to verify the presence of the five proteins in a larger study with at least 150 participants and more than 1,000 blood samples. They will also further analyze the proteins to map their molecular structures, so that an antibody can be identified to bind to one or more of the proteins, providing the basis for a blood test for ischemia. Finally, they will work to verify that their findings also apply to ischemia in stroke.

Risk of Esophageal Cancer Tied to Gene Variants

Esophageal cancer ranks sixth in cancer-related deaths worldwide, and it is becoming more common. According to the American Cancer Society, more than 16,000 people will be diagnosed and more than 14,000 people will die of the disease in the United States this year.

Researchers have found that variations in a common gene pathway may affect esophageal cancer risk. Results of the study, the first to look at the association between variations in genes related to microRNAs (miRNAs) and esophageal cancer, are published in the November issue of *Cancer Prevention Research*.

As modulators of gene activity, miRNAs are thought to play a role in cancer risk. To examine the largely unknown influence of genetic variants of miRNA-related genes on esophageal cancer, researchers looked at the relationships among 41 single-nucleotide polymorphisms (SNPs) in 26 miRNA-related genes and the risk of esophageal cancer. Seven genotypes were significantly associated with esophageal cancer risk, and four more showed at least a borderline significance. The risk of esophageal cancer increased as the number of these genotypes present increased.

Researchers recruited 346 people who were newly diagnosed with esophageal cancer and matched them by age, gender, and ethnicity to 346 people without cancer. Only results for Caucasians were reported because of the low numbers of other races that enrolled. One notable finding was a SNP in the mir423 region that was associated with a significantly lower esophageal cancer risk. The protective effect was significant for smokers and nonsmokers 64 years old and younger, but not for older subjects. Mir423 is also found in leukemia cells and is significantly altered in other diseases, including heart disease and Alzheimer's disease.

Future large-scale, multi-center studies will be undertaken to confirm the researchers' findings. "Our ultimate goal is to construct a comprehensive risk prediction model that includes not only genetic factors, but epidemiological and clinical variables as well, in hopes of predicting the probability of developing esophageal cancer in the general population," said the study's lead author, Xifeng Wu, M.D., Ph.D., a professor at the University of Texas M. D. Anderson Cancer Center.

Study Finds Oral Fluid Drug Test Results Comparable to Urine Testing

According to a recent large-scale study, laboratory-based oral fluid drug testing results are comparable to urine drug testing positive rates for the same classes of drugs. Results of the study, which was sponsored by the U.S. Depart-

ment of Health and Human Services Substance Abuse and Mental Health Services Administration, were presented by J. Michael Walsh, Ph.D., on October 29 at the annual meeting of the Society of Forensic Toxicologists in Phoenix.

Of the 650,000 oral fluid laboratory test results analyzed over five years, 98 percent were conducted with the Intercept test system, the only FDA-cleared in vitro diagnostic laboratory-based oral fluid testing system used to detect commonly abused drugs such as marijuana, cocaine, opiates, PCP, and amphetamines as well as barbiturates, methadone, and benzodiazepines.

Developed, manufactured, and performed by OraSure Technologies (Bethlehem, Penn.), Intercept first screens samples with enzyme immunoassays. Samples that test positive are then confirmed using gas chromatography/mass spectrometry/mass spectrometry. OraSure's laboratory can process and report negative results the same day samples are tested. Positive results are reported within 72 hours.

Tumor Database to Combine Microscopy, Microarray Information

A new database promises one-stop shopping for comprehensive information about patients' tumors. Led by the Research Institute at Nationwide Children's Hospital, Childrens Hospital Los Angeles, and the Ohio Supercomputer Center, the Virtual Microscopy to Microarray project (VM2M) aims to bridge the worlds of pathology, genetics, and medical treatment. By providing specialists with rapid access to genetic information about a patient's tumor and specific cancer type, the database can allow clinicians to tailor treatment to the individual.

"VM2M will pair high-quality microscopy scans of tumors with their specific genetic code . . . and make the information available through a secure online data repository," said Dave Billiter, director of the research informatics core at Nationwide's Center for Childhood Cancer.

VM2M will consist of three main components: high quality digital microscopy scans of tumors, microarrays of the same tumors that detail their specific genetic code, and the new underpinning technology—software, data storage, and network access—that enables viewing the two simultaneously.

Custom-designed software will allow multiple pathologists to quickly, simultaneously, and securely review, via the Internet, digitally formatted, diagnostic-quality microscopy scans of diseased tissue with the corresponding molecular expression data. Virtual microscopy scans are paired with microarray data from each sample.

In the project's initial phase, the group created the prototype database at the Ohio Supercomputer Center, which provided a secure repository and hosted the development platform. The collaborators are now exploring the next phase of development for VM2M by moving into a production-supported environment.

"Once the virtual microscopy field receives FDA approval, clinicians will be able to utilize the VM2M platform for diagnosis," said Billiter. "This will optimize the process of patient diagnosis, review, and treatments that are most appropriate for each individual."

New CLIAC Guidance Will Tackle Molecular Testing

Clinical laboratories can look forward to new guidance on molecular and genetic testing now that the Clinical Laboratory Improvement Advisory Committee (CLIAC), which advises the government on CLIA scientific and technical matters, has adopted a workgroup report on good lab practices for this rapidly expanding area of medicine. The report, adopted at the panel's September meeting in Atlanta, will be published in the *CDC Morbidity and Mortality Weekly Report* later this year or in early 2009.

The report offers guidance on heritable conditions, notes the new CLIAC chair, Elissa Passiment, executive vice president of the American Society for Clinical Laboratory Science. Another workgroup will be organized to report on somatic diseases.

The soon-to-be-available report discusses preanalytic, analytic, and postanalytic phases of testing, including best practices in providing user information about services offered; informed consent and confidentiality; test requests; specimen submission, handling, and referral; test authorization; performance verification and control procedures; proficiency testing; test reporting; retention of records and specimens; and personnel competencies and training.

The CLIA program has opted not to create a specialty for genetic testing, and the guidance is intended to help lab personnel better understand how current CLIA requirements apply to this testing.

Paternity Testing Leader DNA Diagnostics Center Acquired by MTS Health Investors

New York-based private equity firm MTS Health Investors has acquired DNA Diagnostics Center (DDC; Fairfield, Ohio), a leading provider of genetic testing. Ellen Moscovitz, formerly head of LabCorp's DNA testing operations, has been tapped as CEO, and Michael Baird, M.D., will continue on as the laboratory director. Financial terms of the acquisition were not disclosed.

Approximately 70 percent of MTS's business involves biological family relationship testing—such as paternity testing—with the remaining 30 percent focused on forensics and veterinary genetics. "Our growth plan is to continue to grow our core business, including paternity testing and also expand in to other areas," said MTS Managing Director Kenton Rosenberry. Expansion plans include increasing the company's footprint in DNA testing for forensic, veterinary, immigration, and adoption services, as well as genetic testing for disease predisposition.

Much of DDC's current marketing and branding is derived from its involvement in high-profile cases that have garnered significant media attention. For example, DDC's analysis identified Larry Birkhead as the father of the late celebrity Anna Nicole Smith's daughter, and DDC provides DNA testing services for the *Maury Povich Show*.

LabCorp to Help Launch Reference Lab in Abu Dhabi

LabCorp (Burlington, N.C.) has announced plans to establish the National Reference Laboratory (NRL) in Abu Dhabi, the capital of the United Arab Emirates (UAE), as part of an agreement with the health care division of the country's Mubadala Development Company.

Scheduled for completion in 2009, NRL is to be a centralized lab in the UAE offering comprehensive services—including routine and esoteric testing—that are currently sent to Europe and elsewhere outside the UAE. The fully automated lab will be designed to ensure quick turnaround time—as little as within two hours—on critical tests. The lab will also pursue international accreditation by the College of American Pathologists.

This laboratory company joins other international projects currently under development by Mubadala Healthcare. These include the Cleveland Clinic Abu Dhabi, a 360-bed hospital slated to open in early 2011, as well as the Tawam Molecular Imaging Centre, which is due to open next year as part of an operation agreement with Johns Hopkins Medical International.

CMS Finalizes Anti-Markup Rules for Diagnostic Testing

"We believe that allowing billing physicians and other suppliers that cannot satisfy the first alternative to comply with the requirements of the second alternative on a case-by-case basis affords physicians flexibility while addressing our concerns regarding the ordering of unnecessary diagnostic tests," CMS said.

In the final 2009 Medicare physician fee schedule, the Centers for Medicare and Medicaid Services (CMS) announced that it will start applying anti-markup rules to diagnostic testing services (other than clinical lab services) billed by physicians and suppliers, as of January 1.

The rules, to be published in the November 19 *Federal Register*, limit how much Medicare can be billed for such testing when performed in a physician office or within a group practice. The agency had twice before proposed to apply the rules to such testing, but delayed action to get further comment.

CMS has now adopted, with some changes, the alternatives discussed in the proposed fee schedule rule in July for determining whether anti-markup provisions under the Stark self-referral rules apply to the technical component (TC) and the professional component (PC) of diagnostic testing services.

Under the first alternative, the provisions would apply in all cases where 1) the PC and the TC were purchased from an outside supplier or 2) the services were performed or supervised by a physician who does not share a practice with the billing physician or physician organization.

"Sharing a practice" is defined as a situation where the physician performs "substantially all" of his or her professional services for the billing physician or supplier. "Substantially all" means at least 75 percent of a physician's services. In these cases, the anti-markup rules would not apply.

For arrangements that do not satisfy the above, CMS advised, use the "site of service" alternative. The TC of diagnostic testing services performed in the office of the billing physician or other supplier would not be subject to the anti-markup rules.

IVD Stocks Fall 14%; Affymetrix Plummets 45%

In plunging and volatile markets, the G-2 Diagnostic Stock Index dropped an average of 14 percent in the five weeks ended November 7, with 14 stocks down in price and three up. The G-2 index is down 31 percent so far this year, while the S&P is down 36 percent and the Nasdaq has fallen 37 percent.

Losing nearly half of its value was **Affymetrix** (Santa Clara, Calif.), which plummeted 45 percent to close at $3.80 per share with a market capitalization of $240 million. On October 24, the microarray company announced disappointing third quarter results and lowered its full-year revenue forecast, pointing to greater competition, weak industrial spending, and ongoing restructuring charges. Total revenue for the third quarter was $75.2 million, down 21 percent from the $95 million earned in the same period last year. With product sales, service revenue, and royalties all down, the company reported a net loss of approximately $31.8 million for the quarter.

On November 11, Affymetrix announced that it has agreed to acquire privately held Panomics (Fremont, Calif.) for approximately $73 million. Founded in 2000 as Genospectra, the company specializes in measurement tools for gene, protein, and cellular function. Its products include reagents for gene expression, protein expression, and live cell assays. The acquisition is expected to close by the end of 2008.

Meanwhile, one of only three gainers in recent weeks was **Luminex** (Austin, Tex.). Stock in the platform company inched up by 3 percent, ending the period with a share price of $22.48 and a market capitalization of $985 million. The company recently reported strong third quarter results, posting revenue of $28.9 million, up 49 percent compared to the same period last year. Luminex shipped 239 of its testing systems during the quarter, an increase of 19 percent over the third quarter of 2007. Also fueling revenue growth were the company's new partnership with BD Diagnostics' TriPath to create cancer tests and the extension of the agreement with Genzyme Genetics for Luminex's xTAG cystic fibrosis test kit.

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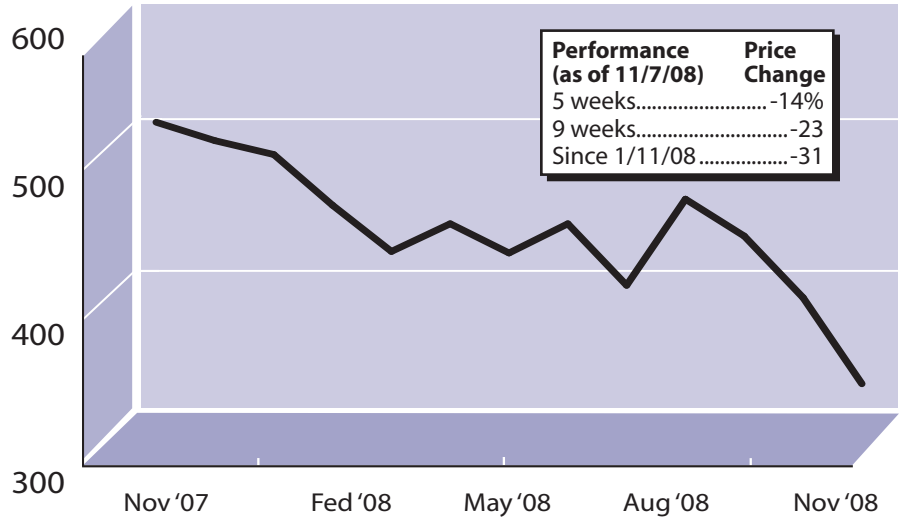
G-2 Diagnostic Stock Index



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	$22.48	3%
Nanogen	0.27	8
Quidel	15.77	4
Down		
Abbott Labs	55.30	-5
Affymetrix	3.80	-45
Abaxis	15.00	-14
Beckman Coulter	50.68	-26
Becton Dickinson	70.73	-12
Bio-Rad	70.01	-25
Clinical Data	11.02	-28
Gen-Probe	45.40	-8
Immucor	27.17	-7
Inverness Medical	22.00	-18
Johnson & Johnson	60.22	-9
Meridian	23.91	-15
Nanosphere	4.91	-29
OraSure	3.36	-21

G-2 Insider

A blood test to predict obesity? . . . It may be as simple as monitoring postprandial changes in blood triglyceride levels. In a study published in the *International Journal of Obesity*, researchers from the Monell Center (Philadelphia, Penn.) found that the degree of change in blood triglyceride levels following a fatty meal may indicate susceptibility to diet-induced obesity. "These findings suggest we may someday be able to use a simple blood test to identify those at risk for obesity," said senior author Mark Friedman, Ph.D.

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In the study, Friedman and lead author Hong Ji, Ph.D., screened rats for vulnerability to diet-induced obesity by measuring the increase in blood triglyceride levels following a single high-fat meal. They then fed the rats a diet high in fat over the next four weeks. The researchers were able to predict which animals would become obese over the four-week period by examining the earlier metabolic response to the high-fat meal: the smaller the triglyceride change, the greater the weight gain.

At present, there are no simple biomarkers that are predictive of susceptibility to diet-induced obesity and therefore no clinical tests that can help to identify those at risk for becoming obese. The study findings suggest that a change in blood triglyceride levels may someday be used as such a tool.

Future studies will investigate the mechanism behind differences in the change in blood triglycerides. "The differences in weight gain associated with high-fat diets indicate that genetically determined factors contribute to obesity," noted Friedman. "We have shown that these genetic factors are related to the body's ability to burn fat. We now need a better understanding of how this relates to blood triglyceride levels."

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