Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Vol. IX, No. 3/November 2008

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WASHINGTON G-2 REPORTS

Established 1979

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Sequenom to Acquire Center for Molecular Medicine

Molecular diagnostics company Sequenom (San Diego, Calif.) has agreed to acquire the Center for Molecular Medicine (CMM; Grand Rapid, Mich.), the advanced molecular pathology laboratory that is a novel joint venture between the Van Andel Research Institute and Spectrum Health. Sequenom will pay approximately $4 million (90 percent in stock) for CMM and receive a 12-year tax incentive package valued at $20 million.

According to Sequenom, the deal will help the company to launch its SEQureDx test for Down syndrome (trisomy 21). The test, which isolates and analyzes circulating fetal nucleic acid from a maternal blood sample, is currently in clinical studies. Sequenom plans to launch in the first half of 2009. The company's first SEQureDx test, for fetal RhD, became available last year. *Continued on p. 3*

California to Cover HIV Screening Costs

The Centers for Disease Control and Prevention's 2006 recommendation of routine HIV screening is one step closer to becoming a reality in the state of California. On September 30, Governor Arnold Schwarzenegger signed into law a bill that will require private insurers to cover the cost of HIV testing regardless of whether the testing is related to a primary diagnosis. The law will take effect in 2009.

The California Health Benefits Review Program (CHBRP; Oakland, Calif.) estimates that the new law will not lead to a spike in HIV testing but will result in a shift in who pays for such testing. "Postmandate, testing currently paid for out-of-pocket or paid by other sources is expected to be paid for by insurance," wrote the independent research group in an April 2008 report to the California legislature.

CHBRP also believes that the legislation will not affect the current $27.46 per-unit cost of HIV testing. For a typical insured population, CHBRP estimates that HIV tests have a total per member per month (PMPM) cost of approximately $0.06. *Continued on p. 2*

▲**HIV Screening Costs,** *from page 1*

California's new law guaranteeing cost coverage for HIV testing comes approximately a year after the state stopped requiring hospital patients to give written consent before being tested for virus. According to the California Office of AIDS, approximately 40,000 people in the state are infected with HIV but are unaware of their disease status.

FDA Clears Cepheid's MRSA/Staph Tests

The United States Food and Drug Administration (FDA) has cleared for marketing two molecular tests to detect methicillin-resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA, typically methicillin susceptible). One test detects MRSA and SA in skin and soft tissue infections and the other in blood culture bottles showing gram-positive cocci. Manufactured by Cepheid (Sunnyvale, Calif.) and cleared for use on its GeneXpert molecular diagnostics platform, both tests provide results in less than one hour, a significant improvement over much slower, culture-based methods.

Cepheid's GeneXpert is an automated molecular diagnostics platform that combines on-board sample preparation with real-time polymerase chain reaction (PCR) amplification and detection. The FDA had previously cleared GeneXpert tests for enteroviral meningitis and Group B streptococcus. On October 7, Cepheid released a CE-marked GeneXpert test for the rapid detection of vancomycin-resistant enterococci (VRE). It is the eighth GeneXpert test to receive the CE Mark and the first test developed and manufactured by Cepheid's Swedish subsidiary.

Discoverers of HPV, HIV Win Nobel Prize

The 2008 Nobel Prize in physiology or medicine will be awarded to Harald zur Hausen for his discovery of human papilloma viruses (HPVs) causing cervical cancer and to Françoise Barré-Sinoussi and Luc Montagnier for their discovery of human immunodeficiency virus (HIV), the Nobel Assembly announced on October 6. Half of the award will go to zur Hausen, and the other half will be split between Barré-Sinoussi and Montagnier.

Going against the dogma of the time, German virologist zur Hausen postulated that oncogenic HPV—which he found to be a heterogeneous family of viruses—caused cervical cancer, a discovery that paved the way for DNA-based HPV testing and led to an understanding of mechanisms of HPV-induced carcinogenesis and the development of prophylactic HPV vaccines.

French virologists Barré-Sinoussi and Montagnier discovered HIV, characterizing the novel retrovirus as the first known human lentivirus. Their discovery was a prerequisite for the current understanding of the biology of the disease, as well as its diagnosis and treatment.

The three scientists and the other 2008 Nobel Prize winners will be presented with their awards in a ceremony in Stockholm on December 10.

▲**Sequenom to Acquire CMM,** *from page 1*

A CLIA-certified, College of American Pathologists-accredited clinical diagnostics laboratory, the CMM performs such advanced testing as CYP450 genotyping, tissue of origin testing, and cell search assays for circulating tumor cells in metastatic breast cancer. Daniel H. Farkas, Ph.D., has served as executive director of CMM since December of 2006. Farkas will continue to oversee the lab and will join Sequenom's management team, which is led by President and CEO Harry Stylli, Ph.D.

In addition to acquiring the CMM laboratory, Sequenom plans to complete a CLIA-certified laboratory facility in San Diego, Calif. that it will use to expand its genetic research activities. The facility will also serve as a West Coast adjunct to the prenatal testing that will be performed by the CMM laboratory.

FDA Clears New CDC Flu Test

On September 30, the United States Food and Drug Administration (FDA) cleared a new flu test developed by the U.S. Centers for Disease Control and Prevention (CDC). The human influenza virus real-time RT-PCR detection and characterization panel (rRT-PCR flu panel) can be used to diagnose human influenza infections as well as influenza A (H5N1) viruses.

The test is run on the 7500 Fast Dx real-time PCR instrument, which is manufactured by Applied Biosystems (Forest City, Calif.) and was cleared by the FDA for diagnostic use simultaneously with the flu panel. Although the test and the instrument received independent 510(k) clearances from the FDA, they are required to be used together as a system for the detection of influenza.

The rRT-PCR flu panel can detect flu virus and differentiate between seasonal and novel influenza from mucus samples taken from a patient's nose or throat. Results are available within four hours, and the system can test multiple samples at once. According to the Department of Health and Human Services (HHS), the test will be available to CDC-qualified laboratories for diagnosing influenza this fall, and some laboratories will be able to obtain reagents at no cost.

HHS Secretary Mike Leavitt touted the public health benefits of the new test, noting that its "application to detect an emergent influenza virus would be especially important in the early stages of a pandemic."

"Because the test can tell the difference between seasonal human influenza viruses and novel viruses, it will also provide qualified laboratories with a means to rapidly detect new influenza viruses that have not been identified yet and that could pose a pandemic risk," said FDA Principal Deputy Commissioner and Chief Scientist Frank Torti, M.D. The new test should also help to ensure the accuracy of influenza testing results among different laboratories that conduct influenza subtype testing.

In developing the test, the CDC collaborated with Applied Biosystems and the Association of Public Health Laboratories (Silver Spring, Md.). Clinical evaluations of the new flu panel were performed by state public health laboratories in Virginia, Iowa, California, Massachusetts, Wisconsin, and Washington.

Congress Passes Legislation to Allow Routine HIV Testing in VA Health System

The United States Congress has passed the Veterans Mental Health and Other Care Improvements Act of 2008 (S. 2162). The sweeping veterans' mental health care bill includes a provision that repeals the 1988 Veterans Benefits and Services law, which has limited the implementation of the Centers for Disease Control and Prevention (CDC) guidelines for routine HIV testing, counseling, and early diagnosis that were issued in 2006. The bill now awaits the signature of the president before becoming law.

Championed by U.S. Congressman Mike Doyle (D-Pa.) and U.S. Congressman Charles Dent (R-Pa.), the provision removes significant barriers to routine HIV testing within the U.S. Department of Veterans' Affairs (VA), allowing for the implementation of broad-scale HIV screening. The VA is the largest integrated health care provider in the United States and the single largest provider of HIV care.

The 1988 Veterans Benefits and Services law that would be repealed if the bill is signed into law includes consent restrictions and impedes any universal HIV testing program unless specific funding for the purpose has been appropriated by Congress. If the law is repealed, the VA would be able to adopt the CDC's recommendation of streamlined counseling and implement routine HIV screening in VA health care settings.

Gene Variant Linked to Liver Disease

Individuals who carry a specific form of the gene PNPLA3 have more fat in their livers and therefore are at a greater risk of developing nonalcoholic fatty liver disease (NAFLD), according to a study published online on September 25 in *Nature Genetics*. The researchers also found that Hispanics are more likely to carry the PNPLA3 gene variant than African-Americans and Caucasians.

"A single variation in the PNPLA3 gene was strongly associated with hepatic fat content, even after adjusting for other factors, such as obesity, diabetes status, and alcohol intake," said senior study author Helen Hobbs, Ph.D., director of the Eugene McDermott Center for Human Growth and Development and an investigator for the Howard Hughes Medical Institute at University of Texas Southwestern Medical Center.

NAFLD is the most common form of liver disease in Western countries. The burgeoning health problem has been shown to affect as many as one-third of adults in America.

"The gene variations we have identified might provide a way to predict who is most at risk for developing fatty liver disease and liver injury in response to environmental stresses such as obesity or infection," said Jonathan Cohen, M.D., professor of internal medicine at UT Southwestern and one of the authors of the study. "Knowing who is at increased risk of developing liver disease could aid physicians in encouraging their patients to make lifestyle changes or take other preventive measures to help mitigate their underlying genetic risk for the disorder."

Molecular Diagnostics Is Largest Growth Area at Alverno Clinical Labs

Molecular diagnostic testing volumes continue to grow at Alverno Clinical Laboratories (Hammond, Ind.), the full-service medical laboratory that is a joint venture of the Sisters of St. Francis Health Services, Resurrection Health Care, and Provena Health. Alverno performs approximately 14 million billable tests annually. Of those, approximately 170,000 are molecular tests.

"Our molecular testing volume is growing exponentially," said Jennifer E. Skeen, Ph.D., Alverno's director of molecular diagnostics and flow cytometry. "I came on board almost three years ago and was brought on to investigate new technologies and rapidly increase our molecular menu. It's our largest growth area as far as new testing and new technology." Skeen notes that in the last two years Alverno has doubled the number of molecular tests, as well as the number of FTEs.

A full-service medical laboratory with a test menu of over 750 tests in both clinical and anatomic pathology, Alverno serves the Chicago area, down to Indianapolis, Indiana, and the Urbana Danville region in Illinois. "We cover a pretty wide geographic area, and the core lab is meant to reduce the Quest [Diagnostics] and LabCorp send-out testing," says Skeen.

Alverno Clinical Labs at a Glance

- Full-service medical laboratory with a test menu of over 750 tests in both clinical and anatomic pathology.
- Joint venture of the Sisters of St. Francis Health Services, Resurrection Health Care, and Provena Health.
- Performs approximately 14 million tests annually; of those, 170,000 are molecular tests
- Employs approximately 1,600 people.

That replacement hasn't quite happened, notes Skeen, but the idea was to provide the majority of laboratory testing for the variety of institutions it serves. "All the STAT-based testing is still performed in the hospital laboratories. So we are actually two companies, the core lab, which is Alverno Clinical Laboratories, LLC, and the hospital lab organization, which is Alverno Provena Hospital Laboratories Inc. Anything that is not STAT is transferred to the core lab where we can utilize economies of scale to bring down the price of laboratory testing."

The full lab system, both the core laboratory and the 27 hospital laboratories, employ about 1,600 people. In November 2007, the molecular department switched from a Monday through Saturday daytime schedule to a 24/7 operation. Skeen says, "I think we're one of the few 24/7 molecular departments in our geographic area."

A big part of Alverno's molecular growth has been for methicillin-resistant Staphylococcus aureus (MRSA) testing. "All of our Illinois hospitals are required to screen for MRSA, and they want us to do the test as rapidly as possible," says Skeen. "With our expanded fleet of couriers we have been able to keep our MRSA turnaround times under twelve hours."

Alverno's highest volume molecular tests are for gonorrhea and chlamydia, nas well as MRSA. These are followed by qualitative hepatitis C testing Factor V Leiden, Factor II (prothrombin), and herpes simplex virus 1 and 2. The laboratory intends to bring on Hepatitis C and HIV viral load testing in the near future.

Recently added tests that have grown rapidly at Alverno include Digene's hybrid capture-based method for detecting human papilloma virus (HPV) and real-time PCR testing for varicella zoster virus (VZV) using Roche's analyte specific reagent for the virus. The VZV assay complements Alverno's PCR testing for HSV 1 and 2 when investigating the cause of skin lesions.

Skeen notes that although they are competing with Quest, they also rely on the nation's largest provider of clinical laboratory services. "They have volumes that we'll never be able to find. They have the ability to capture national economies of scale to significantly reduce the cost of testing, where as a regional laboratory with lower volumes, the same test would cost us four times as much to support," she says.

Dividing and Conquering Molecular Diagnostics at ARUP

University of Utah-owned ARUP Laboratories (Salt Lake City) processes more than 10 million tests annually, and approximately 600,000 of those tests are molecular. The reference laboratory began performing molecular-based tests in 1995. From a single molecular laboratory staffed by two technologists, ARUP now has eight different laboratories that perform molecular tests and employ 170 FTEs. Molecular testing is the fastest-growing area of the laboratory.

ARUP's molecular testing was originally divided among four categories: molecular infectious diseases, molecular genetics, molecular oncology, and sequencing. "We now have eight labs that deal with molecular. They comprise those four areas," says Edward R. Ashwood, M.D., director of laboratories at ARUP. "It's just that we have been splitting them to keep them manageable. To gain efficiencies it was necessary to split them up." The infectious disease labs, for example, have been divided into one that handles hepatitis and HIV testing and one that does non-hepatitis and non-HIV testing. ARUP has also coped with the complexity by establishing a special processing division to help the molecular labs to triage specimens.

ARUP has seen substantial growth in molecular testing, with the exception of HIV testing. "We're seeing a switch from classical microbiology testing over to molecular and that's really quite strong," says Ashwood. "I will say that HIV testing [volumes are] pretty flat."

Castle Biosciences Options Brain Tumor Test

Cancer diagnostics startup company Castle Biosciences (Houston) has optioned a molecular diagnostic test for brain cancer, the company announced on October 7. Developed by researchers at the University of Texas M. D. Anderson Cancer Center, the biomarker-based test is intended to prospectively assess a patient's likelihood to respond to treatment for glioblastoma multiforme (GBM), the most common form of primary brain cancer. The test would be the company's first product.

As many as 20,000 new cases of GBM are diagnosed each year. It is a highly aggressive disease for which all patients are prescribed the same first-line, standard of care treatment of radiation and temozolomide. The M.D. Anderson test has the potential to prospectively stratify a patient's likelihood to respond to this treatment based upon the genetic signature of his or her tumor. The information could assist oncologists in tailoring a treatment plan to that patient.

Formed in September, privately held Castle Biosciences is focused on applying personalized medicine to underserved diseases. The company plans to "identify, in-license, develop, validate, and commercialize multiple prognostic molecular diagnostic assays that have been developed at leading institutions around the United States." The company is led by president and CEO Derek Maetzold, a biopharmaceutical industry veteran who most recently served as officer and vice president for marketing and sales at Encysive Pharmaceuticals.

Mayo Clinic Study Highlights Limitations of Stool DNA Testing for Colorectal Cancer

A first-generation stool DNA test to identify colorectal cancer at its earliest stages has limitations, according to a Mayo Clinic-led study published in the October 7 issue of *Annals of Internal Medicine*. Researchers failed to corroborate the findings of an earlier study that showed stool DNA testing was more accurate than fecal blood testing to detect colorectal cancer.

Stool DNA testing has promised to be an accurate, user-friendly alternative to colonoscopy, which requires fasting, bowel cleansing, a physician visit, sedation, and an invasive procedure. "To prevent colorectal cancer deaths, we need an easy-to-use screening tool that consistently finds precancerous polyps," said David Ahlquist, M.D., lead researcher in the Mayo Clinic study. "Stool DNA testing is evolving quickly and may soon fill that need."

Conducted from 2001 to 2007, the blinded study of 4,482 participants at 22 academic medical centers compared screening effectiveness of widely used fecal blood tests (Hemoccult and HemoccultSensa) with a stool DNA test (PreGen-Plus) in average-risk patients, ages 50 to 80. All participants also underwent a colonoscopy.

After an interim analysis, researchers found that all of the stool tests performed suboptimally, with the stool DNA test detecting 20 percent of cancer and precancerous polyps, compared to 11 percent by Hemoccult and 20 percent by HemoccultSensa.

Given the results, they decided to switch to a second-generation stool DNA test, which featured improvements that addressed problems with sample degradation, accuracy of DNA markers, and DNA detection.

The second-generation DNA test detected 46 percent of the precancerous polyps, compared to 10 percent detected by Hemoccult and 17 percent by HemoccultSensa. "If the premalignant polyps are not detected, cancer cannot be prevented. So this result was most encouraging," says Ahlquist.

Although the American Cancer Society recently endorsed stool DNA testing to detect colorectal cancer, the testing is not yet widely available, has not been approved by the U.S. Food and Drug Administration, and is not covered by most insurers.

Researchers Identify Biomarker for Gout

A team of researchers has identified a trio of gene mutations that are associated with high levels of uric acid in the blood, a risk factor for gout. The researchers developed a genetic risk score that takes into account the number of uric acid-increasing mutations that each person carries, which was associated with up to a 40-fold increased risk for developing gout. The findings were published in the October 4 issue of the *Lancet*.

More than 3 million adults in the United States have gout, a painful inflammation of the joints that can occur with a build-up of uric acid in the blood. Besides a genetic disposition, obesity, a diet high in meat and cheese, excessive alcohol consumption, and certain medications can increase the risk for developing the disease.

The researchers discovered the mutations through genome-wide association studies of more than 20,000 people enrolled in three large population-based studies investigating cardiovascular disease risk factors. After analyzing more than 500,000 genetic variations, they identified two genes, ABCG2 and SLC17A3, as novel risk genes for gout and confirmed the association of a third gene, SLC2A9.

"Genetic risk scores like the one we developed for gout can help alert people at a very early age, well before uric acid levels rise, that they are susceptible to gout," said Josef Coresh, M.D., Ph.D., an author of the study and professor at the Johns Hopkins Bloomberg School of Public Health. "An important unanswered question is whether we can use genetic risk information to motivate people to change their behavior. For gout, we know that moderate changes in diet and alcohol consumption can lower uric acid levels. In the future, we will need to test if identification of high-risk individuals can lead to behavior change."

Becton Dickinson, U.S. Genomics to Collaborate on Rapid Molecular Testing Platform

Becton, Dickinson & Co. (BD; Franklin Lakes, N.J.) and U.S. Genomics (Woburn, Mass.) will collaborate on the creation of a diagnostic platform for infectious disease, the companies announced recently. Additionally, U.S. Genomics raised $4.5 million in private equity funding from BD.

The collaboration will focus on application of U.S. Genomics's Direct Linear Analysis technology (DLA) for the detection of multiple infectious organisms in a single molecular diagnostic test. According to U.S. Genomics, a DLA-based diagnostic platform could provide information to physicians concerning pathogen identity, virulence, and drug resistance within hours, a significant improvement over the time required by current culture-based methods.

"BD is the clear market leader in clinical microbiology, and their deep experience in product development is an ideal complement to our innovative DLA technology and strong research team," said U.S. Genomics CEO John J. Canepa in a statement. "We share the goal of establishing a new, faster, more accurate capability for microbial diagnostics, based on genotype, leading to more effective patient treatment and better outcomes."

U.S. Genomics specializes in commercial applications of single molecule DNA, RNA, and protein analysis. The company's proprietary technologies include those for extraction of high-grade DNA from complex samples, tagging, microfluidics, and genomic mapping. The company's technology platform has been funded to date with $100 million from venture capital firms and U.S. government contracts.

Affymetrix Licenses Technology to Medical Prognosis Institute

GeneChip maker Affymetrix (Santa Clara, Calif.) has licensed technology to Denmark-based Medical Prognosis Institute (MPI) for an undisclosed amount, the companies announced on October 1. Under the nonexclusive deal, MPI will use Affymetrix microarray technology to develop and sell proprietary tests targeted at individual cancer prognosis and prediction of anti-cancer treatment response.

Of 179 new anti-cancer drugs tested in Phase I trials between 1976 and 1993, only 28 percent were considered effective in Phase III. MPI believes the lack of effect is highly correlated to the response rate and is now pursuing the opportunity to identify responders; for example, for failed Phase III cancer drugs.

"Our partnership with Affymetrix enables us to translate our discoveries into robust tools with broad clinical utility to greatly improve the prognosis and treatment of millions of people living with cancer. It also boosts the probability of successful anti-cancer drug development in partnership with drug companies," said Jesper Drejet, president and CEO of Medical Prognosis Institute. "We are confident of being able to obtain regulatory clearance and achieve commercialization within one to two years."

"Agreements such as this continue to validate the need for microarrays for com-

plex signatures for reproducibility and accuracy," added Kevin King, president of Affymetrix.

Affymetrix's GeneChip system 3000Dx is the only microarray instrumentation platform to receive regulatory clearance by the U.S. FDA and is CE marked in the European Union for in vitro diagnostic use. More than 20 different molecular assay tests based on the platform are now under development by Affymetrix and its licensees.

Esoteric Testing Drives Bio-Reference's 18% Revenue Growth in Q3

New Jersey-based Bio-Reference Laboratories' esoteric testing divisions—GenPath and GeneDx—helped boost revenue 18 percent to $77 million for the third quarter of 2008. Revenue at Bio-Reference's national oncology lab, GenPath, grew by 35 percent, while the lab's genetics laboratory, GeneDx, grew by 70 percent in revenue.

Bio-Reference's revenue per requisition also increased to 9 percent to $74.11 from $68.08 for the same quarter in 2007. However, the laboratory company continues to struggle with a higher-than-industry bad debt rate and days sales outstanding figures, although these have also shown some improvement.

The esoteric testing growth follows several quarters of investment in these business areas by the company, including expanding the sales staff, noted CEO Marc D. Grodman, M.D. "The growth that we experienced this quarter is primarily fueled by growth in these areas, even though it's early in the sales cycle for the expanded efforts we implemented," he said in an earnings call. "Given these results, it's not surprising that in this quarter, percentage of revenues attributable to esoteric testing rose to 48 percent compared to 44 percent in the prior year."

OIG to Examine Unbundling of Lab Tests

In 2009, the Department of Health and Human Services Office of Inspector General (OIG) plans to review laboratory test unbundling by clinical laboratories and examine the extent of variation in laboratory test payment rates among Medicare contractors.

These projects are contained in the OIG's 2009 work plan, released October 1. The work plan serves as a road map for what the agency plans to review in the coming year.

In its plan, the OIG says it will determine whether clinical laboratories have unbundled profile or panel tests by submitting claims for multiple dates of service or by drawing specimens on sequential days. The agency will also examine the extent to which the Medicare carriers have controls in place to detect and prevent inappropriate payment for laboratory tests.

The OIG also notes that in 2007, Medicare payments for laboratory services exceeded $6 billion and that prior work by the agency found that Medicare had paid significantly higher prices than other payers for certain laboratory tests. The OIG says it plans to analyze claims data to determine pricing variances among Medicare contractors for the most commonly performed tests.

IVD Stocks Fall 10% as Market Plummets

As the global financial crisis deepened and lending stalled, the G-2 Diagnostic Stock Index lost an average of 10 percent in the five weeks ended October 3, with 15 stocks down in price and two up. The G-2 index is down 20 percent so far this year, while the S&P is down 24 percent and the Nasdaq has fallen 25 percent.

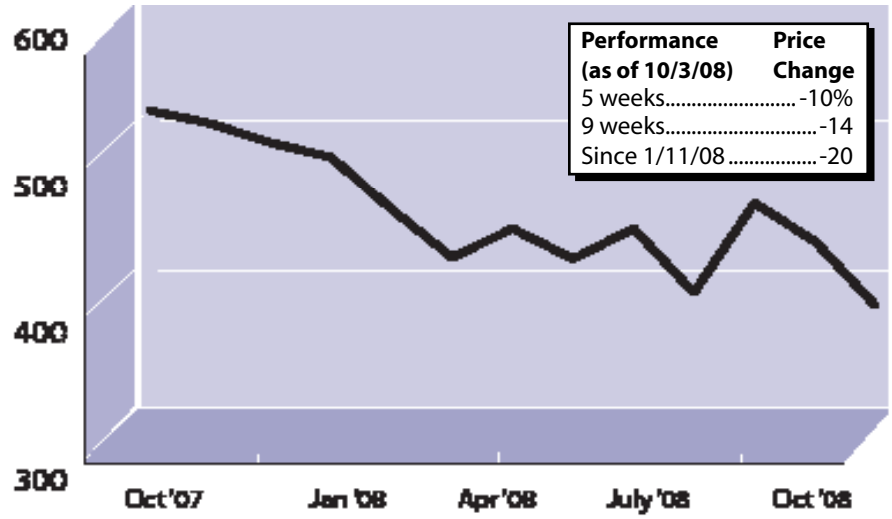
Despite strong financial results, **Immucor** (Norcross, Ga.), a maker of automated instrument-reagent systems for the blood transfusion industry, fell 6 percent, ending the period with a share price of $29.19 and a market capitalization of $1.99 billion. On October 1, Immucor announced results for its fiscal first quarter, which ended August 31. Revenue for the quarter was a record $73.2 million, up 15 percent from $63.6 million in the same period last year. The company attributed most of the revenue boost to price increases in the U.S. market, even as volume there decreased.

One of only two gainers in recent weeks was **Meridian Bioscience** (Cincinnati). The share price of the test maker managed to climb 11 percent to close at $28.24 per share with a market capitalization of $1.09 billion. Meridian recently entered into an exclusive Canadian distribution agreement with Somagen Diagnostics, Canada's largest specialty distributor of clinical laboratory products. The deal is part of Meridian's move to expand distribution outside the United States.

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

Finally, two companies in the index announced an agreement to collaborate on novel tests for early detection of solid tumor cancers. **Becton Dickinson** (Franklin Lakes, N.J.) will develop, market, and sell new biomarker-based cancer tests that use the technology of **Luminex** (Austin, Texas). BD entered the deal through its BD Diagnostics-TriPath division. The tests will use Luminex's multiplexing xMAP technology platform, which allows clinicians to conduct multiple, simultaneous tests on a single patient sample.

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
Abbott Labs	$58.51	3%
Meridian	28.24	11
Down		
Affymetrix	6.94	-15
Abaxis	17.49	-5
Beckman Coulter	68.50	-5
Becton Dickinson	80.24	-6
Bio-Rad	93.33	-9
Clinical Data	15.38	-4
Gen-Probe	49.47	-12
Immucor	29.19	-6
Inverness Medical	26.80	-20
Johnson & Johnson	66.16	-6
Luminex	21.74	-16
Nanogen	0.25	-26
Nanosphere	6.90	-18
OraSure	4.27	-12
Quidel	15.10	-14

G-2 Insider

Where sales and marketing meet diagnostic testing . . . Washington G-2 Reports' inaugural Laboratory Sales & Marketing Conference will focus on strategies to level a playing field dominated by two national labs with national marketing budgets and sales teams. Learn how to compete with the testing giants' latest aggressive moves in the clinical lab market and to respond to the new CLIA lab-driven business models that are taking the in vitro diagnostics market by storm on December 10-12, 2008, at the Hyatt Regency Scottsdale Resort & Spa at Guiney Ranch in Scottsdale, Ariz. Scheduled sessions include:

q "Selling Strategies for the Physician Market: Striking Gold with High-Value Tests," presented by W. Edward Highsmith, Jr., Ph.D., co-director of the molecular genetics laboratory at the Mayo Clinic;

q Brian Buxton, principal and co-founder of Easton Associates, will discuss "Who Will Win the Battle for Sales and Market Share: National Labs, Health System Labs, Independent Labs";

q UniPath CEO Patricia Hughey and UniPath President and Medical Director Michael Venrick, M.D., will present "Selling Pathology Services in a Competitive Market: It's All About the Bottom Line"; and

q Laboratory industry veteran Louis Tzoumbas, now general manager of LabCorp Bay Area, will discuss "Getting Real About Managed Care: What Every Sales Pro Must Know."

References

Affymetrix 408-731-5000

Alverno Clinical Laboratories 800-937-5521

Applied Biosystems 650-638-5800

ARUP 801-583-2787

Becton, Dickinson 201-847-6800

Bio-Reference 201-791-2600

CDC 800-232-4636

Cepheid 408-541-4191

CMM 616-391-4330

CMS 877-267-2323

CAP 847-832-7000

FDA OIVD 240-276-0450

Immucor 770-441-2051

Luminex 512-219-8020

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Sequenom 858-202-9000

U.S. Genomics 781-937-5550

Diagnostic Testing & Technology Report (ISSN 1531-3786) is published by Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Tel: 973-718-4700. Fax: 973-622-0595. Web site: www.g2reports.com.

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