# Diagnostic Testing and Technology Report

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



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## A Renewed Call for Mandatory Genetic Test Registry

A national mandatory registry of genetic tests is "a critical first step in the development of a more transparent, quality-centered system of oversight that will better inform and protect the public," according to the Genetics and Public Policy Center (GPPC) at Johns Hopkins University's Berman Institute of Bioethics. In a review article published in *Public Health Genomics*, GPPC staff members lay out a proposal for implementing such a registry. This proposed initiative echoes the 2008 recommendation of the Secretary's Advisory Committee on Genetics, Health, and Society, which advises the Secretary of the U.S. Department of Health and Human Services (HHS).

While genetic tests are available for more than 1,700 conditions, oversight has not kept pace with the increasing availability and complexity of such tests, GPPC staff members argue. A registry would help to address this issue by providing a universally accessible database of accurate information about genetic tests, including analytic validity, clinical validity, and clinical utility. Such a resource could aid in the decisionmaking of health care providers, payers, and patients.


For full details on the proposed registry, see *Inside the Diagnostics Industry*, p. 5.


## FDA Clears Osmetech's Cystic Fibrosis Genotyping Test

Molecular diagnostics company Osmetech (London) has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its cystic fibrosis (CF) genotyping test. The qualitative multiplex test is cleared for CF carrier screening for adults, as an aid in newborn screening for CF, and as a confirmatory diagnostic test for CF in newborns and children.

The eSensor CF genotyping test is cleared for use on Osmetech's eSensor XT-8 platform, a bench-top molecular diagnostics workstation that incorporates a microarray with electrochemical detection. Osmetech previously received FDA clearance for a CF test that was run on the eSensor 4800 system, the company's first-generation instrument.

In July 2008, the FDA cleared the XT-8 platform along with a genotyping test that can aid in the identification of patients at risk for increased warfarin sensitivity. The test detects and genotypes alleles of the cytochrome P450 (CYP450) 2C9 gene locus and the vitamin K expoxide reductase C1 (VKORC1) gene promoter polymorphism.


*Continued on p. 2*

▲ **Cystic Fibrosis Genotyping Test,** *from page 1*

Earlier this year, Osmetech applied for extended FDA clearance of its warfarin sensitivity test. The extended panel incorporates a number of additional markers, including CYP450 4F2, a biomarker that Osmetech exclusively licensed from the Marshfield Clinic (Marshfield, Wis.).

Other planned additions to the XT-8 test menu include a CYP 2C9 genotyping panel, a venous thrombosis panel (Factor V, Factor II, and MTHFR), and a respiratory virus pathogen panel. Osmetech plans to launch these tests as research-use-only products in 2009 before considering applying for 510(k) FDA clearance. Other tests in development include a CYP 2D6 genotyping panel and tests that help to assess a patient's sensitivity to the breast cancer drug tamoxifen and the anti-platelet drug Plavix.

Osmetech reported 2008 revenues of £352,069 (approximately $574,000, at current exchange rates) compared to £169,283 ($276,000) in 2007. The company attributed the 108 percent change to increased sales of the first-generation CF test as well as currency exchange rate differences.

## LabCorp to Acquire Monogram Biosciences in $155 Million Deal

On June 23, Laboratory Corporation of America (Burlington, N.C.) announced that it had agreed to acquire molecular diagnostics company Monogram Biosciences (South San Francisco, Calif.) in a deal valued at $155 million. The deal is expected to close in the third quarter of 2009.

According to the merger agreement, LabCorp will acquire all outstanding shares of Monogram in a cash tender offer for $4.55 per share, making for an implied total equity value of approximately $106.7 million, or a total enterprise value of approximately $155 million, which includes net debt. LabCorp began the tender offer on July 1.

Monogram announced at the beginning of the year that 2009 revenues are expected to increase over 9 percent to between $66 million and $70 million, which means that the price per revenue multiple could be between 2.6x and 2.2x.

Shortly after the proposed acquisition was made public, several law firms announced that they were investigating potential shareholder claims related to the deal. The investigations are focused on the potential unfairness of the deal price and of the process by which the Monogram board of directors approved the agreement. On June 30, a class action lawsuit was filed in the Superior Court of California challenging the proposed acquisition.

Founded in 1995, Monogram is best known for its pharmacogenomic tests, also known as companion diagnostics. Its Trofile assay can assist physicians in determining whether a patient with a history of HIV drug resistance will respond to the class of antiretroviral therapies known as CCR5 antagonist entry inhibitors. Launched commercially upon the U.S. Food and Drug Administration's August 2007 approval of maraviroc (domestically marketed by Pfizer as Selzentry),

Trofile is a single-cycle recombinant virus assay that directly measures tropism. Monogram has performed more than 58,000 Trofile assays.

The week before LabCorp announced its intent to acquire Monogram, Quest Diagnostics (Madison, N.J.) launched its own lab-developed test (LDT) for HIV tropism. The LDT replaces SensiTrop, the HIV tropism test that Quest offered through a license with Pathway Diagnostics before acquiring the company in December 2008. Quest expects to report results for its new HIV tropism test within seven days of receiving a patient's specimen, compared to Monogram's Trofile turnaround time of approximately 14 days.

### Key Companion Diagnostics

**LabCorp**

| *Test* | *Condition (Drug)* |
|---|---|
| KRAS | Colorectal cancer (e.g., Erbitux, Vectibix) |
| HLA-B* 5701 | HIV (Abacavir) |
| CYP450 | Adverse drug reactions (e.g., antidepressants) |

**Monogram Biosciences**

| *Test* | *Condition (Drug)* |
|---|---|
| Trofile | HIV (maraviroc) |
| PhenoSense | HIV (18 antiretrovirals, including Abacavir) |
| HERmark | Breast cancer (Herceptin) |

Monogram's portfolio also includes its PhenoSense and PhenoSense GT tests for HIV resistance. The company's oncology products include a proprietary method to assess HER-2 status in tissue samples.

Along with maintaining price and controlling costs, advancing its position in personalized medicine is a priority for LabCorp in 2009. The company has cited plans to increase esoteric testing, expand outcome improvement programs, and develop and commercialize companion diagnostics, including KRAS, human leukocyte antigen (HLA), and CYP450 testing.

LabCorp CEO David King called the Monogram deal "a significant step in the execution of LabCorp's strategy of leadership in personalized medicine." He added, "By utilizing LabCorp's national infrastructure to build on Monogram's already strong sales, we will advance our leadership in infectious disease and cancer testing, companion diagnostics, and personalized medicine."

## Nanogen Sells Assets to ELITech Group for $25.7 Million

Molecular and point-of-care diagnostics company Nanogen (San Diego) has completed the previously announced sale of its assets to diagnostics company the ELITech Group (Paris) for $25.7 million. Nanogen filed for Chapter 11 bankruptcy in May.

In August 2008, Nanogen and ELITech had announced plans to merge, but the deal to create an integrated, global in vitro diagnostics company could not be completed by the March 31 deadline.

The assets acquired by ELITech represent Nanogen's two primary businesses: the molecular diagnostic business and the point of care business. ELITech will own

and operate the molecular diagnostic business. Under a separate agreement, Bay City Capital (San Francisco), a life sciences venture fund that helped to finance the deal, will acquire the point of care business and certain license rights to the molecular diagnostic business intellectual propriety.

Founded in 1993 by CEO Howard Birndorf, Nanogen has focused on developing, manufacturing, and selling molecular testing platforms, analyte-specific reagents, point-of-care diagnostic tests, and real-time polymerase chain reaction (PCR) reagents. The company went public in 1998 and since then has accumulated more than $400 million in losses.

According to its Chapter 11 filing, Nanogen had assets of $14.7 million and debts of $41.5 million as of March 27. According to its March announcement of preliminary, unaudited financial results, Nanogen had 2008 revenues of $46.9 million, an increase of 23 percent from the prior year.

## CDC Seeks Industry Input in Establishing Laboratory Best Practices

As Congress takes aim at revamping health care, the Centers for Disease Control and Prevention (CDC) is launching an effort to establish best practices in laboratory medicine. This evidence-based initiative mirrors the comparative effectiveness research (CER)—one of the Obama administration's priorities in overhauling the health care system—that evaluates affordable health care tests and treatments to determine their advantages and disadvantages. CER was allocated $1.1 billion under the American Recovery and Reinvestment Act of 2009.

Called the Laboratory Medicine Best Practices (LMBP) project, the goal of the CDC initiative is to provide evidence-based methods that laboratory professionals can use to evaluate practice effectiveness for improving the quality of health care, to build a more robust knowledge base for the field based on the results of systematic evidence reviews, and to improve health care quality outcomes by identifying pre- and post-analytic practices that effectively improve the use of laboratory testing.

The LMBP project is an important way for laboratories to have a voice during this critical time, said Paul Epner, the project's network administrator. "Although there are no guarantees, when the laboratory profession is isolated physically and intellectually from the medical community-at-large, it is easy to be ignored," he explained. "Comparative effectiveness studies, patient-centeredness, and optimizing the delivery of care are topics that are at the center of much debate in health care. Unless laboratory services participate in the activities, they can hardly be expected to be at the table for the debate."

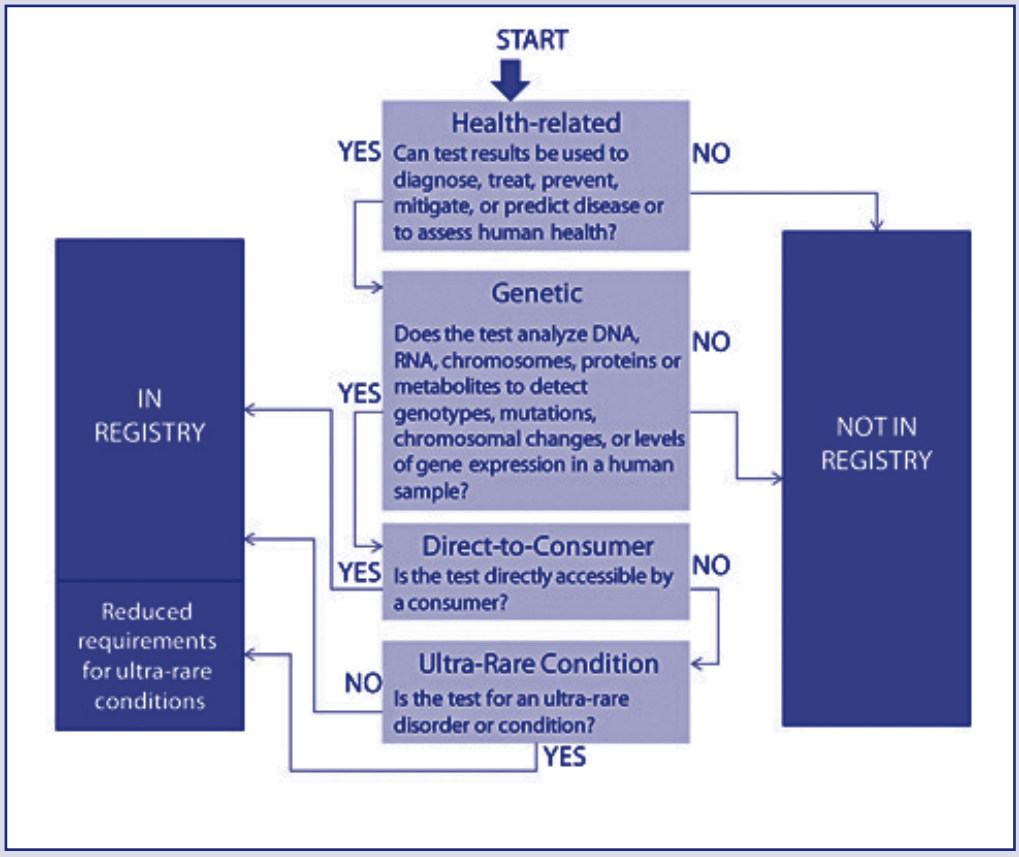
Laboratorians can register at www.futurelabmedicine.org to become engaged in the initiative's activities and to be kept informed of the progress, including the launch of the LBMP Web site. Most immediately, the CDC is looking for labs to submit unpublished data and studies related to the three topics being studied during this pilot phase: patient specimen identification errors, communication of critical laboratory test results, and blood culture contamination.

# Genetics and Public Policy Center Propose 'Blueprint' for Genetic Test Registry

The Genetics and Public Policy Center (GPPC) at Johns Hopkins University is calling for a mandatory registry of genetic tests, describing such an initiative as "a crucial first step toward increasing the quality and transparency of genetic testing." In a review published online on June 29 in *Public Health Genomics*, GPPC staff members Gail Javitt, Sara Katsanis, Joan Scott, and Kathy Hudson propose a "blueprint" for the creation of a genetic test registry in order to expedite its implementation.

***Currently there is no uniform or comprehensive system to assess the analytic and clinical validity of genetic tests before they are offered to patients, and there are no laboratory standards that specifically address molecular or biochemical genetic testing or require laboratories to enroll in proficiency testing programs that assess their ability to perform the tests correctly.***

In April 2008, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), which advises the Secretary of the U.S. Department of Health and Human Services (HHS), recommended that clinical laboratories and others offering testing services be required to submit information about a test's analytic and clinical validity to a publicly accessible laboratory test registry, the authors note. SACGHS intended for such a registry to address "information gaps in the availability of tests and their analytic and clinical validity," according to its 2008 report, and to "empower both consumers and providers by arming them with reliable information about what is known and not known about the quality and validity of tests." However, HHS has yet to act upon the SACGHS recommendation to appoint and fund a lead agency to develop and maintain the registry.




Like SACGHS, the GPPC authors support the creation of a mandatory genetic test registry, with penal-

ties for noncompliance. They anticipate that the majority of those required to register will be clinical laboratories, but the registry should also encompass companies that act as test distributors, providing information about tests and interpreting test results while outsourcing the testing itself to a clinical laboratory. Those businesses located outside the United States that test specimens from individuals in the U.S. or distribute testing services to individuals in the country should also be required to register, the authors recommend.

How broad should a test registry be? Rather than echo calls for a comprehensive registry of laboratory tests, the authors recommend limiting a registry to genetic tests (those that analyze DNA, RNA, chromosomes, proteins, or metabolites to detect genotypes, mutations, chromosomal changes, or levels of gene expression in a human sample), given the rapid growth, high stakes, and significant public health impact of this area of testing.

**Proposed Content for Registry**

- ❑ Test distributor/laboratory
- ❑ Test description
- ❑ Intended use
- ❑ Performance evaluation (validation method, reportable range)
- ❑ Analytic validity
- ❑ Clinical validity
- ❑ Proficiency testing methods
- ❑ Reporting (sample reports)

Source: Javitt et al. (2009) *Public Health Genomics*.

They further propose that the registry be limited to "health-related tests," those that are used in diagnosis, treatment, prediction, or prevention of diseases or conditions, or to assess human health. Additionally, the authors recommend that all health-related genetic tests that are offered directly to the consumer should be included in the registry.

Recognizing the low overall public health impact of genetic tests for rare disorders, the proposed registry would abbreviate submission requirements for those offering genetic tests for ultra-rare disorders. The American College of Medical Genetics' Ultra-Rare Disorders Working Group defines ultra-rare genetic diseases as those that affect fewer than 2,000 individuals in the United States.

In terms of the categories of information that should be included for such tests, the key data would reflect how reliable a test is (analytic validity), how the results relate to current and future disease risk (clinical validity), and how useful the results are in informing patient diagnosis or treatment or in disease prediction, management, or prevention (clinical utility).

Finally, the authors discuss the sources of legal authority that empower the government to mandate the creation of a registry. The federal agencies with the relevant expertise and resources to do so include the National Institutes of Health and the Food and Drug Administration (FDA). While noting that the FDA is an obvious choice for the registry's development, implementation, and enforcement the registry, "Housing the registry at FDA, however, could create unrealistic expectations on the part of the public regarding FDA's role in genetic test oversight," the authors note. "FDA for the most part does not review the safety and effectiveness of [laboratory-developed tests]."

# Only 13% of High School Students Tested for HIV, CDC Survey Finds

*At the end of 2006, an estimated 48 percent of adolescents and young adults infected with HIV were unaware of their infection.*

Only a small fraction of high school students in the United States have ever been tested for HIV, even though this age group comprises a disproportionate amount of the total undiagnosed cases, according to a study that appeared in the June 26 issue of *Morbidity and Mortality Weekly Report* (*MMWR*), a publication of the Centers for Disease Control and Prevention (CDC).

The study analyzed data from the CDC's 2007 Youth Risk Behavior Survey (the most recent data available) and found that nationwide, 12.9 percent of all high school students had ever been tested for HIV, although approximately 90 percent of high school students have been taught about AIDS or HIV.

The prevalence of HIV testing was found to increase with increasing grade and decrease with increasing age at first sexual intercourse. Prevalence of HIV testing was higher among female students (14.8 percent) than male students (11.1 percent), and higher among non-Hispanic black students (22.4 percent) than Hispanic (12.7 percent) and non-Hispanic white students (10.7 percent). The findings suggest that with respect to race and ethnicity, students with the highest group risk are getting tested at higher rates.

The report reiterated the CDC's revised guidelines for HIV testing. Issued in September 2006, the guidelines recommend routine HIV screening for patients in all health care settings, with more frequent screening for those at high risk for infection.

"High schools can enhance their HIV prevention curricula by including information on locations and procedures for obtaining free, confidential HIV testing," note the *MWWR* editors in an editorial appended to the study. "In accordance with state and local policies, school health professionals could refer at-risk students for HIV prevention, counseling, and testing services."

# Source MDx Test May Reduce False Positives in Prostate Cancer Screening

When used in combination with conventional prostate-specific antigen (PSA) screening, a blood test being developed by Source MDx (Boulder, Colo.) in collaboration with Dana-Farber Cancer Institute (Boston) can increase the accuracy of prostate cancer diagnosis and could eliminate thousands of prostate biopsies annually, according to a study led by Dana-Farber researchers.

At the 2009 annual meeting of the American Society of Clinical Oncology, William K. Oh, M.D., and Robert W. Ross, M.D., reported that the six-gene molecular diagnostic test, when combined with a PSA test, accurately detected prostate cancer more than 90 percent of the time. Previous studies suggest that the conventional PSA test is 60 percent to 70 percent accurate in detecting cancer.

The two-year study involved 484 participants: 204 men with known prostate cancer, 110 men with benign prostatic hypertrophy (BPH, which can elevate PSA blood levels), and 170 healthy men in a control group. The researchers sought to measure the accuracy of Source MDx's Precision Profile, a six-gene whole blood RNA transcript-based diagnostic test.

The study found that "the six-gene model was more accurate than PSA alone at predicting cancer if you had it and no cancer if you didn't," said Oh. The test's accuracy improved even more when PSA measurements were added. Combined, the two tests achieved a diagnostic accuracy of more than 90 percent in specificity and sensitivity, and eliminated most of the false positives yielded by the PSA test.

Based on these findings, the researchers are planning to conduct a larger, multicenter clinical trial involving approximately 1,000 men. Source MDx is in talks to license the Precision Profile test, which CEO Karl Wassmann describes as "the first of our family of prognostic, predictive, and early detection oncology tests."

## Phoenix Hospital Will Perform Molecular Test for Brain Cancer Patients

The DNA Diagnostics Laboratory at St. Joseph's Hospital and Medical Center (Phoenix) will be the sole location to perform DecisionDx-GBM, a biomarker-based test for patients that have been diagnosed with glioblastoma multiforme (GBM), the most common form of primary brain cancer. The test, which can be performed on formalin-fixed paraffin-embedded tissue, predicts patient response to first-line standard of care treatment (radiation plus temozolomide therapy).

Based on discoveries made by researchers at the University of Texas M. D. Anderson Cancer Center (Houston), DecisionDx-GBM has been further developed and validated by privately held Castle Biosciences (Friendswood, Texas), a biomarker-based cancer diagnostics company. Castle Biosciences announced that it had optioned the nine-gene expression test from M. D. Anderson in October 2008, only weeks after the company was formed.

"The data indicate that the DecisionDx-GBM assay can serve as the basis for a robust clinical test which, along with existing clinical and other molecular markers, could be used to optimize therapeutic choices for individual patients, analogous to the predictive test developed for optimization of patient therapy in breast cancer," said Howard Colman, M.D., Ph.D., a co-inventor of the assay and assistant professor of neuro-oncology at M. D. Anderson.

DecisionDx-GBM can distinguish GBM tumors that will be sensitive to treatment from treatment refractory tumors. It predicts both progression-free survival and overall survival. According to co-inventor Ken Aldape, M.D., a professor of pathology at M. D. Anderson, the test has been shown to be independent of the current clinical markers of age, Karnofsky performance status (KPS), and methylation status of MGMT, a DNA repair gene.

The test, which Castle Biosciences bills to third-party insurance, can be ordered in all states except California and New York. The company is pursuing the additional licensure required by both states.

Castle Biosciences is focused on applying personalized medicine to underserved diseases. The company plans to "identify, in-license, develop, validate, and commercialize" prognostic molecular diagnostic assays that have been developed at leading U.S. institutions. Its second targeted cancer test is expected to launch later this year.

## *JAMA* Study Links Protein to Type 2 Diabetes Risk

Higher levels of adiponectin, a protein that is produced by fat cells and that has anti-inflammatory and insulin-sensitizing properties, are associated with a decreased risk of type 2 diabetes, according to a study reported in the July 8 issue of the *Journal of the American Medical Association* (*JAMA*).

While previous studies have associated adiponectin with type 2 diabetes, the strength and consistency of the relationship was unclear. Shanshan Li, M.D., M.Sc., of the Harvard School of Public Health (Boston) and colleagues conducted a review and meta-analysis to assess the consistency of the association. The researchers identified 13 studies with a total of 14,598 participants and 2,623 new cases of type 2 diabetes.

The authors found that higher adiponectin levels were associated with a lower risk of type 2 diabetes. This inverse association was consistently observed in whites, East Asians, Asian Indians, African Americans, and Native Americans.

Recent studies have shown that adiponectin levels can be increased with drugs and lifestyle changes. "In addition, adiponectin levels may be useful for identifying persons likely to benefit most from interventions to treat 'dysfunctional adipose tissue' and its metabolic complications," noted the authors. "Future studies should also evaluate whether adiponectin is useful for prediction of type 2 diabetes in addition to established risk factors using statistical techniques appropriate for prognostic analyses."

## Lab Groups Weigh in on Health Care Reform Proposals

As Senate and House committees prepared to consider health care reform bills, the Clinical Laboratory Coalition (CLC) has been quick to pitch its priorities in the run-up to legislative action. CLC members include national lab associations, national lab companies, and device manufacturers.

In comments to Congress and the White House, the coalition urges that clinical lab testing be specifically included in any health benefits package, with no patient copay, and that incentives be provided to promote wellness and prevention programs and personalized medicine.

The health care reform debate is a rare opportunity to raise issues beyond reimbursement, says Vince Stine, Ph.D., director of government affairs for the American Association for Clinical Chemistry (Washington, D.C.). "Typically we are on the chopping block. Now, we can paint a larger picture of our role and interests in improving health care."

Mark Birenbaum, administrator of the American Association of Bioanalysts (St. Louis), agrees that health care reform is a new and challenging legislative focus for the industry. "We will be watching to see how labs fit into the proposals being considered."

Another legislative focus for the lab industry this year is to ensure that Medicare lab fees get their scheduled consumer price index update in 2010. With Congress expected to approve a Medicare physician fee increase, lab groups want to make sure that cuts are not made in Part B spending to help pay for it.

## Biomarker Can Monitor Effectiveness of Novel Brain Cancer Treatment

A protein released by dying tumor cells has been identified as an effective tool in an animal model to gauge the response to a novel gene therapy treatment for brain tumors known as glioblastoma mulitforme. The finding, reported in the July 1 issue of *Clinical Cancer Research*, paves the way for a Phase 1 clinical trial expected to begin in late 2009.

The gene therapy uses a genetically engineered, harmless virus to deliver a combination of proteins and a drug to kill tumor cells, which triggers an ongoing immune response against malignant brain tumors cells. "Using this therapy, we have shrunk and completely eliminated very large brain tumors in animals and have trained their immune systems to develop memory so that recurrent tumors are also destroyed," said Maria G. Castro, Ph.D., co-director of the Gene Therapeutics Research Institute at Cedars-Sinai Medical Center (Los Angeles) and principal investigator of the study. "The biomarker identified in this study will help us determine the effectiveness of the therapy in patients with glioblastoma multiforme."

In this study, the researchers found that a protein released by dying tumor cells may be used as a biomarker to gauge the effectiveness of treatment. This protein, called "high mobility group box 1" (HMGB1), regulates gene expression in healthy cells by binding to the cells' DNA. When cancerous cells are killed, however, HMGB1 is released into the general blood circulation. This research shows that measuring the levels of HMGB1 in the blood could be a noninvasive but essential way to monitor the effectiveness of cancer therapeutics in patients. These findings will be used to fine-tune the therapy as it enters the Phase I clinical trial.

## Psychemedics Teams With UK's Bupa to Market Hair Analysis Assay

Drug testing provider Psychemedics (Acton, Mass.) will market its hair analysis services in the United Kingdom through a recently announced agreement with Bupa Wellness, the health assessment division of one of the largest health care providers in the country. Bupa Wellness, which already offers urine and oral fluid testing, will add Psychemedics hair analysis testing services to its workplace screening programs—whether pre-employment, random, or related to specific incidents.

This expanded marketing effort comes at one of the most challenging times for Psychemedics, as the recession-related decline in employment levels—and pre-employment screening—has slowed volume growth. Results for the first quarter of 2009 revealed a 39 percent drop in revenue to $4.1 million from $5.7 million for the first quarter of 2008. Year-end results were also down for the company—revenue for 2008 was down 7 percent to $23 million compared to almost $25 million in 2007.

"There is no question that these are tough and challenging times," said CEO Raymond C. Kubacki. "However, we have been through tough and challenging times before. While the current situation may be more severe, we, nonetheless, have learned to manage our business in difficult environments. Our focus is on maintaining our profitability and positioning our company for strong long-term growth."

# IVD Stocks Fall 3%; OraSure Plummets 34%

After gaining steadily in recent months, the G-2 Diagnostic Stock Index fell an average of 3 percent in the five weeks ended July 2, with seven stocks down in price, seven up, and two unchanged. The G-2 index is up 9 percent so far this year, while the Nasdaq has gained 14 percent and the S&P is up by nearly 1 percent.

Losing more than a third of its value in recent weeks was **OraSure** (Bethlehem, Pa.). Shares in the oral fluid diagnostics company plummeted 34 percent, ending the period with a share price of $2.62 and a market capitalization of $113 million. On June 25, OraSure announced that the U.S. Food and Drug Administration (FDA) is requiring that the company perform additional clinical trials in support of its premarket approval application (PMA) for the OraQuick test for hepatitis C virus (HCV). Filed during the fourth quarter of 2008, the application seeks approval for use of OraQuick HCV with multiple specimen types, including venous whole blood, fingerstick whole blood, and oral fluid.

Further weighing down OraSure shares were reports of a manufacturing problem that has crippled production of the company's rapid test for HIV. Having depleted its test inventory, OraSure expects that the manufacturing issue will negatively impact its second-quarter numbers, including revenue and gross margin, due to higher unabsorbed production costs and scrap expenses. In the first quarter of 2009, the company reported strong sales of its OraQuick Advance HIV-1/2 test, due in part to "the successful transition of the hospital market to a direct sales model," according to President and CEO Douglas A. Michels.

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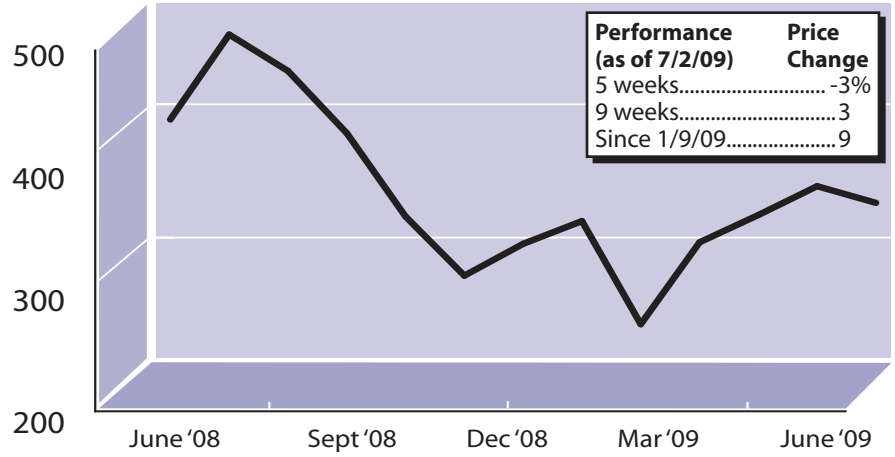
The biggest gainer in recent weeks was rapidly growing **Meridian Bioscience** (Cincinnati), which closed at $22.77 per share on July 2 with a market capitalization of $897 million. The FDA recently cleared the company's rapid test for detection of *Campylobacter*, a common bacterial cause of foodborne illness. Approximately 20 million stool culture tests are conducted each year in the United States to detect the illness, known as campylobacteriosis. Meridian's rapid immunochromatographic test provides patient results in 20 minutes.

## 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 |
|---|---|---|
| Abaxis | $19.48 | 11% |
| Abbott | 46.28 | 3 |
| Beckman Coulter | 55.52 | 1 |
| Becton Dickinson | 69.05 | 3 |
| Inverness Medical | 33.85 | 2 |
| Luminex | 17.73 | 8 |
| Meridian | 22.77 | 18 |
| **UNCHANGED** | | |
| Bio-Rad | 73.41 | 0 |
| Johnson & Johnson | 55.98 | 0 |
| **DOWN** | | |
| Affymetrix | $5.46 | -10 |
| Clinical Data | 10.56 | -11 |
| Gen-Probe | 41.54 | -5 |
| Immucor | 13.42 | -15 |
| Nanosphere | 4.33 | -15 |
| OraSure | 2.62 | -34 |
| Quidel | 14.03 | -3 |

# G-2 Insider

**How often do providers fail to inform patients of clinically significant abnormal test results?** Frequently, according to a study published in the June 22 issue of the *Archives of Internal Medicine*. A retrospective medical record review revealed that failures to inform patients or to document informing patients of abnormal outpatient test results are common, occurring in one of every 14 tests. However, the researchers found that the use of simple processes for managing results is associated with lower failure rates.

*Practices that used a combination of paper and electronic records had the highest failure rates.*

In the first study to estimate the failure to inform rate across a variety of tests and types of medical practice, researchers examined the medical records of 5,434 patients aged 50 to 69 in community-based and academic medical center primary care practices. The analysis focused on 11 blood tests and three screening tests. They also surveyed physicians at the practices about their processes for managing test results.

Of the 1,889 clinically significant abnormal results, 6 percent were not communicated to the patient, and 1 percent were communicated but not documented. Practices that scored highest for test-result management had the lowest rates of failure to inform or document. Notably, practices that used a combination of paper and electronic records, that is, that had a partial electronic medical record (EMR), had the highest failure rates, while those with either full EMRs or only paper records had similar rates. "One approach to reducing failure rates would be to rely on the efforts of individual physicians and to exhort them to try harder to notify patients," noted the authors. "Alternatively, failures to inform could be approached as a systems problem—a problem of organization and incentives—rather than as a failing of individual physicians."

## References

AACC 800-892-1400

Bay City Capital 415-676-3830

Castle Biosciences 281-796-9032

CDC 800-232-4636

Dana-Farber Cancer Institute 617-632-3000

ELITech Group 33-1-41-45-07-10

FDA OIVD 240-276-0450

LabCorp 800-526-3593

Marshfield Clinic 715-387-5511

M. D. Anderson Cancer Center 713-792-2121

Meridian Bioscience 513-271-3700

Monogram Biosciences 650-635-1100

Nanogen 877-626-6436

OraSure 610-882-1820

Osmetech 44-207-849-6027

Psychemedics 978-206-8220

Quest Diagnostics 973-520-2700

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