Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Obama Administration Seeks Data on Role of Laboratory Testing

While there has been bipartisan support for including prevention benefits in the ongoing health care reform efforts, the Obama administration is pushing for more data on how preventive screening and testing measures will affect spending, according to Neera Tanden, a senior adviser in the Department of Health and Human Services' Office of Health Reform. Tanden was speaking at a Sept. 29 press briefing at which the Lewin Group (Falls Church, Va.) released its latest report, *The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement*. The event was sponsored in part by the American Clinical Laboratory Association.

The lack of data linking laboratory screening and testing to cost savings presents "a severe challenge to make the case for prevention," said Tanden. There is concern from the administration about investing in "unproven areas," which explains the push for comparative effectiveness research in the current reform dialogue. And while the administration in no way wants to impose regulations that would stifle diagnostic testing innovation, there is a focus on reining in medical expenditures, she explained. For more on the Lewin Group report, see *Inside the Diagnostics Industry*, p. 5.

Gen-Probe to Acquire Prodesse for $60 Million

Gen-Probe (San Diego) has agreed to acquire molecular diagnostics company Prodesse (Waukesha, Wis.) for approximately $60 million in cash. The purchase price could increase to up to $85 million if Prodesse achieves certain financial and regulatory milestones over the next two years. The deal is expected to close by early November. Meanwhile, in connection with the planned acquisition, Gen-Probe and Prodesse signed an agreement under which Gen-Probe sales representatives in the United States, Canada, and Europe will begin co-promoting Prodesse's products in mid-October.

"We believe acquiring Prodesse supports our strategic focus on commercializing differentiated molecular tests for infectious diseases," said Carl Hull, Gen-Probe's president and CEO, in a statement announcing the deal.

With its assays for chlamydia and gonorrhea, Gen-Probe already dominates the U.S. market for sexually transmitted disease (STD) testing. *Cont. on p. 2*

▲ **Gen-Probe to Acquire Prodesse,** *from page 1*

The company estimates that its revenue from STD testing products will reach $186 million in 2009, accounting for approximately 64 percent of the $291 million market. Gen-Probe has also developed a molecular diagnostic test to detect high-risk strains of the human papillomavirus (HPV) and last year launched a CE-marked version of the test in Europe.

Founded to commercialize a patented methodology developed by researchers at the Medical College of Wisconsin, Prodesse operates two business units: a CLIA-certified reference laboratory and a manufacturing facility that makes its test kits and reagents available to other laboratories.

The U.S. Food and Drug Administration (FDA) recently granted Prodesse special 510(k) clearance for its ProFlu+ assay, which can correctly identify as influenza A positive specimens containing Novel 2009 H1N1 influenza virus. The real-time PCR test was cleared by the FDA in January 2008 for the detection and discrimination of influenza A virus, influenza B virus, and respiratory syncytial virus.

Prodesse's product portfolio also includes in vitro diagnostic tests for human metapneumovirus and *Clostridium difficile* and a research use only (RUO) product for *Chlamydophila pneumonia* and *Mycoplasma pneumoniae*. In April, the company submitted its parainfluenza test to the FDA for 510(k) clearance.

FDA Clears Vermillion's Ovarian Tumor Triage Test

According to the American Cancer Society, approximately 22,430 new cases of ovarian cancer will be diagnosed this year, and 15,280 deaths will be reported as a result of the disease.

The U.S. Food and Drug Administration (FDA) has cleared OVA1, an in vitro diagnostic multivariate index assay (IVDMIA) that can aid in the detection of ovarian cancer in a pelvic mass that is known to require surgery. The test was developed by Vermillion (Fremont, Calif.), the diagnostics company formerly known as Ciphergen Biosystems, in conjunction with researchers at the Johns Hopkins University in Baltimore. Quest Diagnostics (Madison, N.J.) has a three-year exclusive agreement to offer the test to the clinical reference laboratory market in the United States.

IVDMIAs are a novel class of in vitro diagnostic devices that the FDA has defined in draft guidance as combining the values of multiple variables to produce a patient-specific result intended for use in the diagnosis or treatment of a disease or other conditions. This result is "non-transparent and cannot be independently derived or verified by the end user," according to FDA draft guidance.

OVA1 is a qualitative, serum-based test that combines the results of immunoassays for five biomarkers: transthyretin, apolipoprotein A-1, beta2-Microglobulin, transferrin, and cancer antigen 125. The test uses a proprietary algorithm to calculate a single numerical score between 0 and 10 to indicate the likelihood that a pelvic mass is benign or malignant.

OVA1 is intended only for women, 18 years and older, who have already been selected for surgery because of their pelvic mass. It is not intended for ovarian cancer screening or for a definitive diagnosis of ovarian cancer.

"The test is unusual because it's really a triage test," Jon R. Cohen, M.D., Quest's chief medical officer and senior vice president, told *DTTR*. "In gynecology, there's

a pretty clear divide between OB/GYNs who are trained to do most gynecological procedures and gynecological oncologists who are specifically trained to deal with cancer," he explained. "What happens with gynecological malignancies is that if they are malignant at the time of exploration, they can frequently become very large procedures that the gynecologist is not trained to do. The real positive around the OVA1 test is the ability to triage appropriately."

The test would be requested by OB/GYNs once they have a patient worked up for a pelvic mass. "We would hope that gynecological oncologists would also request it on the referral," added Cohen.

The OVA1 test will be available for physician use in the fourth quarter of 2009. Pricing information had not been determined at press time.

CAP Proposes Three-Tiered Oversight of Lab-Developed Tests

The College of American Pathologists (CAP; Northfield, Ill.) has recommended a three-tier, risk-based approach to regulating laboratory-developed tests (LDTs). The proposed changes would encompass claims of clinical validity, as well as specifying scientific and regulatory standards to be applied to all LDTs.

"While the preponderance of laboratory-developed tests present relatively low risk to patients, the increasing use and complexity of some LDTs underscores the need for increased oversight," said CAP President Jared Schwartz, M.D., Ph.D. "CAP's risk-based model employs a public-private partnership to address oversight of these tests in an inclusive, systematic way."

The risk-based classification would be divided into three categories—low, moderate, and high. The classification would be based on claims made, potential risk to patients, and the extent to which its results could be used in the determination of diagnosis or treatment.

In addition to this proposal, CAP also recommends strengthening CLIA accreditation standards on labs using low- and moderate-risk LDTs and requiring FDA review of all high-risk LDTs.

These oversight recommendations are broader in scope than those put forth by the American Clinical Laboratory Association (ACLA), which focuses on one type of LDT: the in vitro diagnostic multivariate assay (IVDMIA). David Mongillo, ACLA's vice president for policy and medical affairs, says that the expanded scope of CAP's recommendations is cause for concern. He added that he looks forward to further discussions with the pathology advocacy group to clarify the primary differences between the groups' proposals.

CAP's proposal was released a day after Don St. Pierre, deputy director of the FDA's office of in vitro diagnostic device evaluation and safety, addressed questions about potential policy changes regarding LDTs on Sept. 24 at Lab Institute 2009.

St. Pierre emphasized that the changes in the policy are more than likely, but nothing would be implemented quickly and not without open discussions with stakeholders. "There needs to be changes, but it's a matter of figuring out what those changes need to be," he explained.

The FDA's primary focus appears not to be on traditional labs but on the small number of "outliers" who take advantage of the system in an attempt to escape FDA oversight. "The FDA has jurisdiction over medical devices, and an LDT is a medical device," said St. Pierre. "If a company decides to make a medical device, they are a medical device manufacturer. Just because you can get a CLIA high-complexity certificate does not mean that everything you do falls outside of the FDA's purview."

However, the FDA's claim to have jurisdiction over medical devices is disputed by ACLA and remains an unresolved legal issue, said Mongillo during a panel discussion that followed St. Pierre's presentation. LDTs are developed in-house for use only by that lab and the results are sold as a service, not marketed as a test kit.

ACLA contends that CLIA regulations along with standards of accrediting bodies are sufficient to ensure the quality of LDTs. If there are issues regarding clinical validity, they should be addressed through CLIA, Mongillo said, "and if necessary, strengthen the bar but do not add another layer of federal oversight, given how tightly regulated the industry already is."

CAP's Three-Tiered Approach to LDT Oversight

Classification	Determining Factors	Oversight	Examples
Low Risk	Result often used in conjunction with other findings to establish diagnosis; does not claim that result indicates prognosis or direction of therapy.	The laboratory internally performs and reviews validation prior to offering for clinical testing; the accreditor will verify that the laboratory performed appropriate validation studies during annual inspections	Cytokeratin; Fragile X
Moderate Risk	Result is often used for predicting disease progression or identifying whether a patient is eligible for a specific therapy; lab may make claims about clinical accuracy or clinical utility.	Lab must submit validation studies to the accreditor for an external review prior to offering the test clinically.	KRAS; HER2
High Risk	Result predicts risk, progression, patient eligibility for a specific therapy, and uses proprietary algorithms or computations so that results cannot be tied to the methods used, or interlaboratory comparisons cannot be made.	Lab must submit a high-risk test to FDA for review prior to offering the test clinically.	Genomic Health's Oncotype Dx

Source: College of American Pathologists September, 2009

Report Highlights Links Between Laboratory Testing and Prevention

As the Obama administration calls for additional information on how preventive screening and testing measures will affect spending, a new report highlights how such testing can improve health care outcomes. Commissioned by the American Clinical Laboratory Association and AdvaMed, *The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement* was prepared by the Lewin Group (Falls Church, Va.), the health care policy research and management consulting firm that is owned by a subsidiary of UnitedHealth Group.

The current lack of data linking laboratory screening and testing to cost savings presents "a severe challenge to make the case for prevention," explained Neera Tanden, a senior adviser in the Department of Health and Human Services' Office of Health Reform, at a Sept. 29 press briefing in Washington, D.C. The Obama administration is concerned about investing in "unproven areas," hence the push for comparative effectiveness research and focus on reining in medical expenditures, she explained.

The Lewin Group report highlights the integral role of laboratory testing in evidence-based improvements in health care and relates case studies of the economic impact of screening and diagnostic testing. Hemoglobin A1c testing for diabetes screening, KRAS mutation analysis to target colorectal cancer treatment, and human papillomavirus testing (HPV) to screen for and diagnose cervical cancer are among the case studies accompanying the report.

"Many of the benefits of laboratory testing are not being realized in the current system," note the authors, attributing this in part to the major challenges posed by payment policies that govern coverage decisions, payment rates, and coding of new tests. Of particular concern is the variable coverage among payers, particularly where novel molecular tests are concerned.

Among the most important aspects of the report is its review of the various, if historically underused, methods to assess and establish the value of laboratory tests. Among the examples cited is a cost-of-illness analysis of rapid methicillin-resistant *Staphylococcus aureus* (MRSA) testing and cost-effectiveness analysis of Factor V Leiden testing.

While the current body of evidence supporting the link between laboratory testing and improved outcomes is growing, it remains limited. "Recent debate about whether savings can be realized from greater federal investment in preventive and wellness services . . . highlights the importance of rigorous, policy-relevant demonstrations on the economic impact of laboratory testing used in screening and diagnosis," stated the report.

The report is available online at
http://www.clinical-labs.org/documents/LewinACLAValueofLabSxandDxReport.pdf

Qiagen Acquires Companion Diagnostics Firm DxS

Qiagen (Venlo, the Netherlands) has acquired DxS (Manchester, United Kingdom), a privately held developer and manufacturer of companion diagnostics, in a deal valued at approximately $95 million in cash plus up to an additional $35 million based on the achievement of specified milestones. Qiagen described the acquisition as part of efforts to step up its presence in molecular diagnostic-based prevention, profiling, and personalized medicine.

DxS, which has 80 employees, is focused on cancer diagnostics. The company offers several clinical and research kits that detect mutations in oncogenes. Its CE-marked TheraScreen line includes real-time PCR-based tests that detect mutations in the EGFR and K-RAS genes. The DxS K-RAS test is expected to be submitted to the U.S. Food and Drug Administration for regulatory approval (PMA) in 2010. Tumor mutation detection kits available for research use include those for B-RAF, PI3K, and BCR-ABL.

Qiagen's existing portfolio includes pyrosequencing-based K-RAS, BRAF, and methylation assays targeting biomarkers, as well as gene expression and miRNA assays for biomarker discovery and instrument platforms to automate these tests.

The senior management of DxS will join Qiagen as leaders of its personalized health care area. DxS's Manchester headquarters will become Qiagen's "Center of Excellence in Pharma Partnering." In addition to its product portfolio and development pipeline, DxS is involved in a range of companion diagnostic partnerships, including those with AstraZeneca, Bristol-Myers Squibb, and Boehringer Ingelheim.

FDA Clears Cepheid's Test for Thrombosis

The U.S. Food and Drug Administration (FDA) has cleared a novel molecular test that can detect Factor II (FII; prothrombin) and Factor V Leiden (FV) genetic variations associated with thrombophilia, an increased risk of blood clots, in just over 30 minutes. The Xpert HemosIL FII & FV test was developed and manufactured by Cepheid (Sunnyvale, Calif.) for use on its fully automated GeneXpert real-time PCR platform.

FVL and FII mutations are the two most common genetic risk factors for venous thromboembolism (VTE). They are present in approximately 5 percent of a heterogeneous population and 45 percent to 63 percent of the thrombophilic population.

A study published in the June 17 issue of the *Journal of the American Medical Association* was unable to establish whether testing for FVL or FII mutations improves outcomes in adults with VTE or in family members of those with a mutation.

The Xpert HemosIL FII & FV test will be distributed by Instrumentation Laboratory (IL; Bedford, Mass.). It is the first test to be commercialized under Cepheid

and IL's 2007 development and distribution agreement for hemostasis molecular diagnostic tests. IL has been exclusively distributing the test in Europe as a CE IVD mark product since March 2008.

This is Cepheid's eighth test to receive FDA clearance. In July of this year, the company received FDA clearance to market its molecular diagnostic test for detection of the bacterium that causes *Clostridium difficile* infection. Its GeneXpert test menu also includes methicillin-resistant *Staphylococcus aureus*, enteroviral meningitis, and Group B *Streptococcus*.

Axial Biotech Launches Test to Predict Risk of Scoliosis

Molecular diagnostics company Axial Biotech (Salt Lake City) has launched its first product: a saliva-based genetic test that can help predict the risk of progression of scoliosis, an abnormal lateral curvature of the spine. Known as the ScoliScore adolescent idiopathic scoliosis (AIS) prognostic test, it is being marketed to spine specialists in the United States by Johnson & Johnson-owned DePuy Spine (Raynham, Mass.).

Approximately 100,000 children are diagnosed with scoliosis every year in the United States, but less than 10 percent of patients progress to a severe curve and require spinal fusion surgery. Patients are observed over several years to determine and assess disease progression.

Performed in Axial Biotech's clinical laboratory, the ScoliScore test analyzes a DNA sample for 53 DNA markers found to be linked to the progressive form of scoliosis. Results are reported to physicians within about three weeks as a score indicating the patient's likelihood of having scoliosis that will progress. The scores are grouped into low, moderate, and severe categories. For patients shown to be at high risk for serious spinal curvature (of 50 degrees or more), physicians can intervene earlier than they would otherwise.

ScoliScore is currently indicated for AIS. An estimated 4 percent of children between the ages of 10 and 16 have the condition, making up 80 percent of all scoliosis cases. The ScoliScore test is designed for male and female patients diagnosed with mild AIS who are from 9 through 13 years of age and who are self-reported as Caucasian. The company is working to expand its use to younger children.

In developing the test over six years, Axial Biotech researchers identified scoliosis-linked DNA markers from nearly a million candidates by using a genealogic database that contains information on more than 30 million ancestors and descendants of the original Utah pioneers. ScoliScore has been validated in three studies with approximately 800 patients with AIS.

Founded in 2002 by Jim Ogilvie, M.D., Kenneth Ward, M.D., John Braun, M.D., and John Climaco, privately held Axial Biotech is focused on developing and commercializing DNA-based diagnostic and prognostic tests for common spinal disorders. The company is currently developing a predictive test for surgical outcomes for patients with degenerative disc disease.

New Immunoassay Can Rapidly Identify Active TB

A new method can rapidly identify active tuberculosis (TB) in patients with negative sputum tests, according to research from the Tuberculosis Network European Trialsgroup. The study was published in the Oct. 1 issue of the *American Journal of Respiratory and Critical Care Medicine*.

The World Health Organization estimates that approximately one-third of the world's population is infected with M. tuberculosis, the bacterium that causes TB, but only 10 percent to 20 percent of those will go on to develop active TB. The rest have latent TB infection, recently redefined as "lasting tuberculosis immune responses" or LTBI, and are at risk for developing active TB at any time.

Active TB is the seventh-leading cause of death worldwide. It can be rapidly diagnosed when the bacterium can be identified on sputum microscopy, but in about half of all cases, the TB bacterium cannot be detected.

"In this study, we showed that a differentiation between active pulmonary tuberculosis and LTBI is possible by the ELISpot test," said principal investigator Christoph Lange, M.D., Ph.D., from the Research Centre Borstel, in Germany.

The researchers found that immune cells specific to the TB bacilli are concentrated in the airways of patients with active tuberculosis. These cells could be readily identified with an enzyme-linked immunospot assay (ELISpot).

The ELISpot test can distinguish between LTBI and active TB by comparing the frequencies of TB-specific T-lymphocytes in the blood versus in the lung. Results are available within one day, while the identification of tuberculosis bacilli by culture takes several weeks.

"Because bronchoalveolar lavage (BAL) is routinely performed in this situation for other diagnostic purposes, the ELISpot does not result in an extra procedure for the patient," explained Lange.

The researchers tested 347 patients suspected of having TB but who were either unable to produce sputum or who had had three consecutive negative acid-fast bacilli sputum culture results. Of the 347 patients, 71 were diagnosed with active pulmonary TB. In patients with active TB, ELISpot results were positive in 65 cases (91.5 percent).

"These findings show us that positive result in the BAL ELISpot was highly indicative of and actual case of active TB," said Lange. "And a negative BAL ELISpot result almost excludes active tuberculosis."

Future research will aim to identify markers of treatment success that will allow patients to safely discontinue taking anti-TB medication. Added Lange, "This will be of great clinical importance to guide the treatment of individuals with LTBI and active tuberculosis, especially in cases of drug-resistant strains of *M. tuberculosis*."

Bostwick Labs Launches American International Pathology Laboratories

In September, Richmond, Va.-based anatomic pathology testing provider Bostwick Laboratories opened the American International Pathology Laboratories (AIPL), a new division staffed by 25 civilian pathologists formerly with the Armed Forces Institute of Pathology (AFIP) at the Walter Reed Army Medical Center in Washington, D.C. The new division will be based in a 30,000-square-foot facility in Silver Spring, Md.

Walter Reed's AFIP is slated for closure by 2011 under the Base Realignment and Closure (BRAC) command by the Department of Defense. It will be succeeded by the Joint Pathology Center, which "will function as the reference center in pathology for the Federal Government and will, at a minimum, provide pathology services to the military healthcare system, Department of Veterans Affairs, and other federal agencies," according to the AFIP.

The AFIP's military pathologists will be reassigned, but the civilian pathologists were facing layoffs when they approached Bostwick CEO David Bostwick, M.D., last March. "What we recognized is that this group of pathologists is absolutely superb, and they've been together for 15 years, or 30 years in some cases," said Evan Farmer, M.D., a dermatopathologist who will be the medical director of the new division. "We thought that the best idea would be to keep this talent together and marry them with the best equipment that we have and could provide them."

Bostwick's vice president of marketing, Brent Sower, declined to comment on the company's financial investment in AIPL. "We're setting up a full laboratory in Silver Spring, with full immunohistochemical capabilities and virtual pathology technology," he explained. "With the personnel and technology we are bringing on, it's clear that this is a big investment for us, but we think it's something that's going to be very successful."

The new division, AIPL, will leverage its government background, but the plan is to also bring its services into the commercial arena. Farmer is focused on highlighting the deep specialized experience of AIPL's pathology staff. "What we don't have are general pathologists who do screenings, and who will consult some things in-house, but then send out the rest," said Farmer. "All of our pathologists are focused on a single area. The pulmonary people only look at pulmonary, the cardiovascular, only look at cardiovascular organ specimens."

Bostwick's entire sales team—which currently numbers 140 representatives across various divisions and is expanding—will be selling AIPL's services. In addition, AIPL's pathologists will be accompanying the reps on sales calls. This is new for many of these pathologists who have spent their careers in government work.

This move into the commercial environment will also be one of the challenges in selling AIPL's services, noted Farmer. "From a business perspective, we need

to make people aware that we exist, explain the value of what we bring to the table that is different from other labs, which is the expertise and the synergy of these pathologists, and get that value equation out into the commercial world and get the specimens in," he added.

HHS Proposes Covering HIV Screening Tests for High-Risk Medicare Beneficiaries

On Sept. 9, the Department of Health and Human Services (HHS) announced a new proposal that would cover HIV infection screening for Medicare beneficiaries who are at increased risk for the infection, as well as women who are pregnant and Medicare beneficiaries of any age who voluntarily request the service.

According to the announcement, the efforts by HHS's Centers for Medicare and Medicaid Services (CMS) mark the first time that Medicare has proposed to expand its list of covered preventive services under a new authority established by Congress. The Medicare Improvements for Patients and Providers Act of 2008 gave CMS the ability to consider whether Medicare should cover "additional preventive services," if certain requirements are met.

In the document, the Medicare agency said it proposes to cover HIV screening with a Food and Drug Administration-approved enzyme immunoassay (EIA), enzyme-linked immunosorbent assay (ELISA), or rapid HIV antibody test for certain populations at risk.

CMS said it will issue a final coverage decision by Dec. 8.

New Rules Protect Patients' Genetic Information

Individuals' genetic information will have greater protection through new regulations issued Oct. 1 by the departments of Health and Human Services, Labor, and the Treasury. The interim final rule is designed to help ensure that genetic information is not used adversely in determining health care coverage and to encourage more individuals to participate in genetic testing.

The rule implements Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA). Under GINA, group health plans and issuers in the group market cannot increase premiums for the group based on the results of one enrollee's genetic information, deny enrollment, impose pre-existing condition exclusions, or do other forms of underwriting based on genetic information. In the individual health insurance market, GINA prohibits issuers from using genetic information to deny coverage, raise premiums, or impose pre-existing condition exclusions.

HHS also issued a notice of proposed rulemaking that would modify the Health Insurance Portability and Accountability Act (HIPAA) privacy rule to prohibit health plans from using or disclosing genetic information for underwriting purposes.

IVD Stocks Up 1%; OraSure Gains 13%

The G-2 Diagnostic Stock Index is up for the third consecutive month, having gained an average of 1 percent in the five weeks ended Oct. 2, with nine stocks down in price and seven up. The G-2 index is up 32 percent so far this year, while the Nasdaq has gained 30 percent and the S&P has gained 15 percent.

OraSure Technologies (Bethlehem, Pa.) climbed 13 percent to close at $2.93 per share with a market capitalization of $153 million. The oral fluid diagnostics company recently announced that it had signed a new 36-month contract for its rapid HIV test with the group purchasing unit of the Premier health care network. Effective Nov. 1, the agreement provides Premier's more than 2,200 member hospitals with prenegotiated pricing and terms for the purchase of OraSure's OraQuick Advance test, which detects antibodies to HIV-1 and HIV-2 in 20 minutes. The point-of-care test has been approved by the U.S. Food and Drug Administration and is CLIA-waived for most specimen types.

Losing ground after steady gains fueled by the outbreak of 2009 pandemic influenza A (H1N1) were **Quidel** (San Diego) and **Becton Dickinson** (Franklin Lakes, N.J.), which each manufacture rapid antigen tests for the detection of various types of influenza. Shares in both companies fell 4 percent to close at $15.61 and $67.30, respectively.

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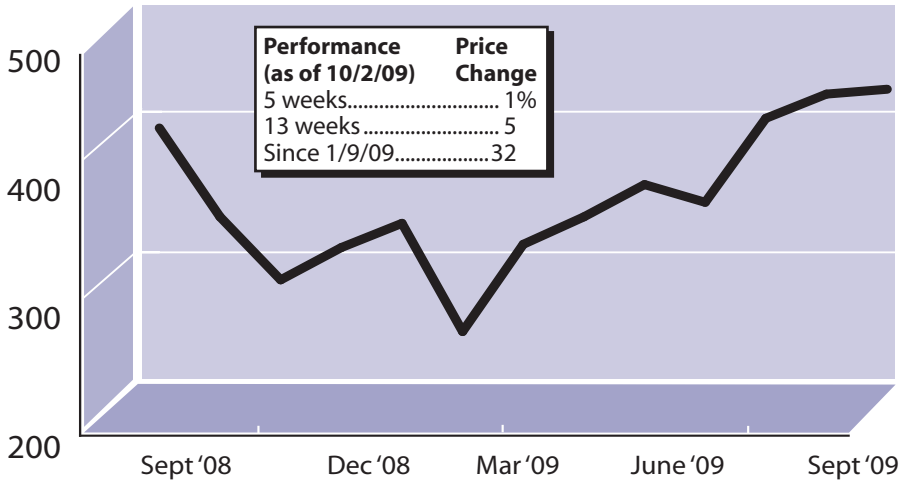
In late September, the Centers for Disease Control and Prevention published another study concerning the higher rates of false negatives with a rapid flu test than with tests that relied on reverse transcription-polymerase chain reaction. "The low sensitivity and low negative predictive value of the test during these outbreaks highlight the limitations of using this test alone to establish diagnosis and aid clinical management," wrote the editors of *Morbidity and Mortality Weekly Report* in a note accompanying the study. "These results affirm current recommendations not to use negative [rapid influenza diagnostic test] results to rule out pandemic H1N1 or to make infection control decisions."

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
Abbott Labs	49.84	9%
Bio-Rad	89.20	2
Clinical Data	16.50	6
Gen-Probe	40.67	7
Inverness Medical	38.74	5
Luminex	16.74	9
OraSure	2.93	13
DOWN		
Abaxis	$25.84	-3
Affymetrix	8.40	-2
Beckman Coulter	66.66	-3
Becton Dickinson	67.30	-4
Immucor	17.72	-1
Johnson & Johnson	59.73	-1
Meridian	24.01	-2
Nanosphere	6.61	-16
Quidel	15.61	-4

G-2 Insider

New gene finding can help predict breast cancer metastasis . . . The gene KLF17 is involved in the spread of breast cancer, according to a study published online on Oct. 4 in *Nature Cell Biology*. Researchers at the Wistar Institute (Philadelphia) found that KLF17 acts to suppress the spread of tumor cells. They also demonstrated that expression of KLF17 together with another gene known to regulate breast cancer metastasis can accurately predict whether the disease will spread to the lymph nodes.

After using a mouse model and RNA interference technology to single out KLF17 from a pool of thousands of candidate genes, the researchers set out to determine whether KLF17 played a similar role in human breast-cancer metastasis. To do so, they reduced (or "knocked down") KLF17 expression in a tagged human-breast-cancer cell line and then transplanted those cells—along with a control group still expressing KLF17—into the mammary fat pads of mice. Within eight to 10 weeks, lung metastases developed in the KLF17-deficient cells, whereas the control cell set did not metastasize, demonstrating that knockdown of KLF17 expression also promotes the spread of human breast-cancer cells.

In a related study, the researchers found that the Id1 gene was up-regulated in KLF17 knockdown cells and down-regulated in KLF17 overexpressing cells, making the combined expression pattern of KLF17 and Id1 a potential biomarker for lymph node metastasis in breast cancer. Previous studies have found that Id1 is deregulated in various types of cancers and is important in the development of embryonic stem cell–like phenotypes in cancer cells. Ongoing studies are further examining KLF17 and ways to activate its tumor suppressing functions.

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