Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Molecular Labs Rise to H1N1 Flu Testing Challenge

As the world braces for a strong reemergence of novel H1N1 influenza, community-based molecular pathology laboratories are being credited for developing and deploying diagnostic tests capable of rapidly detecting and confirming suspected cases of H1N1 flu when reports of the novel strain emerged in April.

At a meeting of the Clinical Laboratory Improvement Advisory Committee on Sept. 1, Jan Novak, M.D., Ph.D., president of the Association for Molecular Pathology (AMP), presented the results of an informal survey of 43 AMP member laboratories conducted during the first week of the H1N1 outbreak. The survey found that 93 percent of the respondents had a molecular assay that could detect and distinguish influenza type A from type B. More than one-third (36 percent) of the laboratories surveyed reported having the capability to distinguish the novel H1N1 strain from seasonal H1 strains.

"By the end of the first week of the H1N1 episode, our own laboratory had identified 39 cases of probable H1N1 infection, only a fraction of which had been corroborated by our state public health laboratory, and confirmed only sometime after day eight," said Nowak, who directs the molecular diagnostic laboratory at Northshore University Health System near Chicago. For more on flu testing, see *Inside the Diagnostic Industry*, p. 5.

Thermo Fisher to Acquire German IVD Company for $470 Million

Thermo Fisher Scientific (Waltham, Mass.) has agreed to acquire German diagnostics company BRAHMS (Hennigsdorf, Germany) for €330 million, approximately $470 million at current exchange rates. Privately held BRAHMS develops, manufactures, and markets specialty tests based on its patented biomarkers. The deal is expected to close in late September.

Founded in 1994, BRAHMS generated 2008 revenues of €75 million (approximately $105 million) with an EBITDA of €15 million (approximately $21 million). The company has around 400 employees and is jointly owned by senior management and private equity firm HBM Partners (Zug, Switzerland).

BRAHMS is focused on diagnostics for sepsis, cancer, fertility, prenatal screening, and thyroid diseases. Its development pipeline is focused on novel biomarkers for bacterial infections, cardiovascular disease, and neurological disorders.

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The company is best known for its procalcitonin (PCT) tests for diagnosis of sepsis. A proprietary biomarker, PCT has been shown to increase rapidly and specifically in response to bacterial infection and sepsis. It is used widely in Europe for early diagnosis of sepsis as well as treatment monitoring. Since 2005, the U.S. Food and Drug Administration has cleared multiple versions of BRAHMS's PCT test, including an automated version for use on the BRAHMS Kryptor platform.

According to Marijn E. Dekkers, president and chief executive officer of Thermo Fisher, BRAHMS assays and instruments will complement Thermo Fisher offerings while its pipeline offers valuable opportunities to commercialize novel diagnostic tests. "In addition, the company gives us a significant reagent manufacturing footprint in Europe," noted Dekkers. "This acquisition reinforces our strategy of building on our leadership in niche specialty diagnostics markets."

BRAHMS will become part of Thermo Fisher's $1.3 billion specialty diagnostics business within its analytical technologies division. The German firm will also form the core of Thermo Fisher's planned European Center of Excellence for its clinical diagnostics businesses. The center is expected to be based at the current BRAHMS headquarters.

Abbott Partners with Pfizer for Lung Cancer Test

Abbott Molecular (Des Plaines, Ill.), the molecular diagnostics business of Abbott Laboratories, has made a deal with Pfizer (New York City) to develop a companion diagnostic that would identify lung cancer patients that would benefit from a candidate drug for the disease.

Abbott will focus on developing a molecular test that can identify the presence of gene rearrangements in non-small cell lung cancer (NSCLC) tumors. The test will be used in patient selection for future clinical trials of Pfizer's candidate drug, PF-02341066.

The oral therapeutic belongs to a class of drugs known as c-met/hepatocyte growth factor receptor (HGFR) tyrosine kinase inhibitors. To be eligible to receive it, a particular genetic translocation that is found in NSCLC tumors and a variety of other cancers, but not in normal cells, must be present.

Pfizer is currently preparing to recruit patients for a Phase 2 trial that will evaluate the safety and efficacy of PF-02341066 in patients with advanced NSCLC with a specific gene profile involving the ALK gene.

Medicare to Limit Coverage of Warfarin Response Testing

Medicare will not cover warfarin response testing unless the beneficiary is in a randomized clinical trial that meets specific guidelines, the Centers for Medicare and Medicaid Services (CMS) has announced.

In a recent final decision, CMS concluded there was not enough evidence to show that pharmacogenomic testing of two different alleles (gene variants) to

predict responsiveness to the anticoagulant drug improves health outcomes in Medicare beneficiaries. Thus, it "is not reasonable and necessary," two criteria for coverage.

The final decision, effective Aug. 3, endorses the warfarin coverage policy that CMS proposed in May for public comment.

Warfarin, marketed most commonly as Coumadin, is a self-administered oral blood thinner. Although widely prescribed, the drug is difficult to dose, due to its narrow therapeutic window. The optimal dose varies and depends on many risk factors including a patient's diet, age, and the use of other medications. Dosage and administration of warfarin must be individualized for each patient according to the particular patient's prothrombin time (PT)/ international normalized ratio (INR) response to the drug.

Warfarin affects the vitamin K-dependent clotting factors, including the C1 subunit of the vitamin K epoxide reductase (VKORC1) enzyme complex and is metabolized by cytochrome P450 (CYP) enzymes in liver cells. Genetic variation in the CYP2C9 and/or VKORC1 genes can, in concert with clinical factors, predict how each individual responds to warfarin.

In its final decision regarding warfarin response testing, CMS left the door open to reconsider based on further evidence development. The agency noted that a clinical study seeking Medicare payment for testing of CYP2C9 or VKORC1 gene variants must compare "the frequency and severity of major and minor hemorrhaging, different thrombolic events, and mortality to patients whose warfarin therapy management does not include pharmacogenomic testing."

In August 2007, the United States Food and Drug Administration (FDA) approved updated labeling for Coumadin to explain that people's genetic makeup may influence how they respond to the drug. Specifically, people with variations in CYP2C9 and VKORC1 may need lower warfarin doses than people without these genetic variations. FDA-cleared kits suitable for testing for VKORC1 and CYP2C9 variants include those manufactured by Nanosphere, AutoGenomics, ParagonDx, Osmetech, and TrimGen.

AlliedPath's New CLIA Lab to Focus on Solid Tumor Testing Services

Taking a page out of neighbor Genoptix's playbook, AlliedPath (San Diego) is launching a specialized pathology testing business, focusing on solid tumor molecular diagnostic testing. The company received CLIA certification from the State of California in late August.

AlliedPath offers molecular tests for disease characterization and therapeutic monitoring of patients who have been diagnosed with lung and colon cancers. In the United States, approximately 365,000 new cases of these cancers are reported every year to the National Cancer Institute.

"There's much more to offering specialized molecular diagnostic testing services than just generating a result."

The founders and leaders of AlliedPath have deep roots in the diagnostic testing industry. One of the company's founders and chief medical officer, Philip Ginsburg, M.D., is the former medical director at Quest Diagnostics and former senior medical director at Gen-Probe. Robin Vedova, AlliedPath's chief business officer, is also a former Gen-Probe executive. Another founder is molecular diagnostic leader Daniel Farkas, Ph.D., who is currently the vice president of clinical diagnostics at the Sequenom Center for Molecular Medicine (Grand Rapids, Mich.).

AlliedPath's leaders are focused on forming partnerships with hospital-based and independent labs and pathology practices that do not offer their specialized services, as well as provide clinical trial testing services. "We are focused solely on solid tumor molecular diagnostics," said Ginsburg. "Therefore, we remain noncompetitive with those companies who we perceive to be our customers and partners, including anatomic pathology labs that are either hospital-based or independent labs."

Like Genoptix, AlliedPath is looking to set itself apart from the national labs by providing superior customer service, including personalized reports. "Our ability to personalize the reports differentiates us from the larger, national labs that are really good at assembly-line testing, but not that great on executing in this specialized testing market," said Ginsburg. There's much more to offering specialized molecular diagnostic testing services than just generating a result.

This personalization starts at the requisition stage, explained Vedova. AlliedPath's user-friendly requisition form offers testing recommendations based on the physician's desired outcome for the patient—such as disease characterization or therapeutic monitoring. "Then we give the physician the recommendation in a language that he or she can understand, rather than technical language from the laboratory," she added.

AlliedPath also promises a quick turnaround time. "Within 72 hours, the physician will have a preliminary report that is actionable," said Vedova.

JAMA Study Links Gene Variant to Liver Disease in Cystic Fibrosis

A genetic variant makes people with cystic fibrosis (CF) much more likely to develop severe liver disease, according to a study published in the Sept. 9 issue of the *Journal of the American Medical Association* (*JAMA*).

An international team of researchers found that CF patients who carry a particular allele of the SERPINA1 gene (also known as alpha-1-antitrypsin or alpha-1-antiprotease) are five times more likely to develop cirrhosis and other liver complications than patients who carry the normal version of the gene.

According to Jaclyn R. Bartlett, Ph.D., the lead author of the study, risk factors such as the SERPINA1 Z allele will allow clinicians to identify CF patients who may be predisposed to develop liver disease. The researchers are now searching for genetic modifiers associated with other complications of CF, including lung disease, intestinal obstruction, and diabetes.

Amid Signs of Increased Flu Activity, IVD Industry Builds Test Portfolio

Although doctor visits for influenzalike illness are down from April 2009, they were higher than usual over the summer months and increased in early September, the Centers for Disease Control and Prevention (CDC) reported recently. Almost all of the influenza viruses identified were the new 2009 H1N1 influenza A virus. While the CDC continues to closely monitor key flu indicators, the diagnostic industry is focused on further developing its portfolio of flu tests.

In late August, Prodesse (Milwaukee) announced that reactivity testing completed by the company had confirmed that its real-time PCR-based ProFlu+ test can correctly identify as influenza A positive specimens containing novel 2009 H1N1 influenza virus. The testing was conducted on cultures of clinical isolates confirmed as 2009 H1N1 influenza virus using the CDC's real-time RT-PCR assay.

Prodesse President and CEO Tom Shannon noted that his company has seen a spike in ProFlu+ orders over the past several months. "We have been extraordinarily busy due to this outbreak," he said. "And our order volumes have increased dramatically."

Prodesse's ProFlu+ test was cleared by the U.S. Food and Drug Administration (FDA) in January 2008 for the detection and discrimination of influenza A virus, influenza B virus, and respiratory syncytial virus. Despite the results of the recent reactivity testing, Prodesse cautions that the clinical performance characteristics of ProFlu+ with H1N1 flu specimens have not been established and that it cannot differentiate influenza subtypes.

Meanwhile, Cepheid (Sunnyvale, Calif.) is fast-tracking the development of a real-time PCR-based flu test for use on its automated GeneXpert System. The test will draw upon work the company completed on a previous influenza project supported through a 2007 contract with the Department of Health and Human Services (HHS) and the CDC.

Cepheid's test will be designed to provide rapid identification of influenza A infection, with specific identification of seasonal H1, seasonal H3, and H1N1 novel strain types. Results should be available within 45 minutes, according to the company.

Cepheid will request that FDA consider its test for emergency use authorization (EUA). The company expects to receive authorization for use during the upcoming flu season and to begin shipping tests beginning in January 2010. The company also plans to make the test available in Europe as a CE-marked product.

Looking ahead, Cepheid plans to further expand its flu panel test by adding additional target identification for influenza B. The company plans to submit a separate 510(k) submission for that product in 2010.

Draft Report Puts Lab-Developed Tests Back in Federal Spotlight

The quality and regulation of laboratory-developed tests (LDTs) is back in the federal spotlight in a new report released Aug. 18 by the Agency for Healthcare Research and Quality (AHRQ) for public comment through Sept. 8.

The draft report is a "horizon scan" summarizing available scientific evidence on the quality of "home brew" or "in-house" molecular tests that are not actively regulated by the Food and Drug Administration and that include molecular tests of potential clinical relevance to the Medicare over-65-year-old population as of Oct. 31, 2008.

The Centers for Medicare and Medicaid Services requested the study to help address its concerns over molecular tests used for diagnostic purposes in symptomatic individuals, as prognostic indicators, to monitor response to therapy, and to select therapies for a known disease entity or adjust medication dosing.

The AHRQ assigned the study to the ECRI Institute Evidence-based Practice Center. The authors cautioned that the findings are their own and do not necessarily reflect the views of the AHRQ.

The study catalogs more than 1,400 molecular tests relevant to the Medicare population offered by 95 different laboratories, identifies the methods and processes developed to assess the analytical and clinical performance of molecular tests, and summarizes the federal regulatory role and quality standards developed by the industry and the medical community.

The report uses the term "molecular test" interchangeably with "molecular genetic test." It also adopts the definition of molecular genetic test recommended by the Clinical Laboratory Improvement Advisory Committee: "an analysis performed on human DNA or RNA to detect heritable or acquired disease-related genotypes, mutations, or phenotypes for clinical purposes."

Excluded from the report are molecular tests used primarily for blood supply screening, tissue typing, epidemiological surveillance, pure research, and forensic purposes. Tests used to screen the pediatric population for inherited diseases of metabolism or other conditions (e.g., screening tests for cystic fibrosis) are also outside the scope of this report.

Regulation of LDTs remains highly controversial within the lab industry. Earlier this year, biopharmaceutical giant Genentech (now part of Roche) and AdvaMed, the trade group representing test manufacturers, separately petitioned the FDA to require that LDTs meet the same premarket review requirements that apply to commercial test kits.

The American Clinical Laboratory Association and the College of American Pathologists oppose the petitions, arguing that CLIA oversight is sufficient to ensure the quality and safety of LDTs and that CMS should play the lead regulatory role with the FDA serving in a consultative capacity.

FDA Clears Luminex's New Cystic Fibrosis Test

The U.S. Food and Drug Administration (FDA) has granted Luminex (Austin, Texas) 510(k) clearance to market a new version of its molecular diagnostic test for cystic fibrosis (CF). The newly cleared test, which can detect 39 CF-causing gene mutations, can be used for carrier screening as well as newborn screening and in confirmatory diagnostic testing in newborns and children. This test is not intended for standalone diagnostic purposes, prenatal diagnostic, preimplantation, or population screening.

CF is a chronic inherited genetic disease caused by mutations in the CF transmembrane conductance regulator (CFTR) gene. More than 1,500 such mutations have been identified to date. According to the Cystic Fibrosis Foundation, more than 10 million Americans are symptomless carriers of a CFTR gene mutation. Approximately 70,000 people worldwide, 30,000 of whom live in the United States, have cystic fibrosis.

Known as the xTAG Cystic Fibrosis 39 Kit v2, the test is an enhanced version of Luminex's xTAG Cystic Fibrosis Kit, which was first cleared by the FDA in May 2005. The newly cleared test can screen for the 23 CFTR gene mutations and four polymorphisms recommended by the American College of Medical Genetics (ACMG) and American College of Obstetricians and Gynecologists (ACOG), and 16 additional CFTR gene mutations. Results are available within a few hours.

The test allows physicians the ability to select the CFTR gene mutations for which they want to test: the 23 ACMG/ACOG-recommended gene mutations or the entire panel of 39 CFTR gene mutations. Additionally, like the first-generation test, the newly cleared test does not require reflex testing.

The test was CE marked in Europe in June along with Luminex's xTAG Cystic Fibrosis 71 Kit v2, which can screen for all of the mutations in the xTAG Cystic Fibrosis 39 Kit v2 plus an additional 32 mutations including those that are typically found in specific ethnic populations.

Gen-Probe Moves Forward with Molecular Test for Prostate Cancer

Gen-Probe (San Diego) has begun a clinical trial intended to secure U.S. regulatory approval of a new molecular test that may help determine the need for a repeat prostate biopsy. Known as Progensa PCA3, the test has already been granted the CE mark for use in the European Union.

PCA3, a prostate-specific gene, is highly overexpressed in prostate tumors. The Progensa PCA3 test uses transcription-mediated amplification to quantify the PCA3 mRNA in a patient urine sample. The resulting output is a PCA3 score that can be used in conjunction with other patient history to more accurately predict biopsy outcomes.

The clinical study is expected to conclude within a year, after which Gen-Probe intends to submit a premarket approval application (PMA) to the U.S. Food and Drug Administration. The company anticipates the trial will enroll approximately 500 men, all of whom have had a negative prostate biopsy, at 10 or more clinical trial sites.

According to the American Cancer Society (ACS), prostate cancer is the second most common type of cancer found in American men (behind skin cancer), and the second-leading cause of cancer death in men (after lung cancer). The ACS estimates that more than 192,000 Americans will be newly diagnosed with prostate cancer in 2009, and that more than 27,000 men will die from the disease.

Clarient Takes Aim at Genomic Health's Oncotype DX

The competitive field of breast cancer prognostic assays continues to add players—all taking aim at the market current's leader, Genomic Health's widely reimbursed Oncotype DX. The newest entry is from Clarient (Aliso Viejo, Calif.), which recently launched Clarient Insight Dx, a test that uses a combination of pathology risk factors and molecular markers to categorize patients as either high or low risk.

This new test is being positioned as a companion to Clarient's current test offerings that analyze molecular markers such as ER, PR, and HER2, explained Raaj Trivedi, the company's vice president of marketing. "Unlike with Genomic Health, our clients are already sending their samples to Clarient for basic breast cancer testing," he explained. "Now when they want to know about the risk for recurrence, we can address that question and they don't need to send it to another lab who may need to rework some of these markers." Another key difference is that the Insight test is run on a formalin-fixed, paraffin-embedded sample, while some other assays require fresh sample.

Trivedi also touts the value of Insight's pathway-based analysis. The assay analyzes the estrogen pathway to determine risk of breast cancer recurrence. "In addition to analyzing that estrogen pathway, we assess whether there are any other major alterations that could circumvent what's going on with the estrogen pathway," he explained. "Even though the estrogen pathway might appear intact, there could be some major genetic alterations that are kicking this tumor into overdrive that have nothing to do with the estrogen pathway."

A foundation of Clarient's sales strategy for the test is targeting current customers who have ordered the Oncotype DX test in the past but for some reason are no longer ordering it. Many of his clients report being frustrated by the lack of explanation behind the scoring methodology of Oncotype DX, and Trivedi believes that Insight's technology addresses these concerns. "We are using immunohistochemistry and FISH technologies, while they are using a set of PCR-based technologies," he said. "We are using technologies that oncologists and pathologists are very familiar with, and we present a report that includes pathway analysis and what is going on with the pathway supporting the score. So we feel that we have a bit more transparency to our assay."

The turnaround time for the Insight Dx test is five to seven days, which is similar to another competitor—Agendia's MammaPrint test. The Amsterdam-based company recently opened a new 3,500-foot CLIA lab in Huntington Beach, Calif. Turnaround time for the MammaPrint test is typically seven days. However, at the current estimated retail price of $3,200, Clarient's price point is lower than that of Agendia's $4,200 MammaPrint.

While the Oncotype DX is widely reimbursed by insurers, Agendia's test is only reimbursed by a handful of insurers. Clarient is working with insurers, and officials are confident that they will receive favorable reimbursement. "We use existing technology to do the testing—a microarray using immunohistochemistry and FISH, which CMS has reimbursed in the past, and we believe will be a strong point for us in getting the reimbursement that we need," said Trivedi.

In addition to reimbursement, the company is also pursuing clearance by the U.S. Food and Drug Administration (FDA). Currently, Insight Dx falls under the agency's in vitro diagnostic multivariate assay draft guidance. The MammaPrint test is cleared by the FDA; Oncotype DX is not.

Trivedi declined to discuss volume or growth projections for the test, but he does believe growth will be bolstered by continued clinical validation. "One of the studies that we have going on right now is hopefully going to be our FDA submission data set," said Trivedi. "We are already processing samples, and as we strengthen the data behind the test, we believe our volumes will continue to ramp up accordingly."

Quest Makes Swine Flu Test Kit Available to High-Complexity Laboratories

On August 20, Quest Diagnostics (Madison, N.J.) announced that the test developed by its Focus Diagnostics subsidiary for detection of the 2009 H1N1 influenza virus is now available in kit form for use by high-complexity clinical laboratories in the United States.

In July, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the test. It is the third test to be authorized under an EUA by the FDA since the public health emergency involving H1N1 was declared on April 26.

The Focus Diagnostics Influenza H1N1 (2009) Real-Time Reverse Transcription Polymerase Chain Reaction (rRT-PCR) diagnostic test qualitatively detects 2009 H1N1 influenza viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, and nasal aspirates from patients with signs and symptoms of respiratory infection. Focus began performing the test in its Cypress, Calif., laboratory in May.

In an EUA issued on July 24, the FDA authorized Focus to distribute the test to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity tests. An amended EUA reflected labeling clarifications regarding the contents of the test kit.

Focus's test is the first commercial test to be granted an EUA for testing for the 2009 H1N1 flu virus. The FDA previously granted the Centers for Disease Control and Prevention (CDC) two EUAs for diagnostic tests.

Lab Groups Aim to Defeat Medicare Copay Proposal

With multiple moving parts in play on health care reform legislation, the clinical lab industry is lobbying hard to defeat a proposal in the Senate that would require a 20 percent copay for Medicare Part B lab services. The lab copay, repeatedly rejected by lawmakers in the past, has resurfaced as the Senate Finance Committee struggles to write a draft reform bill.

The copay is one option to help finance broader health system changes, saving Medicare an estimated $24 billion over 10 years, according to the nonpartisan Congressional Budget Office.

The 26-member Clinical Laboratory Coalition (CLC) has told Finance Committee leaders that it would oppose any reform bill that includes the copay, arguing that it adds new costs for senior citizens and for labs. The coalition includes leading clinical lab and pathology professional associations, national and regional labs, and test manufacturers and distributors.

The American Clinical Laboratory Association, a coalition member, reiterated objections to the copay in an Aug. 31 statement. "The result is not a cost savings to our health care system, but rather a staggering new $24 billion cost-shift to seniors, as well as adding billions more in administrative costs to laboratories," said ACLA president Alan Mertz.

"The cost of billing seniors could equal or exceed the 'savings' reaped from charging the co-insurance on many tests," he noted. For the majority of the top 100 lab procedures, the copay is less than $2, according to the CLC.

Mertz also warned that "the copay would put many small local labs that serve seniors in nursing homes and rural areas out of business, leaving some of the most vulnerable seniors without access to needed tests."

The anti-copay campaign was significantly strengthened when the AARP came out against any new out-of-pocket costs for seniors, said Vince Stine, government affairs program director for the American Association for Clinical Chemistry. "This definitely plays to our benefit," he told Washington G-2 Reports.

At press time, lab groups were set to meet with Obama administration officials to explain why the copay is bad policy and to brief them on Medicare cuts that labs have already absorbed. This year, labs got a fee hike for the first time in five years but face a projected cut of 1.9 percent next year. According to the CLC, "Medicare payments via the fee schedule have been reduced by about 40 percent in real (inflation-adjusted) terms. The annual fee update has been eliminated in 10 of the last 12 years, and over the past 21 years, clinical labs have only received five full updates."

IVD Stocks Gain Another 4%; Bio-Rad Climbs 13%

The G-2 Diagnostic Stock Index gained an average of 4 percent in the five weeks ended Sept. 4, with 11 stocks up in price, four down, and one unchanged. The G-2 index is up 31 percent so far this year, while the Nasdaq is up 28 percent and the S&P is up 14 percent.

The strongest performer of the period was **Bio-Rad Laboratories** (Hercules, Calif.), which gained 13 percent to close at $87.20 per share and a market capitalization of $2.41 billion. The company recently reported quarterly sales of $427.2 million, a decrease of 5.6 percent on a reported basis versus the same period last year. However, when controlling for currency fluctuations, year-over-year sales grew 3.5 percent.

Clinical diagnostics accounted for $274.3 million of Bio-Rad's quarterly sales, a decline of 4.5 percent on a reported basis in comparison to 2008 but representing year-over-year sales growth of 5.8 percent on a currency-neutral basis. In a call with analysts and investors, Chief Financial Officer Christine Tsingos singled out blood virus, quality control, and blood typing products as particularly strong sellers.

Shares in **BD** (Becton, Dickinson, and Co.; Franklin Lakes, N.J.) climbed 8 percent, ending the period at a share price of $62.82 and a market capitalization of $16.54 billion. In early September, the company received a significant order from the Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Department of Health and Human Services for the purchase of consumables such as syringes and needles to be used in national flu pandemic preparedness efforts. BARDA is authorized to purchase approximately $52 million of products from BD through March 2010.

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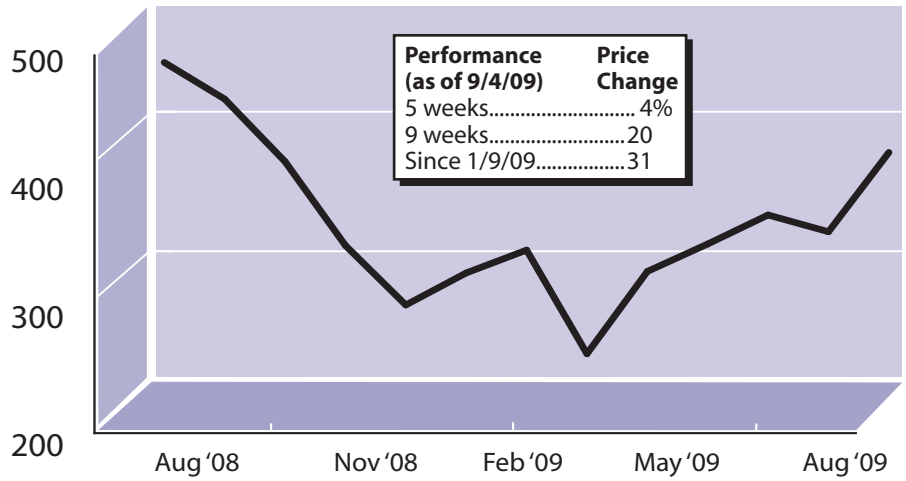
Losing ground in recent weeks was **OraSure** (Bethlehem, Pa.). Shares in the oral fluid diagnostics company fell 8 percent to close at $2.60 with a market capitalization of $116 million. The company recently reported lower than expected quarterly sales that it attributed to a manufacturing issue related to its OraQuick HIV test. Having corrected the issue, OraSure has resumed full-scale manufacturing of OraQuick.

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	$45.63	1%
Beckman Coulter	69.01	10
Becton Dickinson	62.82	8
Bio-Rad	87.20	13
Clinical Data	15.50	5
Gen-Probe	37.96	2
Immucor	17.92	8
Inverness Medical	36.79	9
Meridian	24.46	11
Nanosphere	7.89	12
Quidel	16.21	9
Unchanged		
Johnson & Johnson	60.32	0
Down		
Abaxis	26.63	-1
Affymetrix	8.55	-3
Luminex	15.36	-13
OraSure	2.60	-8

G-2 Insider

Study points to microRNA-based test for oral cancer . . . MicroRNAs, single-stranded RNA molecules that regulate gene expression, are showing promise as early markers of oral squamous cell carcinoma (OSCC), according to a study published in the Sept. 1 issue of *Clinical Cancer Research*.

The average five-year survival rate for OSCC is about 50 percent. "Shockingly, this number has not changed in last three decades," note the study's authors. "Therefore, an early detection method for OSCC is needed to increase long term patient survival."

Researchers at the University of California, Los Angeles School of Dentistry measured levels of microRNAs, single-stranded RNA molecules that regulate gene expression, in the saliva of 50 patients with OSCC and 50 healthy control patients. They detected approximately 50 microRNAs. Two specific microRNAs, miR-125a and miR-200a, were present at significantly lower levels in patients with oral cancer than in the healthy controls.

While the study's findings need to be confirmed by a larger and longer analysis, a salivary microRNA profile could one day serve as a noninvasive and rapid diagnostic tool for the diagnosis of oral cancer. Saliva analytes such as proteins and DNA have previously been used to detect OSCC, which is the sixth most common cancer.

"It is a holy grail of cancer detection to be able to measure the presence of a cancer without a biopsy," said Jennifer Grandis, M.D., professor of otolaryngology and pharmacology at the University of Pittsburgh School of Medicine and Cancer Institute. "So it is very appealing to think that we could detect a cancer-specific marker in a patient's saliva."

References

Abbott Molecular 224-361-7800
ACLA 202-637-9466
AHRQ 301-427-1364
AlliedPath 858-768-5360
Becton, Dickinson 201-847-6800
Bio-Rad 510-724-7000
BRAHMS 49-3302-883-0
CAP 847-832-7000
CDC 800-232-4636
CMS 877-267-2323
Clarient 949-425-5700
FDA OIVD 240-276-0450
Genomic Health 650-556-9300
Gen-Probe 858-410-8000
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