Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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CDC Study Highlights Limitations of Rapid Flu Tests

The April outbreak of novel influenza A (H1N1) virus sent sales of rapid influenza diagnostic tests (RIDTs) soaring, but a new study by researchers at the Centers for Disease Control and Prevention (CDC) highlights the low to moderate sensitivity of these tests compared to those that use real-time reverse transcription polymerase chain reaction (rRT-PCR). The three commercially available and widely used RIDTs evaluated in the study succeeded in detecting novel H1N1 between 40 percent and 69 percent of the time.

Although a positive RIDT result can be used in making treatment decisions, a negative result does not rule out infection with the novel H1N1 virus, concluded the study, which was published in the Aug. 7 issue of the CDC's *Morbidity and Mortality Weekly Report*. A guidance document on RIDTs issued by the CDC in July advised laboratories performing RIDTs to add a statement about the test limitations in the report of results, so that the physician can decide how best to use the test for patient management.

For more on this story, see *Inside the Diagnostics Industry*, p. 5.

FDA Clears Response Biomedical RSV Test

On July 24, the U.S. Food and Drug Administration (FDA) cleared for marketing the rapid test for respiratory syncytial virus (RSV) manufactured by Response Biomedical (Vancouver). The test will be marketed and sold exclusively by 3M Health Care (St. Paul, Minn.), which launched a medical diagnostics division last year as part of a partnership with Response.

The most common cause of bronchiolitis and pneumonia in children under one year of age in the United States, RSV can cause infections of the upper and lower respiratory tracts. Each year, 75,000 to 125,000 children in this age group are hospitalized due to RSV infection.

The 3M Rapid Detection RSV test is a qualitative immunochromatographic assay that is cleared for use on the automated 3M Rapid Detection Reader (Response's RAMP 200 Reader) to detect the presence of RSV F-protein antigens in nasopharyngeal swab, nasopharyngeal aspirate, or nasal wash specimens. Test results are available in 15 minutes. *Continued on p. 2*

▲ **AACC Plays Host To Record Crowd,** *from page 1*

3M Health Care plans to introduce the test in the upcoming RSV season, noted Response Biomedical CEO S. Wayne Key. RSV infections generally occur in the United States from November to April.

The RSV test will be 3M Health Care's second diagnostic product. In 2008, the company began marketing the 3M Rapid Detection Flu A+B Test, which was also developed by Response for use on the RAMP platform. The flu test was cleared by the FDA in April 2008.

In late 2006, Response formed a strategic alliance with 3M to commercialize rapid infectious disease tests worldwide. The company's cardiovascular tests are marketed and sold through a partnership with Roche Diagnostics. The RAMP cardiovascular product line includes NT-proBNP, troponin I, CK-MB, and myoglobin tests.

ASCP Board of Registry, NCA Agree to Form Single Certification Agency

In an agreement effective Oct. 23, two national credentialing organizations will form a single certification agency for medical laboratory personnel, called the ASCP Board of Certification (BOC). The agreement was announced by the Board of Registry (BOR) of the American Society for Clinical Pathologists (ASCP) and the National Credentialing Agency for Laboratory Personnel (NCA). When it takes effect, the NCA will be dissolved as a corporation.

Current and active certifications will be transferred to the new agency; no examinations will be required for the transfer. Medical technologists (MT) and clinical laboratory scientists (CLS) will get a new title: medical laboratory scientist (MLS). The designation will be MLS(ASCP).

Kathleen Becan-McBride, MT(ASCP), BOR chair, said the agreement to come together "will increase the credibility of the clinical lab profession when advocating on legislative and regulatory issues. Also, a single credential and single standard of qualification will simplify entry into the profession for new graduates, and employers will find it easier to set standards for entry-level competency that will ensure patient safety."

The board of governors of the new agency will be composed of five ASCP fellows (pathologists), five ASCP lab professionals, four representatives of the American Society for Clinical Laboratory Science, two representatives of the Association of Genetic Technologists, eight representatives from the eight participating societies respectively, and one public representative.

Quest Gets FDA Emergency Use Authorization for H1N1 Flu Test

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the 2009 H1N1 influenza test developed by Focus Diagnostics, a subsidiary of Quest Diagnostics (Madison, N.J.). The laboratory-

developed test is the third to be authorized under an EUA by the FDA since the public health emergency involving the 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. Use of the test is authorized only for the duration of the declaration of emergency, which is currently set to expire on April 26, 2010.

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. One EUA allows the CDC to distribute the uncleared and unapproved rRT-PCR 2009 H1N1 flu panel to public health and other qualified laboratories. This EUA was later amended to allow additional types of respiratory specimens to be tested and to allow different test components to prevent shortages. A second EUA allowed these same changes to be made to the FDA-cleared CDC rRT-PCR flu panel, which is used as the first-tier test for patient specimens with suspected 2009 H1N1 virus infection.

The FDA has not cleared or approved any tests for the identification of the 2009 H1N1 influenza virus. EUA authority allows the agency to authorize the use of unapproved or uncleared medical products or unapproved or uncleared uses of approved or cleared medical products following a determination and declaration of emergency, provided certain criteria are met.

Beckman Coulter Acquires Olympus's Lab-Based Dx Business for $780 Million

Beckman Coulter (Fullerton, Calif.) has completed its acquisition of the laboratory-based diagnostics business of Olympus (Tokyo), marking the Japanese giant's exit from clinical diagnostics after nearly four decades.

Beckman Coulter paid approximately 76 billion Japanese yen ($780 million) in cash, funded by the proceeds of two $250 million senior note offerings and a common stock offering comprised of approximately 4.7 million shares.

Announced in February, the deal gives Beckman Coulter a business that consists mainly of automated chemistry analyzers and automated blood transfusion systems. In 2008, the Olympus laboratory-based diagnostics division generated revenue of approximately $540 million.

Olympus has explained the divestment as stemming from "the presence of several large existing competitors, an increase in M&A activity, and the entry in recent

years of significant new players from other industries [that] have created a new competitive environment in this market segment."

Beckman Coulter President and CEO Scott Garrett sees the deal as creating valuable opportunities for cross-selling, "the most compelling being promotion of Beckman Coulter's immunoassay products to the loyal base of Olympus' chemistry customers."

OIG Report Recommends CMS Set New Rates for Clinical Lab Fee Schedule

The Centers for Medicare and Medicaid Services (CMS) should request legislative authority to institute a new process for setting "accurate and reasonable" payment rates for clinical diagnostic laboratory tests, the Department of Health and Human Services Office of Inspector General (OIG) recommended in a report issued July 10.

Titled *Variation in the Clinical Lab Fee Schedule*, the report said that if CMS continues to use its two current methods for updating the Clinical Laboratory Fee Schedule (CLFS), "variation that does not reflect actual costs will remain and possibly increase over time."

The OIG found that variation affected nearly all lab tests: In 2007, 97 percent of lab tests had at least one carrier (payment processor) rate that varied from the national limit amount or NLA. The NLA was mandated by a 1985 law that capped carrier rates.

However, the report said that most carrier rates were at the NLA, and the majority of lab test utilization was for lab tests paid at the NLA. Using data from 2007, OIG reported that the existing variation did not appear to reflect geographic differences in cost. Instead, the variation originated from the methods used to establish and update the CLFS. Variation of rates across carriers meant that some carriers—Medicare payment processors—paid different amounts for the same lab test.

Medicare Part B covers most outpatient clinical diagnostic laboratory tests and pays 100 percent of their costs. According to the report, lab tests accounted for 3 percent of all Medicare Part B payments in 2007.

Each laboratory submits claims to the Medicare carrier responsible for the area in which the laboratory is located. These carriers process Medicare Part B payments in 56 carrier localities that correspond mostly with state borders. Each carrier establishes its own fee schedule rate, collectively known as the CLFS, according to the report.

Looking ahead, the report noted that by 2011, the 56 carrier localities are scheduled to be replaced by 15 Medicare administrative contractor (MAC) jurisdictions. "However, MACs will not consolidate payment policies. MACs will continue to administer the same payment policies used in each of the 56 carrier localities."

CDC Finds Rapid Tests May Miss Cases of Novel H1N1 Flu

The low sensitivity of rapid influenza diagnostic tests (RIDTs) means that a negative result does not rule out viral infection, cautioned a preliminary study published in the Aug. 7 issue of *Morbidity and Mortality Weekly Report*.

Researchers at the Centers for Disease Control and Prevention (CDC) evaluated three commercially available RIDTs using 65 clinical respiratory specimens that had previously tested positive either for novel influenza A (H1N1) or for seasonal influenza A (H1N1) or A (H3N2) viruses by real-time reverse transcription polymerase chain reaction (rRT-PCR). They found that while the RIDTs were capable of detecting novel A (H1N1) virus from respiratory specimens containing high levels of virus, the overall sensitivity was low (40 percent to 69 percent) among all specimens tested and declined substantially as virus levels decreased.

Although the RIDTs were capable of detecting novel A (H1N1) virus from respiratory specimens containing high levels of virus, the overall sensitivity was low (40 percent to 69 percent) and declined substantially as virus levels decreased.

For the 45 specimens that had tested positive for novel influenza A (H1N1) by rRT-PCR, the BinaxNOW Influenza A&B test, manufactured by Inverness Medical Innovations (Princeton, N.J.), exhibited a sensitivity of 40 percent. The Directigen EZ Flu A+B test from Becton, Dickinson (Franklin Lakes, N.J.) had a sensitivity of 49 percent, and the QuickVue Influenza A+B test from Quidel (San Diego) detected 31 of the 45 positive samples, for a sensitivity of 69 percent.

The study found that sensitivity of the RIDTs was generally greater for seasonal influenza A (H1N1) and (H3N2) than for novel influenza A (H1N1), although the number of specimens tested was small. Compared with rRT-PCR, the three tests demonstrated sensitivity ranging from 60 percent to 80 percent for seasonal A (H1N1) and from 80 percent to 83 percent for seasonal A (H3N2).

According to a guidance document issued by the CDC in July, factors that might contribute to a lower sensitivity for influenza laboratory tests to detect novel influenza A (H1N1) virus infection include the type of respiratory specimen, quality of the specimen, time from illness onset to specimen collection, the age of the patient, time from specimen collection to testing, and the storage and processing of the specimen prior to testing.

The findings published in *MMWR* are in line with other recent studies reporting that the sensitivity of some RIDTs to detect novel influenza A (H1N1) in clinical specimens ranged from 10 percent to 51 percent. "Overall, the findings in this report demonstrate that these RIDTs are capable of detecting novel influenza A (H1N1) in respiratory specimens, but that many infections will be missed, especially in specimens with low viral titers," said an editorial note that accompanied the report.

Although the editors advise that the results of the study be viewed as preliminary, they conclude that "all results from RIDTs, both positive and negative, when used for clinical decisionmaking in a patient with suspected novel influenza A (H1N1) virus infection, should be interpreted in the context of circulating influenza virus strains in the patient's community, level of clinical suspicion, severity of illness, and risk for complications."

Electronic Health Records Not Ready for Genetic Data

Three-fourths of the health care providers interviewed felt that current EHR systems did not meet their needs for genetic/genomic medicine.

Electronic health record (EHR) systems will need new structure, standardization, and functionality if they are to help integrate genetic information into health care, according to a recent survey of key stakeholders. Led by Maren Scheuner, Ph.D., of RAND Corp. (Santa Monica, Calif.), the study appears in the July issue of *Genetics in Medicine*, the journal of the American College of Medical Genetics.

Researchers conducted telephone interviews with a total of 56 medical geneticists, genetic counselors, primary care physicians, and EHR vendors and specialists regarding the present and future role of EHRs in storing and using genetic information. The responses indicated that state-of-the-art EHRs lack the features needed even to record genetic information in a systematic way, much less use it in medical decisionmaking.

While current EHR systems provide space for information on the patient's family history, there were limitations on how the information could be entered and used. For example, few systems provided clinical decision support to help physicians assess the risk of genetic diseases or provide treatment alerts based on the family history. Systems also varied in the way they handled the security of genetic test results.

Three-fourths of the health care providers interviewed felt that current EHR systems did not meet their needs for genetic/genomic medicine. At the same time, most perceived little to no demand for such capabilities from health care providers. The EHR vendors supported this view. When it came to genetic content, they felt their customers wanted "just the basics."

Top Barriers and Challenges Relating to Integration of Genetics Content into EHRs

- ❑ Time and resources required to enter family history, interrupts workflow, and lack of reimbursement to gather and input family history (reported by 55% of 56 respondents)*
- ❑ Getting complete and accurate family history, concerns about patient-entered data, and reconciling conflicting family history (39%)
- ❑ Clinicians do not understand how to use family history (30%)
- ❑ Privacy concerns, concerns regarding genetic discrimination, and duty to warn at-risk relatives (29%)
- ❑ Lack of demand for genetics content in EHRs (25%)

* Participants could provide more than one response.

Source: Scheuner et al. *Genetics in Medicine* 11(7). July 2009.

Most participants thought that genetic/genomic medicine had yet to have much impact on health information technology and EHRs. However, many felt that genetic information would significantly affect patient care within the next decade, including such areas as risk assessment and management, disease prevention, and personalized medical care. They also thought that EHRs had the potential to affect the delivery of genetic/genomic medicine—for example, in managing genetic information, aiding medical decisionmaking, the use of genetic services, and promoting genetic research.

"However, basic requirements must be addressed by EHR products before they can effectively facilitate adoption of genetic/genomic information," the authors concluded. The study helps identify key areas for improvement of EHRs in recording and displaying family history, documenting and organizing genetic tests and results, providing support for physicians' decisionmaking, and addressing the privacy and security of genetic information.

Urine Test for NGAL Can Predict Kidney Damage

According to studies published online on July 23 in the J*ournal of the American Society of Nephrology* (*JASN*), a laboratory test for urine neutrophil gelatinase-associated lipocalin (NGAL) can help predict if patients will develop acute kidney injury (AKI), a frequent complication in intensive care patients. "As a stand-alone marker, urine NGAL performed moderately well in predicting ongoing and subsequent AKI," noted T. Alp Ikizler, M.D., senior author of one of the studies.

The other *JASN* study indicates that urine NGAL may also help in diagnosing HIV-related nephropathy affecting African Americans and black Africans. "NGAL was very specifically expressed in renal cysts—generating the new idea that NGAL may control the development of cysts in HIV-associated nephropathy," said Jonathan Barasch, M.D., Ph.D., senior author the second study.

NGAL, a protein, is a novel early marker for acute renal injury. Unlike belated and unreliable markers of injury, NGAL levels are raised in the urine within hours after the occurrence of a renal insult, allowing physicians to rapidly initiate treatment.

In the ICU study, patients with higher urine NGAL levels were more likely to develop AKI, even after adjustment for other factors. The increase in NGAL was present before any change in serum creatinine level, the standard test for AKI. Without other information, however, urine NGAL was no more effective in predicting AKI than clinical risk factors. Ikizler notes the study was limited by a lack of information on incidence of death or the need for dialysis and by a lack of information on the patients' initial kidney function level.

In the HIV study, levels of urine NGAL were much higher in patients with HIV-associated nephropathy (HIVAN) than in patients with other forms of kidney disease, with or without HIV.

Studies in mice suggested that NGAL may play an important role in the development of tubular disease and microcysts, which are specific features of HIVAN. Barasch noted that the human component of their study was limited by its small size but highlighted the need for larger studies that definitively measure the NGAL monomer. "If our results are confirmed, measuring urine NGAL might help triage patients into different risk categories," he added.

In September 2005, BioPorto Diagnostics (Gentofte, Denmark) launched an ELISA kit for the detection of NGAL. The company later introduced a rapid (one-hour) version of the kit for early diagnosis of acute renal failure in cardiac surgery, nephrotoxicity, and kidney transplants. The CE-marked kit measures NGAL in urine, plasma, and serum. In 2008, the European Patent Office approved BioPorto's application to patent the cutoff levels needed to distinguish between the larger NGAL rises that indicate kidney injury and the smaller rises that can be due to other conditions.

Through an exclusive licensing agreement with Cincinnati Children's Hospital Medical Center and Columbia University, Biosite (San Diego) has also developed a test for NGAL. Its Triage NGAL test is a point-of-care fluorescence immunoassay that can rapidly quantify NGAL in whole blood or plasma. The CE-marked test is not currently available in the United States.

Study Examines Cost-Effectiveness of UGT1A1 Testing

In 2005, the U.S. Food and Drug Administration (FDA) approved the Invader molecular assay developed by Third Wave Technologies, a UGT1A1 genotype test to help identify patients with a greater risk for decreased UDP-glucuronosyltransferase activity.

A study led by scientists at Weill Cornell Medical College (New York City) examines the cost-effectiveness of uridine diphosphate glycosyltransferase 1A1 (UGT1A1) testing in metastatic colorectal cancer patients. The molecular test can be used to identify specific mutations that affect response to the chemotherapy drug irinotecan (Camptosar). The study will appear in the Sept. 1 issue of *Cancer*.

Using a computer model based on the Medicare payer perspective, the researchers followed hypothetical patients treated with irinotecan for metastatic colorectal cancer. The model assumed that under usual care, patients received a full dose of the drug. With genetic testing, irinotecan dosage was reduced 25 percent in individuals identified using the genetic test as having the UGT1A1*28 variant allele.

"We observed that incorporating UGT1A1*28 testing into the clinical management of patients who have metastatic colorectal cancer treated with irinotecan may result in lower overall medical costs and higher quality-adjusted life expectancy," noted the authors. However, the results depended on treatment efficacy. "That is, if treatment efficacy is not fully maintained after the FDA-recommended dose reduction of irinotecan, then testing will not be a cost-effective alternative."

"Cost-effectiveness evaluations . . . allow us to define in economic terms the value of additional comparative effectiveness research," said Bruce Schackman, M.D., senior author of the study. "In this case, we've determined that further research of up to $22 million should be conducted to study the risks and benefits of dose reductions based on the results of the genetic test."

High Levels of Circulating Blood Cells Linked to Cancer in Children

Endothelial progenitor cells may play a role in the start and progression of metastatic disease in children with cancer, according to a study published in the July 15 issue of *Clinical Cancer Research*. Researchers found that levels of the cells were significantly increased in cancer patients, particularly those with metastatic disease, compared to healthy volunteers.

Researchers at Institut Gustave Roussy (Villejuif, France) measured circulating mature endothelial cells and bone marrow-derived endothelial progenitor cells in pediatric patients with solid tumors. They collected blood from 23 patients with localized disease, 22 patients with metastatic disease, and 20 healthy participants and measured subsets of circulating cells.

While the researchers were not surprised to detect circulating endothelial cells and endothelial progenitor cells in pediatric patients, they were surprised to find these cell levels were significantly higher in patients with metastatic disease, compared to levels found in healthy participants.

"This implies that these endothelial cells most likely play a role in the development of cancer in children," said researcher Françoise Farace, Ph.D., senior author of the study. "We also observed a large range of cell levels in patients with various tumor types. In some cases, very high levels were observed, which means that their role may be very important." Additional studies are needed in larger study populations to confirm that endothelial progenitor cells are implicated in metastasis. If confirmed, these cells could be measured to allow for early detection of metastatic disease and could be targeted by new drugs to prevent the spread of cancer.

ViraCor Labs Merges with IBT Labs to Create Specialty Diagnostic Company with Deep Esoteric Test Menu

Specialty testing providers ViraCor Laboratories and IBT Laboratories have announced plans to merge their operations to offer infectious disease, immunology, and allergy disease testing services through a single company.

"As both of our businesses continued to grow and we saw potential opportunities, it was really a natural fit between immunology and infectious disease testing," said John Martin, president of ViraCor (Lee's Summit, Mo.), a molecular diagnostic testing provider previously focused on infectious disease testing. "I think we were both at a point where we felt that our strengths were better together, as we begin to pursue an aggressive growth pattern."

The combined companies will have a total of over 200 employees, about half of whom work in the laboratory, either on the clinical side or through the companies' pharmaceutical research business. The companies' two laboratory facilities total approximately 60,000 square feet. While neither company would disclose financial details of the merger, Martin said that the combined annual volume is expected to exceed 400,000 samples processed in 2009, and the companies are expected to service more than 4,000 clients throughout the United States.

In the near future, the companies will continue to market themselves under their individual names, said Martin. "For the time being, we will go to market under both names, with the intent on exposing clients to the respective offerings of the full laboratory capabilities," he explained. "Over time, we will evaluate naming and branding strategies."

In recent years, both companies had found themselves moving into the other's specialty area. Nine-year-old ViraCor was beginning to look at offering cellular tests to complement their molecular offerings, explained IBT Laboratories (Lenexa, Kan.) President Maureen Loftus. "Over time, physicians are going to want not only to know the levels for certain pathogens, but from a cellular perspective, [whether] the body functioning appropriately," she explained. "Conversely, IBT has been very strong on the immunology and pathogenic-based cellular tests, and we started to add molecular offerings to complement the molecular offerings. As we started to converge on what ViraCor was doing, we thought that we could get there a lot faster if we were to combine forces."

Moving forward, the primary focus of the short-term growth strategy will be repackaging a comprehensive test menu for physician specialists, who make up part of each company's individual client base, many of whom might not be aware of the other company's test offerings. The focus of long-term growth will be offering a broad-based menu of molecular and cellular immunology testing services.

Both companies have sold primarily to reference and hospital-outreach laboratories, although, of course, it is physicians who are ordering the tests. Nevertheless, Loftus sees continued partnership possibilities. "I think that there is a significant amount that the combined companies offer that the national labs do not," she explained. "But I think it's still very complementary for the national labs to partner with us."

Micronics Receives NIH Grants for Point-of-Care Test Development

Point-of-care test developer Micronics (Redmond, Wash.) has been awarded two grants from the National Institutes of Health (NIH) to further the development of its rapid molecular diagnostic tests for infectious disease. Totaling approximately $1.2 million, the grants will fund research of novel methods for detecting mother-to-child transmission (MTCT) HIV and emerging respiratory infections.

A phase-two Small Business Innovation Research grant from the National Institutes of Health (NIH) will provide approximately $770,000 over two years for the continued development of Micronics' rapid molecular diagnostic infectious disease platform for MTCT HIV. In phase-one studies, Micronics and collaborators at the Centers for Disease Control and Prevention (CDC) demonstrated that the sensitivity of Micronics' cartridge-based test was acceptable to qualitatively detect HIV-1 DNA in infected individuals. During the second phase, Micronics will perform preclinical studies to confirm the assay's limit of detection and compare it with current test methods.

On Aug. 3, Micronics announced its receipt of a second NIH grant. Totaling approximately $440,000, the Small Business Technology Transfer grant is for the development of a rapid method for nucleic acid detection of known and emerging respiratory infections. The grant advances the combined use of two novel molecular diagnostic platforms to detect pathogens at low level and in a point-of-care test format. Micronics will undertake this research in collaboration with the Seattle Children's Research Institute.

Lab Coalition Urges Senators to Reject Medicare Lab Copay

The Clinical Laboratory Coalition (CLC) has registered its "strongest opposition" to implementation of a copayment for Medicare lab services and told key senators it would oppose any measure that includes this proposal. The 26-member coalition is objecting to the 20 percent Part B lab copay proposed by the Senate Finance Committee, saying it is a financial burden to both beneficiaries and laboratories.

In a July 31 letter to Finance Committee Chairman Max Baucus (D-Mont.) and ranking Republican Charles Grassley (Iowa), the coalition noted that Congress has rejected this idea in the past and urged them to reject the lab copay as a "financing mechanism" for health care reform.

Beneficiaries currently are subject to no copay or deductible for Part B-covered lab services. Imposing a copay would shift $23 billion in new costs to beneficiaries, the CLC said, and labs would be required to absorb the costs of billing and collecting the copay. It frequently costs more to collect the copay than the expected copay amount. For the majority of the top 100 lab procedures, the copay is less than $2.

The copay would "contribute to already unacceptable cuts in payment for lab services" and impede advances in promising areas of lab medicine, the coalition concluded. Medicare payments for lab services 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 15%; Affymetrix Surges 66%

Riding a market rally and reports of stronger than expected quarterly financial results, the G-2 Diagnostic Stock Index gained an average of 15 percent in the five weeks ended Aug. 7, with eight stocks down in price, six up, and two unchanged. The G-2 index is up 25 percent so far this year, while the Nasdaq has gained 28 percent and the S&P is up by nearly 13 percent.

The biggest gainer in recent weeks was **Affymetrix** (Santa Clara, Calif.), which ended the period with a share price of $9.07 and a market capitalization of $623 million. On July 22, the GeneChip maker announced operating results for the second quarter. Revenue was down slightly to $81.6 million, as compared to $86.9 million in the second quarter of 2008. However, the company swung to a profit, reporting a net income of $7.3 million, or 11 cents per diluted share. This compares to a net loss of $3.6 million, or 5 cents per diluted share, in the same period last year.

In a conference call with investors and analysts, Affymetrix CEO Kevin King emphasized the company's ongoing efforts to diversify by entering markets such as validation and routine testing. "We believe these high-growth markets are less constrained by research funding and are more likely to generate recurring revenue streams," said King. Approximately 15 percent of the company's second-quarter revenue was derived from sales to the validation and routine test markets, up from the low single-digits a year ago.

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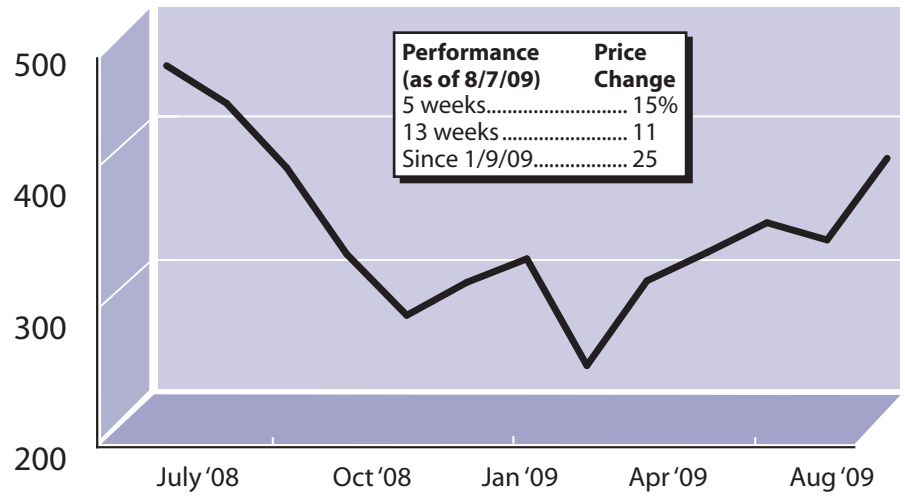
Also soaring on strong quarterly numbers was **Abaxis** (Union City, Calif.). Shares in the point-of-care blood test manufacturer gained 42 percent, ending the period with a share price of $27.61 and a market capitalization of $606 million. For the fiscal quarter ended June 30, Abaxis reported revenues of $29.6 million, up 21 percent as compared with $24.6 million for the comparable period last year. While medical sales in North America were down, overall sales of consumables climbed 40 percent to $20.9 million, boosted in part by the company's distribution agreement with Abbott's point-of-care business.

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	$27.61	42%
Affymetrix	9.07	66
Beckman Coulter	66.28	20
Bio-Rad	83.61	14
Clinical Data	14.45	37
Immucor	17.26	29
Johnson & Johnson	59.90	7
Nanosphere	6.93	60
Unchanged		
OraSure	2.63	0
Quidel	14.02	0
Down		
Abbott	43.84	-5
Becton Dickinson	64.42	-7
Gen-Probe	38.05	-8
Inverness Medical	33.21	-2
Luminex	15.67	-12
Meridian	21.16	-7

G-2 Insider

Prepare for sweeping changes in health care at Lab Institute 2009

Join Washington G-2 Reports for its 27th annual Lab Institute, Sept. 23-25 at the Crystal Gateway Marriott in Arlington, Va. This year's program, "Advancing in the Eye of the Storm," examines fundamental realignments in politics, Medicare and health care reform policy, and personalized medicine on the eve of a historic overhaul of the American health care system. At this year's Lab Institute, you will:

- ❑ Hear from keynote speakers including Newt Gingrich and Rep. Pete Stark (D-Calif.) on the future of health care policy and the latest from Capitol Hill;
- ❑ Go inside the boardroom and hear what the lab industry's top CEOs are saying about what's ahead for the lab and diagnostics industries;
- ❑ Learn about the Obama administration's take on the regulatory process and how it's influencing Food and Drug Administration policy on lab-developed tests;
- ❑ Improve your bottom line and reduce your risk with two intensive half-day workshops on Breaking Down the Barriers to EMR Interoperability and Legal Hot Spots for Labs and Pathologists; and
- ❑ Gain insight into the next generation of diagnostics that unites laboratory testing and products in bold new ways.

View the complete conference program at *www.g2reports.com/labinstitute09*. To register, call John Watkins at 800-401-5937 ext. 4710 or e-mail johnwatkins@ioma.com.

References

Abaxis 510-675-6500
Affymetrix 408-731-5000
Beckman Coulter 800-742-2345
Becton, Dickinson 201-847-6800
BioPorto Diagnostics 45-4529-0000
Biosite 858-805-8378
CDC 800-232-4636
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