Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Issue 09-03/March 2009

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WASHINGTON G-2 REPORTS

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Pathwork Expands Tissue of Origin Test

Pathwork Diagnostics (Sunnyvale, Calif.) has launched a new version of its Pathwork Tissue of Origin test, which analyzes a tumor's gene expression pattern to help identify the source of hard-to-identify tumors. The test was launched in April of 2008 at Pathwork's CLIA-certified laboratory and three months later received U.S. Food and Drug Administration (FDA) clearance for use as an in vitro diagnostic (IVD) test kit. Previous formats of the test were limited to frozen tissue samples, but a version of the test introduced in January can be used with formalin-fixed paraffin-embedded (FFPE) samples. "We now plan to file with the FDA in the hopes of going through the clearance process and making that product available as a kit as well," Pathwork President and CEO Deborah J. Neff tells *DTTR*.

Looking ahead to the rest of 2009, Pathwork plans to continue expanding to other tissue types. "We'll also be looking to expand the test itself and adding some enhancements," said Neff. "After that, we'll look at other applications for the approach that we've used to develop the tissue of origin test, using the multifaceted genomic data and applying our proprietary analytics to come up with these very robust, very reliable clinical tests." For more from *DTTR*'s interview with Neff, see *Inside the Diagnostics Industry*, pp. 5-6.

CDC Panel Assesses Impact of Genetic Testing on Health Outcomes

Are genetic tests effective at reducing morbidity and mortality? This is the key question posed by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group, an independent panel established in 2005 to develop a systematic process for evidence-based assessment focused on genetic tests and other applications of genomic technology. Supported by the National Office of Public Health Genomics at the Centers for Disease Control and Prevention, the EGAPP Working Group (EWG) recently concluded that some genomic tests developed to personalize medical decisions about cancer care are beneficial, while for others the evidence is uncertain and reliance on the test might even lead to poorer medical management of cancer. The recommendations and related evidence reviews appear in the January issue of *Genetics in Medicine*, the journal of the American College of Medical Genetics.

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Tumor gene expression profiles such as Agendia's MammaPrint and Genomic Health's Oncotype DX used in women with early-stage breast cancer to detect those at risk for cancer recurrence, the panel wrote, are based on insufficient evidence to determine whether they offer any improvement in health outcomes. More research will be needed to determine the true value of tumor gene expression profiling in women with breast cancer.

The panel also found insufficient evidence to recommend testing for variants of the gene UGT1A1 in patients undergoing chemotherapy for metastatic colorectal cancer to inform use of the chemotherapy drug irinotecan (Camptosar). The test might be useful in identifying patients at risk of side effects from the drug, but reducing irinotecan dosage may be more harmful than the side effects, so the clinical utility of the UGT1A1 test is questionable, at best, according to EWP recommendations.

However, genetic testing for Lynch syndrome, a hereditary condition that increases the risk of colorectal cancer and some other types of cancer, is useful to recommend screening relatives for the mutations that cause the syndrome and encouraging them to have regular colorectal cancer exams, the panel found.

If a patient tests positive for genes linked to Lynch syndrome, then his or her relatives can be offered genetic testing, the panel wrote. Relatives with positive tests might be offered more frequent screening to detect early colorectal cancer, it recommended. The EWP reported that there is moderate certainty that this type of strategy—involving genetic testing and heightened surveillance where indicated—might be expected to substantially improve individual health outcomes in enough cases to produce a moderate health benefit at the population level.

"The EGAPP Working Group recognizes the enormous potential of genetic testing to improve health care, but also recognizes the potential for harm if tests are widely implemented prematurely," noted Alfred Berg, M.D., M.P.H., chairperson of the working group. "Many genetic tests are well suited to examination through the kind of well-constructed randomized controlled trials that would allow us to determine the balance of benefits and harms with confidence. We understand that most research funding now focuses on discovery rather than translation and that clinical trials can be expensive and lengthy. Nonetheless until better evidence is available, the neutral conclusion of 'insufficient evidence' is the best we can say for some of these tests right now."

Gen-Probe to Acquire Tepnel Life Sciences for $132 Million

Gen-Probe (San Diego) has offered to acquire molecular diagnostics company Tepnel Life Sciences (Manchester, United Kingdom) for 27.1 pence (34 cents) per share in cash, or approximately 92.8 million pounds ($132.2 million). The offer price represents a 126 percent premium to Tepnel's closing price on January 21, the last trading day before the company announced that it was involved in deal talks. The boards of directors at Gen-Probe and Tepnel have unanimously approved

the transaction, which is expected to close in the second quarter of 2009.

"We believe our acquisition of Tepnel will provide immediate access to attractive growth opportunities in transplant diagnostics, genetic testing, and pharmaceutical services, as well as accelerate our ongoing strategic efforts to strengthen our marketing and sales, distribution, and manufacturing capabilities in the rapidly growing European molecular diagnostics market," said Hank Nordhoff, chairman and CEO of Gen-Probe.

With operations in the United States, France, and Belgium, as well as the United Kingdom, Tepnel operates two divisions: 1) research products and services and 2) molecular diagnostics. Its rapidly growing molecular diagnostics business is focused on transplant immunology and genetic disease predisposition testing.

Tepnel's human leukocyte antigens (HLA) testing products were among the first commercial molecular HLA typing kits and would allow Gen-Probe to diversify into the transplant typing market. Tepnel also sells xMAP multiplex assays in the field of transplant diagnostics under a development and supply agreement with Luminex.

Gen-Probe also sees growth potential in Tepnel's pharmaceutical services business, which includes master service agreements with a number of major pharmaceutical clients. Gen-Probe has indicated that it sees this business as an avenue for expansion into the emerging market for companion diagnostics.

FDA Clears Meridian Bioscience's Campylobacter Test

Meridian Bioscience (Cincinnati) has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market a new rapid test for Campylobacter. Known as Premier Campy, the enzyme immunoassay (EIA) qualitatively detects Campylobacter, which is the most commonly diagnosed bacteria for food borne illness in the United States Approximately 20 million tests are conducted each year in the United States to detect the illness, which is usually caused by poorly cooked poultry.

Intended for use by hospital and reference laboratories, Meridian's test has been cleared for the detection of Campylobacter antigens (*Campylobacter jejuni* and *C. coli*) in stool samples of patients with symptoms of gastroenteritis.

The test addresses several concerns associated with culture-based testing, currently the most common method for detecting Campylobacter bacteria. With culture, there is a potential for reduction in sensitivity due to variable culturing procedures, specimen viability, and inhibitory antibiotics in culture media. Premiere Campy's EIA method measures the antigen instead of the bacteria in an environment that is less inhibitory than current culture methods.

The Premier Campy test adds to Meridian's portfolio of rapid tests for food borne illness, including its Premier and ImmunoCard Stat! tests for toxigenic *E. coli*. The Premier Campy test is already distributed to the European market and was also recently approved for sale in Canada.

Medicare Panel to Examine Genetic Testing Coverage

A key committee advising Medicare on coverage policy is preparing for the first of two public forums on the benefits of genetic testing for program beneficiaries. The first forum, set for February 25 at Medicare headquarters in Baltimore, will gather input on the types of evidence required for coverage decisions on genetic testing as a diagnostic laboratory service. The second, tentatively set for May, will look into evidence-based screening uses of such testing.

The Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) has been asked by the Centers for Medicare and Medicaid Services to consider a series of issues at the February 25 meeting, including whether changes in lab test results or time to achieve a target value provide enough confidence to infer that diagnostic genetic testing improves patient outcomes.

In addition to aspects of analytical validity, the MEDCAC meeting is expected to address whether there are "meaningful differences in the desirable and/or necessary characteristics of evidence" about the effect of genetic testing on outcomes for diagnostic, prognostic, or pharmacogenomic testing paradigms.

Ethical issues particular to genetic testing that may alter their methodologic rigor will also be considered, along with the question of whether the age of the Medicare beneficiary population presents particular challenges that may compromise the generation and/or interpretation of evidence regarding genetic testing.

"Medicare may cover a diagnostic test that is used by the beneficiary's treating physician to guide the physician's diagnosis and treatment of the beneficiary's personal condition," notes the list of questions proposed for MEDCAC consideration and posted on the CMS Web site. "This contrasts with a screening test used to identify an occult condition or state in an asymptomatic person."

The American Clinical Laboratory Association (ACLA; Washington, D.C.) has also weighed in with its concerns, urging MEDCAC to consider that differences in the types and uses of genetic tests and the relative newness of the technology would make it difficult and inappropriate to develop a single set of standards applicable to all genetic testing. The level of evidence required can vary depending on the applications of a particular diagnostic genetic test, ACLA added.

FDA Clears Abbott's Cell-Dyn Hematology Instrument

On February 11, Abbott (Abbott Park, Ill.) announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its new hematology instrument, Cell-Dyn Emerald. Aimed at small to midsize hospital laboratories and clinics, the analyzer performs complete blood counts (CBCs), a test routinely ordered to assess a patient's overall health and to screen for a variety of disorders such as anemia and infection.

The compact analyzer weighs less than 20 pounds and includes a full touchscreen monitor to simplify operation. CBC results are available in one minute, and reports include histograms that represent white blood cells, red blood cells, and platelets. The instrument also features barcode-labeled reagents.

Pathwork Diagnostics' Deborah J. Neff on Tissue of Origin Testing

Deborah J. Neff

Among the most exciting and highly anticipated molecular diagnostic tests to appear on the market in recent years is the Pathwork Tissue of Origin test from Pathwork Diagnostics (Sunnyvale, Calif.). Using microarray technology and proprietary analytics, the test can identify the tissue of origin of cancerous tumors, including poorly differentiated, undifferentiated, and metastatic tumors, from frozen tumor samples and now formalin-fixed paraffin-embedded (FFPE) tissue. *DTTR* recently talked with Deborah J. Neff, president and CEO of Pathwork, about the history of the company, the market response to the Tissue of Origin test, and educational and reimbursement issues surrounding the test.

Biospect was founded in 2002 and renamed Predicant Biosciences before becoming Pathwork Diagnostics in July of 2006. Can you tell us about the development of the company?

The company came about from the combination of two groups of people and some investment. It was a core group of scientists that had been creating the technology and trying to see if they could tap into the power of genomics and apply it to clinical problems where there was a need to look at large amounts of data. They chose oncology as the field they wanted to target because there was a lot of unmet need there. That team had been working for two or three years prior to 2006 in core technology development and then there was a small group of business people that had some backing from venture capitalists, and we were looking for the right kind of technology and clinical approach to put together with the business experience and form a company. So we put those two groups of people together and did an A round of funding [of approximately $12 million] and formed the company, and then really focused around taking what was outstanding science and applying it to finishing the development of the test: doing the market work, setting up the company, and getting ready to be able to bring a product to the market.

Pathwork launched the Tissue of Origin test in its CLIA lab in April of 2008. How would you characterize the market response?

We've had really positive feedback about the level of science and the credibility of our studies. They were large studies, and our validation set for the test was over 500 samples. That first test was launched on frozen tissue, which is a sample type that you tend to find in large institutions that also do a fair amount of research. So we had a really positive response but also a large response saying you'd get a lot more samples if the test could be used on formalin-fixed paraffin-embedded (FFPE) samples. [Pathwork launched the FFPE version of the test in January of 2009.]

Who are your primary customers for the test?

We're seeing a group of oncologists that are in active centers, as well as oncologists who are associated with large groups and who have a patient where there is some question about the certainty of the tumor. Or it's coming from a recommendation from a pathologist where that patient sample is being

assessed and they see the value in having the additional information from a genomic test: a molecular look at what it is the origin of the tumor.

At this point, I'd say that we're seeing a fairly broad range of locales in which the test is being ordered. We've had some instances where family members of patients happen to come across our test or have read an article and they talk to their physician about this test and the information gets through that channel.

What response have you seen from the FDA's July clearance of the Tissue of Origin test as an in vitro diagnostic (IVD) kit?
For the FDA kit, we have a handful of customers who are eager to bring that test up in their lab. We don't have anybody [performing it] yet, partly because we're working to make sure that all of the final accessory reagents and the validations are all set, so we would expect that during 2009, we'll have some sites come up that will be performing the test using the IVD kit.

What are the price points of the various formats of the test?
The price we quote for the lab service test, the CLIA test, is $3,750. And for the IVD test, we're still in the process of finalizing that, but it will be in the range of $2,000.

You mentioned doing some grand round presentations about the test. Are there other educational efforts that Pathwork is undertaking or planning?
We're doing a combination of things. We're building a salesforce, so we'll have direct people in the field. We have a clinical team headed by a chief medical officer, and he and several other members of the group are actively out there trying to meet with oncologists and pathologists to help them know about the test and the capabilities. We're setting up some Webinars that will be happening later this spring. We do that to have not only our own people but also some of our chief collaborators and some of the early users talk about the types of cases where the test has been really useful. We have a schedule of industry trade shows through this coming year, so we're picking up the pace there, and we also have a very active study and publication plan to get more out.

What does the reimbursement picture look like for the test?
We're actively right in the middle of that now. We are working diligently with all of the major payors, getting in front of them with information about the clinical utility of the test, getting some advocates—pathologists and oncologists who have used the test and where they've seen it benefit. We're very confident that the test will get a good reimbursement. We've already received a payment, so we're on that track. It takes some time and it takes some work to go through the process, so we feel that we're on schedule for what we would expect, and we've put some programs in place to work closely with people who bring up the IVD test kit so that they have the information that they need to do the filings as an institution running the tests. And for those tests that come through our lab, we'll be working directly with the payors to ensure that we get reimbursement. We've also built a team to do that work with experts whose careers have been based on this: getting new technology and new tests through the system to get reimbursed.

G-2 Survey Finds Labs Planning for Continued Growth of Molecular Testing

Molecular testing continues to grow steadily and rapidly in the clinical laboratory, according to Washington G-2 Report's *2008 Molecular Diagnostic Market Strategic Outlook Survey*. The diverse group of 117 laboratories that participated in the survey predicted that in the next two years molecular diagnostics would account for 19.1 percent (on average) of their total laboratory revenue. In keeping with this steady growth, those same laboratories predicted that in five years molecular diagnostics would account for more than a quarter of total revenues, or 25.4 percent. Respondents predicted that by 2018, molecular diagnostics would account for more than a third of revenues, or 33.5 percent

More than two-thirds (64.6 percent) of laboratories surveyed indicate they are currently offering molecular diagnostic tests of some kind. Slightly less than 9 percent indicate they are planning to offer molecular diagnostic tests. A significant factor in deciding to integrate molecular-based tests is apparent demand as assessed by send-out data, which about 67 percent of labs indicated was likely or very likely to affect their decision.

Clinical impact is another critical factor for labs as they consider which molecular tests to add. A total of 61 percent of laboratories surveyed ranked potential clinical impact of a test as among the factors most likely to affect their decision-making regarding bringing on molecular tests.

Four specific molecular tests ranked highest when laboratories already performing molecular tests were asked which tests they were planning to bring in-house within the next five years. Those four tests are herpes simplex virus (HSV), cystic fibrosis (CF), hepatitis C virus (HCV) quantitative, and CYP450 genotyping.

Approximately 25 percent of laboratories surveyed indicated they planned to offer HSV testing in the next one to two years. Testing for CF ranked second, with 19 percent of respondents indicating they wanted to add it within two years and 14 percent planning to add it in the next three to five years.

Those laboratories that are planning to add molecular capacity named human papilloma virus (HPV), cytomegalovirus (CMV), HER2/neu, and prenatal chromosome testing as the top tests they planned to offer within five years.

In 2005, laboratories surveyed indicated that molecular diagnostics represented an average of 13 percent of total revenues. In 2006, survey respondents indicated that molecular diagnostics represented an average 14.3 percent of total revenue, and in 2007, molecular diagnostics accounted for 15.5 percent of their overall laboratory revenue. From 2004 to 2006, molecular diagnostics substantially increased its presence in the clinical laboratory in terms of revenue. Molecular diagnostics leaped from accounting for an average 13 percent of total lab revenue in 2005 to 15.5 percent in 2007, a jump of 19.2 percent.

Laboratories predicted that molecular diagnostics would represent an average 19.1 percent of their total lab revenue in two years. Not surprisingly, laboratories

surveyed predicted that in five years molecular diagnostics would account for just over a quarter (25.4 percent) of their total laboratory revenue.

In keeping with the growth trend, laboratories surveyed predicted that in 10 years molecular diagnostics would account for approximately a third (33.5 percent) of total revenue. Average revenue predictions jumped 32.9 percent from the two-year prediction to the five-year prediction and 31.8 percent from the five-year prediction to the 10-year prediction. Most notably, from the 2007 estimate of 15.5 percent, laboratories surveyed predicted a 116 percent jump in 10 years to molecular diagnostics, accounting for an average 33.5 percent of laboratory revenue.

Almost every laboratory surveyed indicated that molecular diagnostics was an area that they expected to grow, particularly in the areas of infectious disease and pharmacogenomics and/or predictive testing. There is an eye toward increased automation and multiplex testing, which should translate into higher test volumes and decreased costs, as well as the introduction of new tests.

Washington G-2 Reports estimates that molecular testing will grow by approximately 12 percent in 2009, and with the amount of research and development going into areas of predictive testing, along with an aging population, the pace of growth is not likely to slow in the near future. For more results from the *2008 Molecular Diagnostic Market Strategic Outlook Survey*, see *Business Strategies for Molecular Diagnostics in the Lab 2009*, a new research publication from Washington G-2 Reports.

BloodCenter of Wisconsin Expands to Focus on Molecular Oncology

The Milwaukee-based BloodCenter of Wisconsin has expanded its molecular diagnostic lab by opening a branch focused solely on molecular oncology to capture the growing diagnostic market for hematological malignancies, estimated to be between $1.1 billion and $1.5 billion.

Currently, the test menu is focused on testing related to leukemia and myloproliferative diseases, which are slow-growing blood cancers, explained. Roger Klein, M.D., J.D., who was recently appointed the lab's medical director. He was most recently medical director of the molecular diagnostics lab at H. Lee Moffitt Cancer Center (Tampa, Fla.).

"We're already doing molecular oncology testing, but we want to build ourselves into a national resource and to be a leader in the field, at least in terms of hematopathological diseases, so we are the place that people turn to get the latest and most sophisticated tests," he explained. "We are trying to carve out a specialty niche, where we will be among the first to bring to market a certain test in molecular oncology. We'll do esoteric testing that many will shy away from."

In addition to testing, Klein's lab will offer consultative services. By entering the hematopathological market and offering these value-added services, it might appear that the BloodCenter will be directly competing with the specialty lab Genoptix (San Diego). But Klein said that while Genoptix caters to physicians in private practice, his lab will focus on institutional customers like hospitals and other reference labs.

BRCA Gene Mutations Linked to Prostate Cancer Risk

Men with prostate cancer are at a higher risk of having an aggressive tumor if they have a so-called breast cancer gene mutation, according to a study published in the February 1 issue of *Clinical Cancer Research*. The findings could help to guide prostate-cancer patients and their physicians in making treatment decisions.

The study, involving 979 men with prostate cancer and 1,251 men without the disease, looked at whether participants carried mutations in the BRCA1 or BRCA2 genes. Women carrying mutations in either gene face an increased risk of developing breast cancer, ovarian cancer, or both. All of the study subjects were of Ashkenazi Jewish descent and therefore five times more likely than those in the general population to carry a BRCA mutation.

The researchers focused on two particular mutations in BRCA1 and one in BRCA2. Having any of the three mutations did not increase a man's risk of developing prostate cancer, but for those men who did develop prostate cancer, two of the mutation—BRCA1-185delAG and the mutated BRCA2 gene—increased the risk that tumors would be aggressive or high-grade, as defined by a Gleason score of 7 or above. The Gleason score, based on the microscopic appearance of prostate tissue removed during a biopsy or surgery, rates the aggressiveness of a prostate tumor on a scale from 2 (least aggressive) to 10 (most aggressive).

Prostate cancer patients with high-grade, aggressive tumors (Gleason scores of 7 or above) were 3.2 times more likely to carry the BRCA2 gene mutation than were men in the control group. Carriers of the BRCA1-185delAG mutation were also at increased risk of having an aggressive prostate cancer.

"Our large study shows conclusively that prostate cancer patients with either the BRCA2 gene mutation or the BRCA1-185delAG mutation are more susceptible to aggressive cancers than people without that mutation," says Robert Burk, M.D., professor of pediatrics at the Albert Einstein College of Medicine of Yeshiva University and senior author of the study.

Routine genetic testing for BRCA mutations wouldn't be justified for most men, says Burk, because the prevalence of the mutations in the general population is very low and men with high Gleason scores already know that their prostate cancer is aggressive. However, notes Burk, "our findings might have practical implications for some men diagnosed with early-stage (low Gleason score) prostate cancers, particularly Ashkenazi Jewish men, who are much more likely to have these mutations."

Abbott Licenses Gene-Based Test for Prostate Cancer

Biomarker company Health Discovery Corporation (HDC; Savannah, Ga.) has entered into an agreement with Abbott (Abbott Park, Ill.) to commercialize HDC's new molecular diagnostic tests for clinically significant prostate cancer. Abbott has acquired co-exclusive clinical laboratory rights and exclusive in vitro diagnostic rights for commercialization of the tissue-based prostate cancer test, as well as HDC's urine-based prostate cancer test.

The test identifies a four gene combination that can distinguish grade 4/5 prostate cancer, the most malignant and clinically significant type, from benign prostatic hyperplasia (BPH) and normal prostate. Abbott will share clinical laboratory rights to the test with Clarient (Aliso Viejo, Calif.), and HDC will receive a 30 percent royalty on each test performed.

According to the American Cancer Society, 232,000 new cases of prostate cancer will be diagnosed in the U.S. and an estimated 30,350 deaths will occur from this disease.

Results from Phase I, Phase II, and Phase III double-blinded clinical validation studies using prostate tissues obtained from multiple sites demonstrated a high success rate for identifying the presence of grade 3 or higher prostate cancer cells (clinically significant cancer), as well as normal and BPH cells. The combined results of the recently completed double-blinded clinical validation studies demonstrated that the new gene-based molecular diagnostic test for prostate cancer achieved a sensitivity of 90 percent for correctly identifying the presence of grade 3 or higher prostate cancer cells and a specificity of 97 percent for correctly identifying non-cancer cells (normal and BPH).

HDC uses Support Vector Machines (SVM) technology to develop molecular diagnostic and prognostic tests, as well as digital image analysis in pathology and radiology. The company recently licensed rights to develop a new urine-based test for clinically significant prostate cancer to Quest Diagnostics.

ParagonDx Opens CLIA Lab Offering Warfarin Testing

Molecular diagnostics company ParagonDx (Morrisville, N.C.) has opened its CLIA-certified laboratory and is now offering next-day turnaround testing services for warfarin sensitivity. The laboratory is using ParagonDx's own CYP2C9 and VKORC1 genotyping assay, the first of several warfarin tests cleared by the U.S. Food and Drug Administration (FDA) to provide results in less than one hour and incorporate human genomic quality controls.

Warfarin testing helps physicians prevent excessive bleeding in patients who are taking the anti-coagulant warfarin (Coumadin). Using this test, physicians can understand the genetic component that can aid in achieving the optimal warfarin dose, which has been shown to lower the risk of adverse drug reactions. The FDA relabeled warfarin in 2007 to recommend that patients receive genetic testing prior to the initiation of warfarin therapy.

In April of 2008, the FDA cleared the ParagonDx rapid genotyping assay for warfarin sensitivity to be used for detecting variations in the CYP2C9 and VKORC1 genes. This information may in turn be used as an aid in the identification of patients at greater risk for warfarin sensitivity. The test kit was cleared for use on Cepheid's SmartCycler Dx platform.

ParagonDx will analyze the samples at its CLIA laboratory and provide results the next day, which represents a significant improvement over other labs that can take as long as five days to generate results for this test. The rapid turnaround time provides a significant advantage to patients because they can immediately begin taking the appropriate warfarin dose.

IVD Stocks Up 5%; Abaxis, Clinical Data Are Biggest Gainers

The G-2 Diagnostic Stock Index gained an average of 5 percent in the five weeks ended February 6, with 11 stocks up in price and six down. Over the same period, the Nasdaq inched up by 1 percent, and the S&P 500 lost 2 percent.

Leading the gainers in recent weeks was **Abaxis** (Union City, Calif.). The share price of the test maker climbed 28 percent to close at $18.85 per share with a market capitalization of $380 million. For the fiscal quarter ended Dec. 31, 2008, Abaxis recently reported revenues of $27 million, up 5 percent over revenues of $25.7 million for the comparable period last year, an increase of 5 percent.

Despite widening quarterly losses, biotechnology company **Clinical Data** (Newton, Mass.) gained 23 percent to close at $9.82 per share with a market capitalization of $223 million. The company recently signed a contract that will provide individual Blue Cross and Blue Shield companies with access to the Familion Long QT Syndrome genetic tests for inherited cardiac syndromes. The tests are offered by Clinical Data's PGxHealth division.

Microarray maker **Affymetrix** (Santa Clara, Calif.) continued its downward slide, dropping 9 percent to close at $3.51 per share with a market capitalization of $229 million. The company announced its fourth quarter results on January 28 and posted a wider-than-expected quarterly loss. In a call with investors and analysts, CFO John Batty cited "consolidation and restructuring charges" as well as a goodwill impairment charge of $239 million.

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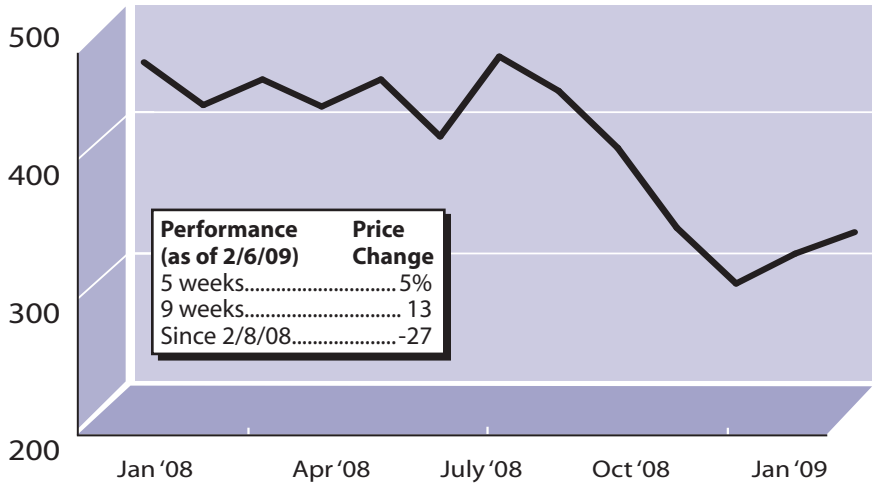
Meanwhile, Richard Rava, a scientific co-founder of Affymetrix, has left the company to become senior vice president of research and development at Artemis Health (Menlo Park, Calif.). Artemis Health, an early-stage company dedicated to the development of noninvasive prenatal diagnostic tests, is focused on the isolation of fetal cells from maternal blood for genetic testing using its proprietary microfluidic technology.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 17 IVD companies.

Up	Price	% Chg
Abbott Labs	$57.15	13%
Abaxis	18.85	28
Beckman Coulter	50.39	17
Becton Dickinson	74.09	4
Bio-Rad	67.63	4
Clinical Data	9.82	23
Gen-Probe	46.58	15
Immucor	28.34	7
Inverness Medical	25.09	20
Luminex	20.70	14
Quidel	13.42	9
Down		
Affymetrix	3.51	-9
Johnson & Johnson	58.50	-1
Meridian	22.24	-4
Nanogen	0.17	-37
Nanosphere	4.84	-5
OraSure	2.78	-13

G-2 Insider

Learn how to make outreach testing work . . . Washington G-2 Reports' and Chi Solutions' 2009 Lab Outreach Conference will focus on how to maximize value, profitability, and service through a slate of session topics that include using blended lab/imaging programs for outreach growth, managing outreach clients in the managed care environment, and developing a sustainable financial model for building outreach profitability. The premier business event dedicated to improving group, hospital, and health system laboratory outreach programs will take place June 8-10 at the Hyatt Regency Mission Bay Spa and Marina in San Diego. Among the confirmed speakers and sessions:

- ❑ **Michael Metzler,** the former COO of St. Elizabeth's Medical Center, and CEO of St. Anne's Hospital, will give a keynote presentation entitled "Know Your Numbers": What You Need to Know About Outreach From a CEO Perspective;
- ❑ **Leslie Wainwright, Ph.D.,** senior vice president at Sg2, will look ahead in a second keynote presentation, "Health Care 2020";
- ❑ Chi Solutions President **Kathy Murphy, Ph.D.,** will provide an exclusive overview of the eighth *National Outreach Survey*, including the five top industry trends; and
- ❑ **Ilke Panzer,** vice president of diagnostic laboratories at the Blood Center of Wisconsin, will discuss "Optimizing Your Test Menu: How a Carefully Designed Molecular Diagnostic Offering Can Impact Your Bottom Line."

For full program details, visit *www.g2reports.com/outreach09*. To register, call John Watkins at 800-401-5937 ext. 4710 or e-mail John at johnwatkins@ioma.com.

References

Abaxis 510-675-6500
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DTTR 3/09

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

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