Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Vol. VIII, No. 4/December 2007

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WASHINGTON G-2 REPORTS

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Hologic-Cytyc Merger Unites Imaging and IVD

Hologic (Bedford, MA) and Cytyc (Marlborough, MA) have closed on their merger, creating a women's health giant that encompasses in vitro and in vivo (imaging) diagnostics. Announced in May, the merger agreement gave Cytyc shareholders 0.52 shares of Hologic common stock and $16.50 in cash for each share of Cytyc common stock held, making the deal worth approximately $6.2 billion. The combined company is known as Hologic, the name that will continue to trade on the Nasdaq.

Now comes the hard part. "We are currently focused on seamlessly integrating these two great companies and realizing the tremendous upside potential our combination creates," said Jack Cumming, Hologic's chief executive officer.

Hologic develops and manufactures imaging technology for digital radiography and breast imaging. The company's core businesses focus on mammography and breast biopsy, osteoporosis assessment, and mini C-arm and extremity MRI imaging for orthopedic applications. Cytyc, now a wholly owned subsidiary of Hologic, is best known for its widely used ThinPrep cervical cancer screening method. The company also has products for preterm birth screening, treatment of excessive menstrual bleeding, and radiation treatment of patients with early-stage breast cancer.

On a November 6 conference call with investors, Hologic management announced that it is forecasting revenue for fiscal year 2008 to increase by more than 130% to $1.7 billion, led by the Cytyc acquisition. Hologic reported revenue of $738.4 million for the fiscal year that ended in September 2007.

Molecular Diagnostics Among Sunquest's Key Priorities

On October 11, private equity firm Vista Equity Partners (San Francisco, CA) closed on its $381.5 million acquisition of the ancillary hospital information systems business of Misys Healthcare Systems. Upon completing the deal, Vista announced the formation of Sunquest Information Systems, which was the name of the business before Misys purchased it in July of 2001.

Sunquest now owns all business assets, technology, and products associated with Misys's hospital systems diagnostic portfolio, including the laboratory, commercial laboratory, and clinical financial products, as well as stand-alone systems for radiology and pharmacy departments. Sunquest will be led by Richard Atkin, the former president of the hospital systems business unit for Misys.

Among Sunquest's major areas for growth is molecular diagnostics, Atkin tells *DTTR*. "The growth in molecular and genomic tests

Continued on p. 2

▲ **Sunquest's Key Priorities,** *from page 1*

is almost like a second wave of outpatient or externally focused lab tests," says Atkin. "More and more protocols are being developed, and more and more are being approved, but they're very complex tests, and we're attracted to that trend because it holds the promise to fundamentally change how healthcare is viewed and delivered, if you move on through to the preventative medicine and pharmacogenomics elements of the lab."

While Sunquest's specific plans are still in development, Atkin notes the diversity of how laboratories of all types handle the increasing prevalence and complexity of molecular tests. "I think almost every institution may have a different view: Does it expand the micro[biology] area? Does it create a specific area? To what extent does the digitization of pathology play into this? And how might radiology fit in?" he asks. "There are probably more unanswered questions than real answers at this point."

Sunquest's plan is to draw upon its expertise in radiology and pharmacy, as well as the lab area, to help users do things more efficiently. "We see that molecular diagnostics is looking to change almost every aspect of workflows in the lab, and therefore the application needs to be enhanced to support that—and not just within the lab, even the ordering and resulting aspects of how a lab works need to be modified," says Atkin. Among the complexities that Sunquest will aim to address are the need for very high-reliability solutions, considering that complex molecular-based protocols are frequently time-intensive and necessitate the combination of data from multiple protocols.

PhenoPath Looks to Capitalize on Pathology Paradigm Shift

PhenoPath Laboratories (Seattle, WA) has made a name for itself by successfully leveraging its expertise in HER2/NEU testing while constantly adding new tests and services. This year, the physician-owned reference laboratory launched both a HER2 validation service and a Web-based results reporting system. Now the focus is staying on the cutting edge of the ever-evolving field of molecular pathology.

PhenoPath performs approximately 64,000 tests annually. About 4,850 of those are molecular, with 4,050 fluorescent in situ hybridization (FISH)-based and 800 B&T cell gene rearrangements. In 2008, they plan to validate a CLL/SLL panel, a multiple myeloma panel, a myelodysplastic syndrome panel, and the Urovysion test for bladder cancer. *DTTR* estimates PhenoPath's annual revenue at $3 million.

Todd S. Barry, M.D., Ph.D.

Founded in 1998 by Allen M. Gown, M.D., a pathologist with particular expertise in immunohistochemistry (IHC), PhenoPath has grown to approximately 60 full-time equivalents, with a list of regional and national clients of all sizes. "We sort of evolved from being a reference lab for chemistries as the demand for prognostic testing—in breast cancer especially—grew into the molecular areas," says Todd S. Barry, M.D., Ph.D., director of PhenoPath's molecular pathology and hematology division.

PhenoPath began by offering HER2/NEU and FISH, added many molecular tests largely related to lymphomas, and continues to grow. "We also do things like evaluate triploidy in molar pregnancies and some of the chromosome translocations like X;18 and 11;22 in oseosarcoma and Ewing's sarcoma," says Barry. "Most of the tests

are associated with lymphomas and leukemias. They're not classic cytogenetics. Molecular is a little bit more complicated than classic cytogenetics. Chromosomes are great, but sometimes interphase FISH is more appropriate."

Barry believes that there is an ongoing paradigm shift in pathology. "We're not just diagnosing a tumor type. We're providing additional information that's not just prognostic, but predictive," he says. "I think a test becomes more standard of care once it gets to the position where it actually tells the clinician how to treat the patients. So I really do think many of these tests, even the role the pathologist plays, will become quite large when the results of a test actually impact how a patient is treated."

"We're not just diagnosing a tumor type. We're providing additional information that's not just prognostic but predictive."

Breast cancer remains a major target for predictive molecular testing. "I think many newer genetic tests that are coming down the pike are going to refine or recapitulate what you're seeing in breast cancer, in other tumors, and maybe even subdividing or subcategorizing what we're seeing in breast cancer patients," says Barry, citing the example of topo-2-isomerase, a biomarker that may help identify patients that will best respond to Andriamycin-based therapies.

One of the things Barry finds both interesting and problematic is the way in which molecular testing is often split off from traditional laboratory testing. "In the classic academic center, the cytogenetics center might be part of the pathology department, but in reality, probably one of their bigger customers is the hematologist, which may very well be in laboratory medicine," he says, predicting that as molecular tests become more targeted, molecular testing will expand even further.

"We need to have some confidence that the result we have is important and there's some negative predictive value as well. That's only going to come full circle when you know those tests are being performed on the neoplastic cells," says Barry. "It's an area that's sort of in between parts of pathology that have been separated: laboratory medicine versus anatomic pathology. It's important to do testing on both areas and not have it sequestered in terms of being a part of pathology."

Genyzme to Buy Diagnostics Division of Canada's DCL

On November 7, Genzyme (Cambridge, MA) entered a deal to acquire the diagnostics division of Diagnostic Chemical Limited (DCL; Charlottetown, Prince Edward Island), which develops and manufactures clinical chemistry reagents and point-of-care tests. Financial terms of the all-cash deal were not disclosed, but DCL's line of clinical chemistry reagents generated approximately $50 million in the 2007 fiscal year. The deal is expected to close by the end of the year.

Genzyme's 26-year-old diagnostics division currently consists of three areas: diagnostic intermediates that serve as raw materials, finished reagent kits for use on clinical chemistry analyzers, and point-of-care tests. The company's clinical chemistry reagent kits include those for HDL and LDL cholesterol, pancreatitis monitoring, and diabetes monitoring. Under the OSOM brand, Genzyme offers point-of-care tests for pregnancy, strep A, mononucleosis, trichomonas, and bacterial vaginosis. The company recently introduced its immunochromatographic test that provides rapid differential diagnosis of influenza A and B in approximately 10 minutes.

DCL offers approximately 50 formulated clinical chemistry reagents. The company's point-of-care offerings are limited to tests for the rapid detection of microalbumin

in urine, including immunochromatographic microalbumin tests marketed under the ImmunoDip brand that are available in CLIA-waived and semi-quantitative (moderate complexity) formats.

According to Genyzme Diagnostics President Donald E. Porgorzelski, the acquisition will allow Genzyme to reshape its formulated reagent product portfolio. The deal includes two DCL facilities, one in Charlottetown and one in Oxford, Connecticut.

PNAS Study Supports Genomic-Based Detection of Acetaminophen Overdose

Overdose of acetaminophen, the active ingredient in over-the-counter pain relievers such as Tylenol, is a leading cause of liver failure in the United States and is often difficult to diagnose. An estimated 50,000 people seek emergency room treatment for acetaminophen overdose each year.

A study published in the November 13 issue of the *Proceedings of the National Academy of Sciences* (*PNAS*) shows that gene expression data from blood cells can predict levels of exposure to acetaminophen, the active ingredient in over-the-counter pain relievers such as Tylenol, well before liver damage can be detected by such methods as serum markers and liver biopsies. The research, conducted by scientists at the National Institute of Environmental Health Sciences (NIEHS), could lead to the development of new genomic tools to detect acetaminophen overdose in humans.

After developing and analyzing gene expression signatures in rats exposed to various doses of acetaminophen, the researchers used microarrays to determine which genes were turned on or turned off in response to the different doses. The signature gene lists were found to predict exposure to toxic versus nontoxic doses with very high accuracy (88.9% to 95.8%), while traditional clinical chemistry, hematology, and pathology methods were approximately 65% to 80% accurate. The researchers also successfully used the rat data to distinguish between human RNA samples from humans who had overdosed on acetaminophen and those of healthy controls.

Now the focus is developing a simple test that can be used to estimate the level of acetaminophen exposure and potential liver damage. "In time, this approach could give physicians a powerful new genomics tool to help patients who cannot estimate how much acetaminophen they consumed," said Richard S. Paules, Ph.D., principal investigator, director of the NIEHS Microarray Core Facility at NIEHS, and senior author of the *PNAS* paper. Such a test could be particularly useful in elderly, suicidal, or semi-comatose patients.

ReliaGene Acquired by Orchid Cellmark for $8.6M

Identity DNA testing laboratory Orchid Cellmark (Princeton, NJ) has completed its purchase of the outstanding stock of ReliaGene Technologies (New Orleans, LA) for $5.6 million in cash and $3 million in Orchid stock. The company announced the deal on October 22, and it closed on November 1.

Privately held ReliaGene, a provider of forensic and paternity DNA analysis services, had 2006 annual revenue of $7.5 million. The laboratory's test menu includes polymerase chain reaction, restriction fragment length polymorphism, mitochondrial DNA sequencing, and Y-chromosome DNA testing. The company was founded in 1990 by Sudhir Sinha, Ph.D., who currently serves as president and laboratory director.

The acquisition is part of Orchid's plan to grow through acquisitions. "There is essentially no customer overlap between the two companies," *Continued on p. 9*

With Cutting-Edge Genetic Testing Platform, Correlagen Expands Into Cardiology

Two-year-old genetic testing company Correlagen Diagnostics (Waltham, MA) was founded to address the need for a commercial genetic diagnostic service that would be both cost-effective and clinically useful. Building such a company required rigorous process automation, robotics, and scientific-knowledge management. Correlagen co-founder and CEO David M. Margulies, M.D., who also co-founded CareInsite (now WebMD), drew upon his extensive background in clinical information systems technology and clinical computing to lead the development of the GeneExplorer system, an integrated platform for diagnostic evaluation of human genetic variation that has led to the development of DNA diagnostics based on analysis of the entire sequence of a particular gene.

Correlagen's clients include clinicians in the field of testing, genetic counselors, and laboratory directors. The majority of the company's clients are in the United States and Canada, with a small percentage in Europe. It also has a strong collaborative relationship with several major academic medical centers, including Children's Hospital Boston, where Margulies served as chief information officer from 1986 to 1990.

From its focus in the area of primary immunodeficiency testing, Correlagen is now aggressively expanding into cardiology, with tests for disorders such as familial hypercholestemia. The company recently launched a genetic test for hypertrophic cardiomyopathy (HCM), an inherited disease that affects one out of 500 Americans and is the leading cause of sudden cardiac death in children and young adults.

While there is no cure for HCM, early diagnosis can encourage those at risk to initiate lifestyle changes and medical interventions, such as beta blockers, calcium channel blockers, and implantable cardioverter-defibrillators. Candidates for HCM testing are individuals with left ventricular hypertrophy that is thicker than 14 millimeters and a family history of cardiac disease and/or sudden cardiac arrest. Blood relatives of a patient with HCM in whom a mutation has been identified are also candidates for genetic testing for HCM, regardless of whether they show HCM symptoms.

Correlagen's eight-gene HCM panel is priced at $4,745, with a capped payment program co-payment of $711.75 (regardless of the extent of insurance reimbursement received by Correlagen, patient responsibility is limited to this portion of the total testing cost). Panels that segment the genes based upon their degree of involvement in HCM and individual gene panels are also available. Results are available within 28 days for HCM panels and within 14 days for individual HCM gene tests.

Recently, Correlagen's Margulies talked with *DTTR* about the company's unique full gene sequence testing approach, how it reports results, and the role of diagnostics in therapeutic monitoring.

What distinguishes Correlagen's testing methodology from that of other laboratories that perform genetic testing?

While most other labs offer only targeted screening for specific mutations in a given gene, Correlagen sequences the entire coding region of each gene it offers testing for. Such full gene-sequence analysis presents a much more sensitive diagnostic method than targeted mutation detection. However, full gene-sequence analysis is also much more difficult and costly to perform than targeted mutation detection, and the results are much more difficult to interpret. Many more variants will be found, and accurate diagnostic interpretation of their pathogenic significance depends in large part on a comprehensive, constantly evolving database of known variation in a particular gene. Due to the complexities surrounding full gene-sequencing tests, they are usually associated with high test cost, long turn-around times, and interpretations that are of limited value to the physicians.

"The high degree of automation in Correlagen's testing platform reduces test cost, making genetic testing more accessible to the patient, and decreases turnaround time, making genetic testing more clinically useful for the physician."

Correlagen has created a highly automated testing platform that incorporates robotic performance of DNA sequencing and software-facilitated result interpretation. A meticulously maintained database of known genetic variation and a proprietary software tool that allows fully automated assembly of comprehensive, understandable, gene- and disease-specific result reports enables result interpretation with a high degree of accuracy and utility. Automated report generation also guarantees consistency of interpretation and enables revisability of interpretation over time, giving rise to an "evergreen" result report. The high degree of automation in Correlagen's testing platform also reduces test cost, making genetic testing more accessible to the patient, and decreases turnaround time, making genetic testing more clinically useful for the physician.

Given the complexity of the data involved, how do you report test results?

Correlagen's reporting system was developed in-house. Reports are assembled from hundreds of different static text modules in a rules-based fashion, driven by genetic principles, patient characteristics, sequencing results, and information stored in Correlagen's variant database. Fully automated report assembly guarantees consistency of reporting and enables revisability of interpretation over time, an essential functionality given the fast pace at which knowledge about the effect of genetic variation is evolving.

Correlagen's reports are much more comprehensive and informative than traditional test reports. At the same time, information within the report is highly structured, so that the physician can easily select the level of detail that is right for him or her. As knowledge changes, both variant scoring and reporting have been designed to produce a revisable (or "evergreen") report.

What are some of Correlagen's most frequently requested tests?

Tests that are requested from and performed by Correlagen on a frequent basis include our line of tests for primary immunodeficiencies, our tests for cardiol-

ogy disorders (hypercholesterolemia and hypertrophic cardiomyopathy), and our tests for research clients working on their own proprietary discoveries.

Tests that have been developed by Correlagen and licensed to others to perform include a comprehensive line of endocrine tests distributed by Athena Diagnostics in the United States, and by other distributors in Europe. The most popular of these are tests for genetic causes of diabetes, tests for osteogenesis imperfecta, and tests for endocrine cancers. In all, we will have tests for approximately 100 disorders in production by year's end.

"In all, we will have tests for approximately 100 disorders in production by year's end."

What criteria do you use in selecting new tests?
Most important is the clinical utility of the test to physicians and their patients. That is, does the test help a doctor and patient to make an important decision about management or treatment? Some of our tests are used to help reach a definitive diagnosis more rapidly and/or less expensively than is otherwise possible. A few tests are useful to help persons with serious illnesses to follow and/or enroll in research protocols. If testing a gene doesn't have compelling clinical utility, we don't create the test.

Other criteria include how strongly variation in the gene has been shown to be associated with a syndrome, the market need for the test based on prevalence of the syndrome, the intellectual property surrounding the gene test, technical requirements to create a robust assay, and, of course, projected returns to the company.

One of Correlagen's aims is to develop gene-based diagnostics that can aid in therapy selection/monitoring. Do you currently offer pharmacogenomic tests?
Correlagen does not currently offer pharmacogenomic tests in the usual sense of the term, that is, tests designed to detect sequence variation in genes associated with drug metabolism. Instead, the results of Correlagen's tests can help to guide therapy by distinguishing between different forms of a genetically heterogeneous disease.

As an example, X-linked lymphoproliferative disease (XLP) is a rare, life-threatening immune deficiency disorder that can be difficult to distinguish from other, less serious causes of immune deficiency, such as X-linked agammaglobulinemia or common variable immune deficiency. The defining characteristic of XLP is extreme susceptibility to Epstein-Barr virus (EBV) - the virus that causes mononucleosis (known as "mono"). In individuals with properly functioning immune systems, EBV will usually pass unnoticed, or in some cases may cause mono. However, in individuals with XLP, infection with EBV can lead to an out-of-control immune response, usually resulting in death within days. The immune system defect that causes XLP can effectively be cured by bone marrow transplantation, but bone marrow transplantation is too risky a procedure to be performed without a definite diagnosis of XLP. Genetic testing can provide such a definitive diagnosis of XLP.

However, Correlagen does have substantial future plans in the area of pharmacogenomics.

Direct Access Testing Grows as Consumers Play Larger Role in Healthcare

Business is booming for the sometimes controversial direct access testing market, especially with a reported 47 million uninsured in the United States. Todd Myers, managing member of direct access testing (DAT) company, Personalized Lab Services (Dunedin, FL), says that in the two years the company has been in existence, it has had "steady, good growth."

At its most basic, DAT is a way of providing healthcare consumers a way to acquire laboratory testing without visiting a physician. It has numerous other names, including "consumer-initiated testing," "patient-directed testing," "direct access to lab services," and "self-ordering." In states where it is permitted, DAT is commonly ordered by an individual without a prior consultation with a physician or a physician's request for testing.

Is Personalized Lab Services simply acting as a middleman between the patient and the lab? "To a degree," says Myers. "What we're doing is facilitating a test for an individual by providing them the proper script, the proper instructions, as well as a doctor's authorization if they don't have a doctor. In a sense what we're doing is third-party billing for lab testing."

Myers goes on to describe it this way: "Personalized Lab Services is a company that focuses on selling testing—either in the form of individual kits or through lab testing in clinical laboratories—that is accessible to the public. Our concept primarily is that we're able to give those without insurance and those that are interested in alternative health practitioners or an alternative healthcare system an opportunity to get the same tests that would be ordered by their doctor and paid for by their insurance."

Personalized Lab Services offers tests in 22 different categories, including allergy testing, cancer detection, sexually transmitted diseases, and nutrition/fitness. Patients visiting the company's Web site can choose a test and, using the location

Most Requested Direct Access Tests

- ❑ HIV-1 antibody test
- ❑ STD Panel
- ❑ Complete blood count with differential
- ❑ Chlamydia and gonorrhea test
- ❑ Herpes simplex virus (HSV) type II IgG
- ❑ Herpes simplex virus (HSV) type I and II IgG
- ❑ Syphilis test
- ❑ Thyroid profile with TSH (thyroid stimulating hormone)
- ❑ Liver function profile

Source: Private MD Lab Services

finder, will be directed to a patient service center near them. Personalized Lab Services's testing menus are handled by Private MD Lab Services. All laboratory work that isn't at-home kit testing is handled by LabCorp.

Upon processing an order, the client is sent a confirmation e-mail that contains requisition papers. "It's really a script that says this individual is taking this test at this location, and here are the requirements, like fasting or no water, for example," says Myers. "They take the script to the patient service center, have the specimens collected, and within 24 hours they receive another e-mail that directs them to a secure Web site where they can get their results."

Myers notes that their in-home testing business and their laboratory business are two separate businesses. Personalized Lab Services employs one physician who is licensed in 33 states, as well as five additional staff members who look at laboratory results. There are another five involved in administrative matters.

One of the controversies surrounding DAT is the issue of appropriate responses to abnormal results and counseling for complex test results. In the case of Personalized Lab Services, abnormal results are flagged. Personalized Lab Services's physician reviews these tests and arranges for contact with the patient, suggesting that they seek medical advice when needed.

Myers notes that the at-home HIV test is their most-acquired test, followed by an at-home drug testing kit for marijuana. According to a recent survey of a handful of DAT companies, the most frequently requested tests include those for HIV, chlamydia, and prostate specific antigen, as well as lipid panels and ABO/Rh blood typing.

Among the factors driving the market for DAT are the consumer desire to comparison shop, direct marketing of laboratory testing to consumers, consumer privacy concerns, convenience, and the trend of consumer-directed healthcare.

In a statement on how CLIA affects the availability of this testing, the Centers for Medicare and Medicaid Services (CMS) notes that CLIA authorizes regulation of laboratories that conduct testing, not the individuals who order the tests or receive test results. Therefore, CLIA regulations and standards do not differentiate between facilities performing DAT and facilities performing provider-ordered testing. All facilities that meet the definition of "laboratory" under CLIA must obtain an appropriate CLIA certificate prior to conducting patient testing, including DAT.

▲ **ReliaGene Acquired by Orchid Cellmark,** *from page 1*

said Orchid president and CEO Thomas Bologna. "And we believe the combined forensic casework, [Combined DNA Index System], and paternity laboratory testing volumes should increase our operational efficiencies."

Orchid has four laboratories in the United States: two for forensic testing and two for paternity testing. The company also has a lab in the United Kingdom that, in addition to human identity testing, serves the agricultural market with testing for selective trait breeding.

Roche Extends Tender Offer for Ventana

Roche (Basel, Switzerland) still isn't giving up its efforts to acquire tissue-based cancer diagnostics company Ventana Medical Systems (Tucson, AZ), even though Ventana continues to rebuff the diagnostics giant's bids. On October 29, Roche extended its tender offer for Ventana to January 17 from the previous expiration date of November 1.

Designated Roche CEO Severin Schwan said that the $3 billion ($75 per share) offer was "fair and full." Ventana CEO Christopher Gleeson calls the offer "inadequate" and says that Roche's tactics are "futile and costly," adding that "virtually all of our investors agree with us that $75 is a non-starter, and they recognize that we are gaining real momentum in our marketplace."

Roche commenced its tender offer on June 27, 2007. The $75-per-share offer price represented a 44% premium to Ventana's June 22 close price of $51.95 and a 55% premium to its three-month average of $48.30. Since June 22, shares of Ventana have spiked 66%, closing on November 2 at $86 per share.

G-2 Honors Award Winners at 25th Annual Lab Institute

Dennis Weissman, founder and executive editor Washington G-2 Reports, is the recipient of G-2's 2007 Laboratory Public Service National Leadership Award, an annual honor that recognizes an individual who has made a significant contribution to the public interest through accomplishments that directly enhance the lab profession. Bridget Kreger, a third-year student in the medical laboratory science program at the University of Vermont, is this year's recipient of the Dennis Weissman/Washington G-2 Reports's Scholarship for Excellence in Clinical Laboratory Sciences. Weissman and Kreger received their awards in a special presentation on October 11 at Lab Institute in Arlington, Virginia.

Weissman, one of the nation's leading experts on the clinical diagnostic laboratory and pathology sectors, founded Washington G-2 Reports in 1979. Since then, his work with and on behalf of laboratory professionals has led many to think of him as "a kind of general commissioner of the laboratory industry," one Lab Institute attendee told *DTTR*. In 2004, Weissman started a consulting firm, Dennis Weissman & Associates, which provides public policy and strategic business intelligence and advice for the healthcare industry.

Kreger was selected for her leadership potential and excellence in the clinical laboratory sciences curriculum. She serves as a student representative on the University of Vermont's Curriculum and Planning Committee and also participates in laboratory research. According to Paula Deming, Ph.D., the university's program director for medical laboratory science, Kreger "is extremely well-rounded and has demonstrated the ability to successfully troubleshoot, solve problems, and multitask; qualities that are essential for success in the clinical laboratory."

The Lab Public Service award was sponsored by Kellison & Company (Warrensville Heights, OH), while the Scholarship for Excellence in Clinical Laboratory Sciences was sponsored by Per-Se Technologies (Alpharetta, GA), which is now part of McKesson.

IVD Stocks Fall 2%; Abaxis Gains 17%

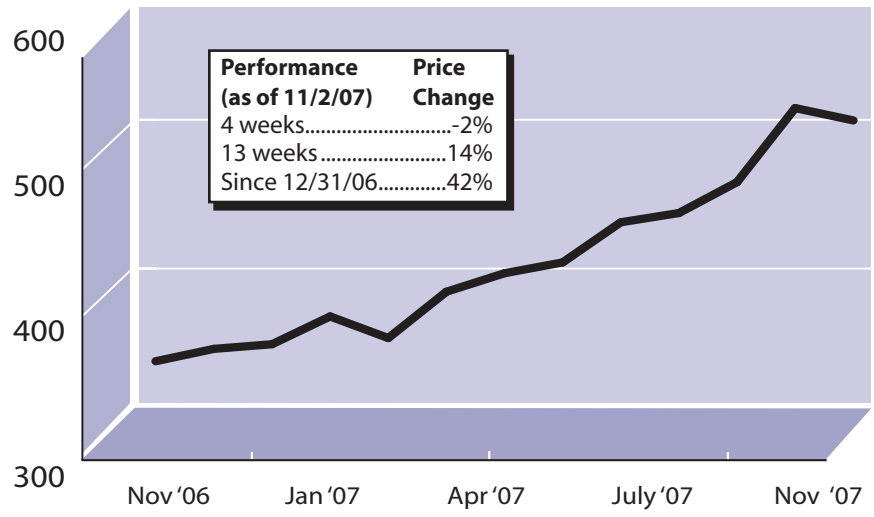
The 18 stocks in the G-2 Diagnostic Stock Index fell an unweighted average of 2% in the five weeks ended November 2, with 11 stocks down in price, three unchanged, and four up. Year to date, the G-2 Index is up a whopping 42%, fueled by a consolidation spree, while the Nasdaq has gained 16% and the S&P 500 Index is up 7%.

Leaving the G-2 Index this month in the wake of closed merger and acquisition deals are **Dade Behring** and **Cytyc**. On November 6, **Siemens** (Erlangen, Germany) completed its $7 billion acquisition of Dade, which is being integrated into Siemens Medical Solutions Diagnostics. In late October, **Hologic** (Bedford, MA) closed on its merger with **Cytyc** (see p. 1).

The newest addition to the index is **Nanosphere** (Northbrook, IL), the nanotechnology-based molecular diagnostics company that went public on November 1, only weeks after receiving FDA approval for two of its DNA-based tests. The company took in gross proceeds of $113 million in its initial public offering, which priced 7 million shares of its common stock at $14 per share and sold an additional 1.05 million shares to its underwriters as part of an over-allotment option. After four days of trading, Nanosphere shares were up 50% to a closing price of $21 per share. The company's revenues for fiscal year 2006 totaled $1.1 million.

One of the few climbers in recent weeks was **Abaxis** (Union City, CA), which jumped 17% to $29.50 per share for a market cap of $679 million. The point-of-care blood testing company recently announced quarterly revenue of $25.2 million, up 20% over the comparable quarter last year, a boost that was largely attributed to strong instrument sales in both the medical and veterinary business areas. Chairman and CEO Clint Severson told investors and analysts that the company has recently made "a number of adjustments to our manufacturing operations to improve efficiencies with an eye toward enhancing operating margins."

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 18 IVD companies.

UP	Price	% Chg
Abaxis	$29.50	17%
Clinical Data	27.03	4
Inverness Medical	64.65	15
Meridian	32.34	2
UNCHANGED		
Gen-Probe	68.01	0
Nanogen	0.75	0
Quidel	19.70	0
DOWN		
Abbott Labs	54.05	-1
Affymetrix	24.77	-10
Beckman Coulter	70.61	-6
Becton Dickinson	82.78	-1
Bio-Rad	92.28	-3
Immucor	31.85	-18
Johnson & Johnson	64.78	-2
Luminex	15.64	-8
OraSure	9.28	-11
Third Wave	8.90	-2
Ventana	86.00	-3

G-2 Insider

Get the lowdown on key legal issues related to diagnostic testing at **Washington G-2 Reports's Lab Law, Compliance, and Liability Summit**, Dec. 5-7, 2007, at the Hyatt Regency Pier 66 in Fort Lauderdale, Florida. The conference will focus on how to manage the risks involved in laboratory-developed testing, personalized medicine, genetic testing, and intellectual property, among other areas.

Alston & Bird's **Peter Kazon** and **William Manion, M.D., Ph.D.**, president, and CEO of Molecular Diagnostics Partners, will present case studies on how laboratories are managing risk and reducing liability as they move to performing more esoteric testing and conveying more complex clinical information.

Mollie Roth, corporate counsel and vice president of business development at Diaceutics, will address the legal issues in personalized medicine, including how clinical laboratories, diagnostic companies, and pharmaceutical companies can effectively collaborate to address the inherent risks.

Dennis Ernst, the director of the Center for Phlebotomy Education, will be joined by attorney **John P. Jacoby** of McDonald Hopkins to discuss how to decrease risk and liability in specimen collection practices, including tissue sample misreading, lab errors, communication of results, and documentation.

To register or for a complete conference program, go to *www.g2reports.com* or call 1-800-401-5937, ext. 2.

Company References

Abaxis 510-675-6500

Correlagen 781-647-0626

DCL 902-566-1396

Genzyme 617-252-7500

Hologic 781-999-7300

Nanosphere 888-837-4436

Orchid Cellmark 609-750-2200

Personalized Lab Services 727-738-0439

PhenoPath 888-927-4366

ReliaGene 504-734-9700

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Ventana Medical Systems 520-887-2155

Diagnostic Testing & Technology Report (ISSN 1531-3786) is published by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Tel: 212-244-0360. Fax: 212-564-0465. Order line: 212-629-3679. Web site: www.g2reports.com.

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