Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Stephanie Murg, Managing Editor, smurg@ioma.com

Vol. VII, No. 1/September 2006

CONTENTS

WASHINGTON G-2 REPORTS

Established 1979

New Molecular Tests Promise Earlier Cancer Detection

Cancer research is all about profiling. Journals teem with new gene-expression, protein, and messenger RNA profiles that are associated with certain types of cancer and their outcomes. But testing and clinical management for many cancers still relies largely on anatomy: Where is the tumor? How big is it? Has it spread? As molecular oncology continues moving from bench to bedside, cancer diagnostics are becoming smaller, more accurate, faster, and less dependent on the trained eye of a pathologist.

Newly developed tests for breast, prostate, and bowel cancer are helping clinicians not only to diagnose cancer but also to refine the clinical prognosis, which can in turn be used to make better, more informed treatment decisions. Additionally, several recent studies have looked at how all of that gene expression data might be used to predict clinical outcomes. And what comes after microarrays? Nantotechnology-fueled cancer diagnostics are already in development. For a closer look, see this month's *Inside the Diagnostics Industry*, pp. 5-6.

Ventana Medical Systems To Buy Vision Systems For $346M

Ventana Medical Systems (Tucson, AZ), a global supplier of automated diagnostic systems to the anatomical pathology market, has announced that it will acquire Vision Systems (Melbourne, Australia) for $346 million in cash. The merger agreement has been unanimously approved by the boards of both companies and is expected to close in the fourth quarter of this year.

"This merger is a transformational event for our companies," said Christopher Gleeson, president and CEO of Ventana, in a conference call with investors and analysts on August 14. "The combination creates a leading global supplier of anatomical pathology solutions, with approximately 1,550 employees and an estimated combined revenue in the twelve months through the end of June 2006 of approximately $300 million."

Nine-year-old Vision Systems develops and manufacturers instruments and reagents for anatomical pathology and research laboratories. The company has operations in Australia, the United Kingdom, and the United States. Revenue for the fiscal year ended June 30 of this year is estimated at $80 million, which represents a growth rate of about 35% over 2005.

➥ *p. 2*

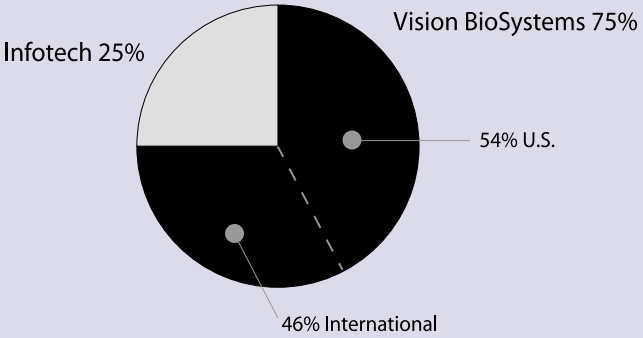
▲ **Ventana Medical Systems,** *from page 1*

Vision Systems has two primary businesses: Vision BioSystems, which designs and manufacturers such clinical diagnostic instruments as tissue processors and staining systems as well as the novacastra brand of antibodies for biopsy-based detection of cancer and infectious disease, and Infotech, the company's core product development engine. The Infotech division provides R&D and product development services to diagnostics and life sciences companies.

"The combination is an ideal fit of two highly complementary businesses in terms of product mix, core capabilities, and geographic presence," said Gleeson. "Not only that, our corporate cultures are very similar." Among the synergies expected from the merger are the combined company's ability to strengthen its advanced staining systems, accelerate workflow product offerings, and expand its antibody menu.

Vision Systems 2006 Revenue

Estimated 2006 Revenue: $80 million



Source: Analyst and *DTTR* estimates

"The market share that Vision has today in the areas where we compete is very small," said Gleeson. "This acquisition is all about growth. It's all about acquiring capability, bringing two companies together that have tremendous opportunity to work together."

The majority of the top 50 U.S. cancer research centers, including the Mayo Clinic, use Ventana's instruments, which automate the viewing of microscope slides. This year, independent of the acquisition, the company expects growth of about 20% for 2006 revenue between $236 and $238 million. The company's 2005 revenue was $199.1 million.

Affy To Launch Million-SNP Chip

Affymetrix (Santa Clara, CA) has announced its plan to launch a GeneChip containing one million single nucleotide polymorphisms (SNPs). The product, which will debut early next year, will sell for around $500. In the wake of the announcement, the company has reduced the price of its two-chip 500,000-SNP genotyping set to $250. Additionally, the 500K set will be available as a single array by the end of the year.

AFFY CHIP

"Our business strategy over the past decade has been to use our manufacturing leverage and technical innovations to give customers more data per dollar each passing year," said Stephen P.A. Fodor, Ph.D., the founder, chairman, and CEO of Affymetrix. "That strategy was instrumental in growing the gene expression market, and we believe that reducing the price per SNP will significantly increase the overall genotyping market opportunity, particularly where large sample populations are required."

The technological advancements, which enable higher throughput and larger-scale experiments, come as the result of Affymetrix's ongoing collaboration with researchers at MIT's Broad Institute and Harvard to refine genotyping algorithms. Microarray pioneer Affy sold its first commercial microarray in 1994 and has since installed more than 1,400 systems worldwide.

Prodesse Makes The Most of Growing Demand For ASRs

As it builds an impressive roster of clients for its infectious disease assay technology, analyte-specific reagent (ASR) developer and reference laboratory Prodesse (Waukesha, WI) has signed license agreements with Roche (Basel, Switzerland) and Invitrogen (Carlsbad, CA) to use the technologies of both companies to develop and validate molecular diagnostic assays.

Prodesse, a leader in multiplex PCR, focuses on infectious disease diagnostics. Founded to commercialize a novel, patented technology developed by researchers at the Medical College of Wisconsin, the company operates a CLIA-certified reference laboratory as well as a manufacturing facility. Prodesse's reference lab was established in 1995. Three years later, the company began offering ASRs, enabling other CLIA labs to develop and validate their own assays based upon Prodesse's technology.

The license agreement with Invitrogen gives Prodesse access to Invitrogen's LUX (Light Upon eXtension) reagents, which are a starting point for a range of drug discovery and molecular diagnostic applications, including gene expression studies, biomarker analysis, and functional genomics experiments. Highly sensitive and specific, LUX also enables users to examine multiple diagnostic targets in a single experiment.

Through its newly signed IVD Patents License Agreement with Roche, Prodesse has gained the right to manufacture real-time products that laboratories can use to develop and validate assays for the detection of Influenza A, Influenza B, respiratory syncytial virus (RSV), and human metapneumovirus with the additional authority to convey rights to the service provider.

Prodesse's Analyte Specific Reagents (ASRs)

Available Now	*In Development*
Influenza A Virus*#	Enterovirus*
Influenza B Virus*#	L pneumophila*
RSV*#	Parainfluenza Virus*
Human Metapneumovirus*#	Salmonella*
C pneumoniae*	Shigella*
M pneumoniae*	Campylobacter**
B pertussis*	West Nile Virus#
Parainfluenza Virus#	

*=Real Time (designed for such real time instruments as the ABi 7500, BioRad iCycler iQ, Cepheid SmartCycler, Corbett Research Rotor-Gene 3000, and Roche LightCycler 2.0)
#=Standard Platform (designed for amplification on conventional thermocyclers with detection performed using microtiter plate)
Source: Prodesse

In early August, Prodesse reported that Columbia University Medical Center, New York-Presbyterian Medical Center, and Kaiser Permanente have used Prodesse's analyte-specific reagents to develop RT-PCR assays for Influenza A, Influenza B, and RSV. Viromed, a subsidiary of LabCorp, also uses Prodesse ASRs for these molecular assays.

"By the end of the year we will be targeting 10 respiratory organisms in real time," said Prodesse CEO Tom Shannon. The company plans to begin FDA clearance submission process for these products early next year, at which time it will also move into non-respiratory detections.

Abbott Sees Growth In Molecular And Point-Of-Care, Gets Regulatory Nods

Abbott (Abbott Park, IL) saw second-quarter sales growth of nearly 18% in its medical products division, led by growth in its vascular business but also boosted by double-digit sales growth in its molecular and point-of-care businesses. In the first half of 2006, Abbott's diagnostic sales totaled $1.9 billion, up 4.4% on the previous year.

The company recently received 510(k) clearance from the FDA to market its i-STAT BNP cartridge, a new point-of-care diagnostic test used to quickly assess the level of brain natriuretic peptide (BNP) in patients in critical-care settings. BNP is secreted into the bloodstream during congestive heart failure, a condition that is usually tricky to diagnose because of its nonspecific symptoms, such as shortness of breath. Early diagnosis and treatment of heart failure in the emergency department has been shown to reduce length of stay by 35% and mortality for admitted patients by 60%.

Abbott's single-use BNP cartridge is designed for use with the i-STAT System, a hand-held blood analyzer that can be used at the point of care. Results are available in about 10 minutes. The i-STAT system can also test for blood gases, electrolytes, chemistries, coagulation, hematology, and glucose markers.

The FDA has also approved Abbott's Prism hepatitis B surface antigen (HBsAg) and HBsAg Confirmatory test. These tests can be used to screen donated blood for HBsAg. The Prism blood screening system was approved for use in the United States with the HBcore test for hepatitis B, which was introduced in October. The system can run 160 samples per hour. Additional hepatitis and retrovirus screening tests are under FDA review.

New FDA Task Force To Tackle Tiny World Of Nanotech

According to the National Nanotechnology Initiative, nanotechnology is "the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications." A nanometer is a billionth of a meter. A human hair is about 80,000 nanometers wide.

The FDA has formed an internal FDA Nanotechnology Task Force, which is charged with determining regulatory approaches that encourage the development of safe and effective FDA-regulated products that use nanotechnology materials. The task force will recommend ways to identify and address gaps in knowledge or policy related to nanotechnology, particularly the potentially adverse health effects from these products.

The chemical or physical properties of materials on a nanoscale often differ from those of their larger counterparts. For example, nanotechnology materials may have increased biological or optical activity.

The task force will chair a public meeting on October 10 designed to help the agency understand how developments in nanotechnology may lead to beneficial or adverse health effects. The group will also evaluate the effectiveness of the agency's regulatory approaches with regard to nanotechnology, explore opportunities to foster innovation, and consider how to best communicate with the public concerning the use of nanotechnology materials in FDA-regulated products. The task force is expected to submit its initial findings and recommendations to the FDA commissioner within nine months of the public meeting.

From Biopsy To Base Pairs: New Molecular Tests Promise Earlier Cancer Detection

Even the most skilled of pathologists and the most powerful of microscopes cannot see the molecular changes that take place at the earliest stages of cancer. That's why molecular diagnostics are increasingly seen as the standard of care when diagnosing many cancers, and why new predictive and diagnostic cancer tests are appearing in the scientific literature—and the clinical laboratory—every day.

Gene Expression Profiling: Beyond the Fishing Expedition

When microarray analysis first came on the scene, researchers rushed to carry out what were sometimes derided as expensive "fishing expeditions," sweeping studies that aimed to see how gene expression was altered in certain disease states. Although many of these studies yielded interesting results along with massive quantities of data, they revealed surprisingly little overlap in their findings. A study published in the August 10 issue of the *New England Journal of Medicine* addressed this issue by using gene expression profiles of 295 tumor samples for which patient survival data was available to compare five prognostic or predictive gene expression-based models.

"An important and unanswered question is whether these assays actually disagree or agree concerning outcome predictions for the individual patient," says Charles M. Perou, M.D., a professor at the University of North Carolina School of Medicine and senior author of the paper. Perou and his team found that four predictors showed "significant overlap" in their outcome predictions on individual breast cancer patients, even though there was little gene overlap.

Of the three predictors showing the greatest coincidence, two were the main assays that are commercially available and being used to guide clinical trials: the so-called 70-gene good-versus-poor outcome model, which is used in Agendia's MammaPrint test, and the recurrence score model, which Genomic Health uses in its OncoType DX assay. These two models were in 77% to 81% agreement in their ability to classify outcomes. "This is good news for breast cancer patients," concluded Perou. "It means that different groups have independently arrived at tests that agree with each other and that they all do add information not provided by existing clinical tests."

"Molecular expression profiles have the potential to identify the dominant growth and survival networks (networks of proteins in the breast cancer cell that enable its growth and survival) assessed by the various predictive assays," wrote Joyce O'Shaughnessy, M.D., in a related *NEJM* editorial. "There is a great, unmet need in the treatment of estrogen receptor (ER)-negative and HER2-negative basal cancers and ER-positive, high-grade cancers, because the major molecular networks that sustain these cancers are not yet known."

Cancer Testing That Guides Therapy

In another study in the same issue of the *NEJM*, researchers used gene expression profiles to refine prognosis in early-stage non-small-cell lung cancer (NSLC), a condition that uses a staging scheme that is thought to be an imprecise predictor of the prognosis of an individual patient. The authors note that, for example, approximately 25% of patients with stage IA NSLC have a recurrence of the disease after surgery, suggesting the need to identify patients in this subgroup for more effective therapy.

The authors first identified gene expression profiles that predicted the risk of recurrence in 89 early-stage NSLC patients and then used this test, which they termed the lung metagene model, to evaluate several additional patient cohorts. They found that their test predicted recurrence for individual patients significantly better than did clinical prognostic factors and was consistent across all of the various early stages of NSLC.

The new diagnostic model also predicted a subgroup of stage 1A patients who were at a high risk for recurrence and who might be best treated with adjuvant chemotherapy. The information would allow clinicians to avoid giving a patient potentially toxic chemotherapy unnecessarily. The authors described their study as "a critical first step in the use of genomic tools as a strategy to refine the prognosis and improve the selection of patients appropriate for adjuvant chemotherapy."

Nano: The Final Frontier?

How much more accurate and sensitive can cancer diagnostics get? Harvard University researchers are using scanning arrays of silicon nanowires to detect molecular markers of cancer. The markers they were looking for, which included prostate specific antigen (PSA), PSA-a1-antichymotrypsin, and carcinoembryonic antigen, constituted only one hundred-billionth of the protein present in a drop of blood, yet they were able to pinpoint the exact type of cancer present faster than any other test. Since the arrays detect molecules suspended in fluids, they could one day be used on a point-of-care basis to test drops of blood directly.

"A nanowire array can test a mere pinprick of blood in just minutes, providing a nearly instantaneous scan for many different cancer markers. It's a device that could open up substantial new possibilities in the diagnosis of cancer and other complex diseases," says author Charles M. Lieber, a professor of chemistry at Harvard and an author of the *Nature Biotechnology* paper in which the findings were published last October.

According to Lieber, nanowire arrays could easily be scaled up to detect many different cancer markers. The ability to assess the presence of multiple biomarkers simultaneously is particularly appealing for complex diseases such as cancer. "Patterns of multiple cancer markers might provide the information necessary for robust diagnosis of disease," wrote the authors. "Detection of markers associated with different stages of disease pathogenesis could further facilitate early detection."

Research Drives Comprehensive Molecular Testing At City Of Hope Lab

CMDL's "Epidiomics Vision": Molecular diagnosis in the context of molecular epidemiology and bioinformatics to guide the physician in the age of personalized predictive and preventive medicine.

At the City of Hope National Medical Center's Clinical Molecular Diagnostic Laboratory (CMDL; Duarte, CA), it's all about context. The CMDL is guided by what it calls the "Epidiomics Vision" of "molecular diagnosis in the context of molecular epidemiology and bioinformatics to guide the physician in the age of personalized predictive and preventive medicine." Fittingly, it is the laboratory's strong ties to epidemiology, bioinformatics, and genetic research that have helped the eight-year-old CMDL to build a growing molecular test menu of impressive breadth, depth, and complexity.

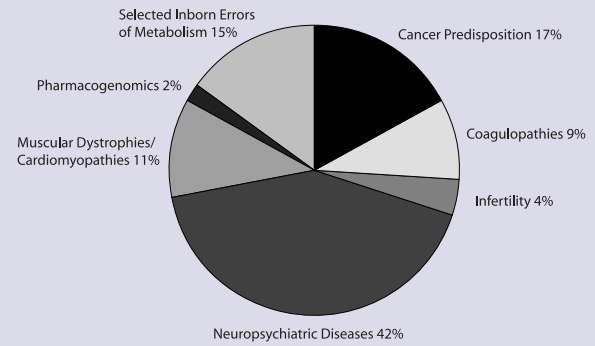
The City of Hope National Medical Center is one of 39 National Cancer Institute-designated Comprehensive Cancer Centers in the United States. The CMDL, which operares independently of the medical center's general reference laboratory, prides itself on expert genotype to phenotype analysis in the context of a molecular epidemiology collaborative group and a methodology development group.

The CMDL tests approximately 3,000 samples annually. The laboratory's yearly revenues are $3 million to $5 million and growing. They offer tests on between 30 and 40 genes for about 50 different diseases including ataxia-telangiectasia mutated (ATM), prostate cancer, Charcot-Marie-Tooth disorder Type 2 (Lamin A/C), and numerous others. "Most of our tests are comprehensive analyses," says Steven Sommer, M.D., Ph.D., the laboratory's director. "We often have more than one test per gene; typically one test reflexes to another if a mutation is not found."

The CMDL has three broad areas of specialization or concentration: cancer genetics, neuropsychiatric genetics, and selected inborn errors of metabolism such as cystic fibrosis, muscular dystrophy, hemophilia, and Marfan syndrome.

The CMDL was created in 1998 and initially employed three people. It currently employs 12 technologists, two genetic counselors, four mutation experts who are either M.D.s or Ph.D.s and board eligible or board certified by the American College of Medical Genetics (ACMG), and one bioinformatics specialist.

CMDL's Genetic Test Offerings By Disease*



*The laboratory also offer complementary testing, including an X-linked mental retardation panel, microsatellite instability analysis, dosage analysis (detection of heterozygous deletions and duplications), custom candidate gene DNA testing, case control analysis, and custom molecular epidemiology services. Source: CMDL and *DTTR*

The laboratory continues to have high growth, both in the volume of the current test menu and by the addition of new tests. The laboratory has had a six-fold increase in test volumes in the last two years.

"We perform not only the clinical tests, but we perform research on many of the genes, so we specialize in providing the ultimate in what we call phenotype/genotype analysis," says Sommer. "We have four co-directors in other laboratories, and they're each experts in their fields. I chair the Department of Molecular Diagnostics and the Department of Molecular Genetics, which is a research department. The initial tests the clinical laboratory offered were ones in genes that I had a long-term research presence in."

HemoCue Develops Point-Of-Care WBC

HemoCue (Angelholm, Sweden) has developed a single-analyte point-of-care testing system for determining total white blood cell count. Known as HemoCue WBC, the simple test can be performed in a doctor's office, with results available in minutes. The company premiered the system at last month's meeting of the American Association of Clinical Chemistry and now has its sights on a CLIA waiver.

Elevated total WBC is usually a sign of bacterial infection. "Our new point-of-care system for measuring total WBC will help physicians prescribe antibiotics to patients in need of it without unnecessary delay and to avoid prescribing it to patients where it has no effect," says Stellan Lindberg, HemoCue's director of research and development.

Large-scale testing of HemoCue's new WBC system is slated to begin early next year in clinics in Sweden and the United States. The system is expected to be commercially available by the second quarter of 2007. Pricing information is not yet available, a company representative tells *DTTR*.

Privately owned HemoCue develops, manufacturers, and markets point-of-care diagnostics in over 120 countries. Its major products include hemoglobin, glucose, and urine albumin testing systems. About 200,000 of the company's B-Hemoglobin and B-Glucose instruments have been installed worldwide since their introduction 20 years ago.

Earlier this year, HemoCue contracted with the American Red Cross to supply the organization with its Donor Hb Checker system, a point-of-care system for hemoglobin screening of blood donors.

FDA Clearances For Sysmex Hematology Analyzers

Sysmex (Kobe, Japan) has received FDA clearance for its new XS-1000i automated hematology analyzer. The instrument has been cleared for use in clinical laboratories and physician offices. Additionally, the company's XT-2000i and XT-1800i analyzers have just been cleared by the FDA for the analysis of cerebrospinal fluid, as well as serous and synovial fluids.

Aimed at smaller clinical laboratories and physicians' offices, the XS-100i uses fluorescent flow cytometry and hydrodynamic sheath flow technology for such operations as white blood cell analysis, CBC testing, and platelet cell counting. The list price for the XS-100i is $85,000, a company representative tells *DTTR*.

Now cleared for body fluid analysis (automated white blood count and red blood count), Sysmex's XT-series analyzers are designed for mid-volume laboratories. "Superior analytical sensitivity afforded by the use of fluorescent technology for leukocyte counting and differentiation is what gives Sysmex products the ability to excel in this arena," said Ian Giles, M.D., director of scientific affairs for Sysmex America (Mundelein, IL).

Gene Logic Trims Slumping Genomics Division And Teams With FDA

In the wake of a 67% ($9.5 million) decline in second-quarter revenue for its genomics division, Gene Logic (Gaithersburg, MD) has announced that it will restructure the division, cutting about 80 jobs effective October 5 for an estimated savings of $8 million in salary and benefit costs. The cuts are the result of a larger, ongoing strategic review of the business that the company plans to complete this month.

Meanwhile, the company has entered into an agreement to provide the FDA with genomic data and analytical tools that will help them to address priorities outlined in the agency's March 2005 Pharmacogenomics Guidance Document and the 2006 Critical Path Initiative Report.

Among the services included in Gene Logic's genomics division are microarray data generation and analysis, drug target and biomarker discovery, and predictive toxicology. No cuts are planned for the company's other two divisions: preclinical services and drug repositioning.

For the first half of this year, the genomics division reported an operating loss of $9.9 million, down a whopping 494% on the operating profit of $2.5 million during the first half of 2005. The company attributed the slump to lower than expected sales and cautioned that the results would "adversely impact operating results for the division for the foreseeable future."

Shortly after announcing the losses and planned restructuring, Gene Logic entered into an agreement to provide the FDA with access to some of the company's genomic data, including gene expression data from thousands of normal tissue samples, and its Genesis Enterprise System for genomic data management. The FDA is expected to use the data and software to evaluate voluntary genomics data submissions (VGDS) to help inform the agency of the types of emerging technologies that are being used to identify relevant biomarkers.

According to Gene Logic Vice President Donna Mendrick, Ph.D., "The FDA is receiving sufficient toxicogenomics and toxicology data from Gene Logic to readily provide benchmarks for dose and time responses of drugs known to induce toxicity and control compounds, thereby augmenting their internal capabilities to provide meaning to VGDS."

Dade Behring Expands Drug Testing Portfolio

Clinical diagnostics giant Dade Behring (Deerfield, IL) has launched tests for the illegal drug Ecstasy and for the immunosuppressant drug Tacrolimus. Both tests will be available on Dade's Dimension family of chemistry analyzers as well as the company's V-Twin and Viva-E drug testing analyzers. As of June 30, Dade had a total of 39,300 instruments installed worldwide.

Ecstasy, or MDMA (3,4 methylenedioxymethamphetamine), is a synthetic, psychoactive drug that acts as both a stimulant and psychedelic. According to the most

recent *National Survey on Drug Use and Health*, an estimated 450,000 people in the United States age 12 and older used MDMA in the past 30 days.

Spurring demand for Ecstasy testing are proposed guidelines by the Substance Abuse and Mental Health Services Administration (SAMHSA) to make testing for the drug mandatory as part of regulating workplace drug use. Washington G-2 Reports estimates that drugs-of-abuse testing accounted for just under $1 billion, or about 2%, of all clinical laboratory testing in 2005.

Tacrolimus is widely used to prevent transplant rejection, but it has a narrow window of effectiveness and therefore requires close monitoring by physicians. When run on the Dade's Dimension system, the Tacrolimus test does not require a manual pretreatment step, the only test on the market that eliminates this potential source of contamination.

Each year, about 50,000 people worldwide receive organ transplants. Dade already offers tests for cyclosporine, another immunosuppressant drug, and the company has indicated that it is committed to further expanding its range of transplant diagnostics.

With Revenues Soaring, Chembio Submits CLIA Waiver Applications

So far, it's been a good year for Chembio (Medford, NY): The diagnostics company received approval letters from the FDA for pre-market applications (PMAs) for its two rapid HIV test products, Sure Check HIV 1/2 and HIV 1/2 Stat-Pak; introduced Dual Path, a new platform that it will use to create new rapid tests; and saw revenues for the first half of the year rise by 75% compared to the same period in 2005. Next on the company's to-do list: obtain CLIA waivers for the rapid HIV tests and release PrimaTB Stat-Pak, a rapid test for tuberculosis.

Of the estimated 850,000 to 950,000 persons in the United States infected with HIV-1, 25% are thought to be unaware of their status.

Chembio's revenue growth for the first half of the year is attributable to increased sales of its rapid tests for HIV and for Chagas, a disease that is endemic in much of Latin America and affects 16 to 18 million people, killing 50,000 annually. Rapid HIV revenue for the first six months of 2006 increased approximately 143% to $1.42 million, an increase of 143% over the same period from last year's revenue of $584,000. Chagas testing revenue spiked to $942,000 from last year's $36,000.

Having received FDA PMA approval in May of this year for its Sure Check HIV and HIV Stat-Pak tests, Chembio has recently applied for CLIA waivers for both products. FDA marketing approval is a prerequisite for submitting a CLIA waiver application. If granted, the waivers would extend use of these tests to about 190,000 laboratory entities nationwide, including physician offices and clinics.

With the CDC's new recommendations for routine HIV testing, increasing international demand for HIV diagnostics, and the possibility for FDA approval for over-the-counter sales of rapid HIV tests, the future looks bright for Chembio.

IVD Stocks Steady; Affy Plummets While Inverness Jumps 18%

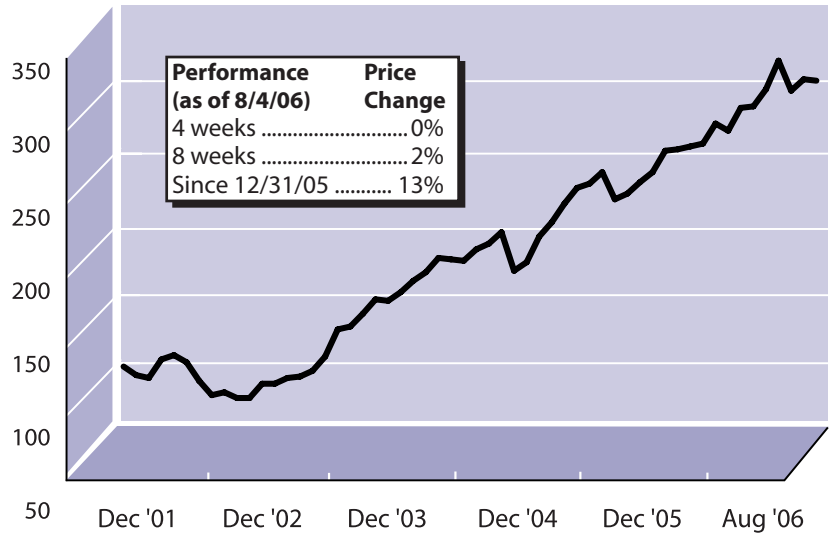
The 21 stocks in the G-2 Diagnostic Stock Index held steady in the four weeks ended August 4, with 10 stocks up in price, 10 down, and one unchanged. Year to date, the G-2 index is up 13%, while the S&P 500 is up 2% and the Nasdaq is down 5%.

The market remains fickle when it comes to microarray maker **Affymetrix** (Santa Clara, CA), which dropped 22% to $20.03 per share for a market capitalization of $1.4 billion. On August 1, the stock price reached a three-year low of $17.50 in the wake of its announcement of lower than expected revenues for the second quarter. Additionally, as part of a review into the timing of its stock options grants, the company announced that by the end of the third quarter, it will restate some financial results between 1997 and 2003. Affy previously filed for an extension on its filing for the second quarter of this year and said that its first-quarter SEC filing should not be relied upon.

Despite posting a second-quarter loss of $10.6 million in the face of hefty restructuring charges, **Inverness Medical Innovations** (Los Angeles, CA) was up 18% to $32.95 for a market capitalization of $1.1 billion. The company recently signed a worldwide licensing agreement with **StatSure Diagnostic Systems** (Framingham, MA) to market and distribute StatSure rapid HIV blood tests in consumer and professional markets. StatSure will be responsible for completing the development and for manufacturing the product, as well as for performing clinical trials and obtaining regulatory approvals.

Meridian Bioscience (Cincinnati, OH) was down 16% to $20.50 for a market capitalization of $560.8 million. Although its profit for the third quarter was up by almost 40%, the company fell short of analysts' revenue estimates. The company's third-quarter revenue increased by 5% to $26.6 million from $25.4 million last year, while analysts had pegged it at between $27.9 million and $26.8 million.

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 21 IVD companies.

UP	PRICE	% CHG
Abbott Labs	$47.24	9%
Abaxis	23.18	8
Bayer	48.79	5
Becton Dickinson	66.00	10
Bio-Rad	68.70	5
Digene	41.17	6
Immucor	20.04	5
Inverness Medical	32.95	18
Johnson & Johnson	63.53	5
Third Wave	2.96	4
UNCHANGED		
Dade	40.63	0
DOWN		
Affymetrix	20.03	-22
Beckman Coulter	51.90	-8
Biosite	41.80	-10
Cholestech	11.24	-14
Cytyc	23.99	-4
Gen-Probe	53.09	-1
Meridian	20.50	-16
OraSure	9.30	-1
Quidel	8.66	-6
Ventana	45.94	-2

G-2 Insider

Don't miss the **24th Annual Lab Institute:** ***Making Connections Work***, September 27-30, 2006, at the Crystal Gateway Marriott, Arlington, Virginia. This year's Institute features some of the lab industry's most influential business and government leaders, including:

Thomas Mac Mahon, chairman and CEO of LabCorp, will assess the state of the United States laboratory industry and describe key issues and changes on the horizon.

Pete Stark, U.S. Representative (D-CA), will join American Clinical Laboratory Association President **Alan Mertz** in evaluating the key issues that labs and pathologists face on Capitol Hill.

Evan Jones, chairman and CEO of Digene, will address the exploding market for molecular testing, including the benefits and concerns of molecular testing and what they mean to labs.

Ronald Weinstein, M.D., will draw upon his experience as the chairman of UltraClinics to discuss how telepathology can improve services to hospitals and clinics.

Kerry Hicks, chairman and CEO of Health Grades, will analyze the factors driving consumer-driven healthcare and why quality and price transparency are critical as this movement takes hold.

In all, the Lab Institute conference will feature presentations and panel discussions from more than 70 laboratory experts and government officials. For a complete program go to ***www.g2reports.com*** or call 1-800-401-5937, extension 2.

Company References

Abbott (POC) 609-443-9300

Affymetrix 888-362-2447

Chembio 631-924-1135

City of Hope CMDL 888-826-4362

Dade Behring 847-267-5300

Gene Logic 301-987-1700

HemoCue 800-881-1611

Invitrogen 760-603-7200

Prodesse 262-446-0700

Roche (Diagnostics) 317-845-2000

Sysmex 847-996-4500

Ventana Medical Systems 520-887-2155

DTTR Subscription Order or Renewal Form

❑ **YES**, enter my one-year subscription to the ***Diagnostic Testing & Technology Report (DTTR)*** at the rate of $419/yr. Subscription includes the ***DTTR*** newsletter and electronic access to the current and all back issues at *www.ioma.com/g2reports/issues/DTTR*. Subscribers outside the U.S. add $50 postal.*

❑ I would like to save $174 with a 2-year subscription to ***DTTR*** for $664.*

❑ **YES**, I would also like to order ***Lab Industry Strategic Outlook 2005: Market Trends & Analysis*** for $995 ($795 for Washington G-2 Reports subscribers). (LR37)

Please Choose One:

❑ Check enclosed (payable to Washington G-2 Reports)

❑ American Express ❑ VISA ❑ MasterCard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Ordered by:

Name _____

Title _____

Company _____

Address _____

City _____ St _____ ZIP _____

Phone _____ Fax _____

e-mail address _____

*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere.

Return to:
Washington G-2 Reports,
3 Park Avenue, 30th Floor,
New York, NY 10016-5902
Tel: (212) 629-3679
Website: *www.g2reports.com*

For fastest service:
Call (212) 629-3679
or fax credit card order
to (212) 564-0465

DTTR 9/06

 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.

Stephanie Murg, Managing Editor; Dennis Weissman, Executive Editor; Janice Prescott, Sr. Production Editor; Perry Patterson, Vice President and Group Publisher; Joe Bremner, President.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 212-244-0360, ext. 2.