Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

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FDA Clears First IVDMIA, Gets An Earful At Public Meeting

Just days before its public meeting on the draft guidance for in vitro diagnostic multivariate index assay (IVDMIAs), the FDA cleared the first such device. The MammaPrint test, developed by Agendia (Amsterdam, Netherlands) determines the likelihood of breast cancer recurrence. Agendia has sold the test in Europe since 2005.

MammaPrint uses microarray analysis to predict whether existing cancer will metastasize based on the activity patterns of 70 genes linked to tumor recurrence in a sample of a surgically removed breast cancer tumor. An algorithm produces a score that determines whether the patient is deemed low risk or high risk for spread of the cancer to another site.

The recent decision makes MammaPrint the first cleared IVDMIA device, a designation created several months ago in the FDA's draft guidance document concerning the need for these complex molecular tests to meet premarket review and post-market device requirements even when the tests are developed and used by a single laboratory. As part of its application for marketing clearance for MammaPrint, Agendia submitted data from a study using tumor samples and clinical data from 302 patients at five European centers. The FDA will soon publish a special controls guidance document describing types of data that should support claims for genetic profiling for breast cancer prognosis.

On February 8, the FDA held a public meeting to discuss its draft guidance document. For more on that meeting and IVDMIAs, see *Inside the Diagnostics Industry*, pp. 5-6.

GE Adds IVD With Abbott Purchases, Quest Acquires HemoCue

So far, 2007 is proving a good year for IVD acquisitions. As predicted in last month's issue of *DTTR*, General Electric (GE; Fairfield, CT) announced that they have entered into a definitive agreement to acquire two businesses of Abbott Diagnostics (Abbott Park, IL)—the primary in vitro diagnostics business and the point-of-care diagnostics business (formerly known as i-STAT)—for $8.13 billion in cash. The transaction is expected to close by the end of the second quarter of this year.

Continued on p. 2

▲ **GE Adds IVD,** *from page 1*

Also betting on point-of-care (POC) or "near patient" testing is Quest Diagnostics (Lyndhurst, NJ), which has acquired POC testing company HemoCue (Angelholm, Sweden) from the private equity firm EQT II B.V. in a cash transaction valued at approximately $420 million.

Diagnostics, along with security, energy services, and "green" products, is among the growth platforms singled out by GE CEO Jeffrey Immelt, who recently dumped two of the conglomerate's slow-growing businesses—advanced materials and reinsurance.

The Abbott acquisitions will substantially expand GE Healthcare's diagnostic portfolio, which already includes in vivo diagnostic imaging systems and molecular imaging, and bolster their competitive position just as Siemens is pushing aggressively into the diagnostic testing space with their recent acquisitions (and subsequent merger) of Bayer Diagnostics and Diagnostic Products Corporation (DPC).

The newly merged entity, Siemens Medical Solutions Diagnostics, is headquartered in Tarrytown, New York, and Los Angeles, California, and has approximately 8,000 employees. It will specialize in clinical chemistry, patient tests, laboratory automation, and hematology. It is also developing product lines in molecular diagnostics, including pharmacogenomic testing. In 2005, DPC and Bayer Diagnostics generated combined sales of $2.3 billion, and Siemens spent about $7.4 billion on the acquisitions.

Point-of-care (or near patient) testing is a $6 billion market that represents 13% of the in vitro diagnostics market. It is also one of the fastest-growing market segments, with annual growth of between 8% and 10%.

Siemens is now touting itself as "the world's only full-service diagnostics company," in its bringing together under one roof medical imaging, laboratory diagnostics, and clinical IT. GE can now make a similar claim, and the pressure is on for the medical systems division of Philips to expand beyond its core strengths in imaging.

Meanwhile, Abbott is hanging on to its molecular diagnostics and diabetes care businesses. Abbott's in vitro diagnostics business, including the point-of-care segment, is expected to generate net sales of approximately $2.7 billion in 2006.

Quest's acquisition of HemoCue is a strategic test-menu builder, not unlike its purchase last year of infectious disease testing leader Focus Diagnostics, and a powerful boost for the lab giant's stake in the $6 billion POC testing market. With annualized revenues of approximately $90 million, HemoCue is the leading international provider in POC testing for hemoglobin, with a growing share in glucose and microalbumin testing.

The company recently developed HemoCue WBC, a single-analyte point-of-care testing system for determining total white blood cell count. The test can be performed in a doctor's office, with results available in minutes. The company debuted the system at last year's meeting of the American Association of Clinical Chemistry and now has its sights on a CLIA waiver. Large-scale testing of HemoCue's new WBC system is slated to begin shortly in Sweden and the United States. The system is expected to be commercially available by the second quarter of 2007.

With 340 employees, 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. Distribution is through a network of six wholly owned subsidiaries along with franchises and third-party distributors in more than 100 countries.

Last 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.

Schering-Plough And OraSure To Develop Rapid POC Oral HCV Test

Schering-Plough Corporation (Kenilworth, NJ) and OraSure Technologies (Bethlehem, PA) will collaborate on the development and promotion of a rapid oral test for the detection of antibodies to the hepatitis C virus (HCV), utilizing OraSure's OraQuick technology platform. HCV, the most common blood-borne infection in America, affects approximately four million people or about one in every 50 adults, according to the Centers for Disease Control and Prevention.

The agreement brings together OraSure, developer and manufacturer of the only FDA-approved rapid oral fluid HIV-1/2 test, and Schering-Plough, which develops HCV therapies.

According to Douglas A. Michels, president and CEO of OraSure Technologies, Schering-Plough will help to introduce OraSure's point-of-care oral HCV test once it receives FDA approval. "We believe a rapid oral fluid HCV test has significant commercial and medical value in that it will help identify more individuals who are infected, thus enabling them to receive appropriate treatment," added Michels.

Under the terms of the agreement, Schering-Plough will reimburse OraSure for a portion of the costs incurred by OraSure to develop the rapid oral HCV test and also will provide certain promotional support in the physicians' office market in the United States. All sales of the HCV test will be made by OraSure, and OraSure will retain the rights to market and sell the test in all markets throughout the United States. Tests sold to U.S. physicians' offices will be co-branded and will incorporate OraSure's OraQuick brand name and "Be In Charge," the name of Schering-Plough's HCV patient support program. The agreement has an initial term of two years from the date that the test is first sold commercially.

Earlier this year, Roche Diagnostics submitted its HCV viral load monitoring test for FDA review. Known as the COBAS AmpliPrep/COBAS TaqMan HCV test, it provides quantitative information about the HCV virus present in a patient's blood. Information about a patient's "viral load" can then be used to monitor therapeutic response.

G2's LabCompete Conference Highlights Niche Player Genova

Senior executives from hospital laboratories and independent reference laboratories nationwide met in Phoenix in December to discuss strategies for competing in an environment where costs are squeezed, technology is changing, electronic medical records are rapidly gaining hold, and two giant national labs hold signifi-

"The average revenue per patient is around $160. Our gross profit on that is about 50%."

cant market share. The forum was LabCompete: Strategies for 2007, Washington G2 Reports' inaugural conference on how to compete and gain market share in the clinical laboratory industry. A standout presentation was that of Ted Hull, president and CEO of Genova Diagnostics (Asheville, NC), a small specialty laboratory that operates largely outside of managed care.

Tapping into a consumer-driven market, Genova offers customized testing that patients pay for mostly out of pocket, creating enviable and sustainable profit margins and allowing the company to offer cutting-edge tests. "The average revenue per patient is around $160," explained Hull. "Our gross profit on that is about 50%. We're still pretty small, so we have plenty of room to grow." The company's average days sales outstanding (DSO) is 32, while their bad debt rate is less than 1%.

"What makes us different is our panel-driven approach," said Hull. Over 95% of the analytes that Genova tests for are not exclusive to the company. What is unique is the way Genova combines esoteric and standard-of-care tests in a functional, systemic approach that includes colorful, graphical results reports. Testing panels are designed to assess the function of an overall system, such as digestion. For example, the company's comprehensive cardiac profile combines traditional lipid testing with independent risk factors and measurement of lipid sub-fractions.

Specializing in noninvasive testing for digestive diseases, Genova partners with gastroenterologists and has two proprietary tests. The first, pancreatic elastase 1 (PE1), tests for the only noninvasive marker that correlates with the secretin-pancreozymin test, which is regarded as the gold standard for assessment of exocrine pancreatic function. Genova also has an exclusive on testing for calprotectin, which correlates with 111-indium-labeled leukocyte excretion, as well as histologic and endoscopic grading of disease activity in ulcerative colitis. This test enables clinicians to distinguish between patients with inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS), and to monitor therapy for IBD.

Founded in 1987 with an initial focus on stool testing, Genova now has approximately 150 employees and has expanded testing into immunology, endocrinology, nutrition, and genomics.

The next LabCompete conference is planned for February 2008, at Loews Ventana Canyon Resort in Tucson, Arizona.

Ciphergen Initiates Clinical Trials For Ovarian Cancer Triage Test

Ciphergen Biosystems (Fremont, CA) has initiated a clinical trial to evaluate its ovarian cancer triage test, a molecular diagnostic assay that is designed to differentiate women with ovarian cancer from those with benign pelvic masses. There is currently no reliable way to distinguish a benign ovarian tumor from a malignant one before performing surgery on a pelvic mass. The current standard of care is physical and radiological exam.

Ciphergen plans to enroll 700 to 1,000 patients at approximately 20 clinical trial sites and expects to submit trial results to obtain FDA clearance for the test. Ciphergen has a strategic alliance with Quest Diagnostics focused on commercializing the ovarian tumor triage test.

Industry Players Seek Clarification, Offer Criticism On IVDMIA Guidance

"We made an attempt in the guidance to define what an IVDMIA is. Judging from the comments that have been received, we didn't do a spectacular job, and we'll be working very hard to improve this."

Over 350 biotechnology and laboratory industry players, including lobbyists and government officials, assembled in Gaithersburg, Maryland, on February 8 for the FDA's day-long public meeting on its recently issued draft guidance for in vitro diagnostic multivariate index assays (IVDMIAs).

The public forum came just days after the agency cleared the first such device, Agendia's MammaPrint breast cancer prognostic test, which was cleared through the De Novo 510(k) process. This process is used in cases where there is no previously cleared device with the same intended use. The FDA does not believe that the risk of the device is high enough to warrant the sponsor's submission of a PMA, so a 510(k) is submitted, and the test is down-classified into Class II.

A common theme of the meeting's 31 presentations was the call for greater clarity and specificity in the FDA's definition of an IVDMIA and the agency's plans to regulate this new and rapidly developing area of testing. "There were certainly lots of requests for clarification, mainly centered around what the timeline for enforcement might be and how the FDA could provide better definitions of what is and what is not an IVDMIA," FDA science policy advisor Elizabeth Mansfield, Ph.D., told attendees at Washington G-2 Reports' second annual molecular diagnostic conference the day after the public meeting on IVDMIAs. She went on to characterize the FDA meeting as "successful."

In discussing the guidance itself, Mansfield emphasized that the FDA's release of the IVDMIA guidance on the same day as Q&A guidance on the analyte specific reagent (ASR) rule "was not intended to imply a link between ASRs and IVDMIAs, as some people have suspected." She described the newly designated IVDMIA device class as "a narrow niche" and one that doesn't include very many tests. "We're thinking 10 to 20 at this point," said Mansfield. "But perhaps there are more."

Why is the FDA seeking to regulate IVDMIAs? "We think that they have a novelty and a risk profile that's different than other homebrew devices," said Mansfield. "The indices that are used are based on new combinations of analytes that are empirically determined, and they require a prior knowledge base. We also believe that the risk of these tests is not mitigated by the business model of the developer."

An IVDMIA Does All of the Following:

- ❑ Uses clinical data to empirically identify an algorithm;
- ❑ Employs the algorithm to calculate a patient-specific result, such as a "classification," "score," or "index"; and
- ❑ Produces a result that cannot be interpreted by a well-trained healthcare provider without the help of the test developer.

Source: FDA

IVDMIAs submitted for clearance will be evaluated using a model that assigns risk based on the intended use of the test. "If you've been through the FDA premarket review process before, you would recognize it if you came with an IVDMIA," added Mansfield.

In a presentation on behalf of the Genetic Alliance, Sharon Terry, the interest group's president and CEO, expressed the view that "the existing industrialized manufacturing regulatory model of the twentieth century will not overlay well in the new era of personalized medicine. We want federal authorities to be looking forward to this new age."

American Clinical Laboratory Association (ACLA) President Alan Mertz offered the FDA three recommendations to achieve the IVDMIA draft guidance's goal. First, Mertz advocated that the FDA issue a proposed rule to address the issue through the formal notice and comment rule-making process rather than through sub-regulatory guidance. He also urged the FDA to consider proposals to narrow and clarify its definition of IVDMIAs. Finally, he recommended that the FDA work with the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) to address its concerns through enhancement and better enforcement of CLIA regulations.

Linked Factors ACLA Suggests FDA Consider When Defining IVDMIAs

- ❑ Employs a new, single-source test system;
- ❑ Uses patient and/or clinical data derived from one or more in vitro diagnostic assays together with a proprietary, nonpublished algorithm;
- ❑ Generates a patient-specific, binary result that is intended definitively to diagnose a condition or to direct behavior for the cure, mitigation, treatment, or prevention of disease; and
- ❑ Presents significant safety and effectiveness risks not present in test systems that have become part of the standard of care.

Source: ACLA

"As written, the draft guidance could be interpreted to apply to many well-established tests that are part of the standard of care," said Mertz. "Upon citing examples of such tests to the FDA, ACLA was informed by FDA officials that it was not their intent to include such well-established tests within the scope of the draft guidance, and FDA requested our assistance in clarifying and narrowing the definition of IVDMIAs to conform to its intended application."

Among the factors that Mertz suggests would exclude a device from being designated an IVDMIA are low-risk consequences of invalid or inaccurate test results, transparent algorithms, interpretation support for clinicians, CPT code assignment, and payer recognition.

According to Mansfield, the FDA has had already "had numerous meetings with companies and laboratories who have come in with tests attempting to determine if this [IVDMIA] review will apply to them."

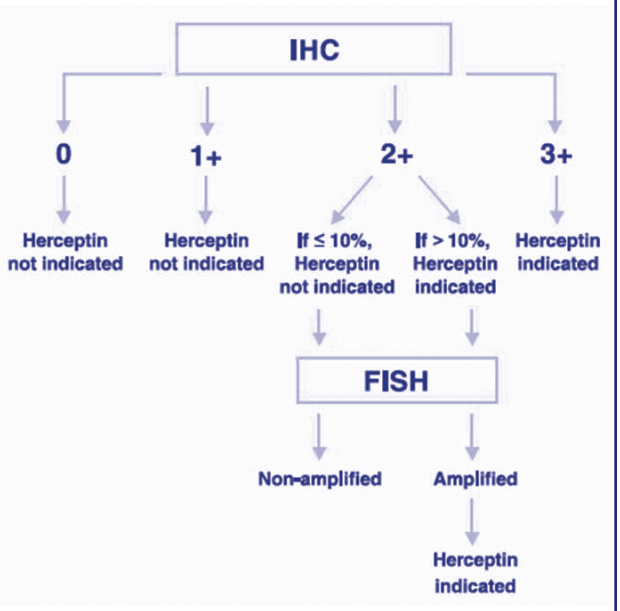
The public has until March 5 to submit formal comments about the draft guidance. Comments may be submitted to *www.fda.gov/dockets/comments*.

Ventana Gets FDA Approval For Pathway Her-2/neu Antibody Test

Ventana Medical Systems (Tucson, AZ), which makes tissue and slide preparation systems, has received FDA approval for its Pathway Her-2/neu (4B5) rabbit monoclonal antibody. The antibody can be used as an aid in assessing breast cancer patients being considered for treatment with Herceptin. It is also approved for use on the Ventana Image Analysis System.

Made by Genentech, Herceptin is a cancer treatment that targets Her-2, which causes breast cancer cells to grow more rapidly and makes chemotherapy less effective. Ventana's newly approved Pathway antibody is intended to detect the presence of the HER-2 antigen in sections of formalin-fixed, paraffin-embedded normal and neoplastic tissue.

Proposed Her-2/neu Testing Algorithm



Source: Ventana, USCAP (2000) and ASCO (2000) Meeting Abstracts

Osmetech Sells Critical Care Division To Focus On Molecular Diagnostics

Molecular diagnostics company Osmetech (London, England) has completed the sale of its Critical Care Division to IDEXX Laboratories (Westbrook, ME) for $44.9 million in cash. Osmetech acquired the Critical Care Division from Roche Diagnostics in 2003 for $2.7 million.

With the proceeds from the sale, together with existing resources, Osmetech plans to accelerate the expansion and development of its molecular diagnostics division, which is based in Pasadena, California. As part of this strategy, the company plans to progress with the development and commercialization of the existing product pipeline, including the second generation of its eSensor instrument.

Osmetech's FDA-cleared eSensor is a kit-based Cystic Fibrosis (CF) carrier detection system that uses DNA microarray technology. Each kit includes all reagents necessary for PCR amplification and mutation detection in a single box. Reports include a summary "carrier" or "non-carrier" call, plus individual carrier status for each of the 23 CF markers recommended by the American College of Obstetricians and Gynecologists and the American College of Medical Genetics. The company's other platform, Opti Gene, allows for the detection of DNA and RNA targets, using PCR or RT-PCR based assays.

Other goals for the company include securing licensing agreements that will add assay content for their existing instrument platforms, continuing to explore selec-

tive acquisition opportunities relevant to the molecular diagnostics market, and negotiating licensing agreements and entering into strategic partnerships in non-healthcare markets.

"Osmetech is now well funded and in an excellent position with its two instrument platforms to capitalize on the significant opportunities to build a business with considerable value with the prospects of high margins," said CEO James White. "Our FDA-approved test for Cystic Fibrosis has been launched and good progress is being made with our CYP 450 test that targets the personalized medicine market, a growth area for molecular diagnostics."

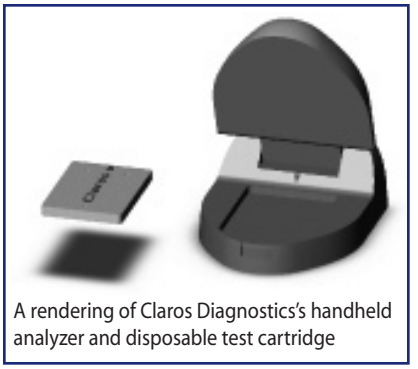
Based in London, Osmetech has operations in Atlanta, Boston, and Pasadena in the United States, serving the near-patient testing market and targeting small- to medium-sized hospitals. The company built its molecular diagnostics business largely through acquisitions, having purchased Molecular Sensing in 2004 and Clinical Micro Sensors in 2005.

Claros Diagnostics Raises $7.8m To Develop POC Platform

Claros Diagnostics (Woburn, MA) has raised $7.8 million in Series A financing to develop its handheld immunoassay system that can be used at the point of care (POC), with an initial focus on established prostate cancer diagnostics. The funding round was led by Oxford Bioscience Partners and also included Bioventures Investors, Accelerated Technologies Partners, and Commons Capital.

Incorporating a lab-on-a-chip configuration (micro-fluidics and proprietary amplification chemistry), Claros's POC system produces quantitative results with the ease-of-use of rapid qualitative diagnostic test strips. The system consists of a disposable, credit-card sized cartridge with preloaded reagents that can test for multiple markers simultaneously using fingerstick blood and a hand-held analyzer that is similar to an over-the-counter glucose meter. Results are available in 10 minutes and wireless, wired, or printer output options are available.

Claros will initially focus on developing its diagnostic platform for urological cancer, incorporating an established panel of biomarkers, anchored by prostate-specific antigen (PSA). Data from quantitative PSA tests drive urologists's decisions to perform approximately 1 million prostate biopsies annually.



A rendering of Claros Diagnostics's handheld analyzer and disposable test cartridge

"Our initial focus is the development of a point-of-care assay for established prostate cancer diagnostics, which we believe will provide significant incentives for both physician and patient," said Michael J. Magliochetti, Ph.D., president and CEO of Claros. "The applications of our technology platform extend well beyond cancer diagnostics, encompassing infectious disease, women's health, and critical care, as well as the potential for companion diagnostics to existing therapeutics."

Privately held Claros was founded in 2004 by David Steinmiller, Vincent Linder, Ph.D., and Samuel Sia, Ph.D. Steinmiller and Linder now serve as the company's chief operating officer and chief technology officer, respectively, and Sia chairs the scientific advisory board.

Roche's CoaguChek XS System Gets FDA Clearance For Physician's Office Use, Patient Self-Testing

Roche Diagnostics (Basel, Switzerland) has obtained FDA clearance for its latest point-of-care (POC) anticoagulation monitoring device, the CoaguChek XS System, for physician's office use and self-testing by patients on warfarin therapy.

Providing results in one minute from a small drop of fingerstick blood, the CoaguChek XS System can help healthcare professionals perform in-office prothrombin time (PT/INR) testing more effectively. It is the only anticoagulation monitoring system to perform onboard quality control in the reagent chamber. The system also neutralizes therapeutic levels of heparin and LMW heparin, enabling physicians to do POC testing on a broad range of anticoagulated patients.

Performing PT/INR (clotting time) testing at the point of care allows healthcare professionals to make dosage adjustments and talk with patients immediately, while with a venous blood sample, the process can take up to several hours or even a few days.

Today, in the United States, four out of five PT/INR tests at the point of care are done using the CoaguChek system, which is Roche's third generation of point-of-care anticoagulation monitoring devices.

RedPath Combines Pathology, Molecular Diagnostics

RedPath CEO Mary Del Brady

Pittsburgh-based RedPath Integrated Pathology is hoping to fill an existing critical need by merging cutting-edge molecular technology tools with standard pathology practice, focusing first on cancer diagnostics. Founded in 2004 by Dr. Sydney Finkelstein, RedPath is built on a proprietary, patented Topographic Genotyping platform, a high throughput molecular profiling system.

"What we have is a breakthrough approach that helps to reduce diagnostic unknowns or missed diagnosis," says Mary Del Brady, president and CEO of RedPath. "It's a molecular-based technology, and we integrate it with standard pathology practice, so what we end up doing is facilitating more definitive diagnoses where the standard practice could not."

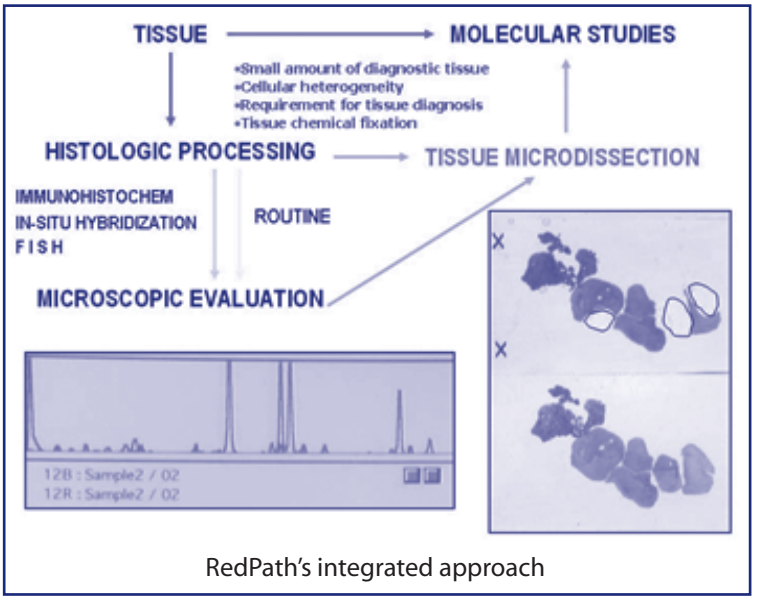
Their highest-volume test is for early pancreatic cancer diagnosis, a cancer for which about 80% of diagnoses are made at a late stage. "Obviously there was a real need to find a tool as a way to enable earlier and more definitive diagnosis," says Del Brady. "We've experienced good market adoption on this indication around the country."

RedPath's technology, known as PathFinderTG, can be used on a variety of tissue types, including solid tumors from standard formalin-fixed biopsy slides, cytology smears, and fine needle aspirated (FNA) solids and fluids. "We use our patented technology to manipulate and extract the DNA, amplify it, and then perform a mutational fingerprint on it," says Brady. A panel of between 15 and 20 markers is customized based on the organ system and application.

RedPath operates as a commercial laboratory, providing diagnostic tools and support to pathologists and clinicians. They don't expect pathologists or surgeons to perform their jobs any differently. "We hope that we don't threaten the pathologists, that

they can appreciate that this is a very powerful tool, which will help them do their jobs better and complement the skills of pathologists," says Brady. "We don't ask for all the cases—just the hard ones and where there is still some question left."

In 2007, RedPath expects to handle about 3,000 cases, double that of 2006. Last September, they raised $4 million in a Series A equity financing round and intend to use those funds to increase sales and marketing activities and scale-up operations. According to Brady, the company has experienced measured growth. "From an operations standpoint, we've been able to operate at a break-even level, but we need to resolve all the reimbursement issues so that we can do a total ramp-up of the sales effort," she says. "What we're doing this year is building marketing structure that will match what we're hearing from our target audience; we're building our information systems infrastructure that will be able to support a company in rapid growth. We really see a big gear-up in 2008 and beyond."



RedPath's integrated approach

According to RedPath, their technology has been validated with a 95% accuracy rate, and over 150 peer-reviewed articles have been published about it. Brady doesn't feel they are limited to clinical diagnostics, either. "Our platform is really broad enough it can be valuable in drug discovery, theranostics, and treatment effectiveness, so as we ramp up the service business, we also intend to explore the other markets as well. We are one of those small but growing group of companies that are really applying knowledge gained through the whole genomics revolution into everyday clinical practice."

Designer Diagnostics Moves TB Test Kit Into Human Clinical Trials

Designer Diagnostics (Las Vegas, NV), a subsidiary of Nutra Pharma (Boca Raton, FL), which develops drugs for HIV and multiple sclerosis, is moving its tuberculosis (TB) test kit into human clinical trials after receiving positive results from in vitro studies. The company is in discussions with leading tuberculosis research institutes in the United States to complete human trials of the test kit technology.

Over 14.6 million people worldwide have active TB disease, and over one-third of the world's population have the TB bacterium in their bodies. New TB infections occur at a rate of one per second. Normal culturing methods can take as long as 10 weeks to produce results, where Designer Diagnostics test kits have shown similar results within 10 days.

Designer Diagnostics is engaged in the research and development of diagnostic test kits designed to be used for the rapid identification of infectious diseases, such as TB and mycobacterium avium-intracellulare (MAI).

IVD Stocks Rise 5%; Affy Climbs 28%, Luminex Gains 24%

For 2007, the G-2 Diagnostic Stock Index has added four new stocks: **Clinical Data**, **Luminex**, **Nanogen**, and **Stratagene**. Bayer has been removed from the index following the completed acquisition of its diagnostics division by Siemens on January 3 of this year.

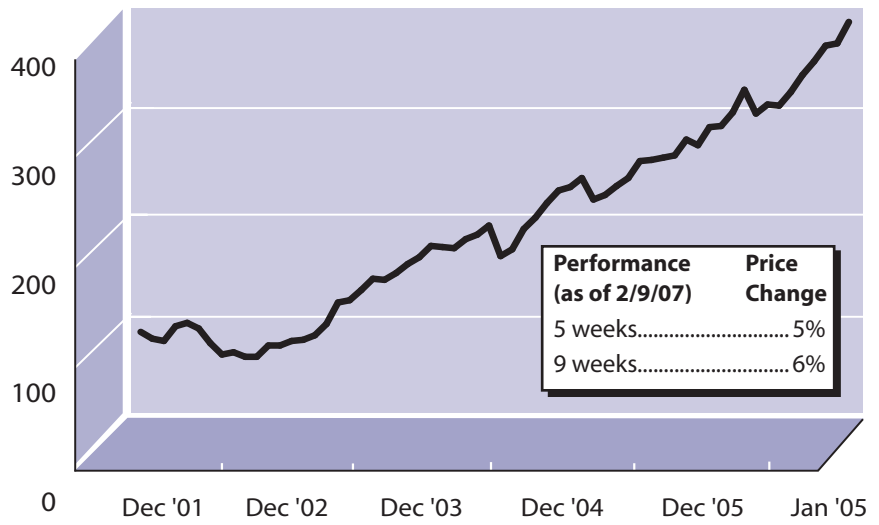
The 24 stocks in the G-2 Diagnostic Stock Index rose an average of 5% in the five weeks ended February 9, with 17 stocks up in price and seven down. So far this year, both the S&P 500 and the Nasdaq are up 2%.

Ever-volatile **Affymetrix** (Santa Clara, CA) was up 28% to $27.83 per share for a market capitalization of $1.86 billion. Although the GeneChip maker's fourth-quarter profit dropped 72% on falling sales and rising costs, its revenue of $104.2 million beat analysts' estimates, which averaged $99.2 million. In December, Affy began shipping a new chip that can simultaneously measure 500,000 genetic variations.

Luminex (Austin, TX) was up 24% to $15.85 per share for a market capitalization of $500 million. Like Affy, Luminex shares climbed on better than expected fourth-quarter results. Luminex posted $53 million in revenue, an improvement of 23% over the fourth quarter of 2005. The company plans to close on its acquisition of Tm Biosciences by the end of the first quarter.

Meanwhile, **Inverness Medical Innovations** (Waltham, MA) rose 11% to $42.64 per share for a market capitalization of $1.67 billion. The manufacturer and marketer of rapid diagnostic products just acquired substantially all of the assets of privately held First Check Diagnostics (Lake Forest, CA) for approximately $25 million in cash. First Check specializes in the rapidly growing field of home testing for drugs of abuse, including marijuana, cocaine, methamphetamines, and opiates. The company also sells tests for alcohol abuse, cholesterol monitoring, and colon cancer screening. First Check had 2006 revenues of approximately $11 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 24 IVD companies.

Avg. % Price Change, 5 weeks ended 2/9/07

	Price	% Chg
Up		
Abbott Labs	$52.27	5%
Abaxis	21.56	11
Affymetrix	27.83	28
Becton Dickinson	77.50	11
Bio-Rad	85.88	5
Clinical Data	17.98	9
Cytyc	29.55	2
Dade	43.21	9
Digene	50.10	3
Immucor	32.61	2
Inverness Medical	42.64	11
Luminex	15.85	24
Meridian	29.11	17
Quidel	13.35	3
Stratagene	8.05	8
Third Wave	5.30	13
Ventana	42.31	1
Down		
Beckman Coulter	65.71	-1
Biosite	53.44	-3
Cholestech	17.57	-4
Gen-Probe	51.33	-2
Johnson & Johnson	65.60	-2
Nanogen	1.50	-19
OraSure	8.13	-5

G-2 Insider

Hexaplex developer working on multiplex POC test for bioterrorism agents . . . Kelly Henrickson, M.D., a professor of pediatrics and microbiology at the Medical College of Wisconsin, has been awarded a grant to develop cost-effective, point-of-care (POC) diagnostics for bioterrorism agents. The new integrated test may provide results within one to two hours. The Medical College of Wisconsin, Children's Hospital, Children's Research Institute, and Nanogen will participate in carrying out the work of the grant.

Henrickson previously developed the Hexaplex diagnostic test, a respiratory virus multiplex RT-PCR-EHA for rapid, accurate, simultaneous detection of the seven most common lower respiratory viruses, including several varieties of influenza. The test is performed by Prodesse (Waukesha, WI) for a list price of $290.00. The Hexaplex technology is the basis for an array of multiplex PCR products for the rapid detection of microbes responsible for such illnesses as aseptic meningitis, chicken pox, encephalitis, herpes, influenza, pneumonia, SARS, shingles, and West Nile virus.

"Our laboratory has pioneered a flexible, rapid, sensitive, and specific method of simultaneously detecting multiple pathogens," says Dr. Henrickson. "We have recently developed two BioTplex assays that detect many (15) category 'A' bioterrorism agents. However, new amplified DNA detection and nucleic acid purification methods beyond those used in the Hexaplex diagnostic test allow for the development of a single 'point-of-care' device that may enhance the speed, flexibility, throughput, and cost effectiveness of multiplex assays."

Category 'A' Bioterrorism Agents

— *Variola major* (smallpox)
— *Bacillus anthracis* (anthrax)
— *Yersinia pestis* (plague)
— *Clostridium botulinum toxin* (botulism)
— *Francisella tularensis* (tularaemia)
— A group of RNA viruses that cause hemorrhagic fevers (VHFs)

Company References

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