Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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EPO Takes Bite Out Of Myriad's BRAC Analysis Patents

The European Patent Office (EPO) has announced that it will amend two patents relating to the Myriad Genetics' BRACAnalysis test for breast and ovarian cancer. The EPO's decision will allow Myriad to keep patents on specific gene probes for mutations of the BRCA1 gene, but removes Myriad's claims for diagnostic methods.

Opposition to Myriad's patents was filed by six different groups in Europe in August 2002, including the Institut Curie, a Paris-based cancer research organization. Their concern was that the patents were too restrictive, giving Myriad a virtual monopoly on genetic testing for hereditary breast and ovarian cancer. Myriad charges $2,975 for its BRACAnalysis test and requires that all samples be tested at its laboratory in Salt Lake City. The company is expected to generate some $62 million of revenue from genetic testing this year with double-digit net profit margins (*see page 10*).

European laboratories have developed their own methods of BRCA1 testing, and the EPO's decision should allow them to use these methods at their own labs at a substantial cost savings. In addition, some have argued that Myriad's test was not completely effective in finding large DNA deletions or rearrangements [Benowitz S (2002) *JNCI* 94(2):80-81]. A spokesman from Myriad did not returned phone calls from *DTTR* seeking comment.

Roche Gets Full Clearance Of AmpliChip CYP450

On December 23, the FDA cleared the CYP2D6 gene on Roche's AmpliChip Cytochrome P450 Genotyping Test, and on January 11 the second gene (CYP2C19) on the microarray was cleared. The complete test kit and instrument system have now been cleared and will soon be available at the major reference labs and academic medical centers in the United States, according to Walter Koch, Ph.D., senior director of pharmacogenomics at Roche Molecular Diagnostics.

Roche initially filed its 510K for AmpliChip CYP450 in September 2004 under the FDA's *de novo* classification, which was established in 1997 for lower-risk diagnostic products for which there is no predicate device. Roche has not yet set a U.S. price for the test kit. However, the test became available in Europe in mid-2004, and Roche charges 400 euros, or about $521 per test kit. The test needs to be taken only once in a lifetime. *Continued on p. 2*

▲ **Roche Gets Full Clearance of AmpliChip CYP450,** *from page 1*

Heino von Prondzynski, head of the diagnostic division at Roche, tells *DTTR* that Roche generated roughly one million Swiss francs from European sales of Amplichip CYP450 in 2004. Ultimately, he expects worldwide test kit sales to peak at 100 million Swiss francs (US $85 million) per year. He says Roche is developing additional AmpliChip products and believes the worldwide market for microarrays will become a multi-billion dollar market.

AmpliChip CYP450

The size of a credit card, the AmpliChip contains 15,000 short stretches of DNA, representing 31 genetic variations in the CYP2D6 and CYP2C19 enzymes that belong to a family of genes called cytochrome P450. The purpose of the test is to determine whether a patient processes drugs at a normal, slow, or fast rate. Patients treated with drugs that are extensively metabolized by CYP2D6 and CYP2C19 enzymes are at increased risk for experiencing toxicity with standard dosing, while ultra-rapid metabolizers may not achieve therapeutic levels of the same drug.

According to Koch, the two enzymes affect about 25% of commonly prescribed medications, including anti-depressants, anti-psychotics, beta- blockers, tamoxifen, and benzodiazepines. The labeling on the test kit doesn't limit its use to any particular drug class, but Koch believes the greatest use for the test will be for determining the metabolism for patients taking drugs used to treat severe depression, schizophrenia, bipolar disorder, and attention deficit/hyperactivity disorder (ADHD).

Over the next two years, Koch says Roche plans to launch two more microarray products; the first will help classify the type of leukemia a patient has for treatment decisions with the anticancer drug Gleevac. Roche is also developing an AmpliChip product that detects known P53 gene mutations. P53 is a tumor-suppressor gene that is associated with 50% of all cancers.

Despite the FDA's clearance of AmpliChip CYP450, the first microarray ever cleared for test kit sale in the United States, Koch says that each new microarray that Roche develops will be unique and have its own regulatory process.

Roche's Microarray Schedule

AmpliChip CYP450 Test—Pharmacogenomics

— Rollout started in Europe 2Q04; United States 1Q05
— Psychiatry first target market as algorithms to aid dose adjustments exist
— First steps include awareness, education, reimbursement
— Clinical studies underway focused on psychiatry and cardiology

Leukemia Microarray – Classification

— Expect to offer for research use only in late 2005
— Distinguishes sub-classes of leukemia
— Potential to reduce complexity and turnaround time by replacing other research methods/technologies

AmpliChip P53 Test – Mutational Analysis

— Expect to offer for research use only in 2006
— Detects known P53 gene mutations in human cells
— Research collaborations in pharmaceutical studies planned (e.g., Roche MDM2 inhibitor trials)

Source: Roche

On the question of whether or not the FDA has created a standard regulatory path for future microarray clearance decisions, Steven Gutman, M.D., director of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety, tells *DTTR*, "I don't think we have made a final decision on exactly how we might handle all future clearance decisions for multi-gene tests. I suspect that with increasing review experience our perspective may change, but I cannot predict an exact path for all future submissions."

Quest Working On New Leukemia/Lymphoma Blood Tests

The American Cancer Society estimates that there will be 91,200 new cases of leukemia and non-Hodgkin lymphoma diagnosed this year in the United States and 43,180 deaths.

Quest Diagnostics (Teterboro, NJ) says it's in the process of validating new blood tests for diagnosing and monitoring leukemia and lymphoma that could reduce the need for the standard bone marrow biopsy. The new tests could be on the market in homebrew form by year's end, according to Gary Samuels, spokesman from Quest.

Quest gained access to the technology through an exclusive licensing agreement with the University of Texas M.D. Anderson Cancer Center (Houston, TX), which owns the rights to the technology and is seeking patents. Terms of the transaction were not disclosed.

The testing method utilizes probes to look for proteins (CD20, CD33, and CD52) and tumor-specific DNA and RNA in blood plasma. Quest says the method could offer cancer patients an alternative to bone marrow biopsies, which require the painful extraction of tissue specimens with a bone-piercing needle.

Pricing for the new tests has not yet been determined, but Samuels says the tests will decrease detection and monitoring costs, allowing physicians to assess patients more frequently. The current test on bone marrow specimens (Leukemia/Lymphoma Evaluation) costs a little less than $50 per marker (list) or about $950 for a 20-marker test.

The technology underlying the new tests was developed by Maher Albitar, M.D., while he was chief of the leukemia section in the Department of Hematopathology at M.D. Anderson. In mid-2003, Albitar left M.D. Anderson to become medical director for Hematology at Quest Diagnostics.

Albitar discovered that in hematologic diseases, tumor cells pour their DNA, RNA, and proteins into circulation and these components can be detected in plasma. Previously, the common assumption had been that only proteins that were secreted (made by the tumor cell and then transported to the surface and released into plasma) could be present in the plasma. Most proteins are not secreted but rather embedded in the cell surface or inside the cell. The breakthrough was finding that non-secreted, cell-surface proteins as well as their DNA and RNA are actually in the plasma and can be detected.

Expanding market share in the anatomic pathology market has become a top priority for Quest. Over the past 12 months, the company has added nearly 100 pathologists to its staff. The company now employs about 300 pathologists, including 22 hematopathologists, according to Samuels.

Beckman Coulter Names Scott Garrett Chief Executive

Scott Garrett

Beckman Coulter (Fullerton, CA) has named Scott Garrett, age 55, as chief executive effective February 21. Garrett, who has also joined Beckman's board of directors, succeeds retiring CEO Jack Wareham, 63. Garrett joined Beckman in June 2002 and became president and chief operating officer in December 2003.

Wareham will continue as chairman until the company's annual shareholder meeting on April 7. His replacement in this position will be Betty Woods, an 11-year veteran of the company's board, who will become non-executive chairman at Beckman. Woods served as president and chief executive officer of Premera Blue Cross—formerly Blue Cross of Washington and Alaska—and chief executive officer of Premera, the holding company of Premera Blue Cross.

Ventana Wins LabCorp Contract

Ventana Medical Systems (Tucson, AZ) has announced a multiyear agreement to supply its BenchMark XT tissue staining systems to LabCorp (Burlington, NC) facilities nationwide. BenchMark XT is an automated slide-staining system for medium- to high-volume laboratories. Financial terms of the deal were not disclosed.

Bio-Rad Gets FDA Approval For Rapid HIV 1 & 2 Test

Bio-Rad Laboratories (Hercules, CA) has received approval from the FDA for a rapid test for detecting HIV antibodies. Bio-Rad said the single-use test kit will be available in the United States this month, and is the first approved by the FDA that distinguishes between the HIV-1 and HIV-2 viruses. HIV-1 is the more common type of the virus. The company said the Multispot HIV-1/HIV-2 Rapid Test can be used on both fresh and frozen serum and plasma samples, and produces results in about 10 minutes.

Abbott To Commercialize Cleveland Clinic's MPO Cardiac Test

Abbott Diagnostics has entered into a licensing agreement with The Cleveland Clinic for the development of an automated lab test to detect myeloperoxidase (MPO), an enzyme found in white blood cells. Research conducted at The Cleveland Clinic and published in the October 23, 2003 issue of *The New England Journal of Medicine* linked elevated MPO levels with the risk of heart attack (see *DTTR*, March 2004, pp. 1-2).

Terms of the agreement give Abbott non–exclusive rights to The Cleveland Clinic's existing technologies relating to MPO as a risk indicator for cardiovascular disease. PrognostiX Inc., an affiliated company of The Cleveland Clinic, will provide support during the development process. Other terms of the agreement were not disclosed.

Piper Jaffray Health Care Conference Highlights

Beckman Coulter wants to double its immunodiagnostics business in the next five years.

Investment bank Piper Jaffray held its 17th annual Health Care Conference in New York City, January 25-27. More than 150 healthcare companies gave presentations to an audience of some 1,500 hedge fund and mutual fund managers. Fourteen laboratory and diagnostic companies were among the presenters. Here are some highlights:

Jay Steffenhagen, vice president of corporate strategic planning at Beckman Coulter (Fullerton, CA), said Beckman is seeking to grow its immunodiagnostics business by 15% to 20% annually for the next five years to reach $1 billion in revenue. Beckman's immunodiagnostics revenue was $502 million in 2004, up 15% on a constant currency basis from 2003.

Steffenhagen said the biggest opportunity continues to be taking share from Abbott. "We think 30% to 40% of Abbott's customers are ripe to switch," he noted. "Up until its problems with the FDA, Abbott was like IBM. Lab directors felt they could never be faulted for choosing Abbott. Now everyone else is seen as legitimate suppliers," he added. Today, Bayer is Beckman's most frequent competitor in the immunoassay market, according to Steffenhagen.

He said Beckman is aiming to raise its immunoassay menu from 50 tests today [40 in U.S.] to 70 tests by 2006. Tests currently under development include CMV IgG, CMV IgM, Anti-TPO, Intact PTH, DHEA-S, and Anti-Intrinsic Factor.

Meanwhile, Steffenhagen noted that Beckman currently has its lab automation systems placed at more than 150 sites in the United States. "Up until now automation was the realm of early adopters, but now the U.S. is waking up for automation," he said. The adoption of automation in Europe is moving more slowly. "They are reluctant to reduce staff," he noted.

Brad Smith, executive vice president, chief legal officer at **LabCorp** (Burlington, NC), said LabCorp has been keeping a close watch on Correlogic's ongoing discussions with the FDA over its protein-pattern ovarian cancer test.

LabCorp and Quest Diagnostics each have licenses agreements to market the test, but launch has been delayed for more than a year by the FDA. The FDA claims that the software that analyzes the blood protein patterns to detect cancer is a medical device that requires the agency's approval. Smith noted that the FDA is also concerned that the test yields too many false positive results that could lead to unnecessary operations. But he said that Correlogic'c test is far more accurate than the CA125 test, which is on the market. "The FDA may be acting especially cautious because their decision will set a precedent for 11 or 12 other tests at Correlogic," he added.

Separately, Smith noted that OB/GYNs are rapidly adopting Digene's HPV test as a reflex test for indeterminate Pap tests. However, he said the adoption rate for the "DNA Pap" (i.e., Pap test plus HPV test) for initial cervical cancer screenings has been slow. Current guidelines suggest that women over 30 who test negative on their Pap and HPV tests can be screened every three-years and

LabCorp is creating more specialized sales groups to sell its gene-based tests.

Smith believes physicians may not want to lose patients for that long of an interval.

Meanwhile, Smith said he's very optimistic on new automated thin-layer Pap systems. He said LabCorp has installed systems at its Burlington, North Carolina lab and is rolling them out to other sites. LabCorp performs nine million Pap tests per year; 80% are converted to thin-layer (80% Cytyc's ThinPrep and 20% TriPath's SurePath).

Smith said managed care companies are pushing harder for reimbursement cuts. To fend off the cuts, LabCorp is offering lab test data mining and opening up more patient service centers to help reduce leakage.

LabCorp currently employs about 800 sales reps and is in the process of creating more specialized sales group akin to pharmaceutical detail people. These groups will get special training in gene-based tests and target high-value physician practices like urologists and gastroenterologists, said Smith.

Tom Grant, chairman and chief executive of **LabOne** (Lenexa, KS), says the company is building a new 136,000 square-foot facility in Cincinnati at cost of approximately $24 million. The primary automation and chemistry systems being installed are from Olympus, which LabOne is standardizing across the company, according to Grant.

Managed care companies have become more willing to contract with regional labs, according to LabOne's Grant.

He said LabOne will move its existing Cincinnati operations (4,000 requisitions per day) into the new space this July. The company entered the Cincinnati area in January 2004 through the acquisition of the core lab operations of The Health Alliance of Greater Cincinnati for $42.4 million. Grant said LabOne has expanded the salesforce in Cincinnati and begun marketing in Columbus, Dayton, and Louisville. LabOne is also looking for acquisitions that it can consolidate into its Cincinnati lab, he added.

Grant said the administration at Health Alliance has been pleased with the service levels provided by LabOne, which has long-term agreements to provide reference testing for the Health Alliance hospitals and management of their six inpatient labs. Working with the local pathologists and lab employees has been more of a challenge, said **Phil Spencer**, executive vice president of healthcare marketing at LabOne. "They're still operating in hospital mode [rather than commercial lab mode]," noted Spencer. He believes the upcoming transition into the new lab facility will help speed the cultural change for the former Health Alliance employees.

Meanwhile, Grant said that managed care companies have recently become more willing to add regional labs to their list of in-network labs. "They want to add alternatives to Quest and LabCorp," he noted. He said adding a regional lab can help managed care companies shrink leakage to higher-costing hospital and small independent labs. In addition, he finds that managed care companies are reducing the menu of tests that they will reimburse physician office labs for performing.

Finally, Grant noted that LabOne was one of the first drugs of abuse testing labs to offer OraSure's oral testing kits for employee drug screening. "We do a few

thousand oral tests per day, but I've been a little disappointed that this market hasn't grown faster," he said.

Bill Kozy, president of **BD Diagnostics** (Sparks, MD), a division of Becton Dickinson, said the company is devoting a big portion of its salesforce to the launch of its automated microbiology system, BD Phoenix, in Japan. BD Phoenix was launched in Europe in 2003 and in the United States in 2004.

Kozy said BD Diagnostics is also seeking to expand the menu for its ProbeTec molecular testing system. More than 1,000 BD ProbeTec systems have been placed worldwide, including more than 500 in the United States, but the current menu includes only Chlamydia/gonorrhea, M. tuberculosis, and L. pneumophila. Kozy said the next tests to come to market will be a panel for atypical pneumonia that will include tests for Legionella, Chlamydia, and Mycoplasma. He noted that each year five to seven million people in the developed countries get some type of pneumonia that can't be identified.

BD expects its blood glucose testing business to reach $75 million in sales this year.

Meanwhile, Kozy said it's too early to say how Medicare's drastic cuts in flow cytometry reimbursement will affect BD's flow cytometry business. BD generates about $100 million per year from sales of flow cytometry systems in the United States. Effective Jan. 1, 2004, Medicare cut reimbursement for flow cytometry lab procedures by an average of 40% to 50% (including technical and professional components).

Meanwhile, Kozy said that BD has finally gotten over some of the quality problems that have hindered the launch of its Latitude and Logic blood glucose testing products. This fiscal year (ends June 30), sales are expected to climb to $75 million versus $42 million in fiscal 2004.

Jim Reid-Anderson, chairman and chief executive of **Dade Behring** (Deerfield, IL), said that since the company's bankruptcy reorganization in late 2002, Dade's debt burden has been reduced from $1.5 billion to $495 million (as of Sept. 30, 2004). He also noted that Dade has $600 million in tax loss carry forwards, which will provide $10 million to $15 million in annual tax benefits for the next 18 years. "Over the next two to three years there will be consolidation in the industry and we're well positioned to participate," said Reid-Anderson.

Kim Blickenstaff, chairman and chief executive of **Biosite** (San Diego, CA), said the company's BNP test revenue climbed 57% in 2004 to reach $162 million. He estimates that the total worldwide BNP test market is more than $200 million and that Biosite has a 75% share. "This market is a lot larger than we thought. It could grow to an $800 million market. . . . The big question is will BNP testing used for risk-assessment of heart failure," he said.

The worldwide BNP testing market could quadruple to $800 million, according to Biosite's Blickenstaff.

He noted that Biosite has been waiting two years to get a waiver decision from the FDA for its BNP test. Late last year the company submitted additional data requested from the FDA.

Meanwhile, Blickenstaff said Biosite submitted its new rapid stroke panel to the FDA on Dec. 31, 2004. The test is a rapid immunoassay intended for use in conjunction with neurological imaging (e.g. CT scans) as an aid in the assessment and diagnosis of cerebral ischemia (stroke). He believes this market could

represent as much as $410 million of annual revenue, assuming 8.2 million tests per year priced at $50 per test. Biosite is aiming to launch the test in the United States in the first half of 2006.

Greg Schiffman, senior vice president and chief financial officer of **Affymetrix** (Santa Clara, CA), said the company is doubling the amount of information it can place on gene chips every nine months. Currently, Affymetrix can fit six million probes on a single chip.

In addition to its partnership with Roche Diagnostics (see pp. 1-2), Affymetrix recently signed a deal with Veridex, LLC (Warren, NJ), a Johnson & Johnson company. The 15-year non-exclusive agreement gives Veridex access to Affymetrix's GeneChip technology to create and market microarrays for cancer.

Affymetrix also recently signed a deal with Institut Curie (Paris, France). The agreement will allow Institut Curie to perform large-scale clinical studies on cancer using GeneChip microarrays. The first two projects will focus on identifying important genetic markers for cancer prognosis, including markers to help predict breast cancer relapse and to determine the likelihood of tumors in the eye spreading further.

"The clearance of the AmpliChip CYP450 answered skeptics who questioned if there would ever be an FDA-cleared microarray on the market," he said. Affymetrix earns its cost plus a royalty for every AmpliChip it manufactures for Roche, according to Schiffman.

John Puisis, chairman and chief executive of **Third Wave Technologies** (Madison, WI), says Third Wave will submit applications to the FDA for its Factor V Leiden and Factor II coagulation tests this year. "We are comfortable in knowing what the FDA wants in molecular diagnostic application submissions," said Puisis. He noted that the approval process may go quicker for Third Wave because the company's tests run on common systems that are already on the market (e.g., Qiagen for sample prep and Tecan readers).

Puisis expects Third Wave to increase its molecular diagnostic revenue from $15 million in 2004 to $23-$26 million in 2005, including $10-$11 million from coagulation tests, $6-$7 million from Cystic Fibrosis, and $5-$7 million from hepatitis C genotyping.

In addition, he said that Third Wave will soon roll out an ASR for HPV testing that includes

Experts See Slow Adoption of Molecular Diagnostics

The Piper Jaffray conference featured a roundtable of experts who discussed the outlook for molecular diagnostics. The consensus was that the adoption of new molecular diagnostics will be slower than most expect. Doug Harrington, M.D., CEO of Specialty Laboratories cited educating payers on the value of new tests will continue to be very difficult. "It takes two years to get a CPT code and clinicians and managed care lag Medicare," he noted.

Thomas White, Ph.D. chief scientific officer at Celera Diagnostics, observed that the cystic fibrosis gene was found in 1989, but utilization of cystic fibrosis genetic analysis did not take off until after the American College of Obstetricians and Gynecologists recommended screening in late-2001.

Ron McGlennen, M.D., president of Access Genetics, the need for simpler methods of DNA and RNA extraction, and the need for more integration and automation from sample collection through analysis. "Morphology won't be replaced by molecular diagnostics," he added.

Finally, Gail Page, president of the diagnostic division at Ciphergen, cited the need for reagent manufacturers and laboratories to do more extensive clinical studies on new tests. "There's a need for studies that involve more than just 20 patients at one site," she said.

probes for 15 high-risk HPV types. The company is also developing ASRs for CYP450 tests that will be focused on specific drugs.

Charles Fleischman, president and chief operating officer of **Digene** (Gaithersburg, MD), said the company will soon begin a direct-to-consumer advertising campaign that will include magazine and Internet ads as well as TV commercials in three (as yet undisclosed) pilot cities. The ads will tell viewers that the cause of virtually all cervical cancer is HPV, and will suggest that they ask their doctors and tell their friends about Digene's HPV test.

Fleischman said that Digene will increase its number of physician office detailing reps from 30 at year-end 2004 to 65 reps by June and 80 reps by June 2006.

Guidelines developed by participants from the National Cancer Institute, the American Society of Colposcopy and Cervical Pathology, and the American Cancer Society suggest that women over age 30 get a traditional Pap test and an HPV test. The guidelines extended the interval of testing to three years if both tests are negative. But some OB/GYNs don't want to lose the annual visit from their patients and are resisting HPV testing. Fleischman noted that there are other reasons for an annual visit, including mammograms. "If physicians and women want to have a shorter interval, then that's their decision," he added.

Specialty Labs is seeking to expand its presence in anatomic pathology.

Doug Harrington, M.D., chief executive officer of **Specialty Laboratories** (Valencia, CA), said the company has completed its move into a new laboratory and headquarters facility in Valencia, approximately 30 miles north of Specialty's former locations in Santa Monica, California. The new facility, which measures 198,000 square feet, is nearly twice the total size of the company's former space. Lease payments will total $3.5 million per year for Specialty.

Specialty had $43.6 million in the bank as of Sept. 30, 2004. Harrington said the cash will be used to increase automation, make acquisitions, and add new tests and services, especially in the area of anatomic pathology. Specialty's currently offers a menu of 2,500 tests; recent additions include TPMT mutation analysis, HIV Phenoscript, LDL subfractions, and cystic fibrosis genotyping for 70 genetic mutations.

Specialty recently became a preferred reference lab for the nation's two largest GPOs, Premier and Novation, and Harrington said the company will see the benefits in the second half of the year. "Many times we were a secondary reference lab for hospitals because we didn't have the right GPO contracts," he noted.

Patrick Sullivan, chairman and chief executive of **Cytyc Corp.** (Marlborough, MA), said that Cytyc had placed approximately 150 of its ThinPrep Imaging Systems in the United States at yearend 2004. He expects to ship another 120 to 130 imaging systems this year.

Sullivan noted that Medicare has established a specific code for automated thin-layer cervical cancer screening (CPT 88175) and set reimbursement at $37 per slide. He calculates that labs can earn a profit of $20 for each Pap test they perform using Cytyc's imaging system compared with a profit of $12 for manual thin-layer tests. His calculations assume reimbursement of $37 for the imaging test minus $4.50 in labor, $7 for supplies, and a $5 to $6 imaging fee.

Sullivan expects Cytyc to generate about $50 million from imaging fees in 2005. Overall, he expects the company to post revenue of between $485 million and $505 million in 2005, up from approximately $391 million in 2004. His goal is to grow to $1 billion in annual revenue by 2008.

Myriad is using its highly profitable genetic-testing business to fund its drug development efforts.

Peter Meldrum, chief executive of **Myriad Genetics** (Salt Lake City, UT), said Myriad is expected to increase its genetic testing revenue from $43.3 million in fiscal year 2004 to $61.8 million in fiscal year 2005 (ends June 30). The company currently markets four homebrew tests that assess the risk of developing hereditary breast, malignant melanoma, and colorectal cancers.

Meldrum said Myriad's genetic testing business has a net profit margin of 14% and is generating $1 million per month in cash flow. New tests in development include predictive tests for prostate cancer, Type II diabetes, and depression. Myriad has also begun working on gene-based tests for helping doctors make more accurate drug prescriptions for patients on an individualized basis, according to Meldrum.

Ron Zwanziger, chief executive of **Inverness Medical Innovations** (Waltham, MA), said the company will soon launch its IMI SmartCheck INR for self testing of prothrombin time for mechanical heart valve patients. Zwanziger said SmartCheck requires a blood sample of just three microliters and weighs 163 grams (with batteries) versus 10 microliters and 455 grams for Roche's market leading CoaguChek monitor. The pricing for the monitor and test will be "differentiated and highly competitive," he said.

In addition, Zwanziger said Inverness is developing a home test for congestive heart failure (CHF) that will combine testing for the BNP or pro-BNP markers with Urotensin, a peptide that has been found to be elevated in CHF patients. According to a study conducted at the University of Leicester, the combination of pro-BNP and Urotensin markers significantly improves the accuracy of diagnosis for CHF versus using either marker alone. Zwanziger said further studies are taking place at Mayo Clinic and Inverness hopes to have a rapid test for BNP or pro-BNP with Urotensin on the market in late 2006.

Thomas White, Ph.D., chief scientific officer of **Celera Diagnostics** (Alameda, CA), a 50/50 joint venture of Celera Genomics and Applied Biosystems, estimates the company will generate an estimated $60 million to $70 million of revenue (including distributor mark ups) in the fiscal year ending June 30, 2005, up from $45.9 million in fiscal 2004. Cash losses of $30 million to $40 million are expected in fiscal 2005, according to White.

Current products include FDA-cleared ViroSeq for HIV genotyping plus ASRs for cystic fibrosis genetic analysis, and HCV viral load and genotyping.

Through a collaboration with LabCorp, Celera is developing tests for Fragile X Syndrome and HPV. White believes the Fragile X testing has the potential to become as widespread as cystic fibrosis. In addition, he says Celera has discovered markers that can predict the risk of heart attack, stroke, and stenosis (a condition in which the aortic valve narrows, which obstructs blood flow). He expects Celera to develop tests that identify people at elevated risk for cardiovascular disease, including those who would benefit most from statin therapy.

IVD Stocks Up 5% YTD; Cholestech Leads With 61% Jump

The 21 stocks in the G-2 Diagnostic Stock Index are up an unweighted average of 5% year to date through Feb. 4, 2005, with 14 stocks up in price, six down, and one unchanged. Over the same time frame, the S&P 500 Index is down 1% and the Nasdaq is down 4%.

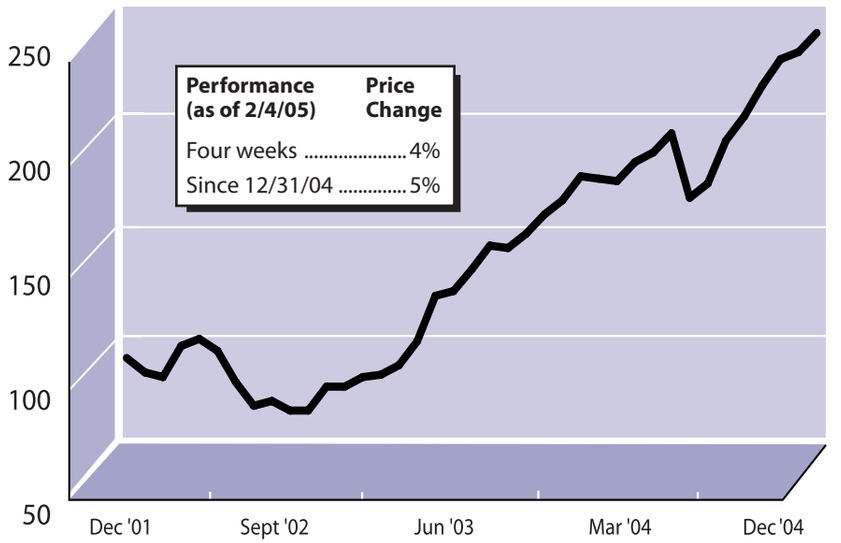
Since hitting a low in September 2002, the G-2 Diagnostic Stock Index has risen by 203% for an average annual gain of 56%.

The top gainer so far this year is **Cholestech** (Hayward, CA), which is up 61% to $13.20 per share for a market value of $190 million. The company recently reported a net profit of $1.7 million, or $0.12 per share, for the three months ended Dec. 31, 2004 versus a net loss of $4 million, or -$0.28 per share, for the same period a year earlier; revenue was up 9% to $14.6 million.

In addition, a study recently published in the *Journal of the American College of Cardiology* said the Endo-Pat 2000 System may have a role in detecting early heart disease. Endo-Pat 2000 was developed by Itamar Medical (Caesarea, Israel and Boston, MA) and is distributed in the United States by Cholestech, which anticipates launching the product later this year.

The device, which has been cleared by the FDA, consists of three parts. First, two disposable probes are placed on the fingers of the individual being tested by employing reactive hyperemia peripheral arterial tonometry. A portable unit connects to and operates the probes, while signal analysis and the endothelial dysfunction report are generated via a laptop computer. The system does not require blood to be drawn and provides results in 15 to 20 minutes.

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.

% Price Change, Year-to-Date as of 2/4/05

UP	Price	% Chg
Affymetrix	42.99	18
Becton Dickinson	59.28	4%
Bio Rad	58.60	2%
Biosite	62.25	1%
Beckman Coulter	70.09	5%
Cholestech	13.20	61%
Dade Behring	58.21	4%
Digene	26.35	1%
Gen-Probe	49.54	10%
Immucor	31.14	32%
Inverness Medical	25.35	1%
Johnson & Johnson	66.24	4%
Meridian	17.51	1%
Ventana	70.14	10%
UNCHANGED		
Diagnostic Products	55.03	0%
DOWN		
Abaxis	13.01	-10%
Abbott Labs	45.52	-2%
Cytyc	25.51	-7%
OraSure	5.92	-12%
Quidel	4.62	-9%
Third Wave	8.02	-7%

G-2 Insider

There's still time to register for the upcoming Washington G-2 Reports' conference: ***Building Profitability in a Competitive Outreach Market*** this March 31 to April 1 at the Renaissance Concourse Hotel in Atlanta. Among the many topics that will be discussed are critical factors in making outreach alliances work, the strategic role of AP in outreach growth, practical tools for measuring profitability, and capitalizing your outreach program.

Highlights of the program will include a keynote from Thomas M. Sodeman, M.D., chairman, Laboratory Medicine, Northshore Long Island Jewish Health System Core Laboratory, titled *Laying the Foundation for a Profitable Outreach Program*.

In addition, more than 10 innovative case studies will be presented, including:

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- ❑ **New England Pathology** — Find out how to take the lead in pathology
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