Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

Medicare To Cover Immunoassay-Based FOBTs

The Centers for Medicare & Medicaid Services (CMS) has issued a decision memorandum stating its intent to cover immunoassay fecal occult blood tests for colorectal cancer screening for Medicare beneficiaries aged 50 years and older. The final coverage decision, which will include an effective date and reimbursement level, will be published in the *Medicare National Coverage Determinations Manual*, which will be released within weeks.

The decision to cover immunoassay-based FOBTs for screening purposes combined with the potential for a reimbursement level in the $13 to $28 range spells a major revenue opportunity for laboratories and the three IVD companies that manufacture these tests. It will also add another weapon in the fight against colorectal cancer, which kills 57,100 men and women each year, but can be successfully treated if caught early.

FDA-Cleared Immunoassay-Based FOBT Products

FlexSure OBT (Beckman Coulter) cleared 1996
InSure (Enterix Inc.) cleared 2001
Instant-View (Alfa Scientific) cleared 2002

Source: FDA

"We're very excited about this news and anxious to see what the reimbursement level will be," says Doug Farnham, manager of occult blood testing products at Beckman Coulter. Beckman has suggested a reimbursement level of $21-$22 to CMS. For details, see *Inside the Diagnostics Industry*, pp. 5-8.

FDA Says Roche AmpliChip Will Need Premarket Review

Roche Diagnostics says it has stopped marketing its AmpliChip CYP450 microarray on an ASR basis after receiving an October 29 letter from Steven Gutman, M.D., director of the agency's Office of In Vitro Diagnostic Device Evaluation and Safety. In the letter, Gutman said the "OIVD believes the technological characteristics of the AmpliChip would cause it to differ from existing or reasonably foreseeable ASRs such that the AmpliChip would not be exempt from premarket notification." The removal of the AmpliChip from the ASR market comes only about four months after its trumpeted launch in June and will significantly delay Roche's major strategic initiatives in the fledgling field of microarrays.

➡ *p. 2*

▲ **Roche AmpliChip,** *from page 1*

In addition to denying ASR status, Gutman indicated in his letter that Roche may need to seek a de novo classification for the AmpliChip CYP450 microarray under section 513(f). This would involve a lengthier regulatory process than if a 510(k) classification was granted.

A Roche spokeswoman says the company "continues to have conversations with the FDA to determine the appropriate regulatory path for products in this new category." In the meantime, she says that Roche believes it can market AmpliChip CYP450 under the FDA's research-use-only (RUO) designation.

Timeline for Roche's Microarray Adventure

January 2003	Roche pays $70 million to Affymetrix for non-exclusive license to its microarray and instrument technologies
June 2003	Roche announces launch of AmpliChip CYP450 as an analyte-specific reagent (ASR)
July 2003	FDA sends letter to Roche that questions ASR classification of AmpliChip CYP450
July 2003	Roche proposes new rules for bringing ASR products to market
October 2003	Roche stops marketing AmpliChip CYP450 as an ASR after receiving another letter from FDA

Source: *DTTR*

But the FDA's letter to Roche now has other vendors of microarrays that are marketed under the ASR label holding the bag. At least four companies, including Nanogen (San Diego), Orchid Biosciences (Princeton, NJ), Third Wave Technologies (Madison, WI), and the Abbott/Celera joint venture, are currently marketing microarrays for clinical testing for conditions like cystic fibrosis, Factor V Leiden, CFTR (for coronary heart disease), and ApoE (for Alzheimer's Disease).

Meanwhile, the FDA continues to publicly state that it is working on developing new proposed rules for ASRs, but can't set a timetable for their release. However, at several different industry conferences within the past month, including Washington G-2's *Lab Institute* (October 8-11) and IBC's *Chips To Hits* conference (October 27-31), FDA officials have hinted that they are leaning toward regulating microarrays as products that fall outside of the ASR classification.

The FDA's Steve Gutman, M.D., tells DTTR *that IVD companies should assess their microarray products to determine if their novelty is consistent with exemption from premarket review. He says they should contact the FDA for input if they have any doubts.*

Separately, Roche says a clinical study using AmpliChip CYP450 microarrays has been initiated at the University of Kentucky College of Medicine (Louisville). Recruitment has begun for 4,000 patients being treated with drugs for a range of mental illnesses at hospital settings. The multi-year, large-scale study will try to confirm earlier pilot studies that have shown that individuals with genetic variations that caused them to metabolize certain drugs poorly suffer higher rates of serious adverse drug reactions and endure longer and more costly treatment cycles.

Finally, Roche says that it has informed CombiMatrix Corp. (Mukilteo, WA) that it will not be launching Roche's matriXarray product suite in 2003, as previously indicated by Roche. The product suite is being developed under an agreement between CombiMatrix and Roche. No new launch date has been set.

CombiMatrix had initially entered into a worldwide license, supply, research, and development agreement with Roche back in July 2001. Under the terms of the 15-year agreement, Roche was to purchase, use, and resell CombiMatrix's microarrays and related technology for rapid production of customized microarrays for research and clinical diagnostic use.

FDA Issues Guidance On Pharmacogenomics Data

The FDA has issued a new document—Draft Guidance for Industry: Pharmacogenomic Data Submissions—that outlines when drug companies must submit pharmacogenomic test information when developing new drugs. The move presages the day when most new drugs reaching the market could be linked with genetic tests that will help tailor prescriptions to patients' individual genetic makeups.

The guidance provides specific criteria and recommendations on submission of pharmacogenomic data to investigational new drug applications (INDs), new drug applications (NDAs), and biological license applications (BLAs).

Under the proposal, drug developers holding INDs would be required to submit pharmacogenomic data if: 1) the test results will be used for decision making in any clinical trial; 2) the sponsor is using test results to support scientific arguments pertaining to the safety, effectiveness, or dosing of the drug; 3) The test results constitute a valid biomarker for safety outcomes in human or animal studies.

Submissions of pharmacogenomic data for NDAs or BLAs would be required if, among other things, the data would be used in the drug label or as part of the scientific database being used to support approval.

The FDA plans to issue further guidance on co-development of pharmacogenomic tests and pharmaceuticals in the near future. The draft guidance is available on the FDA's website at: *www.fda.gov/cder/guidance/5900dft.pdf*.

Abbott Ready For Re-Inspection By FDA

Abbott Diagnostics (Abbott Park, IL) says its third-party quality systems consultants, Bio-Reg (Beltsville, MD) and AccuReg (Plantation, FL), have co-certified the new quality system procedures put in place at its Lake Forest diagnostic manufacturing facilities.

Abbott spokesman Don Braakman says the company is now working with the FDA on re-inspection of the facilities and their quality systems. Braakman refused to give a timetable as to when the FDA might complete its review. But assuming a favorable resolution, he says the first tests Abbott will reintroduce to the marketplace will include ferritin, folate, and vitamin B12. A failure to meet FDA quality system regulations has forced Abbott to suspend the sales of roughly 60 immunoassays in the U.S. market since early 2000.

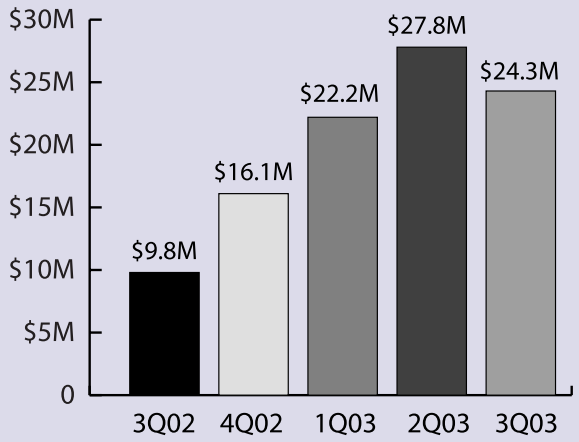
Meanwhile, Abbott reports that third-quarter revenue for its U.S. diagnostics business declined 13% to $250 million from $289 million in the same period a year earlier. Abbott says the decline was partially offset by a more than 25% increase in its molecular diagnostics unit. On a worldwide basis, Abbott reported third-quarter diagnostic growth of 3% to $756 million (excluding currency impact, worldwide diagnostic sales were down 3%).

Biosite Takes Aim At New Markets For BNP Testing

Biosite (San Diego) and its key Triage BNP point-of-care test for diagnosing heart failure are under assault from automated BNP tests from Bayer and Roche (*see DTTR, November 2003, p. 11*). In the three months ended Sept. 30, 2003, Biosite reported the first sequential dip in sales of Triage BNP (see graph).

On an October 22 conference call, Tom Watlington, senior vice president of commercial operations for Biosite, said that year to date through September 30, the company had lost 100 hospital accounts to Bayer's new BNP test and another 42 accounts to Roche's proBNP test.

Triage BNP Test Revenue



Source: Biosite

Biosite is still the dominant provider of BNP tests with a total of 2,251 customers (including about 100 physician offices). But the company faces continued pressure from Bayer and Roche, plus Abbott is hoping to have a BNP test on the U.S. market early next year.

Triage BNP Test sales account for more than half of Biosite's total revenue and had been the company's main growth driver. To offset the competitive threat from Bayer, Roche, and Abbott, Watlington said Biosite has developed an automated version of its Triage BNP Test in partnership with Beckman Coulter and filed a 510(k) application with the FDA; marketing is expected to begin in first-quarter 2004.

In addition, Watlington said Biosite is also focusing more marketing efforts on the physician office market. However, he said this segment was "progressing more slowly than we expected." He cited the need for more physician education on the benefits of BNP testing and also indicated that price was a barrier. "We're launching a marketing campaign aimed at eliminating this issue [price]," he said. He also noted that Biosite is hoping to get CLIA-waived status for Triage BNP early next year.

Finally, Watlington said that Biosite was ramping up marketing efforts in France, Germany, Belgium, and the United Kingdom.

LabCorp Signs Exclusive Deal For $300 Liver Fibrosis Assay

LabCorp (Burlington, NC) says it has signed an exclusive agreement to use BioPredictive's testing technology for quantitatively determining the amount of liver fibrosis, and its rate of progression, in hepatitis C (HCV) patients. LabCorp will market the test under the brand name HCV FibroSure at a list price of $300. The test uses a combination of six serum markers in a patented algorithm to predict fibrosis and necroinflammatory activity in the liver. BioPredictive is a French start-up from Paris University, created in 2002 to develop noninvasive tests.

Medicare Coverage Should Boost Immunoassay-Based FOBTs

In 1970, the Hemoccult-brand FOBT was launched by SmithKline and French Laboratories (now part of Beckman Coulter) and for the past 33 years guaiac-based FOBTs have been the primary screening method for colorectal cancer. But all that could change now that CMS has stated plans to cover immunoassay-based FOBTs for colorectal cancer screening for Medicare beneficiaries aged 50 years and older.

The CMS decision follows an update to guidelines for the early detection of colorectal cancer put forth by the American Cancer Society (ACS-Atlanta) earlier this year (see January/February 2003 issue of the cancer journal *CA: Cancer Journal for Clinicians*). The ACS's recommendations for colorectal cancer screening now include the statement: "in comparison with guaiac-based tests for the detection of occult blood, immunochemical tests are more patient-friendly, and are likely to be equal or better in sensitivity and specificity."

Screening can detect early stage colorectal cancer when it is very amenable to treatment, as evidenced by the fact that 90% of patients diagnosed with localized disease are alive five years after diagnosis, according to the American Cancer Society.

Immunoassay-based FOBTs detect the human hemoglobin present in occult (hidden) blood using antibodies specific to the human hemoglobin molecule, while guaiac-based FOBTs detect peroxidase activity and are not specific for human hemoglobin. Clinical studies have shown that immunoassay-based FOBTs are more accurate than guaiac-based tests because they eliminate false positive results due to the consumption of certain foods such as red meat or the use of common medications including aspirin.

Immunoassay-based FOBTs also offer the potential to raise patient compliance with guidelines calling for annual screening for the over 50 population. Currently, only about 13 million of the 80 million Americans over the age of 50 are screened for colorectal cancer each year, according to data from Centers for Disease Control's National Center for Health Statistics. This figure includes screens using either guaiac-based FOBTs, flexible sigmoidoscopy, double contrast barium enema, or colonoscopy. But guaiac-based FOBTs are by far the most common screening method accounting for an estimated 10 million to 12 million of the total 13 million colorectal cancer screens done each year.

Immunoassay-based FOBTs may lead to an increase in screenings because (unlike guaiac-based FOBTs) they do not require any dietary or prescription drug restrictions prior to taking the test.

For laboratories, the Medicare coverage of immunoassay-based FOBTs at a price that is likely to fall in the range of $13 to $28 is a welcome relief to the meager $4.54 that guaiac-based FOBTs are now reimbursed (CPT code G0107 for screening/82270 for diagnostic test).

Another big benefit to labs could be higher compliance. Today, most labs lose money from guaiac-based FOBTs because only about one out of every three patients who are given a sample collection package return it back to the lab for testing. In other words, some 25 million to 30 million guaiac-based FOBT tests are handed out each year, but only 10 million to 12 million are ever returned back

Unlike some of the other immunoassay-based vendors, Beckman has no exclusive distribution agreements for its immunoassay-based test and will offer it to all labs.

to the lab. The expense of the unused test collection packages is borne by the labs.

The higher reimbursement for immunoassay-based FOBTs (plus potential higher compliance) should allow the three IVD manufacturers with FDA-cleared kits (Beckman, Enterix, and Alfa Scientific) to charge a premium price for their kits compared with the average $1 to $4 that labs now commonly pay for guaiac-based tests (three slide versions). Profiles of the three vendors begin on page 6.

Assuming appropriate Medicare reimbursement, **Beckman Coulter** (Fullerton, CA) intends to bring its FlexSure OBT product back into the market, according to Doug Farnham, manager of occult blood testing products. FlexSure OBT had been cleared by the FDA in 1996, and Beckman began marketing this immunoassay-based FOBT in late 1997. But Farnham says that managed care companies and Medicare carriers had reimbursed the test at the guaiac-based FOBT levels. As a result, FlexSure OBT was not profitable to either Beckman or the labs that performed it, so Beckman took it off the market in late 2001.

However, Farnham says Beckman is now looking to bring FlexSure OBT back onto the market as soon as possible. Beckman already has the majority of the market share for guaiac-based FOBTs through its Hemoccult and Hemoccult Sensa products, which the company currently sells in equal proportions, according to Farnham. But he says Beckman is now eager to shift its attention to the FlexSure OBT product. "If you're going to lose market share, it's better to lose it to yourself," he adds.

Enterix Inc. (Falmouth, ME) has a "first-to-market" distribution agreement with Quest Diagnostics for its InSure test, an immunoassay-based FOBT. The agreement makes Quest the de facto exclusive lab for InSure.

A head-to-head study of InSure versus Beckman's FlexSure OBT (detailed in Enterix's FDA clinical trial data) showed little difference in the sensitivities of the two competing tests. The study, which was based on a high-risk population of 240 individuals, yielded a sensitivity for colorectal cancer of 87% for InSure and 91% for FlexSure OBT. For small adenomas (<10mm), the sensitivity of both tests was 27%. Specificity studies associated with the clinical trial data showed InSure at 98% and FlexSure at 90% to 94%.

Craig Sands

However, a key differentiator between InSure and competing tests is its ease of use, according to Craig Sands, chief executive of Enterix. With InSure, a long-handled brush is used to collect toilet water from around the stool, rather than actual fecal samples. The toilet-water sample is then dabbed onto a test card that is sent to a Quest lab. Sands says competing tests from Beckman require patients to perform the unpleasant task of smearing their own stool onto a collection card. In addition, he notes that InSure requires that samples be taken on only two days versus three days for competing FOBTs.

Sands says InSure is already covered by most health insurance companies, including Aetna, United Health, Cigna, and Oxford, which generally reimburse more than $28 for the test. The recent Medicare decision should lead to coverage from even more health insurers, he adds.

Enterix was founded in 1997 by its chief scientific officer, Howard Chandler, and its chairman, Max Wawhinney. The company raised $7.5 million in 2001 from a group of Australian venture capital investors that included Deutshe Asset Management, Macquarie Technology Fund, and Innovation Capital. In connection with its distribution agreement, Enterix received an undisclosed investment from Quest in May 2003. Enterix has a total of 25 employees, including 15 in Australia and 10 in the United States.

Alfa Scientific Designs (Poway, CA—just north of San Diego) received FDA clearance for its Instant-View Fecal Occult Blood Test in 2002. The test, which is CLIA waived, has a rapid lateral flow design and is available in a cassette or dipstick format. Alfa Scientific sells the test directly and through distributors at prices that average about $3.50 per test (25 tests/kit at $87.50).

To perform the test, a sample is added to a collection tube and shaken to mix with an extraction buffer. Four drops of the supernatant in the collection tube are then placed into the sample well of the test-cassette, or the dipstick is placed in the collection tube. Visual results are available in five to ten minutes.

Alfa Scientific is a privately held company founded in 1996 by its president Naishu Wang, M.D., Ph.D. In addition to Instant-View, Alfa Scientific makes tests for drugs of abuse, fertility, and infectious diseases (hepatitis and H. Pylori).

The new Medicare coverage could entice Roche, Abbott, Dade, or Ortho-Clinical to develop or license a test for introduction into the United States.

Of course the new Medicare coverage for immunoassay-based FOBTs is sure to bring additional competition into the market. One likely contender is **Fujirebio Inc.** (Tokyo), which markets its Immudia-HemSp test in Japan and Australia and could seek FDA clearance.

Meanwhile, other companies have developed wholly different technologies for detecting colorectal cancer. Profiles of four of these companies begin below.

Exact Sciences (Marlborough, MA) began marketing its DNA-based PreGen-Plus test for colorectal cancer on August 13 through an exclusive distribution agreement with LabCorp. The company has not yet released any volume figures for the test, which has a list price of $795 (approximately $500 after discounts).

On October 11, results from a multi-center study of PreGen-Plus versus Beckman's Hemoccult II test were released at a satellite symposium of the American College of Gastroenterology 2003 conference in Baltimore. The study, which was based on 4,000 analyzed specimens from an average-risk population, showed an overall sensitivity of 52% for PreGen-Plus versus 13% for Hemoccult II. Exact, which spent $10 million to fund the study, is hoping to publish the data in a peer-reviewed journal.

"Reimbursement is always the biggest issue for any new test," said Don Hardison, chief executive of Exact, on an October 27 conference call with analysts. In reference to immunoassay-based FOBTs, Hardison said, "I don't believe physicians are looking for another more extensive fecal occult blood test." For more on Exact, see page 1 in the October 2003 issue of *DTTR*.

Myriad Genetics (Salt Lake City) markets two genetic tests for colorectal cancer. Familial forms of colorectal cancer were estimated in 1997 to account for

10% to 30% of all cases according to the American Society of Clinical Oncologists.

Colaris, which has a list price of $1,950, is a predictive test for hereditary nonpolyposis colorectal cancer. It detects disease-causing mutations in two genes, MLH1 and MSH2. Individuals who carry one of these two colon cancer genes have a greater than 80% lifetime risk of developing colon cancer. Myriad says that individuals who test positive can then receive earlier and more frequent monitoring and removal of pre-cancerous lesions.

Myriad also markets Colaris AP, which detects mutations in the APC gene, which cause a colon polyp-forming syndrome known as familial adenomatous polyposis (FAP), and a more common variation of the syndrome known as attenuated FAP (aFAP). Individuals who carry a deleterious mutation in the APC gene have a greater than 80% lifetime risk of developing colon cancer. The price for Colaris AP is $1,685.

Myriad markets these tests to oncologists through its own 100-person salesforce and performs the tests at its lab in Salt Lake City. Myriad also has an exclusive agreement with LabCorp that covers the primary care physician market.

International Medical Innovations Inc. (Toronto) is seeking to partner with a commercial lab in the United States so it can introduce its ColorectAlert test on an ASR basis, according to spokesman Andrew Weir. He believes reference labs could market the test at a price of $25 to $35.

ColorectAlert identifies a cancer-associated sugar in a sample of rectal mucus, which is taken during a routine digital rectal exam. The test does not require any dietary restrictions on the part of patients. The sample is smeared onto a small card with a membrane surface, and sent to a laboratory. At the laboratory the sample is treated with the enzyme galactose oxidase, and then stained with Schiff's reagent, which produces a color change.

Clinical study results presented at the 94th Annual Meeting of the American Association for Cancer Research in Washington, DC, in July 2003 showed that ColorectAlert detects 54% of early-stage (Duke's Stage A and B) colorectal cancers and 49% of all cancers with 85% specificity. The data included results from three studies totaling 1,787 high-risk patients tested at St. Michael's Hospital in Toronto.

Biomerica Inc. (Newport Beach, CA) markets a guaiac-based FOBT, named EZ Detect, directly to consumers in drugstores and online. EZ Detect is the top-selling brand in the over-the-counter market. EZ Detect requires no stool handling. The user simply drops a test tissue into the toilet bowl, and if blood is present, a blue-green color will appear within two minutes. The price for a three-test pack is $12.

However, Biomerica has suffered substantial recurring losses from operations over the last couple of years, and there is doubt as to whether the company can continue as a going concern. In the three months ended August 31, 2003, Biomerica reported a net loss of $217,964 versus a net loss of $111,370 in the same period a year earlier; revenue was up 4% to $2.164 million. Cash and equivalents totaled $343,263 as of August 31, 2003.

Leonard Blasts Gene Patents At Lab Institute Conference

"As a practicing physician, it's very frustrating to be told I can't do certain testing," says Dr. Leonard, a molecular pathologist who is also a former president of the Association for Molecular Pathology.

In a presentation at Washington G-2's recent Lab Institute 2003, October 8-11, Debra Leonard, M.D., Ph.D., director of the molecular pathology lab at the University of Pennsylvania Health System (Philadelphia), argued that gene patents were limiting her ability to practice medicine. Leonard expressed growing frustration with commercial reference labs that, through gene patents or exclusive licenses, required certain tests to be performed only at their facilities or charge exorbitant prices for sub-licensing rights.

Leonard cited Athena Diagnostics (Worcester, MA), which aggressively enforces its exclusive rights to the ApoE 4 allele and related tests for diagnosing Alzheimer's disease. Athena requires testing for this gene variant to be performed only at its facilities and it charges $195 per specimen. That's nearly double the $100.50 that UPenn had been charging, according to Leonard. She also cited Myriad Genetics (Salt Lake City), which holds patents on the BRCA1 and BRCA2 genes and charges approximately $2,700 for its BRCAnalysis test for determining increased risk of breast cancer and ovarian cancer.

Leonard said the high prices charged by Athena and Myriad limit access of their tests to the uninsured and underinsured. In addition, she said the "sole-provider" model limits the ability of doctors and their patients to get second opinions from other labs. It also limits competition between labs based on price and quality of service, according to Leonard.

Leonard also cited cases where gene patent owners were seeking to extract prohibitively high licensing fees from labs seeking to use their patents. For example, Miami Children's Hospital Research Institute (MCHRI) charges a fee of $12.50 to labs that test for Canavan disease and puts a cap on the number of tests any clinical lab can do. MCHRI holds patents on DNA tests for Canavan disease mutations—the mutations impair normal brain development in children and lead to death by age 10 to 15. (*See related story on page 10.*) Leonard said that while $12.50 may not sound like a lot of money, it adds up when you're performing a panel of tests that may include 10, 20, 30, or more mutations.

Executives from Athena and Myriad did not return phone calls from *DTTR* seeking comment on Leonard's remarks. But a common rebuttal is that gene patents and the associated high prices and licensing fees for genetic tests are necessary to help fund the expensive research activities undertaken by commercial labs. However, Leonard contends that most patented genes to date have been found by not-for-profit research organizations and universities that have received federal funding for their research. The commercial labs then gain exclusive licensing of the researchers patented claims. So the public winds up paying twice, first to fund the research and then again through high test prices, according to Leonard.

Leonard said she supported bipartisan legislation introduced last year *(see DTTR, April 2002, pp. 1-3)* that would have given physicians and medical researchers unrestricted access to patented genes for use in clinical testing and non-commercial genetics research. But the bill died last year when one of its co-sponsors, Rep. Lynn Rivers (D-MI), lost a bid for re-election.

However, the other co-sponsor, Rep. Dave Weldon (R-FL) remains in office. A spokeswoman from his office tells *DTTR* that Weldon is working to re-introduce the bill, although no timeline has been set.

Miami Children's Hospital Settles Canavan Gene Patent Case

The parties have reached a settlement in Greenberg et al. versus Miami Children's Hospital (MCH) and Reuben Matalon, M.D., Ph.D. This lawsuit was pending in federal court in Miami and concerned the gene patent for Canavan disease, an incurable childhood disease. The plaintiffs in the lawsuit were the Canavan Foundation and the National Tay-Sachs & Allied Diseases Association, and Daniel Greenberg and David Green.

The seeds of the case began in 1987 when Daniel Greenberg and his wife, parents of two children with Canavan disease, convinced Dr. Matalon to try to identify the gene responsible for the disease and develop an affordable carrier and prenatal test. The research began when the Greenbergs provided Matalon with numerous blood and urine samples from their children. The family and nonprofit groups, including the Canavan Foundation, located and convinced other affected families to contribute samples and a confidential database was created.

This database was crucial to Matalon, who identified the Canavan gene in 1993 along with an accurate prenatal and carrier screening test while working at MCHRI. Then without informing any of the Canavan families and organizations, Matalon and the hospital filed a patent in 1994 for the gene and the test.

After the patent (US 5,679,635) was issued in 1997, the American College of Obstetricians and Gynecologists recommended that all Jewish women of central and eastern European descent be tested to determine if they are Canavan carriers. And in 1999, MCH began to enforce its patent and collect royalties for the patented genetic test. The hospital claimed this was necessary to recover some of the $5 million it spent developing the test.

In October 2000, Greenberg et al. filed their lawsuit against MCH and Matalon alleging breach of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion, and misappropriation of trade secrets. In the lawsuit, the Canavan families and organizations sought injunctive relief to prevent MCH from restricting access to prenatal and carrier testing for Canavan disease and from impeding research on finding a cure or therapies for Canavan disease through enforcement of its patent.

The confidential settlement allows license-free use of the Canavan gene in research to cure Canavan disease, including in gene therapy research, genetic testing in pure research, and in mice used to research Canavan disease. In addition, the Canavan Foundation, National Tay-Sachs & Allied Diseases Association, Daniel Greenberg, and David Green have agreed not to further challenge MCH's ownership of the Canavan gene patent. And MCH will continue to be able to license and collect royalty fees for clinical testing for the Canavan gene mutation.

IVD Stocks Rise 1% In Latest 5 Weeks; TheraSense Jumps 57%

***Roche** non-voting equity shares, which trade on the Zurich stock exchange, are up 18% to 113.25 Swiss francs so far this year. Shares of **Bayer**, which trade on the German stock exchanges, are up 10% to 22.53 euros.*

The 20 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 1% in the five weeks ended Nov. 6, 2003, with eight stocks up in price, one unchanged, and eleven down. Year to date, the G-2 Index is up 67%, while the S&P 500 Index is up 20% and the Nasdaq is up 48%.

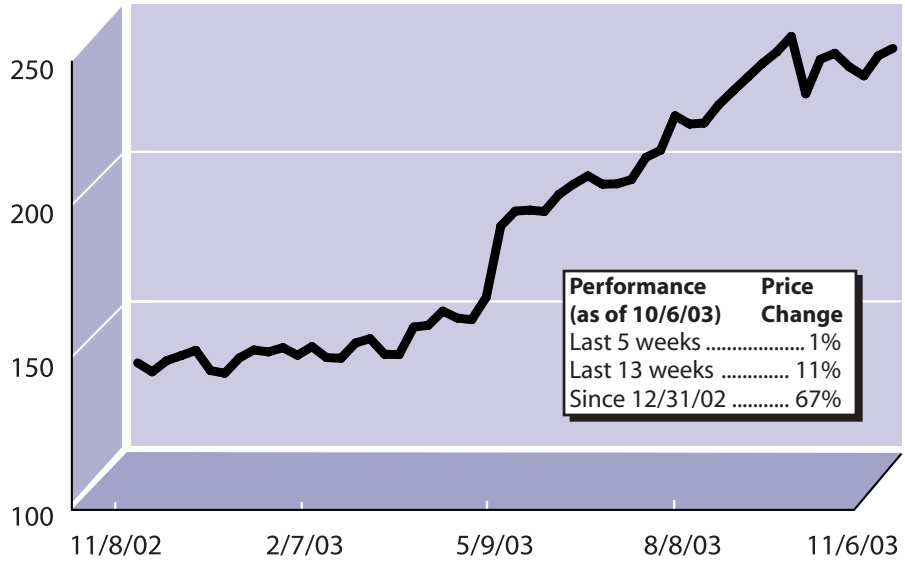
Shares of **TheraSense** (San Diego) jumped 57% to $18.55 per share for a market cap of $814 million. The company recently reported its first profitable quarter. In the three months ended September 30, the company recorded net income of $2.7 million versus a net loss of $9.3 million in the same period a year earlier; revenue was up 49% to $58.2 million. TheraSense says the increased revenues were principally the result of increased sales of its FreeStyle test strips and FreeStyle system kits.

Diagnostic Products Corp. (DPC-Los Angeles),which was up 14% to $41.96 for a market cap of $1.2 billion. The Company reported third-quarter net income of $17 million versus $9.9 million; revenue was up 18% to $93.7 million. DPC shipped a total of 198 Immulite analyzers in the third quarter including 113 Immulite 2000s. The total number of Immulite shipped is now over 8,700.

Other stocks moving up included **Gen-Probe** (San Diego), which was up 11% to $30.05 per share for a market cap of $1.4 billion. Gen-Probe completed a 2-for-1 stock split on September 30. **Beckman Coulter** (Fullerton, CA) was up 10% to $51.28 for a market cap of $3.2 billion.

Stocks moving down included **Digene** (Gaithersburg, MD), which fell 15% to $35.95 per share for a market cap of $730 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 20 IVD companies.

Avg. % Price Change, 5 weeks ended 10/6/03

UP		
Beckman Coulter	51.28	10%
Bio Rad	54.42	4%
Dade Behring	31.25	4%
Diagnostic Products	41.96	14%
Gen-Probe	30.05	11%
Igen	58.16	1%
Immucor	31.30	8%
TheraSense	18.55	57%
UNCHANGED		
Meridian	10.15	0%
DOWN		
Abbott Labs	$42.25	-1%
Becton Dickinson	36.40	-2%
Biosite	25.79	-7%
Cholestech	7.60	-7%
Cytyc	13.00	-14%
Digene	35.95	-15%
Inverness Medical	24.70	-7%
i-STAT	12.48	-14%
Johnson & Johnson	49.17	-2%
Quidel	7.73	-5%
Ventana	40.70	-1%

G-2 Insider

Bayer To Sin Off Chemicals Business

In a surprise announcement, Bayer Group (Leverkusen, Germany) has unveiled plans to shed most of its chemicals business and parts of its polymers unit that together make up a fifth of group sales. Just last month, this publication had speculated that Bayer might be maneuvering to spin off its healthcare unit, which includes diagnostics.

Bayer says it will bring the chemicals/polymers business, with sales of 5.6 billion euros ($6.4 billion), into a new company that would be spun off to Bayer shareholders or sold in an initial public offering by early 2005. Bayer plans to focus on healthcare, agrochemicals and a new material science business, marking the end of the firm's four-pillar strategy and its withdrawal from chemicals. Investors have been pushing Bayer to breakup its conglomerate structure for years (*see DTTR, February 2001, p. 1*).

Holland Named President of Ortho-Clinical Diagnostics

Johnson & Johnson (New Brunswick, NJ) has named Cliff Holland as worldwide president of its Ortho-Clinical Diagnostics Division (OCD) effective November 30. Holland, who has a 25-year career at J&J, currently is worldwide president of the company's Ethicon division, which develops and markets surgical products in the areas of wound care and treatment.

Holland will fill the void left when Catherine Burzik resigned from her position as president of OCD to become executive vice president of Applied Biosystems Group (Foster City, CA) effective Sept. 2, 2003.

Company References

Abbott Labs 847-937-6100
Alfa Scientific 858-513-3888
Beckman Coulter
714-871-4848
Biomerica 949-645-2111
Biosite 858-455-4808
Enterix 207-781-4990
Exact Sciences 508-683-1200
International Medical
Innovations 416-222-3449
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317-849-9350

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