Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

What's Next For Correlogic?

The past 12 months have been tumultuous for Correlogic Systems (Bethesda, MD), which has developed a novel software system for analyzing blood protein patterns to detect cancer. In March, the company and its distribution partners, Quest Diagnostics and LabCorp, were notified by the FDA that their first product, an ovarian cancer test named OvaCheck, may need a premarket approval before it can be marketed for clinical use.

And now it's become public that two researchers from the National Cancer Institute (NCI) and the FDA have had consulting arrangements with a competitor, Biospect (South San Francisco), even though they were already working under a cooperative research and development agreement (CRADA) with Correlogic. Even more interesting is news that Richard Klausner, M.D., former national director of NCI, helped found Biospect shortly after resigning from NCI in September 2001 and now sits on the company's board of directors.

Peter Levine, president of Correlogic, tells *DTTR* that he first learned of Biospect and its ties to NCI officials in July 2003 from a colleague in the lab business. Levine says the news literally made him sick. But with a congressional investigative panel now looking into the situation, he says Correlogic has refocused its attention on bringing OvaCheck to the market. For more details, see *Inside the Diagnostics Industry*, pp. 5-7.

Myriad Genetics Loses Patent For Test In Europe

On May 18, the European Patent Office (EPO—Munich) revoked a patent held by Myriad Genetics (Salt Lake City) covering its genetic test for predisposition to breast cancer. The EPO said the patent was revoked because of a "lack of inventive step." The patent (EP 699 754) was granted to Myriad in early 2001 and has been the subject of controversy in Europe ever since. Opposition to the patent was filed in October 2001 by a number of parties including the Institut Curie, a Paris-based cancer research organization. Critics have contended that Myriad is abusing a monopoly position by charging $2,975 for its complete breast cancer test, BRACAnalysis, and not allowing other labs to perform it. Labs in Europe will now be able to perform the test on their own at a cost of roughly $700 to $800. Bill Hockett, a spokesman for Myriad, tells *LIR* that Myriad plans to appeal the EPO decision. ➥ *p. 2*

In March 2002, former Rep. Lynn Rivers (D-MI) introduced legislation that would have given physicians and medical researchers unrestricted access to patented genes. The bill died with the end of the 107th Congress.

▲ **Myriad Genetics Loses Patent,** *from page 1*

Europe is not the only place where Myriad has encountered resistance. Early last year, Ontario's Ministry of Health and Long-Term Care announced plans to defy Myriad's Canadian patents by performing genetic tests for breast cancer for high-risk women at seven hospital laboratories (*see DTTR, March 2003, page 1*). Myriad had initially threatened to sue the Canadian province for patent infringement but has since backed off that threat. "We're trying to exhaust all other avenues before we begin the legal process," says Hockett.

Hockett says that the situations in Europe and Canada have had little effect on Myriad because the company generates nearly all of its revenue in the United States. In the nine months ended March 31, 2004, Myriad's revenue from genetic testing increased by 19% to $30.2 million; gross profit increased to $20.3 million from $16.1 million. "The company believes that the profit margins for predictive medicine products [now at 67%] are not only exceptional in the molecular diagnostic industry today but have the potential to increase further, eventually into the mid-70% range, resulting in margins comparable to those delivered by many pharmaceutical companies," stated Myriad in a press release.

Hockett says that Myriad gets most of its genetic testing revenue from its BRACAnalysis test, followed by its Colaris and Colaris AP tests for detecting hereditary risk for colon cancer, and its Melaris test for skin cancer. In February, Myriad raised the price of its BRACAnalysis to $2,975 from $2,760. Hockett says that profits from Myriad's genetic testing business are being used to help fund its drug research and development efforts.

Myriad Genetics in Brief *($000)*

	9 mos. ended March 31, 2004	9 mos. ended March 31, 2003	% Change
Total revenue	$41,576	$48,617	-14.5
Genetic testing revenue	30,209	25,329	19.3
Research revenue	11,367	23,288	-51.2
Net loss	-30,159	-17,744	NA
Cash and investment securities	$99,083	$130,555	-24.1

Separately, Hockett notes that Myriad, which employs a sales force of 100 people, has no immediate plans to resume direct-to-consumer advertising for BRACAnalysis. Myriad ran television and radio commercials for BRACAnalysis in Denver and Atlanta from September 2002 to February 2003. Hockett says the ads greatly increased demand, but created bottlenecks at the genetic-counseling stage. He says each patient typically gets about eight hours of counseling, and there simply aren't enough genetic counselors available to handle the increased demand generated from consumer advertising.

BioMerieux IPO Could Be Valued At More Than $1.5 Billion

BioMerieux (Marcy l'Etoile, France) has filed a regulatory document with the French stock market regulator Autorite des Marches Financiers for a possible initial public offering. The move was prompted by investment firm Wendel Investissement's desire to sell its 34.5% stake in the company. Other shareholders in BioMerieux are the Merieux family, with a 59.7% stake, and Groupe Industriel Marcel Dassault SA, which owns 5.1%.

The IPO document, which was filed on May 6, says the company plans to list its stock on a Paris stock exchange. BioMerieux says it has no plans for a listing on a U.S. stock exchange.

What Are Comparable IVD Companies Selling For?

	Market Cap	2003 Revenue	Market Cap/ Revenue
Beckman Coulter	$3,728M	$2,192M	1.7x
Bio-Rad	1,442	1,003	1.4x
Dade Behring	1,900	1,436	1.3x
Diagnostic Products	1,224	381	3.2x

Source: *DTTR*

Based on valuations of comparable IVD companies, *DTTR* estimates that BioMerieux could be valued at anywhere between 1.3 times and 3.2 times its annual revenue. This would put BioMerieux's potential market capitalization in the range of $1.5 billion and $3.6 billion.

The other alternative could be for a big IVD company to step in and acquire Wendel Investissement's stake in a private transaction. From a strategic standpoint, *DTTR* believes Bio-Rad Laboratories, Dade Behring, or maybe even Gen-Probe might make the best fit. From a political standpoint, BioMerieux would probably prefer Bayer or Roche as a suitor.

In 2003, BioMerieux reported net income of 55.1 million euros (US $67.4 million), down from €61.1 million (US $74.7 million); revenue declined by 3.1% to €914.5 million ($1.118 billion). BioMerieux's revenue was up 5.3% after adjustments for currency fluctuations.

BioMerieux has a total of 5,336 employees worldwide. Its North American operations (United States and Canada) have 1,402 employees and are headquartered in Durham, North Carolina. In 2003, BioMerieux generated revenue of 252 million euros ($307.2 million) from North America, down 7.7% from €272.9 million ($332.6 million) in 2002. BioMerieux's revenue was up 9.2% in North America after adjustments for currency fluctuations, making it the company's fastest-growing region.

BioMerieux greatly expanded its presence in the United States when it acquired Organon Teknika's diagnostic unit in July 2001 for $263 million.

But BioMerieux's U.S. operations have been struggling with manufacturing issues. In September 2003, the company said it was voluntarily recalling 2,204 chlamydia test kits because 60 tests were found to be ineffective about six months before their expiration date.

In April, the U.S. Food and Drug Administration inspected the company's Durham facility after receiving complaints from customers and over questions about several of its processes, the company's prospectus notes. BioMerieux says it is in the process of responding to the FDA and plans to have corrective action in place by this summer. And in May, the company issued a recall of 39,000 Vitex GPS cards, which are used to determine which antibiotic patients should use to fight infections, saying they could give wrong answers.

BioMerieux at a Glance *(in millions of euros)*

	2003	2002	2001
Revenue	914.5	943.7	799.3
Operating income	102.1	120.0	75.0
Net income	55.1	61.1	33.7

Source: BioMerieux

Roche Plans To Soon Submit AmpliChip CYP450 Application

Roche intends to submit applications for its AmpliChip CYP450 microarray to the FDA and European regulatory authorities by year's end, Greg Heath, Ph.D., senior vice president of clinical genomics at Roche Molecular Diagnostics, told stock analysts at a May 6 meeting in New York City. Heath said that he expects European approval in a matter of months, but did not venture a guess as to when U.S. approval might be obtained.

Roche had initially launched the AmpliChip CYP450 in the United States as an analyte-specific reagent (ASR) in June 2003, but was soon forced to stop marketing the product when the FDA questioned its status as an ASR. Earlier this year, the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) issued a letter to Roche stating that AmpliChip CYP450 could not be classified as an ASR.

In the letter, OIVD director Steven Gutman, M.D., suggested that if AmpliChip CYP450 is found not substantially equivalent, Roche should submit a premarket notification application and seek *de novo* classification. And Gutman tells *DTTR* that "Products for p450 whether submitted by Roche or other companies could use existing data to request a de novo 510(k). This information has been shared with several companies interested in this product line....It is possible for this test or others like it with a strong literature base to be eligible for de novo review."

The de novo classification was established in 1997 as part of the FDA Modernization Act. In an April 20 presentation at an IVD industry conference, Ruth Chesler, a scientific reviewer at OIVD, noted that the de novo classification is intended for lower-risk diagnostic products for which there is no predicate device. She said that the de novo classification may enable manufacturers to get their product to the market quicker.

Examples of De Novo Classifications for IVD Products

Test/Manufacturer	*Date Received*	*Decision Date*	*Process Time*
CellSearch/Veridex	5/21/2003	1/21/2004	245 days
Factor V Leiden/Roche Diagnostics	11/17/2003	12/17/2003	30 days
West Nile Virus Igm/Panbio Limited	6/16/2003	7/8/2003	22 days
Breath Nitric Oxide/Aerocrine AB	4/5/2002	4/30/2003	390 days
Endotoxin Activity/Spectral Diagnostics	6/7/2002	6/16/2002	374 days
Triage BNP/Biosite	11/8/2000	11/20/2000	12 days
S. Cerevisiae/Inova Diagnostics	3/6/2000	8/16/2000	163 days
Biotinidase/Wallac Inc.	7/7/1999	2/15/2000	223 days
Average			182 days

Source: *DTTR* from FDA files

To date, the FDA has given eight IVD products de novo classifications—more formally known as the Class III designation—with an average process time of 182 days. Most recently, the FDA classified Veridex's CellSearch system as a Class III device taking 245 days from the time Veridex initially filed its application (*see page 10*). But Roche's Factor V Leiden kit for its LightCycler real-time PCR instrument, which was the first-ever DNA-based genetic disorder test cleared by the FDA for human testing, took only 30 days.

The designation of Class III status for Roche's AmpliChip CYP450, or a competing product, would mark the first time that the FDA has cleared a microarray, or DNA chip, for sale to the clinical market.

Protein-Pattern Technology Takes Center Stage In NIH Controversy

Correlogic's protein-pattern technology must be awfully good. How else can you explain why five current and former high-ranking officials from the National Cancer Institute (NCI), a unit of the National Institutes of Health, and the FDA (*see table on page 6*) would risk their careers and reputations to help get a competing firm working on similar technology off the ground?

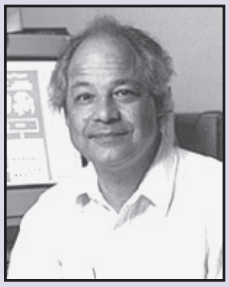
The Timeline of Events

The idea behind Correlogic and its protein-pattern technology for identifying cancer began in the late 1990s. That's when Peter Levine, a former government trial lawyer who had specialized in the evaluation of data patterns and the presentation of computer-generated evidence in litigation, and Ben Hitt, Ph.D., a biochemist who had served as senior principal software engineer for Raytheon Systems, crossed paths and began talking about starting a company that would capitalize on advances in pattern-recognition technology, which solves problems by searching for patterns in huge volumes of data.

Emanuel Petricoin, PhD

In June 1999, the pair had lunch with Emanuel Petricoin, Ph.D., who was then co-director of the Clinical Proteomics Program, a new joint venture of the NCI and FDA. At this meeting, the notion of detecting cancer by looking at protein patterns rather than single biomarkers was discussed.

In May 2000, Hitt and Levine formed Correlogic and signed a research agreement with the Clinical Proteomics Program. Within 12 months, researchers at the FDA, NCI, and Correlogic had developed a system for detecting protein patterns associated with ovarian cancer. Hitt was credited as the inventor of the core algorithms that power Proteome Quest, the software that is used to create computational "models" of disease states, while the concept and process for identifying blood protein patterns associated with specific diseases was invented by Hitt, Levine, and scientists at the FDA and NCI, including Petricoin.



Lance Liotta, MD, PhD

On Feb. 16, 2002, a paper published by *The Lancet* showed that in an analysis of 116 blinded blood samples—50 from patients with cancer and 66 with non-malignant disease—Correlogic's method was able to correctly identify all 50 cases of ovarian cancer, including all 18 Stage I cases. The single flaw in the performance was predicting ovarian cancer in three of 66 control cases. Overall, the test had a predictive value of 94% (50 of 53) vs. 35% for CA-125, the current standard for testing for ovarian cancer. The data produced in the study was a joint effort of Correlogic and the FDA/NCI Clinical Proteomics Program. Correlogic's partners were Petricoin and Lance Liotta, M.D., Ph.D., a researcher for the NCI.

After publication of the results, Petricoin stated in an FDA press release, "We're particularly excited about the potential of this technique to diagnose additional types of diseases. It may also be able to provide an early warning of impending toxicity."

In light of the encouraging results, in April 2002, the research agreement between Correlogic, the FDA, and the NCI was converted into a cooperative research and development agreement (CRADA), and Petricoin and Liotta were

Greenwood's subcommittee on consulting deals was prompted by a report in the LA Times that documented hundreds of payments, totaling millions of dollars, by drug and biotech companies to NIH scientists.

named as co-principal investigators. One of the goals of this CRADA was to develop a strategy for commercialization of protein pattern recognition tests, first for ovarian cancer.

It's at this juncture that the relationship between Correlogic, the FDA, and the NCI started to go sour. Sometime between May and August 2002, NCI decided to unilaterally sponsor clinical trials on the ovarian cancer test instead of executing a clinical research CRADA with Correlogic.

On June 18, 2002, Biospect was incorporated with a mission statement—"developing technology for identifying and assaying protein biomarker patterns"—that was virtually identical to Correlogic's. Richard Klausner, M.D., is listed as a founder, a board member, and a paid consultant to Biospect. Klausner had resigned from his position as national director for the NCI on Sept. 30, 2001.

In addition, Carol Dahl, Ph.D., former director at NCI's Office of Technology and Industrial Relations, has served as vice president for strategic partnerships at Biospect. And Svetlana Shtrom, Ph.D., former technology development specialist at NCI, currently serves as director for business development at Biospect. While at NCI, Shtrom was responsible for negotiating the CRADA with Correlogic.

Finally, there's Petricoin and Liotta, who each entered into consulting contracts with Biospect in late 2002. Liotta was paid $49,375 by Biospect between December 2002 and May 2004 for consulting services, according to records from the NIH. Payments to Petricoin have not yet been made public. Petricoin and Liotta were not available for interviews with *DTTR*.

NCI and FDA Employees and Their Ties to Biospect

Name	*Role at NCI or FDA*	*Role at Biospect*
Richard Klausner, M.D.	Served as director of NCI from Aug. 1, 1995 through Sept. 30, 2001	Helped found Biospect in early 2002 and is also on board of directors
Carol Dahl, Ph.D.	Former director, Office of Technology and Industrial Relations, at NCI	Served as vice president for strategic partnerships
Lance Liotta, M.D., Ph.D.	Currently chief of the Laboratory of Pathology at NCI	Worked as a paid consultant from December 2002 through May 2004
Emanuel Petricoin, Ph.D.	Currently lead microbiologist at FDA's Center for Biologics Evaluation and Research	Worked as a paid consultant from October 2002 through May 2004
Svetlana Shtrom, Ph.D.	Technology development specialist at NCI (negotiated CRADA agreement with Correlogic)	Serves as director for business development

Source: *DTTR* from NIH and Biospect Websites

The circumstances of Correlogic, Biospect, which recently renamed itself Predicant Biosciences, and their relationships with NCI and FDA employees have now fallen under the microscope of U.S. Rep. James Greenwood (R-PA), chairman of the Energy & Commerce oversight and investigations subcommittee. Greenwood held a special hearing on May 18 to look into possible conflicts of interest between the consulting arrangements Petricoin and Liotta had with Biospect.

Top NIH researchers can earn as much as $300,000 in government salaries and tens of thousands more from outside consulting jobs.

During the hearing, both researchers noted that their consulting agreements with Biospect had been cleared by their bosses at the NCI and FDA, although they were kept secret from Correlogic. Liotta said he saw no conflict of interest because Correlogic is developing software for protein-pattern analysis, while Biospect is developing diagnostic equipment.

Even after Correlogic found out about the consulting agreements and complained to officials at the NIH in mid-2003, the arrangements were allowed to stay intact. It was only in the days before the Greenwood hearing that Petricoin and Liotta ceased their relationships with Biospect. (Klausner was asked to testify at the May 18 hearing, but refused).

"It was obvious to others in the broad diagnostic, biotech industry that Biospect was a competitor of ours. Anyone who did even just a casual read of Biospect's [press releases] could see that," says Correlogic's Levine. Executives at Biospect did not return phone calls from *DTTR* seeking comment.

"What company will want to enter into a CRADA with NIH if this is the way conflict-of-interest issues are managed? This isn't transparency. This is an outrage," said Greenwood in his opening remarks for the May 18 hearing.

"As a result of these secret deals, progress appears to have slowed on a public-private partnership that could lead to prompt commercialization of lifesaving, ovarian cancer diagnostic tests," Joe Barton (R-TX), chairman of the House Energy and Commerce Committee, said. "Public trust has been damaged."

The Fallout

Following the May 18 hearing, Lester Crawford, acting commissioner of the FDA issued a press release stating, "In light of recent questions about possible conflicts of interest involving HHS agencies, I have also directed a comprehensive review of all current outside activity requests from all FDA employees. Once that review has been completed, FDA will issue a final policy on the review and approval of outside activities."

Elias Zerhouni, M.D., director of the NIH, has ordered all agency employees to report the financial details of any consulting payments received from pharmaceutical or biotech over the last five years or face dismissal. The financial information will be turned over to members of Congress.

The NIH relaxed its rules covering outside income and activities in 1995 in an effort to attract better researchers and im-

Life After the NCI

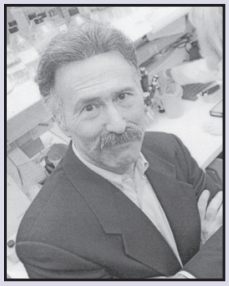
Since resigning as director for the NCI on Sept. 30, 2001, Richard Klausner, M.D., has led a busy life. In addition to helping found Biospect in early 2002, Klausner is listed as a co-founder and board member of Infinity Pharmaceuticals (Cambridge, MA), a drug discovery firm. According to Delaware's Division of Corporations, as well as Infinity's own Web site, Infinity was incorporated in February 2001. (Note: Rep. Greenwood is investigating Klausner's relationship with Infinity while he was still NCI director.)

In addition, Klausner is a scientific and strategic advisor to GenPath Pharmaceuticals (Cambridge, MA), which describes itself as "a biotechnology start-up founded to discover and develop breakthrough drugs to fight cancer as well as other disorders with a genetic basis." GenPath was founded in early 2002.

Finally, Klausner became executive director for global health of the Bill and Melinda Gates Foundation in May 2002.

prove its science. Now some members of the subcommittee are pushing for a complete ban on any NIH employee accepting outside consulting jobs. Speaking at the May 18 hearing, Rep. Diana DeGette (D-CO) said that unless NIH accepted a "blanket restriction on outside compensation, serious conflicts of interest and the appearance of conflicts of interest will continue."

Greenwood intends to hold another hearing, focusing on other possible conflicts of interest in June.



Peter Levine

What's Next for Correlogic?

Levine says that Correlogic is trying to move past the current controversy and complete negotiations with the NCI on a clinical research CRADA for the OvaCheck test. Did Petricoin's and Liotta's involvement with Biospect slow down progress on bringing OvaCheck to market? "That's difficult to assess at this point. It's like the classic onion case. Every time a layer is peeled away, there's another layer of information," answers Levine.

Will Correlogic file a lawsuit against Petricoin, Liotta, the NCI, or FDA for possibly sharing trade secrets with a competitor and violating the CRADA agreement? "We have no plans to sue. The last thing we want to do is get tangled up in a lawsuit with this branch of the government. We want to normalize our relationship with the NCI and continue work on OvaCheck," says Levine.

Levine says that he met with officials from the FDA in March to discuss whether or not a premarket review for OvaCheck would be necessary. He says that Correlogic remains in contact with the FDA, but no conclusions have been reached yet. "I can't imagine that this issue will hang out too much longer," he says.

Levine believes that OvaCheck should be allowed to be marketed by its distribution partners, Quest Diagnostics and LabCorp, as a laboratory-developed, or "homebrew," test.

The process for performing an OvaCheck test involves Quest or LabCorp obtaining a patient blood specimen at one of their patient service centers. The specimen is then shipped to either Quest's Nichols Institute (San Juan Capistrano, CA) or LabCorp's Center for Molecular Biology and Pathology (Research Triangle Park, NC), explains Levine. He says that Quest or LabCorp then does the prep work on the specimen, including mass spectrometry. This data is then sent electronically to Correlogic via T1 lines. Correlogic then runs this data through its pattern-recognition software programs and sends the results back to Quest or LabCorp, whose professionals review the results and share them with the patient's doctor.

Under an agreement signed in late 2002, Quest and LabCorp are the only two companies licensed by Correlogic to market OvaCheck. Under the terms of the agreement, Correlogic will receive signing, milestone, and per-test royalty or service fees, as well as development fees for additional refinements to the technology. Additional terms have not been disclosed.

Ag Chief Says New Mad Cow Cases Would Not Surprise Her

The USDA's total budget for this one-time testing program is $69.9 million, or $280 per animal tested, assuming 250,000 tests are performed.

The U.S. Agriculture Department has begun expanded national testing for mad cow disease with plans to test between 200,000 and 400,000 animals for the brain-wasting condition over the next 12 to 18 months. This level is 10 times more than the total of 20,543 animals that were tested last year.

The expanded testing program is in response to the nation's first mad cow case found at a Washington state dairy farm last December. With more testing, more infected animals are expected to be found. "There is certainly a likelihood we will find more [diseased] cows," Agriculture Secretary Ann Veneman said during a conference on food safety sponsored by the Consumers Federation of America.

Rapid testing for bovine spongiform encephalopathy (BSE), the formal name for mad cow disease, will be performed at 12 state-operated labs around the country, including Washington State University's Animal Disease Laboratory (Pullman), Colorado State University Veterinary Diagnostic Laboratory (Fort Collins), and Kissimee Diagnostic Laboratory, Florida Department of Agriculture and Consumer Services (Kissimee).

The USDA has licensed rapid BSE tests from five manufacturers: Bio-Rad, Idexx Laboratories, Roche Diagnostics, Abbott Diagnostics, and Pierce Biotechnology (Rockford, IL). These manufacturers are expected to sell their tests to the university labs at approximately $10 to $12 per test.

Each university lab is responsible for choosing its own vendors. Turnaround time for the rapid tests is 24 hours to 72 hours. Specimens with positive or indeterminate test results will be sent to the USDA's National Veterinary Services Laboratory in Ames, Iowa, for confirmatory testing that could take four to eight days.

The new program begins at a time when the USDA's credibility has been undermined by two recent incidents: A Texas animal that showed symptoms similar to mad cow disease was not tested; and it was revealed that the Agriculture Department secretly allowed imports of Canadian hamburger and beef despite a ban imposed after that country's first mad-cow case last year.

In April, the USDA denied Creekstone Farms Premium Beef (Arkansas City, KS) the right to test every slaughtered beef animal for BSE, which would have opened up a Japanese market for the privately owned producer and packer. The cost of testing more than 300,000 head—estimated at $6 million—would have been absorbed by Creekstone Farms' customers. Some meatpacking companies have sought to do their own testing to satisfy concerns of big beef importing nations like Japan, which banned all U.S. beef after the first mad cow case was discovered.

Bio-Rad To Acquire ML Geneworks For $47 Million

Bio-Rad Laboratories has agreed to acquire ML GeneWorks (Waltham, MA), a private biotechnology company with 300 employees, for $47 million in cash and the assumption of certain liabilities. Bio-Rad said ML Geneworks is the parent company of ML Research, which develops thermal cycling instruments and reagents used to amplify DNA.

Veridex And Immunicon Plan Fall Launch of CellSearch System

Veridex LLC (Raritan, NJ), a Johnson & Johnson company, has announced plans for a fall 2004 launch of the CellSearch System, which is used on breast cancer patients to help determine the effectiveness of their cancer treatment. The CellSearch system was developed in collaboration with Immunicon Inc. (Huntington Valley, PA), which raised $48 million from an IPO in April (*see DTTR, June 2004, p. 11*).

The CellSearch system helps physicians find circulating tumor cells (CTC) in a blood sample. The CTC are then counted by a pathologist with the aid of Veridex's CellSpotter analyzer. The more CTC in the blood sample, the less effective the cancer treatment is.

The CellSearch system was cleared by the FDA in January under a de novo classification. Reagent pricing information and lab reimbursement information for CellSearch is not yet available.

Ventana Keeps Inform HPV System On The Market

On March 18, the FDA sent a letter to Ventana Medical Systems (Tucson, AZ) telling the company that its Inform HPV system and related HPV probes will need premarket clearance from the agency. Ventana has been marketing the system, which is used as a reflex test to ASCUS Pap tests, as an analyte specific reagent (ASR). Ventana says that it met with officials from the FDA on April 7 and discussed the labeling and promotion of its HPV ASRs. Ventana says it has addressed the FDA's concerns and will continue to sell its HPV system and probes as ASRs.

Judge Halts Ventana's Sales of Benchmark and Discovery

In separate news, Judge Rya W. Zobel of the U.S. Federal Court in Boston has issued a permanent injunction against Ventana, halting the sale of its Benchmark and Discovery tissue-staining instruments, which allegedly violate patents held by CytoLogix Corp. (Boston).

Ventana had already taken the BenchMark system off the market following a Boston Federal District Court jury's decision in December 2003. The jury found Ventana liable for patent infringement, although the jury found that the infringement was not willful and that Ventana was not liable for misappropriation of trade secrets. CytoLogix's patents were found to cover the use of independent slide heating regulation of slide samples on a moving platform in Ventana's BenchMark and Discovery system.

CytoLogix says that damages owed by Ventana could be between $25 million and $30 million. Executives from Ventana were not available for comment at press time.

Privately held CytoLogix developed its slide-staining technology for its Artisan product line, which stain tissue for cancer diagnosis. In September 2002, CytoLogix sold its Artisan product line to DakoCytomation (*see DTTR, October 2002, p. 10*). DakoCytomation is not involved in the dispute between CytoLogix and Ventana.

IVD Stocks Up 2%; Immucor, Gen-Probe Up Big

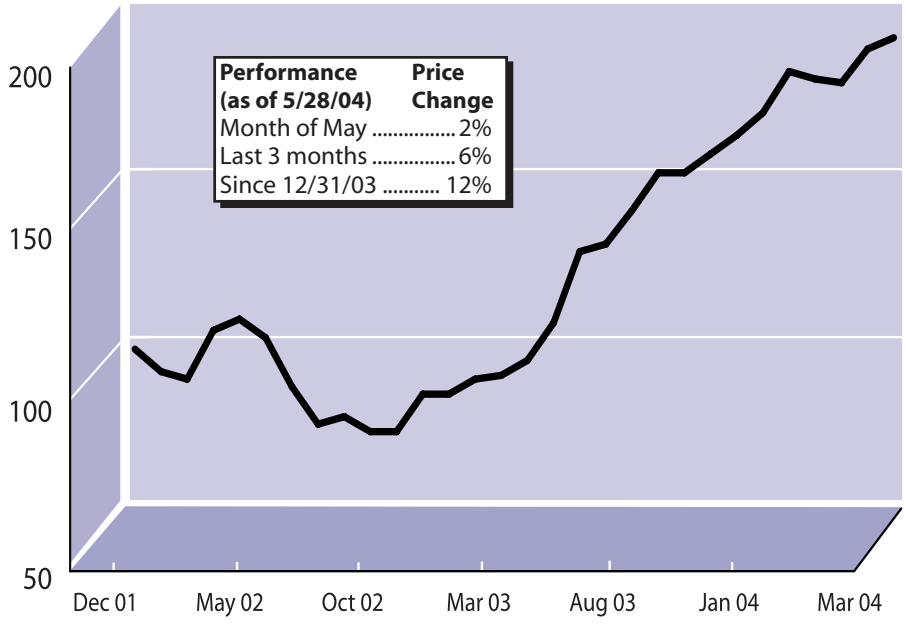
The 20 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 2% in the month of May, with 10 stocks up in price, two unchanged, and eight down. Year to date, the G-2 Index is up 12%, while the S&P 500 Index is up 1% and the Nasdaq is down 1%.

The best-performing IVD stock in May was **Immucor** (Norcross, GA), which rose 27% to $31.19 per share for a market cap of $610 million, or nearly six times the company's annual revenue of $110 million. Immucor was boosted by news that the FDA has cleared its Galileo blood-banking analyzer for marketing. A high throughput instrument, Galileo can process up to 224 different samples at once. Immucor already has more than 120 Galileo installations in Europe producing more than one million test results monthly.

Gen-Probe (San Diego) was up 26% to $41.94 per share for a market cap of $2.1 billion, or more than eight times the company's annual revenue of $250 million. The company recently reported net income for the first quarter of 2004 of $19.7 million ($0.39 per share), compared to net income of $8.7 million ($0.18 per share); revenue was up 66% to $76.5 million.

Quidel Corp. (San Diego) slipped 18% to $5.60 per share for a market cap of $175 million, or less than two times the company's annual revenue of about $100 million. **OraSure** (Bethlehem, PA) was down 12% to $7.39 per share for a market cap of $325 million, or approximately six times its annual revenue of $50 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.

% Price Change, 4 weeks ended 5/28/04

UP		
Abaxis	18.67	5%
Beckman Coulter	60.50	8%
Biosite	39.77	1%
Cytyc	21.90	2%
Digene	39.01	10%
Gen-Probe	41.94	26%
Immucor	31.19	27%
Inverness Medical	19.39	3%
Johnson & Johnson	55.71	3%
Ventana	51.65	5%
UNCHANGED		
Becton Dickinson	50.32	0%
Third Wave	4.85	0%
DOWN		
Abbott Labs	$41.21	-6%
Bio Rad	56.12	-4%
Cholestech	9.55	-2%
Dade Behring	44.65	-3%
Diagnostic Products	42.12	-1%
Meridian	10.07	-8%
OraSure	7.39	-12%
Quidel	5.60	-18%

G-2 Insider

The long-anticipated "pharmacogenomics revolution" has to date been more evolutionary than revolutionary. There are only a handful of gene-based tests on the market today that help physicians make more personalized drug prescriptions. The most common include DakoCytomation's Hercept test for determining if a breast cancer patient will respond favorably toward Herceptin, and various genotyping tests for determining the best mix of drug treatments for hepatitis and HIV patients.

Although the human genome was decoded more than three years ago, the introduction of new pharmacogenomic tests has been surprisingly weak. Pharmaceutical companies don't seem to be taking full advantage of the potential for personalized medicine, probably because it limits the market potential for new and existing drugs.

Consider the experimental cancer drug Tarceva, developed by Genentech and OSI Pharmaceuticals, which was recently shown to extend survival of late-stage lung cancer patients. The news was announced at the annual meeting for the American Society of Clinical Oncology in New Orleans on April 26 and set off speculation that the drug may reach the market by year's end and have sales of more than $1 billion a year.

But later that week, a study published in the *New England Journal of Medicine* identified the genetic mutation associated with a good response to AstraZeneca's drug Iressa, which attacks lung cancer in a way similar to Tarceva. If large-scale studies show that the only people who benefit from Iressa or Tarceva are those with the mutation, that might limit their market to as little as 10% to 15% percent of lung-cancer patients. That would knock a potential $1 billion market down to $100-$150 million.

It remains to be seen if AstraZeneca, Genentech, or OSI Pharmaceuticals will pursue a test for this mutation in conjunction with the use of their drugs. But it seems obvious where their economic interests are positioned.

Company References

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