# Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979


## Will Correlogic's "Breakthrough" Cancer Testing Technology Gain Market Acceptance?

A novel protein pattern blood testing technique developed by Correlogic Systems (Bethesda, MD) for the early detection of various cancers has shown tremendous promise in research studies. For example, in a study published early last year in the British medical journal *The Lancet*, the Correlogic method was shown to have an overall predictive value of 94% for detecting ovarian cancer versus 35% for the traditional test, CA-125.

"This is something we've been waiting for. A simple cancer blood test would revolutionize the treatment for cancer. [The Correlogic test] appears to be the biggest breakthrough in cancer diagnostics ever," John Kovach, M.D., director of the Long Island Cancer Center at Stony Brook University (Stony Brook, NY), told the audience at the Wachovia Securities Cancer Diagnostics Conference in New York City, April 10. Kovach is an internationally known expert in cancer treatment and research who has no financial relationship with Correlogic.

Of course, successful research studies do not guarantee acceptance in the marketplace by laboratories and physicians. The real test for Correlogic's new technology is set to begin within the next few months when homebrew versions of its ovarian cancer test hit the market. For more on Correlogic and the outlook for its protein pattern testing technology, see *Inside The Diagnostics Industry*, pp. 5-7.

### Correlogic At A Glance

***Technology:*** Proteome Quest, protein pattern recognition software for detecting cancer

***Founded:*** May 2000

***Founders:*** Peter Levine, chief executive; Ben Hitt, Ph.D., chief science/technology officer

***Headquarters:*** Bethesda, MD

***Initial Funding:*** $1M from three angel investors

***Laboratory Partners*:** Quest Diagnostics and LabCorp

*For ovarian cancer test only

## Inverness Gets FDA Okay For Digital Pregnancy Test

Inverness Medical Innovations (Waltham, MA) has received clearance from the FDA to sell the first home pregnancy test with a digital read out. Mache Seibel, M.D., medical director for Inverness, tells *DTTR* that the company's Clearblue Easy Digital represents the first major innovation in home pregnancy tests since Unipath introduced the first one-step test in 1988. He says that Inverness plans to begin shipping the new test in July and ➥ *p. 2*

▲ **Inverness Gets FDA Okay,** *from page 1*

expects it to reach store shelves by September. Retailers that have already agreed to sell Clearblue Easy Digital include Walgreen's, CVS, and Wal-Mart.

The digital display on Inverness' Clearblue Easy Digital test spells out "pregnant" or "not pregnant," eliminating the need to interpret colored lines for a result on traditional home pregnancy tests, according to Doug Guarino, spokesman for Inverness. The new Inverness test also displays an "error" message if the test has been performed improperly. The test is expected to have a retail price of approximately $15 each versus average prices of roughly $8 to $12 for traditional pregnancy tests.

The intellectual property used to develop the digital test was acquired by Inverness through its $150 million purchase of Unipath in December 2001. The test will be manufactured at Inverness' manufacturing plant in Bedford, England. Guarino adds that Inverness is planning to introduce a digital test for ovulation in the first half of 2004.

Separately, Inverness has announced settlement of its pregnancy test patent litigation with Pfizer Inc. (New York City). In connection with the settlement, Inverness will manufacture Pfizer's E.P.T. pregnancy tests for five years, beginning in June, 2004. Pfizer will make certain payments to Inverness before the start of the supply arrangement.

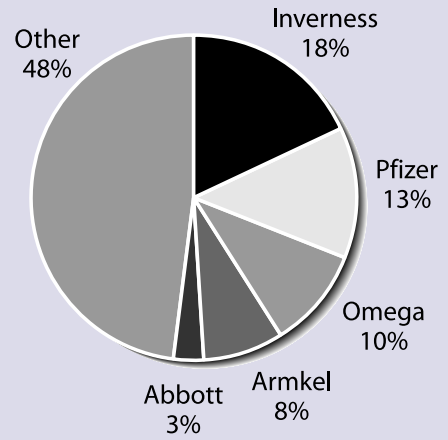
Inverness had sued Pfizer claiming that its E.P.T. tests infringed on Inverness's rapid assay lateral flow patents. in March, a New Jersey district judge ruled that Pfizer Inc. (New York City) was in "likely" violation of the patents and denied Pfizer's request for a stay of this injunction pending appeal, but required Inverness to post a $35 million bond before the injunction becomes effective. Thus Inverness could have posted the bond and immediately cut off E.P.T. shipments to retailers.

Under the settlement, the parties have agreed to permanent injunctive relief and dismissal of certain claims and counterclaims. The settlement does not provide for any damage award.

Inverness said it expects the deal to add approximately $3 million to $3.8 million to its net earnings in 2004 and between $4.5 million and $5.3 million in 2005.

*DTTR* estimates that the worldwide market for pregnancy tests represents approximately $500 million in annual sales at the manufacturer's level (ovulation prediction tests are another $100 million). Inverness's Clearblue and private-label pregnancy tests currently generate an estimated $90 million in annual revenue for an 18% worldwide market share. Pfizer's E.P.T. test generates some $65 million in annual sales for a 13% market share, followed by Omega Pharmaceuticals with an estimated $50 million, or 10% share, Armkel LLC with $40 million, or an 8% share, and Abbott, with $15 million, or a 3% market share.

**Worldwide Market For Pregnancy Tests: $500M**




Source: *DTTR* estimates

## Abbott To Distribute Artus SARS Test

Abbott Laboratories (Abbott Park, IL) has signed a worldwide marketing and distribution agreement with Artus GmbH (Hamburg, Germany) for the first commercial test to detect a form of the coronavirus suspected of causing severe acute respiratory syndrome (SARS). Artus is a privately held company formed in 1998 as a spin-off from the Bernhard-Nocht-Institute for Tropical Medicine (Hamburg).

The test, which uses polymerase chain reaction (PCR—licensed from Roche), was introduced by Artus in April to countries in Asia and Europe. The Abbott agreement will "supplement" this existing distribution network, according to Artus. Under the agreement, Artus will manufacture the test and Abbott will distribute it in the U.S., Canada, Germany, the United Kingdom, and Austria through its molecular diagnostics alliance with Celera Diagnostics (Alameda, CA). Abbott will also help Artus submit the test to the FDA.

An Abbott spokesman says the price per test has not been determined yet. "Our focus right now is on the public health need—to ensure that this test is made widely available to the clinical laboratories, health care professionals, and patients who need it," he adds.

As noted in the last issue of *DTTR* (*page 3*), Roche Diagnostics is planning to have an internally developed SARS test ready for the research market within weeks at a price of $10 to $15 per test.

## SARS Threat Raises Demand For i-Stat Analyzers In China

i-Stat Corp. (East Windsor, NJ) says it's in the process of filling an emergency order of 395 i-Stat analyzers to China to monitor critical pulmonary function changes (*i.e.*, acute respiratory failure) in ICU patients. Heal Force Development (Hong Kong and Shanghai) is the company's distributor in China.

Bill Moffitt, chief executive at i-Stat, says the increased demand has been spurred by the onset of SARS in China, where hospitals have been using i-Stat analyzers to monitor patients who may be progressing toward acute respiratory failure. "SARS patients may experience rapid deterioration in lung function and often require mechanical ventilation. Frequent and rapid blood gas analysis is critical in monitoring such patients that are in acute respiratory distress," explains Greg Shipp, M.D., vice president of medical affairs at i-Stat.

i-Stat entered the China market in 1997 and had approximately 1,000 analyzers placed at year-end 2002. Moffitt says that i-Stat's revenue from China is growing by more than 50% per year and is approaching 5% of the company's overall annual revenue of $60 million.

For the three months ended March 31, i-Stat reported a net loss of $1.1 million vs. a net loss of $4.4 million in the same period a year earlier; revenue was $15.4 million vs. $14.4 million. i-Stat sold approximately 3.5 million cartridges in the first quarter of 2003, up 29% from shipments in the first quarter of 2002 of approximately 2.7 million units and up 6% from shipments of 3.3 million units in the fourth quarter of 2002.

# Olympus Nears Launch Of Remote Monitoring Services

Olympus America (Melville, NY), a unit of Olympus Optical Co. (Tokyo, Japan), plans to begin beta-testing Internet-based remote monitoring services for its analyzers within weeks and will launch a full rollout of the service by the end of the year, according to Stephen Wasserman, group vice president for diagnostic systems at Olympus America.

To provide the service, Olympus is using a device relationship management (DRM) software system made by Axeda Systems Inc. Other IVD companies utilizing Axeda's DRM software include Beckman Coulter and Abbott Laboratories.

The DRM software will automatically and continuously monitor the vital signs for Olympus instruments, including its AU400E, AU640E, AU2700, and AU5400 analyzers. Real-time alerts will be sent to Olympus service offices when an instrument is found to be operating outside preset performance standards. Wasserman says Olympus is aiming to have the service added to all existing customers with Internet access within the next year; it will also become a standard feature on newly placed analyzers.

Olympus instruments currently require an average of about three on-site service visits per year to fix instrument breakdowns, according to Wasserman. He estimates that the new remote monitoring service will eliminate approximately one-third of all emergency service visits. The new service will also allow Olympus to remotely monitor customer inventories and reportable test volume data, he adds.

# Roche Extends Immunoassay Contract With AmeriNet

*Roche's immunoassay business currently has approximately 9,000 systems placed worldwide with annual sales of $500 million, growing by better than 20% per year*

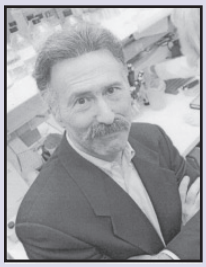
Roche Diagnostics Corp. (Indianapolis, IN) has extended a contract to provide immunoassay instruments and reagents to members of AmeriNet (St. Louis, MO), a group purchasing organization with more than 1,800 hospital members. Covered under the new contract are Roche's Elecsys instruments and assays for proBNP, troponin T, PSA, D-Dimer, and the hepatitis portfolio, as well as therapeutic drug monitoring and drugs-of-abuse assays.

The three-year contract became effective on June 1 and has a total value of close to $500 million, according to Roche. Mark Moyer, spokesman for AmeriNet, notes that AmeriNet will maintain existing immunoassay contracts with Beckman Coulter and Ortho-Clinical Diagnostics.

Meanwhile, Roche and Igen International (Gaithersburg, MD) continue their negotiations to try to reach an out-of-court settlement for a license dispute over Igen's "Origen" technology for immunoassays, which is the backbone of Roche's Elecsys system.

On February 24, in Richmond, Virginia, the U.S. Court of Appeals for the Fourth Circuit heard oral arguments in Roche's appeal of a Maryland district court judge's decision to let a jury award of $505 million to Igen stand. Each company has since submitted supplemental material to the Fourth Circuit, and a final decision is expected within weeks unless the two companies can reach a settlement first.

# Correlogic's Ovarian Cancer Test Nears Market Introduction



*Peter Levine*

Market introduction for Correlogic's novel ovarian cancer test, Proteome Pattern Blood Test, is set to begin within months, according to chief executive Peter Levine. In a nutshell, the Correlogic test uses a proprietary software program to analyze blood protein patterns generated by a mass spectrometer.

The company signed licensing agreements with Quest Diagnostics (Teterboro, NJ) and LabCorp (Burlington, NC) in November 2002 for the commercialization of the test. Quest and LabCorp each tell *DTTR* that they are in the process of putting testing procedures in place for homebrew versions of the test at their esoteric testing labs. Quest plans to run the test at its Nichols Institute (San Juan Capistrano, CA) and LabCorp will perform testing at its Center for Molecular Biology and Pathology (Research Triangle Park, NC). The licensing agreements also cover any potential FDA-approved versions of the test as well.

Richard Bender, M.D., medical director for hematology/oncology at Quest's Nichols Institute, tells *DTTR* that the Correlogic test will initially be used as a compliment to the CA-125 test (formally known as cancer antigen 125).

CA-125 is used to monitor therapy during treatment for ovarian cancer and to monitor patients after treatment. The test is also sometimes used to follow high-risk women who have a family history of ovarian cancer but who do not yet have the disease. Medicare currently reimburses labs a maximum of $29.07 for CA-125 under CPT Code 86304.

Levine says that Quest and LabCorp perform a combined total of more than 300,000 CA-125 tests per year. He says that pricing for Correlogic's test has not yet been finalized, but he anticipates that it will be priced in a range similar to that of genotyping tests, which generally sell for $200 to $400 each.

The high cost of the test is largely a function of the expensive equipment needed to perform it, says Levine. A complete system costs roughly $600,000 to $1 million and includes 1) an automated sample handler; 2) a protein separation and/or ionization system; 3) a mass spectrometer; and 4) protein pattern recognition software developed by Correlogic.

Levine notes that Quest and LabCorp are currently the only two companies licensed by Correlogic and the terms cover only its ovarian cancer test. He says that Correlogic will seek licensing deals for other tests it is developing with its protein pattern blood testing technology, including tests for prostate and breast cancer.

Typically, Correlogic's licensing deals with laboratories include a four- to five-year term of exclusivity for a specific test. The laboratory pays Correlogic an 8% royalty on test sales and the royalty drops to 5% after the exclusivity period ends, according to Levine.

Ben Hitt, Ph.D., chief science and technology officer at Correlogic, is the inventor of the core algorithms that power Proteome Quest, the software that is used to

create computational "models" of disease states. The "hidden patterns" concept and process for identifying blood protein patterns associated with specific diseases was invented by Hitt, Levine, and scientists at the FDA and the National Cancer Institute. Levine says that Correlogic will pay undisclosed royalties to the National Institutes of Health for its exclusive license to the hidden-patterns technology once commercial test sales begin.

**Challenges To Market Adoption Of Correlogic's Ovarian Cancer Test**

*DTTR* observes that the Correlogic method may encounter market resistance because it analyzes protein patterns rather than a specific biomarker as most lab tests do. In addition, the estimated 10-fold increase in the expected cost of the Correlogic ovarian cancer test versus CA-125 could be hard for third-party payers to accept.

Levine contends that potential objections from physicians, patients, third-party payers regarding both price and the novel use of protein patterns will be overcome over time, given the ability of the Correlogic's test to detect ovarian cancer at its early stage.

According to the American Cancer Society (ACS), the five-year survival rate for ovarian cancer is 95% if diagnosed and treated when the disease is localized. But the survival rate drops to 31% once it has reached an advanced stage and metastasized. An estimated 25,400 women in the U.S. will be diagnosed with ovarian cancer this year and 14,300 will die from the disease, according to estimates from ACS.

Levine notes that the CA-125 test usually only discovers ovarian cancer after it has reached an advanced stage and survival rates are low. In early stages, when treatment is most effective and the survival rate is high, the CA-125 test is able to detect abnormal antigen levels no more than 60% of the time.

In contrast, a paper published by *The Lancet* on Feb. 16, 2002, showed that in an analysis of 116 blinded blood samples—50 from patients with cancer and 66 with non-malignant disease—the 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.

**Top Five Sites of Cancer Deaths For Women—2003 Estimates**

| | *New Cases* | *Deaths* |
|---|---|---|
| Lung | 80,100 | 68,800 |
| Breast | 211,300 | 39,800 |
| Colon | 74,700 | 28,800 |
| Pancreas | 15,800 | 15,300 |
| Ovary | 25,400 | 14,300 |

Source: American Cancer Society

The *Lancet* study was conducted by researchers from the FDA/National Cancer Institute (NCI) Clinical Proteomics Program, Northwestern University Medical School, M.D. Anderson Cancer Center, and Correlogic.

What's more, on April 9, 2003, NCI announced that Correlogic, NCI, and FDA scientists had achieved further improved results. The team was able to detect ovarian cancer with 100% accuracy—again identifying all of the cases of ovarian cancer—but without any false positives.

Levine says that NCI-funded clinical trials for the test will begin soon. He hopes to submit a 510k application to the FDA within one year. Initially, Correlogic will seek to have the test approved for monitoring women for recurrence of ovarian cancer. This is the same designation of use for CA-125, although CA-125 is also used extensively by physicians "off-label" for testing women at high risk for ovarian cancer. Ultimately, Levine believes the Correlogic test could be used as a screening test for ovarian cancer.

In addition, Levine notes that Correlogic's protein pattern testing technology has shown promise in detecting prostate cancer. In a study published on Oct. 16, 2002 in the *Journal of the National Cancer Institute*, researchers found that the technology correctly identified 95% of prostate cancer cases (36 of 38) from a set of 266 blinded patient blood samples.

Most significantly, researchers were able to rule out prostate cancer for 71% of men with intermediate PSA scores (4-10), which would have allowed them to avoid an unnecessary biopsy procedure. Currently, most men with PSA scores between 4 and 10 are recommended for a biopsy, even though 75% to 80% of them do not have prostate cancer. The study was conducted by researchers from the FDA/NCI, the University of North Carolina Lineberger Comprehensive Cancer Center, and Correlogic.

Levine says that Quest and LabCorp each have an option to bring the protein pattern prostate cancer test to market in homebrew form as well as any FDA-approved versions of it. However, he notes that Correlogic's efforts have been focused on moving toward a clinical trial for the test and beginning the exploration of detecting aggressive versus indolent forms of the cancer.

**Operating On A Shoestring Budget**

Of course, innovative technology and promising clinical research do not guarantee market adoption. The IVD industry is littered with start-up companies with "breakthrough technologies" that never materialized into meaningful sales in the marketplace. Remember Careside, DNA Sciences, Avocet Medical, etc.? Each of these companies ran through tens of millions of dollars to bring their products to an uncertain market.

Meanwhile, *DTTR* estimates that Correlogic will bring its ovarian cancer test to market by year's end for less than $5 million. The company is majority owned by Levine and Hitt, and three other investors have provided $1.1 million to obtain a minority stake. Aside from some undisclosed milestone payments from Quest and LabCorp, Correlogic has received no other funding since its inception in May 2000.

"We run a tight ship. We've been able to make great strides on limited resources," notes Levine. The company employs only nine FTEs plus three contracted consultants at a small office/lab in Bethesda, MD. The key to operating on a shoestring budget has been Correlogic's ability to leverage off its relationships with FDA/NCI, university hospitals, and Quest and LabCorp. Such frugality should help Correlogic endure the likely long road to achieving market acceptance for its tests.

# PDI To Form Physician-Detailing Squad For Digene HPV Test

Digene Corp. (Gaithersburg, MD) has hired PDI, Inc. (aka, Professional Detailing Inc.—Saddle River, NJ) to establish a physician-detailing sales organization dedicated solely to promoting Digene's HPV Test in the U.S. The contract represents yet another example of the way that IVD companies are seeking to mimic the sales and marketing practices used by pharmaceutical companies (*see DTTR, October 2002, p. 12*).

Under the agreement, PDI is expected to organize approximately 34 professionals to be in place by August 2003. PDI will manage the sales professionals through August 2004, and Digene has an option to extend the agreement for another year.

In March, Digene received FDA approval for the use of its Hybrid Capture 2 High-Risk HPV DNA Test with a Pap test for cervical cancer screening in women age 30 and older. Digene is marketing the test under the trade name: "DNAwithPap." Digene believes adjunctive screening to assess the presence or absence of high-risk HPV types represents a $400 million market potential in the U.S.

PDI, which employs over 3,000 sales and marketing people, is primarly focused on providing product specific support to drug companies like Pfizer and Allergan. Total revenue for PDI is nearly $300 million per year.

In an effort to diversify its revenue stream, PDI formed a new division called PDI Medical Devices and Diagnostics in 2001. The division has more than 100 FTEs and has already won marketing contracts with Becton Dickinson, Roche, certain divisions of Johnson & Johnson, and PharmaNetics. Services provided by PDI include sales support, recruiting and management along with medical education programs for target audiences.

# FDA Clears Bio-Rad's Rapid Test For Aspergillus Infection

The FDA has cleared for marketing the first rapid laboratory test for aspergillus galactomannan, an invasive fungal infection that can occur in leukemia patients, organ and bone-marrow transplant patients, and patients whose immune systems are compromised by illness or chemotherapy. The test will allow doctors to diagnose the infection quicker and begin treatment with anti-fungal drugs sooner than in the past.

The test, Platelia Aspergillus EIA, manufactured by Bio-Rad Laboratories (Redmond, WA), detects the fungus antigen in blood. Results are available in about three hours. By comparison, the standard culture method of testing for aspergillus takes a minimum of four weeks before results are available.

Although the number of invasive aspergillus cases in the United States is estimated to be only a few thousand per year, the disease has a mortality rate of more than 50%.

The FDA said it cleared the product after studies at three cancer centers showed the test could accurately identify the presence or absence of the aspergillus antigen. The centers tested 1,890 blood samples collected from 170 patients. Thirty-one pa-

tients had proven or probable invasive aspergillosis. The test correctly identified 25 of the 31 people who had aspergillus antigen.

When 148 patients without signs or symptoms of invasive aspergillosis were tested, the test correctly identified 132 of the 148 as not having the antigen.

## Italian Regulator Slaps Blood Glucose Test Makers With $35M Fine

Italy's antitrust authority, the Autorita Garante della Concorrenza e del Mercato (Rome), has fined five IVD companies a total of 30.5 million euros (US $35 million) for alleged price fixing on blood glucose tests.

The five firms are the Italian units of Roche, fined nine million euros; Ortho-Clinical Diagnostics, 7.5 million euros; Bayer, six million euros; Abbott, two million euros; and Italy's Menarini SpA, six million euros.

The watchdog said the five companies orchestrated marketing strategies in order to block competition for blood glucose tests and offered identical prices to pharmacies and to the national health service.

A spokesman from Roche says its Italian unit will appeal the decision. He claims the similarity of the test makers' prices is the result of a health care reimbursement system that has prompted many Italian regions to set a ceiling for the price of diabetes tests. In those regions where they put a ceiling on prices, it is very natural that price levels of the different providers of these glucose meters are very similar, according to the spokesman.

## IVD Stocks Trading At Average 29x Free Cash Flow

Since the start of the year IVD stocks have jumped an unweighted average of 38%, according to the G-2 Diagnostic Stock Index (see p. 11). As a result, the enterprise value of IVD companies (including two lab companies—Quest Diagnostics and LabCorp) is now equal to an average multiple of 29.1 times free cash flow for the latest 12-month period ended March 31.

The most richly valued IVD company is **Biosite** (San Diego, CA), which trades at an enterprise value/free-cash-flow multiple of 96.9 times. Investors have poured money into Biosite shares based on the tremendous growth in its Triage BNP Test for diagnosis of congestive heart failure. In the first-quarter, for example, Biosite reported BNP test sales of $22.2 million, up more than 400% from $4.1 million last year. Biosite currently has an estimated 95% share of the BNP market with its only competition being Roche which launched its proBNP test in January. But, Bayer is expected to get FDA approval for its BNP test by year's end, and Abbott should have a test on the market early next year.

Other richly valued IVD companies include **Immucor** (Norcross, GA), which sells blood-banking instruments and reagents and trades at a multiple of 44.7 times, and **Ventana Medical Systems** (Tucson, AZ), which is focused on the pathology market and trades at a multiple of 44.3 times.

**Cytyc Corp.** (Boxborough, MA) has the lowest valuation—trading at 11.6 times its free-cash-flow basis. Investors have turned away from Cytyc due to concerns that Digene's HPV test might gain share in the cervical cancer screening market over the long term.

### IVD Company Valuations

| Company | Enterprise Value[1] | Cash Flow From Oper. | Capital Expenditures | Free Cash Flow[2] | Enterp. Value/ Free Cash Flow |
|---|---|---|---|---|---|
| Abbott Labs | $76,074.2 | $3,962.3 | $1,256.4 | $2,706.0 | 28.1 |
| Beckman Coulter | 3,342.8 | 339.8 | 137.1 | 202.7 | 16.5 |
| Becton Dickinson | 11,587.3 | 836.7 | 252.8 | 583.9 | 19.8 |
| Bio-Rad | 1,701.6 | 108.4 | 44.8 | 63.7 | 26.7 |
| Biosite | 645.5 | 22.8 | 16.1 | 6.7 | 96.9 |
| Cytyc | 1,070.0 | 100.14 | 7.7 | 92.4 | 11.6 |
| Dade Behring | 1,668.4 | 153.2 | 105.8 | 47.4 | 35.2 |
| Diagnostic Products | 1,135.6 | 76.5 | 35.1 | 41.4 | 27.4 |
| Gen-Probe | 844.8 | 46.5 | 17.2 | 29.3 | 28.9 |
| Immucor | 299.3 | 11.3 | 4.6 | 6.7 | 44.7 |
| Johnson & Johnson | 155,485.9 | 8,047.0 | 2,157.0 | 5,890.0 | 26.4 |
| LabCorp | 5,109.0 | 467.7 | 72.1 | 395.6 | 12.9 |
| Meridian | 154.3 | 14.5 | 2.6 | 11.9 | 13.0 |
| Quest Diagnostics | 7,506.2 | 601.8 | 151.4 | 450.4 | 16.7 |
| Quidel | 159.1 | 13.3 | 3.8 | 9.5 | 16.7 |
| Ventana | 422.8 | 15.1 | 5.6 | 9.5 | 44.3 |
| Unweighted Average | | | | | 29.1 |

[1]Enterprise value=market capitalization as of June 6 plus net debt

[2]Free cash flow=cash flow from operations minus capital expenditures for 12 months ended March 31, 2003

Source: *DTTR* from company financial statements

## Abbott, Promega To Collaborate On RNA Sample Prep

Abbott Laboratories (Abbott Park, IL) and Promega Corp. (Madison, WI) have agreed to co-develop a system to purify and extract viral RNA from patient samples using Abbott's magnetic particle technology. The system will be manufactured by Promega and distributed by Abbott.

The RNA extraction system will be used in Abbott's m1000, an automated sample preparation system for molecular diagnostics that will be introduced later this year, Abbott said. The system will allow laboratories to fully automate viral load assays, saving time and allowing them to increase throughput, according to Bill Linton, president of Promega.

Promega, with about $130 million in annual sales, provides about 1,200 products for genomics, proteomics and cellular analysis, molecular diagnostics, and human identification.

# IVD Stocks Up 7% In Latest 5 Weeks; TheraSense Jumps 36%

***Roche** non-voting equity shares, which trade on the Zurich stock exchange, are up 5% to 101 Swiss francs so far this year. Shares of **Bayer**, which trade on the German stock exchanges, are down 8% at 18.75 euros*

The 21 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 7% in the five weeks ended June 6, 2003, with 14 stocks up in price and seven down. Year to date, the G-2 Index is up 38%, while the S&P 500 Index is up 12% and the Nasdaq is up 22%.

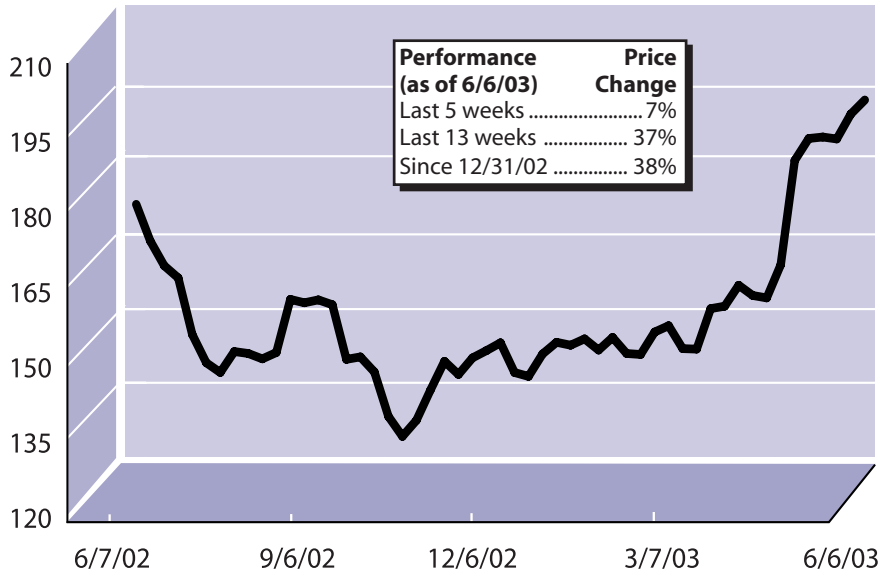
Shares of **TheraSense** (Alameda, CA) were up 36% to $11.48 per share for a market cap of $468 million. The company recently announced plans to provide a progress update on its continuous glucose monitor, currently under development, at the upcoming American Diabetes Association's (ADA) 63rd Scientific Sessions Conference in New Orleans, Louisiana, June 14-16. Two posters will be displayed: "The TheraSense, Inc. Continuous Glucose Monitor: Preliminary Clinical Results from a Subcutaneous Sensor with a Wireless Connection to a Hand-Held Display / Alarm," and "What is the Relationship between Venous and Subcutaneous Glucose Concentrations? Results from the TheraSense Continuous Glucose Monitor."

**Digene** (Gaithersburg, MD) was up 32% to $26.35 per share for a market cap of $477 million. The company recently announced a net loss of $619,000 for the three months ended March 31, 2003, as compared with a net loss of $3.3 million in the same period last year; revenue was up 19% to $17 million.

**Bio-Rad Laboratories** (Hercules, CA) was up 27% to $62.05 per share for a market cap of $1.6 billion. Bio-Rad shares have jumped on the chance that the company will benefit from increased testing for "mad cow" disease after a case was confirmed in Canada.

Meanwhile, shares of **Cytyc Corp.** (Boxborough, MA) fell 23% to $10.78 and **Biosite** (San Diego, CA) was down 12% to $43.86 per share.

## 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, 5 weeks ended 6/6/03**

| UP | Price | % Chg |
|---|---|---|
| Abbott Labs | $45.21 | 7% |
| Beckman Coulter | 42.03 | 5% |
| Becton Dickinson | 40.19 | 13% |
| Bio-Rad | 62.05 | 27% |
| Dade Behring | 23.40 | 2% |
| Diametrics | 1.30 | 48% |
| Digene | 26.35 | 32% |
| Gen-Probe | 39.97 | 21% |
| Inverness Medical | 18.48 | 5% |
| i-STAT | 7.70 | 7% |
| Meridian | 9.08 | 4% |
| Quidel | 5.95 | 1% |
| TheraSense | 11.48 | 36% |
| Ventana | 26.50 | 13% |
| **DOWN** | | |
| Biosite | 43.86 | -12% |
| Cholestech | 10.78 | -10% |
| Cytyc | 10.78 | -23% |
| Diagnostic Products | 38.90 | -3% |
| Igen | 35.23 | -9% |
| Immucor | 20.31 | -4% |
| Johnson & Johnson | 52.75 | -7% |

# G-2 Insider

**Quest and LabCorp preparing for battle of the colorectal cancer tests.** Quest Diagnostics (Teterboro, NJ) has signed an agreement with Enterix (Falmouth, ME) to offer InSure, Enterix's proprietary, FDA-cleared immunoassay test for colorectal cancer (*see DTTR, June 2003, p. 1*). Terms of the agreement were not disclosed. But the agreement will pit the Quest/Enterix team against the PreGen-Plus test from the rival LabCorp/Exact Sciences team.

The Centers for Medicare and Medicaid Services are currently in the process of formulating coverage and reimbursement decisions for use of InSure as a screening test, and a final decision is likely to be made within weeks. Meanwhile, LabCorp is planning to soon introduce a "homebrew" version of the DNA-based PreGen-Plus test.

The stakes are high, as an estimated 10 to 13 million of the traditional fecal occult blood tests for colorectal cancer are currently performed in the U.S. each year, and there is general agreement in the lab industry that this test needs to be improved upon.

Separately, Enterix has announced new clinical study data—*Screening for Colorectal Cancer: Direct Comparison of a Brush-Sampling Fecal Immunochemical Test for Hemoglobin with Hemoccult*—that shows that InSure was 85% sensitive for the detection of colorectal cancer in a broad range of patients relative to a figure for those same patients with Hemoccult II SENSA of only 39%. The data was released at the Digestive Disease Week conference held in Orlando, FL, May 17-22.

### Company References

Abbott Labs
847-937-6100

AmeriNet 800-388-2638

Bio-Rad 510-724-7000

Biosite 858-455-4808

Correlogic 301-214-4030

Digene 301-944-7000

Enterix 800-531-3681

EXACT Sciences
978-897-2800

Inverness 781-647-3900

i-Stat 609-443-9300

LabCorp 336-584-5171

Olympus America
631-844-5690

PDI 201-258-8450

Quest Diagnostics
201-393-5000

Roche Diagnostics
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TheraSense 888-522-5226







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