Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Established 1979

Digene HPV Test Cleared For Screening Use

Digene Corp. (Gaithersburg, MD) has obtained approval from the U.S. Food & Drug Administration for expanded use of its test for human papillomavirus (HPV). The new indication allows the test to be used for cervical cancer screening in conjunction with a Pap test for any woman age 30 and older.

Digene's test—HC2 High-Risk HPV DNA Test—had initially been cleared by the FDA in March 2000 as a follow-up test for women with abnormal Pap test results. The test uses DNA probes to identify 13 of the high-risk types of HPV associated with the development of cervical cancer.

On an April 1 conference call with analysts, Evan Jones, chairman and chief executive of Digene, noted that the FDA decision expands the potential U.S. market for Digene from 3 million follow-up tests per year to approximately 30 million to 35 million screening tests. ➡ *p. 10*

SARS Discoveries Pave Way For Rapid Diagnostic Test

Development of a rapid test for severe acute respiratory syndrome (SARS) appears imminent now that scientists in Canada and the U.S. have sequenced the genetic code for the disease and the World Health Organization has identified the virus that causes it.

Prior to these discoveries, development of a fast, reliable test for SARS has proved to be problematic. The WHO has been collaborating with a network of 11 laboratories on three different tests, but two of them—an ELISA assay and an immunofluorescence assay—don't work until relatively late in the course of the illness (10-20 days). A third test that uses PCR (polymerase chain reaction) technology has been found to produce too many false-negatives.

Currently, doctors worldwide diagnose SARS patients by a combination of unusual symptoms, including high fever, difficulty breathing, a dry cough, and contact with someone suspected of having SARS. As of April 15, the disease has sickened 3,235 people worldwide and killed 154. In the U.S. there are 193 suspected cases but no deaths to date. About 4% of all people who contract SARS, a severe form of pneumonia, die from it.

Despite Record Fines, Stock Woes, Abbott's CEO Scores Big

Abbott Labs' stock plunged 28% in 2002, wiping out some $24 billion in shareholder value. Meantime, CEO Miles White is on Fortune magazine's list of 12 "piggy offenders," a group who made multi-millions while their company returns lagged the S&P. The compensation committee chairman said White's comp "reflected [strong] 2001 Abbott performance"

Abbott Laboratories (Abbott Park, IL) awarded its chairman and chief executive, Miles White, total compensation of $72 million last year (up 57% from $46 million in 2001), according to the company's latest shareholder proxy statement. White's 2002 compensation included a salary of $1.5 million, a bonus of $1.25 million, restricted stock worth $11.5 million, "other" compensation of $140,937, and stock options with a potential value of $57.7 million (assuming 10% annual stock appreciation).

Last year's generous pay package was awarded to White despite the fact that the company's diagnostics manufacturing operations in Lake County, IL, were still found to be in non-conformance with the U.S. Food & Drug Administration's quality system rules after a follow-up inspection in late 2001/early 2002. As a result, Abbott recorded a $129 million write-off in 2002 for payments to the government and related charges. This came on top of the $100 million fine Abbott paid to the government after signing a consent decree with the FDA in November 1999 over diagnostics manufacturing quality concerns. Abbott could be subject to more penalties if the FDA concludes after another inspection that the diagnostics operations are still not in conformance.

Furthermore, Abbott reports that its diagnostics business continues to suffer as a result of the consent decree with the FDA, which limits sales of the company's immunoassay products in the U.S. In the three months ended March 31, 2003, Abbott's U.S. diagnostics sales fell 10% to $270 million. Worldwide diagnostics sales were up 6% in the first quarter to $723 million.

Meanwhile, in what looks like a David vs. Goliath struggle, an individual who owns 240 shares of Abbott Laboratories common stock has proposed that Abbott's top executives get no bonuses, pay raises, or stock options in any year in which Abbott is required to pay any fines to government agencies in excess of $15 million. The proposal is contained in Abbott's 2003 proxy statement and will be voted on by shareholders at the company's annual meeting on April 25.

It is highly unlikely that this proposal will gather a significant number of votes. Abbott's 13-member board—headed by White and including two other Abbott executives—has recommended that shareholders vote against it. In the 2003 proxy the board states: "Linking executive compensation to a single dimension such as settlement decisions is inappropriate. Abbott's total compensation program is competitive and performance-driven, aligning compensation with the achievement of annual and long-term goals and the company's values."

Abbott's Recent Government Fines

Year	Government Action	Payment to Government ($MM)
1999	Consent Decree with FDA	$100.0
2001	Dept. of Justice Settlement with TAP Pharmaceutical*	437.5
2002	Continued Payment from 1999 Consent Decree	129.0
Total		$666.5

*Abbott's TAP Pharmaceutical Products Inc., a joint venture with Takeda Chemical Industries, entered into an agreement with the U.S. government to settle matters relating to the marketing of TAP's prostate cancer drug, Lupron. In December 2001, TAP paid $875 million to settle this matter and Abbott's share was $437.5 million.

Source: *DTTR* from Abbott's 2003 proxy statement

Bayer, Matsushita Form Viterion TeleHealthcare

Pramod Gaur, Ph.D., president of Viterion

Bayer Diagnostics (Tarrytown, NY) and Matsushita Electric Industrial Co. (Osaka, Japan), best known for its Panasonic brand, have established a joint venture named Viterion TeleHealthcare LLC (Tarrytown) that will market telehealthcare diagnostic products to home healthcare agencies and disease management companies. Formation of the joint venture represents an expansion of an original relationship between Bayer and Matsushita that began in May 2001 (*see DTTR, July 2001, p. 4*).

Matsushita is contributing its technology and manufacturing capabilities to Viterion, and Bayer is handling marketing and distribution.

Commercialization of the joint venture's first product, the Viterion 500 TeleHealthcare System, is set to begin within the next 60 days. The system is comprised of three components: a patient terminal, network server software, and physician terminal software. The patient terminal weighs less than 20 pounds and is designed to use regular plug-in power at a patient's home. The terminal has extensions that allow patients to measure various vital signs such as temperature, blood pressure/pulse, blood glucose, etc. The terminal collects these data and then sends via phone line to a network server. The physician terminal software allows providers to view patient data stored on the server via the Internet as well as communicate with the patient by e-mail and video/phone camera.

Pramod Gaur, Ph.D., president of Viterion, tells *DTTR* that the system, which was cleared by the FDA in March 2001, has been successfully tested at approximately 200 sites. He says Viterion will sell each terminal and related equipment for about $7,000 per system plus recurring service charges of $75 to $100 per month.

Gaur says the system should enable home healthcare agencies, for example, to become more efficient. He notes that they generally get a global reimbursement of $3,000 per patient per 60-day episode from Medicare. The typical homehealth patient suffers from some form of chronic illness, such as diabetes, asthma, or congestive heart failure, and requires 15 to 18 nurse visits over the course of 60 days at a cost of $75 to $90 per visit. Gaur says the Viterion system can eliminate a few nurse visits per episode of care, thus allowing home healthcare agencies to make more efficient use of their nurses, who are in scarce supply.

Roche Signs $100+ Million Deal With Epigenomics

Roche Diagnostics (Basel, Switzerland) and the privately held Epigenomics (Berlin, Germany and Seattle, WA) have signed a three-year agreement to develop a range of molecular diagnostics and pharmacogenomic cancer tests.

Terms call for Roche to make an upfront payment to Epigenomics of 4 million euros (US $4.3 million). Roche will also provide R&D funding, milestone payments, and royalties on product sales. Roche says that if all planned products are successfully launched, the total value of the agreement could exceed 100 million euros (US $106 million).

Development efforts will be based on Epigenomics' DNA-methylation technology, which examines bits of methane and methyl chemicals in the body that latch on to

genes and act as "on" and "off" switches. Epigenomics compares patterns of methylation in diseased and healthy tissues to detect cancer at the earliest stages. Initial efforts will focus on tests to detect prostate, breast, and colon cancers.

Epigenomics will be responsible for marker discovery, identification, and pre-validation. Epigenomics' DNA-methylation technologies will be incorporated into Roche's existing and future PCR platforms and into the recently licensed microarray technology from Affymetrix (*see DTTR, March 2003, p. 1*). Diagnostic test development, clinical trials, product manufacturing, regulatory submissions, and all sales and marketing worldwide will be handled by Roche. The first test from the collaboration is expected to be on the market in 2006.

CDC Reviewing Myriad's Ads for Genetic Tests

In a sign that direct-to-consumer advertising of genetic tests could face restrictions, the Centers for Disease Control & Prevention has begun an investigation into the impact of a major multimedia campaign run by Myriad Genetics (Salt Lake City, UT) for its BracAnalysis test.

Myriad ran the campaign in Denver and Atlanta from September 2002 until this February. It was the first campaign for a genetic test to use television, radio, and magazine advertisements. Myriad spent $3 million to run commercials on "The Oprah Winfrey Show," "Live with Regis & Kelly," and other TV shows, and took out ads in *Better Homes and Gardens* and the *Ladies Home Journal*.

Bill Rusconi, vice president of marketing at Myriad, says the ads were aimed at women with a family history of breast or ovarian cancer. Myriad's BracAnalysis costs $2,760 and determines whether women carry a mutation in the BRCA1 or BRCA2 genes, which increase the risk of developing breast cancer. Among the general population of women, the chances of carrying one of the mutations is approximately 1 in 500 (or about 0.2%).

The ads, which can be viewed at *www.myriad.com*, ask: "Does breast or ovarian cancer run in your family? You can reduce your risk. We can help." The ads were designed to reach each member of the target audience (women ages 25 to 54) an average of about 17 times over the course of the five-month campaign. Rusconi says the ad campaign boosted Myriad's Website and phone inquiries by a factor of 40.

But the Office of Genomics & Disease Prevention (OGDP) at the CDC is concerned that the campaign alarmed some women unnecessarily. It is sending 2,400 questionnaires to consumers and doctors in Denver and Atlanta plus two other cities where Myriad did not advertise (Seattle and Raleigh). Muin Khoury, M.D., Ph.D., director of OGDP, tells *DTTR* that the goal is to determine whether women sought more medical advice because of the advertising, whether their knowledge of genetic testing increased, and whether their fear of genetic testing increased.

Khoury says the findings could be used to inform future policy decisions on direct-to-consumer marketing of genetic tests. The HHS Secretary's Advisory Committee on Genetics, Health & Society will decide whether to address the issue at or after its first meeting in mid-June.

The Big Picture For The IVD Industry: Sales Grew 6% In 2002 To Reach $21.6B

Worldwide IVD sales were up 6% to $21.6 billion last year, according to an exclusive analysis by *Diagnostic Testing & Technology Report (DTTR)* of financial reports from the 10 largest diagnostics manufacturers.

Worldwide sales of routine lab reagents and equipment (i.e., chemistry, immunoassay, and hematology) grew by only an estimated 3% in 2002 to reach $15.8 billion. Industry growth drivers were blood glucose testing, up 15% to $4.5 billion, and molecular diagnostics, up 20% to $1.3 billion.

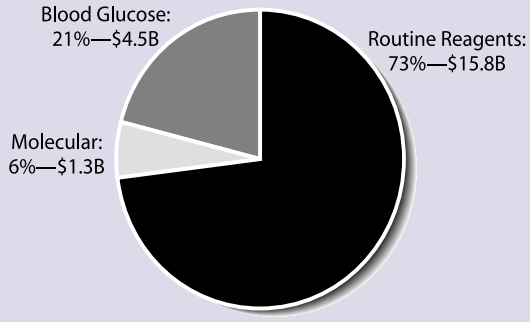
Johnson & Johnson gained the most market share in 2002, while Abbott Diagnostics, which saw sales decline by 1%, lost the most ground. For summary financial results for each of the top 10 IVD companies, see pp. 6-8.

Roche Diagnostics (Basel, Switzerland) posted an operating profit of 1.131 billion Swiss francs (US $836 million) in 2002, up 14% from 993 million in 2001; revenue, excluding the applied science unit, was 6.665 billion Swiss francs (US $4.814 billion), up 5% from 6.329 billion Swiss francs. Roche Diagnostics' revenue growth in 2002 in local currencies (*i.e.*, after adjustments for exchange rate fluctuations) was approximately 12%.

Roche Diagnostics' fastest-growing business area was molecular diagnostics, which grew by 11% to 977 million Swiss francs (US $703 million); growth was 19% in local currencies. Roche cited AmpliScreen tests for screening donated blood, its clinical tests for chlamydia/gonorrhea, and viral load tests for hepatitis B and C as the growth drivers. Key product launches scheduled for this year include the CYP450 AmpliChip ASR (through a collaboration with Affymetrix), an AmpliScreen West Nile Virus assay, and a hepatitis C genotyping test.

Roche Diagnostics' largest business area, blood glucose monitoring, grew by 8% to 2.511 Swiss francs (US $1.816 billion); growth was 14% in local currencies. Key product launches scheduled for this year include the Accu-Chek Advantage III Meter and Accu-Chek Compact Super Fast Strips.

The $21.6B IVD Industry



Source: *DTTR*

Abbott Diagnostics (Abbott Park, IL) saw its operating earnings drop to $220 million in 2002 from $357 million in 2001; revenue fell 1% to $2.897 million. The company continues to suffer from its consent decree with the FDA, which limits sales of its immunoassay products in the U.S. Abbott reports that worldwide immunochemistry sales declined by 2% last year to $2.03 billion.

Johnson & Johnson (New Brunswick, NJ), which operates Ortho-Clinical Diagnostics (OCD) and

Top 10 IVD Manufacturers' Worldwide Revenue *($MM)**

Company	2002 Revenue	2001 Revenue	% Chg	2002 Market Share
Roche Diagnostics[1]	$4,814	$4,571	5	22%
Abbott Diagnostics	2,897	2,929	-1	13
Johnson & Johnson	2,436	2,117	15	11
Bayer Diagnostics[2]	2,224	2,191	2	10
Beckman Coulter[3]	1,575	1,485	6	7
Dade Behring	1,282	1,232	4	6
BioMerieux[4]	1,091	1,023	7	5
Becton Dickinson[5]	1,077	1,006	7	5
Sysmex[6]	484	397	22	2
Bio-Rad[7]	455	418	9	2
Top 10 total	18,335	17,369	6	85
Other IVD companies	3,236	3,065	6	15
Total IVD Market	21,571	20,434	6	100%

*Revenue figures for each company are based on reported results without adjustments (1) Roche revenues exclude applied science division and are based on an exchange rate of $1 USD = 1.384 Swiss francs. (2) Bayer revenues are based on exchange rate of $1 USD = 0.917 euros. (3) Excludes revenue from Beckman's life science research division. (4) BioMerieux's revenues are based on exchange rate of $1 USD = 0.917 euros. (5) Includes Becton's diagnostic systems and immunocytometry divisions; for fiscal years ending September 30. (6) Sysmex's 2002 revenue is based on company's forecast of 58,000 million yen for fiscal year ended March 31, 2003 with an exchange rate of $1 USD = 120 yen. (7) Excludes revenue from Bio-Rad's life science division.

Source: *DTTR* from company reports

Lifescan, posted total IVD revenue of $2.436 billion in 2002, up 15% year-over-year (up 13% in local currencies).

OCD, which is focused on the central laboratory and blood banking markets, recorded a 7% increase in 2002 sales to $1.094 billion. Leading growth were OCD's immunoassay products, especially its Vitros ECi infectious disease assays. Worldwide immunoassay sales at OCD jumped 28% in 2002 to $275 million, according to data from the investment bank SG Cowen Securities (New York City).

Lifescan, the number two player in blood glucose monitoring, reported a 23% jump in revenue to $1.342 billion. Lifescan sales benefited from the acquisition of the blood glucose monitoring business of Inverness Medical in late 2001; market share gains made by Lifescan's One Touch Ultra test product also contributed to growth.

Bayer Diagnostics (Tarrytown, NY) reported revenue of 2.039 billion euros (US $2.224 billion) in 2002, up 2% from 2.009 billion euros in 2001 (up an estimated 6% in local currencies). The standout performer at Bayer Diagnostics was its Advia Centaur high throughput immunoassay system, which grew by 31% to reach 340 million euros (US $371 million). Revenue for Bayer Diagnostics' largest product line, Ascencia Elite blood glucose monitoring, was up 5% to 515 million euros (US $561 million).

Significant acquisitions completed in 2002 included the purchase of Visible Genetics Inc. (VGI—Toronto, Canada) on Oct. 11 for approximately US $65 million, or approximately three times VGI's annual revenue of roughly $20 million. The acquisition boosts Bayer's total molecular diagnostics business to over $100 million per year.

Meanwhile, effective Jan. 1, 2003, Bayer Group transformed its organizational structure into a management holding company with four legally independent corporate units for healthcare (including diagnostics), agrochemicals, polymers, and chemicals. The move could be a precursor to a major overhaul at Bayer that might include divestitures or joint ventures.

Beckman Coulter (Fullerton, CA) posted net income of $135.5 million in 2002, down from $141.5 million in 2001; revenue, excluding life science research, was up 6% to $1.575 billion. The four primary business units of Beckman's diagnostics division are routine chemistry, $579 million, up 6% year-over-year; hematology, $457 million, up 6%; immunodiagnostics, $383 million, up 9%; and flow cytometry, $156 million, up 4%.

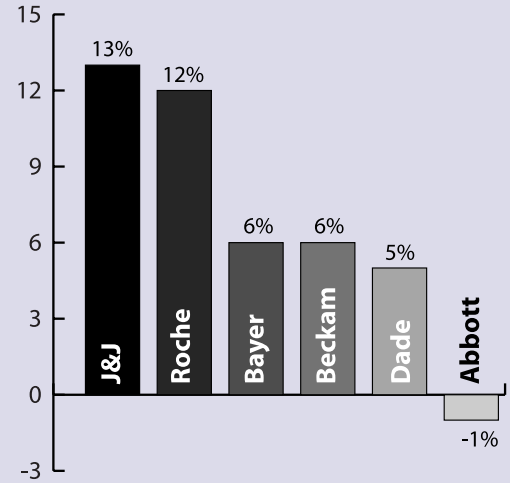
Beckman's 6% growth rate (also up 6% in local currencies) is impressive given the fact that the company does not have a presence in the faster-growing molecular diagnostics and blood glucose monitoring markets. Key growth drivers included the company's Access immunoassay system, which grew sales by 17% to $165 million in 2002, according to data from SG Cowen.

Growth in Beckman's immunoassay business is expected to accelerate this year given Abbott's FDA issues plus the introduction by Beckman of its first high-throughput immunoassay system (i.e., the UniCel DxI 800).

Dade Behring (Deerfield, IL) increased sales by 4% to reach revenue of $1.282 billion in 2002 (up 5% in local currencies). Though Dade, like Beckman Coulter, does not participate in the high-growth molecular diagnostics and blood glucose monitoring markets, it outpaced the industry-wide growth rate of 3% for routine lab reagents and equipment.

Dade's largest product segment is routine chemistry/immunoassay, where the company generated $794 million in sales in 2002, up 8% year-over-year. Within this segment, the company's Dimension RxL and Dimension XPand, which perform chemistry and heterogeneous immunoassay testing on the same system, are driving growth.

IVD Manufacturers' Growth Rates*



*After foreign exchange adjustments
Source: SG Cowen

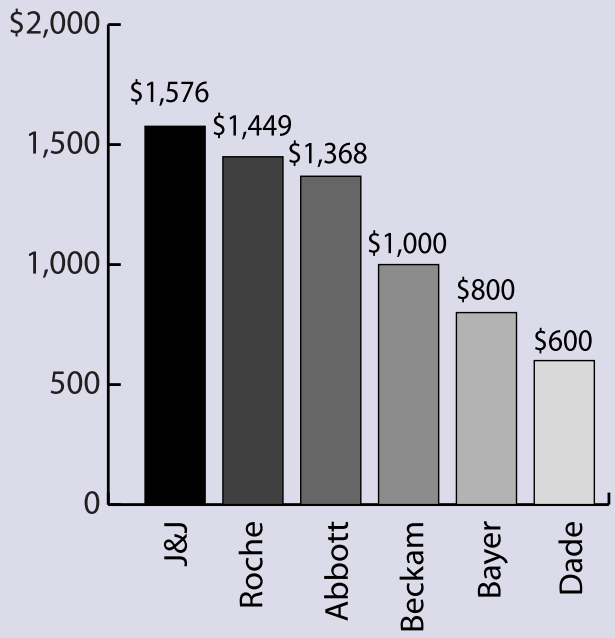
Dade, which completed a Chapter 11 bankruptcy reorganization on Oct. 3, 2002, ended the year with outstanding debt totaling $772 million, or about half of its pre-restructuring level.

BioMerieux (Marcy-l'Etoile, France) generated revenue of slightly more than one billion euros in 2002 (US $1.091 billion), up approximately 7% from 938 million euros in 2001. BioMerieux's U.S. revenues increased by more than 10% last year to about $250 million.

The company's largest business line is microbiology, which comprises roughly 50% of total sales. Key products include the Vitek ID susceptibility system. And BioMerieux picked up the BacT/Alert automated blood-culturing product line through its acquisition of Organon Teknika in June 2001.

Immunoassay systems, which account for roughly 35% of sales, are BioMerieux's fastest-growing business. It has approximately 13,000 Vidas immunoassay systems placed worldwide, including about 2,000 in the U.S. In addition, the company is nearing the launch of Vidas Probe, a dual platform that will allow existing Vidas immunoassay customers to add DNA probe technology and thus perform both immunoassays and molecular diagnostics on a single platform.

US IVD Revenue-2002 *($MM)*



Source: *DTTR* estimates and company reports

Becton Dickinson (Franklin Lakes, NJ) increased its IVD sales by 7% to reach revenue of $1.077 billion in the fiscal year ended Sept. 30, 2002. The company's microbiology/virology business grew by 6% to $599 million, while its flow cytometry business was up 9% to $478 million.

The big news at Becton Dickinson has been its decision to enter the blood glucose monitoring market with the launch of two new products: the BD Logic Blood Glucose Monitor and BD Latitude Diabetes Management System. The company's goal is to generate $40 million to $50 million of revenue from the products this fiscal year and gain a 10% market share (*i.e.* , $450 million) over the next five years.

Sysmex Corp. (Kobe, Japan), which is focused on hematology, coagulation, and automated urinalysis systems, is Japan's largest IVD company. The company has forecast revenue of 58 billion yen (US $484 million) for the fiscal year ended March 31, 2003, up 22% from 47.5 billion yen in the previous fiscal year. All of the growth was the result of the acquisition of International Reagents Corp. (Kobe, Japan), which became a wholly owned subsidiary of Sysmex on April 1, 2002. In the U.S., Roche distributes Sysmex's hematology products, and Dade Behring distributes its coagulation products.

Bio-Rad Laboratories' (Hercules, CA) clinical diagnostics business is focused on several specialty testing markets, including quality controls, autoimmune testing, diabetes monitoring, genetic disorders testing, and blood virus screening. Clinical diagnostics revenue grew 9% in 2002 to $455 million. Contributing to growth was the acquisition of Quantase Ltd. (Perth, Scotland), which specializes in newborn screening tests and has annual estimated revenue of $10 million to $20 million.

Bio-Rad also operates a life science business that generated $429 million of revenue in 2002, up 13% year-over-year. Growth in this business has been spurred in recent years by sales of its market-leading BSE test for "mad cow" disease in Europe and Japan.

International Technidyne Launches Hemoglobin POC Analyzer

International Technidyne Corp. (ITC—Edison, NJ), a division of Thoratec Inc. (Pleasanton, CA), has launched its Hgb Pro Professional Hemoglobin Testing System, a CLIA-waived analyzer for testing total hemoglobin in physician offices.

Hgb Pro consists of a portable, battery-powered analyzer, which weighs about four ounces, and single-use test strips. The analyzer provide results in less than 30 seconds. Larry Cohen, president of ITC, tells *DTTR* that the analyzer will sell for about $240 (including a starter pack of 25 test strips), and test strips will sell for about $1 each. Total hemoglobin is reimbursed by the Medicare Part B lab fee schedule under CPT code 85018 at $3.31 per test.

Physicians use quantitative measurements of total hemoglobin to check for conditions such as anemia and internal bleeding. Other than blood glucose, it is the most widely used in-office diagnostic test, according to Cohen. He estimates that roughly 50 million total hemoglobin tests are performed at physician offices in the U.S. each year. The current market leader for physician office total hemoglobin testing is HemoCue, a Swedish company with U.S. headquarters in Lake Forest, CA.

Meanwhile, Thoratec's annual report shows that ITC generated $46.4 million in revenue in 2002, up 12% from $41.6 million the previous year. The growth was driven primarily by increased sales of ITC's point-of-care blood coagulation testing products.

Spectral Diagnostics Gets FDA Clearance For Sepsis Test

Spectral Diagnostics Inc. (Toronto, Canada) has received FDA clearance for its Endotoxin Activity Assay (EAA) for identifying patients at risk for developing severe sepsis on admission to the intensive care unit. EAA is a rapid test that measures endotoxin in the blood. High levels of endotoxin indicate high risk of severe sepsis, a deadly illness caused by overwhelming infection of the bloodstream by toxin-producing bacteria. It can stem from infections acquired in the community, such as pneumonia, or it may be a complication of the treatment of trauma, cancer, or major surgery at a hospital. The Centers for Disease Control & Prevention estimates that 750,000 people develop severe sepsis each year in the U. S. and more than 200,000 of them die. Severe sepsis occurs in 2 of every 100 hospital admissions.

Assets Of World Diagnostics Sold In Foreclosure Sale

World Diagnostics (Miami Lakes, FL) has announced that its assets have been sold to creditors in a foreclosure sale arising from a sustained default on its senior secured debt. The company had put itself on the auction block earlier this year but was unable to find a buyer or strategic partner. World Diagnostics was formed in 1997 with the goal of distributing diagnostic tests throughout the world. But the company was never able to post more than a few million dollars in annual sales and had accumulated losses of approximately $8 million through year-end 2002.

Adoption of the DNA Pap is not likely to come quickly or easily. For example, it has taken nearly 7 years for thin-layer methods to reach a 60% market share vs. the traditional Pap smear

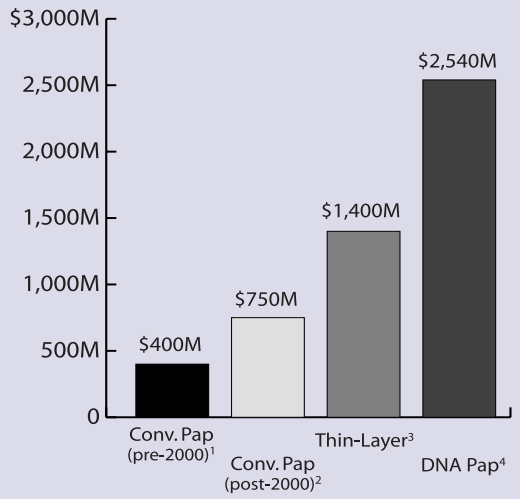
▲ **Digene HPV Test Cleared,** *from page 1*

In the conference call, Jones said Digene will begin marketing the expanded use of its HPV test within 30 to 60 days. But some question marks remain. Most importantly, it is unclear whether private payers and Medicare will cover the combined Pap test and HPV test, which has been dubbed the "DNA Pap." And, if they do cover it, how much they will reimburse labs? Jones expects payers to readily embrace the test and that the reimbursement level will become clearer over the next six months.

Currently, traditional Pap tests are reimbursed by Medicare at $14.76, while thin-layer Pap tests made by Cytyc Corp. (Boxborough, MA) and TriPath Imaging (Burlington, NC) are reimbursed at $28.31 each. When used as a follow-up to Pap tests with abnormal results, Digene's HPV test is currently reimbursed under CPT code 87621 at $49.04. Private payer reimbursement rates are similar.

Thus, reimbursement for the DNA Pap test could potentially be as high as $77.35 (thin-layer Pap test + HPV test). But *DTTR* observes that the government and private payers are likely to balk at such a high price for a screening test that is likely to be performed tens of millions of times each year. Furthermore, it should be remembered that Medicare reimbursement for traditional Pap tests was only $7.15 as late as 1999. It took an act of Congress (i.e., 1999 Balanced Budget Refinement Act) to get Medicare to double the rate to $14.60, effective Jan. 1, 2000. An update for inflation instituted this year brought the rate to its current $14.76.

Estimated Annual Expenditures For U.S. Cervical Cancer Screening



1) Assumes 50M conventional Pap tests/yr at average reimbursement of $8 each; 2) Assumes 50M conventional Pap tests/yr at average reimbursement of $15 each; (3) Assumes 50M thin-layer Pap tests/yr at average reimbursement of $28 each; 4) Assumes 33 million DNA Pap tests/yr at average reimbursement of $77 each.

Source: *DTTR* estimates

Another key question that needs to be answered is how frequently the DNA Pap should be performed given its high sensitivity. Clinical trial data cited by the FDA have shown that women who have normal Pap test results and no HPV infection are at very low risk (0.2%) for developing cervical cancer. Because of the test's effectiveness, the American Cancer Society recently issued a preliminary recommendation that women who test negative using the DNA Pap get tested just once every three years. Most private payers currently cover a Pap test annually and Medicare provides coverage once every two years.

In terms of the potential market size, Jones noted that Digene currently charges labs approximately $22 to $25 per HPV test when used as a follow-up to an abnormal Pap test. He said that this amount is likely fall to $15 to $20 per test as volumes increase due to expanded usage from the new FDA clearance. Jones estimates that approximately 30-35 million DNA Pap tests could ultimately be performed in the U.S. each year. This indicates a market potential of at least $450 million (*i.e.*, $15 per test x 30 million tests = $450 million).

IVD Stocks Up 6% In Latest 5 Weeks; i-Stat Pops 49%

***Roche** non-voting equity shares, which trade on the Zurich stock exchange, have fallen 10% to 86.45 Swiss francs so far this year. Shares of **Bayer**, which trade on the German stock exchanges, are down 31% at 14.12 euros*

The 21 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 6% in the five weeks ended April 4, 2003, with 18 stocks up in price and 3 down. Year to date, the G-2 Index is up 10%, while the S&P 500 is unchanged and the Nasdaq is up 4%.

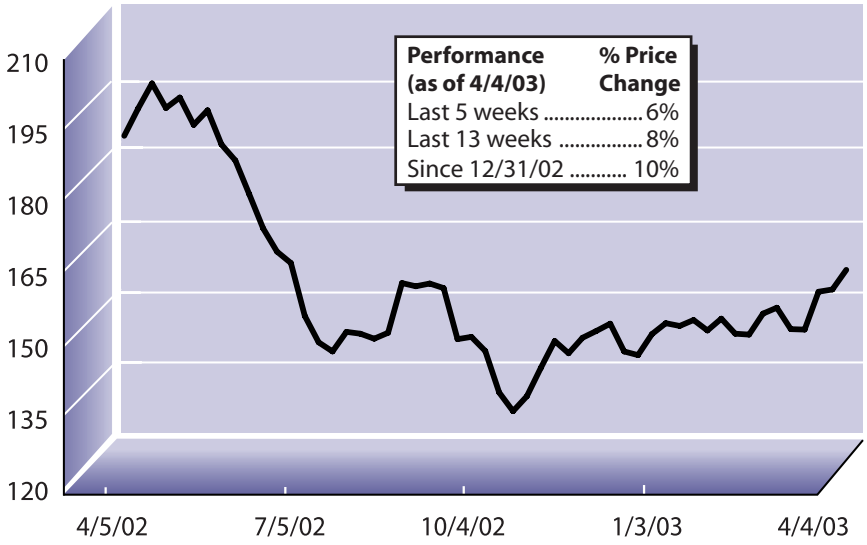
Shares of **i-Stat Corp.** (East Windsor, NJ) jumped 49% to $5.94 per share for market cap of $119 million. The company reported fourth-quarter 2002 results that indicate it is nearing profitability. Since formation in 1983, i-Stat has accumulated losses totaling $283 million. Net loss for fourth-quarter 2002 was $260,000 vs. a net loss of $1.8 million in the same period a year earlier; revenue fell 9% to $15.9 million.

Meanwhile, i-Stat says it continues to build up its salesforce in anticipation of the expiration of its marketing agreement with Abbott Laboratories, due on Dec. 31, 2003. The company has already hired 11 of 12 sales consultants, who will focus on gaining new hospital clients, and has hired 5 of 15 sales specialists, who will focus on expanding sales from existing clients.

Diametrics (Roseville, MN), which makes the IRMA system for hand-held analysis of blood gas/electrolytes, fell 66% to $0.63 per share for a market cap of $17 million. The company recently reported a fourth-quarter 2002 net loss of $3.2 million vs. a net loss of $796,000 in the same period a year earlier; revenue fell to $1.9 million from $6.4 million. Diametrics says it has hired The Seidler Companies to assist in potential sale of the company.

Digene Corp. (Gaithersburg, MD) was up 21% to $20 per share for a market cap of $362 million. The company recently received clearance from the FDA for use of its Digene HC2 HPV Test in conjunction with the Pap test in cervical cancer screening for women over age 30 (*see page 1*).

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 4/4/03

UP	Price	% Chg
Abbott Labs	$40.18	13%
Beckman Coulter	34.30	4%
Bio-Rad	36.35	1%
Biosite	42.33	35%
Cholestech	7.97	25%
Cytyc	12.92	1%
Dade Behring	18.85	1%
Diagnostic Products	39.01	1%
Digene	20.00	21%
Gen-Probe	24.60	2%
Igen	35.49	8%
Immucor	22.02	12%
Inverness Medical	20.11	16%
i-Stat	5.94	49%
Johnson & Johnson	57.84	10%
Meridian	7.82	3%
Quidel	3.75	19%
Ventana	20.04	3%
DOWN		
Becton Dickinson	34.01	-1%
Diametrics	0.63	-66%
TheraSense	6.96	-19%

G-2 Insider

Hospitals should expect Medicare payment cuts next year as lawmakers try to hold down the program's spending, Thomas Scully, administrator of the Centers for Medicare & Medicaid Services, told hospital leaders at a recent meeting of the Federation of American Hospitals.

Scully's warning came on the heels of a report released March 17 from Medicare's Board of Trustees that showed that Medicare spending rose 8.5% last year to $266 billion. That's 2% faster than government analysts had expected. Furthermore, the report said that spending over the remainder of this decade is now projected to be substantially higher than was estimated just one year ago. The outlook will become even more worrisome with the likely addition of an expensive new prescription drug benefit.

"[The spending growth is] not good. It's not good for you, it's not good for anybody," said Scully. He warned that lawmakers were likely to take notice of the increase when it comes time to set Medicare payment rates for next year. "Congress...is not going to miss that," he said. Indeed, the Medicare Payment Advisory Commission (MedPAC), which advises Congress on Medicare payment policy, is recommending cuts of between 0.4% and 0.6% to hospitals in fiscal 2004. Meanwhile, a separate report from the Centers for Medicare & Medicaid Services estimates that Medicare Part B lab spending rose 10.5% last year to $4.8 billion.

This means that, after several years of relative stability, hospital lab budgets could come under the gun once more. And that's not good news for lab suppliers.

Company References

Abbott Labs 847-937-6100

Bayer Diagnostics 914-631-8000

Beckman Coulter 714-871-4848

Digene 301-944-7000

Epigenomics 206-883-2900

International Technidyne 800-631-5945

i-Stat 609-443-9300

Myriad Genetics 801-584-3600

Roche Diagnostics 317-849-9350

Spectral Diagnostics 416-626-3233

Viterion 914-333-6600

World Diagnostics 305-827-3304

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