Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

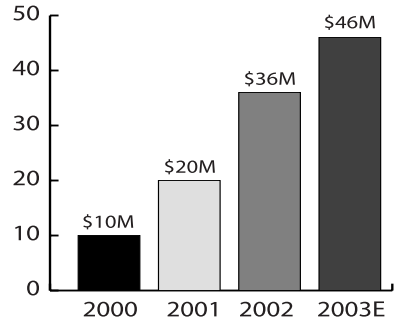
Established 1979

New ACS Guidelines Likely To Propel HPV Testing

The American Cancer Society (ACS—Atlanta, GA) has issued new cervical cancer screening guidelines that include a preliminary recommendation that human papillomavirus (HPV) DNA testing for high-risk HPV types, together with a Pap test, be used in primary screening for women age 30 and over. ACS is the first major medical group in the U.S. to advocate testing for HPV in routine cervical cancer screening. The recommendation should give a major boost to the adoption of HPV testing, which is currently approved by the U.S. Food and Drug Administration for use only as a follow-up for Pap tests with indeterminate results.

Digene Corp. (Gaithersburg, MD) has the only HPV test on the market that has been cleared by the FDA. And the company is making hay while the sun shines. For the fiscal year ending June 30, 2003, Digene expects to generate roughly $45 million to $47 million of revenue from its HPV test, up nearly 30% from the previous year. Evan Jones, chairman and chief executive of Digene, believes the total annual market for DNA-based HPV test kits in the U.S. could ultimately reach $400 million.

Digene's Worldwide HPV Revenues*



* For fiscal years ending June 30
Source: Digene and *DTTR* estimates

But Digene won't have the HPV testing market all to itself for long. Roche Diagnostics is developing its own HPV test kit, and Ventana Medical Systems recently introduced a "home brew" test. For more details, see *Inside The Diagnostics Industry*, pp. 5-8.

Becton Dickinson Enters Glucose Monitoring Market

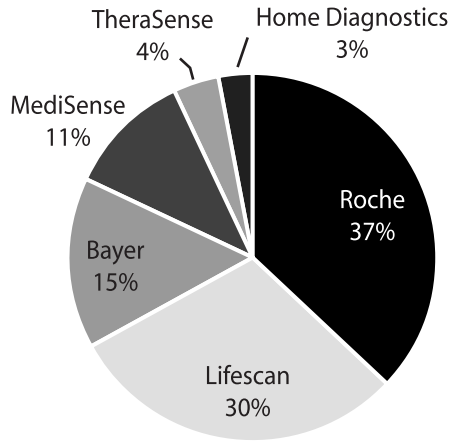
Becton Dickinson (Franklin Lakes, NJ) has entered the $4.5 billion blood glucose monitoring market with the introduction of two new FDA-cleared products, the BD Logic Blood Glucose Monitor and the BD Latitude Diabetes Management System, both of which will be available in the U.S. As part of the new product launches, Becton Dickinson has entered into two separate contracts with Medtronic MiniMed, the diabetes management business of Medtronic Inc. (Minneapolis, MN), and Eli Lilly (Indianapolis, IN) to help with sales and marketing efforts.

Continued on p. 2

▲ **Becton Dickinson,** *from page 1*

At a meeting to discuss the product launch with analysts in New York City on January 8, Edward Ludwig, chairman and chief executive of Becton Dickinson, said the two new products would gain share in the already competitive blood glucose monitoring field because they each: 1) use the thinnest lancet available (33 gauge) to minimize pain and test strips that require a minimal amount of blood (.3 microliters); and 2) deliver test results in just five seconds. Ludwig said that no existing competitors offer blood glucose monitors with this combination of small sample size and quick results (*see table*).

Market Share For Worldwide $4.5B Blood Glucose Monitoring Market In 2002



Source: *DTTR* estimates and company reports

The Becton Dickinson products are approved by the FDA for fingerstick samples only—not for less painful sample collecting areas like the forearm or thigh. However, the company believes that since its lancet and required sample size are so small, the finger prick won't be that painful anyway.

Ludwig said Becton Dickinson will offer the monitors to patients for free (as is industry practice) and sell the test strips at a price that is comparable to the market leaders (i.e., Roche and Lifescan). He anticipates that Becton Dickinson will generate $40 million to $50 million of revenue from its new blood glucose monitoring products in the current fiscal year ending Sept. 30, 2003.

Over the next five years, Ludwig anticipates that Becton Dickinson can gain a 10% market share in blood glucose monitoring—a market that generated total worldwide sales of approximately $4.5 billion in 2002 with annual growth of roughly 10%-15%. Ludwig estimates that Becton Dickinson will break even on its new blood glucose monitoring business in fiscal year 2004 and become profitable thereafter. Manufacture of Becton Dickinson's new blood glucose monitors and test strips will be handled by Nova Biomedical (Waltham, MA) under a long-term contract.

Comparative Glucose Monitor Characteristics

Product	*Manufacturer*	*Blood Volume (microliters)*	*Test Time (seconds)*	*Lancet Size (gauge)*
Logic/Latitude	Becton Dickinson	0.3	5	33
One Touch InDuo	J&J/Lifescan	1	5	28
One Touch Ultra	J&J/Lifescan	1	5	28
Accu-Chek Active	Roche	2.0	5	NA
Accu-Chek Compact	Roche	3.5	15	28
Accu-Chek Advantage	Roche	4.0	25	28
Glucometer DEX	Bayer	3-4	30	28
Glucometer XL	Bayer	2	30	28
Precision Q.I.D.	Abbott/MediSense	3.5	20	28
Precision Xtra	Abbott/MediSense	3.5	20	30
Precision Sof-Tact	Abbott/MediSense	2-3	20	NA
TheraSense FreeStyle	TheraSense	0.3	15	25

Source: Company reports, Banc of America Securities LLC estimates

Medtronic MiniMed Contract

Under the terms of the worldwide agreement, Medtronic MiniMed will distribute a cobranded version of the BD Logic Blood Glucose Monitor and test strips. The two companies will focus their marketing efforts on diabetes patients using Medtronic MiniMed insulin delivery pumps. Medtronic MiniMed has an 85% market share for insulin pumps in the U.S. Its primary market is the 800,000

to 1 million individuals who suffer from Type 1 diabetes—a severe form characterized by a complete lack of insulin secretion by the pancreas. Type 1 diabetes patients using insulin pumps require their blood glucose levels to be tested an average of five times per day, according to Ludwig.

Eli Lilly Contract

Terms of the agreement call for Eli Lilly to utilize its U.S. diabetes sales force to provide marketing support for the BD Latitude Diabetes Management System, which is a fully integrated hand-held system that includes a blood glucose monitor, lancing device, test strips, and storage for an insulin pen and needles. There will be no sharing of revenues between the companies. Becton Dickinson will earn revenue from the sale of test strips for the system, while Eli Lilly will earn revenue from the sale of insulin and insulin pens. Eli Lilly is the biggest manufacturer of insulin for the U.S. market.

Metrika Gets FDA Clearance For HbA1c Home Test

Metrika (Sunnyvale, CA) has received FDA clearance to sell its A1cNow diabetes monitor over-the-counter, without a prescription. As a result, A1cNow has become the first glycated hemoglobin (aka, HbA1c) test available for patient self-testing at home. Today, nearly all HbA1c testing is performed at laboratories and requires patients to make a visit to a hospital or physician office to have blood drawn by venipuncture in the arm.

HbA1c indicates the body's average glucose metabolism over the past two-to-three months. The American Diabetes Assn. (ADA—Alexandria, VA) recommends that diabetes patients test their HbA1c levels on a quarterly basis. The goal is to keep HbA1c levels below 7% to minimize potential complications of diabetes, such as blindness, stroke, heart disease, and kidney failure. In the U.S., there are 11 million people diagnosed with diabetes and another 5 million undiagnosed, according to ADA.

Metrika's A1cNow monitor is a disposable, pager-sized device that provides quantitative HbA1c results in about eight minutes from a drop of blood from the fingertip. The A1cNow test is currently available through mail order and over the Internet at a retail price of $22.95 per kit, or $108.95 for a package of 10 kits (i.e., $10.90 each). Metrika says the test will soon be available at drug stores as well.

The nearest competitors to Metrika in the HbA1c home testing market include several companies that market sample collection kits that allow patients to take their own blood sample at home and then mail in the specimen for testing at a clinical laboratory. Test results are then provided directly to the patient, typically within one to three days.

BioSafe Medical Technologies (Lincolnshire, IL) received FDA clearance for its HbA1c home specimen collection kit in December 1999. BioSafe sells the collection kit and test service directly to patients for $24.95 per test. Testing services are performed by a BioSafe clinical laboratory in Chicago.

FlexSite Diagnostics (Palm City, FL) received FDA clearance for its A1c At-Home specimen collection kit in 1997. The collection kit and test service sell for $24.95 plus $3.95 for shipping and handling. Testing services are performed by a FlexSite clinical laboratory in Florida.

Diabetes Technologies (Thomasville, GA) received FDA clearance for its Accu-Base Hemoglobin A1c specimen collection kit in August 2002. The collection kit and test service are being marketed by SpectRx Inc. (Norcross, GA) and sell for approximately $20. Testing services are provided by contract through Premier Labs (Kansas City, MO).

Celera Diagnostics' HIV-1 Genotyping Test Gets FDA Clearance

Celera Diagnostics (Alameda, CA) has received marketing clearance from the FDA for its ViroSeq HIV-1 Genotyping System. The system will be manufactured by Celera and distributed by Abbott Diagnostics.

Genotype tests, such as Celera's ViroSeq, detect mutations in the HIV-1 viral genome that confer drug resistance. Physicians use this information to better understand a specific patient's resistance profile and adjust drug therapy accordingly.

Each year, more than 150,000 HIV genotyping tests are conducted, and over 40,000 new cases of HIV infection are diagnosed in the U.S. alone, according to John Sninsky, PhD, vice president of discovery research at Celera. Most physician offices and hospitals refer their genotyping tests to larger reference labs that use proprietary "home brew" tests that do not require FDA approval. HIV-1 genotyping has been a lucrative market for the big labs. For example, Medicare covers genotype analysis of HIV-1 under CPT code 87901 at a maximum allowable rate of $359.69.

But FDA clearance of a HIV-1 genotyping test kit could make it easier for smaller labs to bring the test in-house. Celera's ViroSeq is the second HIV-1 genotyping test to be cleared by the FDA. In September 2001, Visible Genetics (Toronto, Canada), which was recently acquired by Bayer Group, gained FDA clearance for its TruGene HIV-1 test.

OraSure Begins Shipping OraQuick Rapid HIV-1 Tests

OraSure Technologies (Bethlehem, PA) says that it has shipped more than 50,000 OraQuick Rapid HIV-1 Antibody Tests to Abbott Laboratories. Abbott distributes the OraQuick test in the U.S. under a co-exclusive agreement that allows OraSure to sell the test directly as well. OraSure expects sales to Abbott to exceed $4 million in 2003. A spokesman for Abbott says the test will be sold to lab customers for $9 to $15 per kit, depending on discounts for volume.

OraSure received FDA approval of the OraQuick test in November 2002 (*see DTTR, December 2002, p. 3*) for use at CLIA-licensed laboratories. In addition, Mike Gausling, chief executive of OraSure, says the company is now working with the FDA to finalize a protocol for seeking a CLIA waiver and obtain approval of an Investigational Device Exemption required to perform oral fluid clinical trials for the test.

HPV Testing Emerging As A Major Market

Major medical authorities worldwide now recognize that human papillomavirus (HPV), a sexually transmitted virus, is the primary cause of cervical cancer. In fact, according to an article in the August 1999 *Journal of Pathology*, cancer-causing HPV types have been found to be responsible for more than 99% of all cervical cancer cases.

For the past 60 years, Pap testing, including traditional Pap smears and more recently liquid-based methods, has been the principal means of cervical cancer screening. Approximately 50 million to 60 million Pap tests are performed annually in the U.S. As a result, incidence of the disease has been reduced by roughly 75% since the 1940s. Nonetheless, approximately 5,000 women in the U.S. die annually from cervical cancer, which is highly preventable if detected early. Many of these deaths could be prevented if existing Pap test screenings were expanded to reach underserved populations, but another portion could be saved if a more sensitive and specific test were used.

In response to the need for a more definitive test for cervical cancer, Digene developed a DNA-based test for HPV called the Hybrid Capture2 HPV test. The test was cleared by the FDA to be used as a follow-up to equivocal or abnormal Pap test results in March 1999. To date, the Digene test remains the only HPV test that has been cleared by the FDA.

Evan Jones

It costs Digene roughly $1-$3 to manufacture each HPV test kit, and Digene charges lab customers approximately $20 per test. Labs are reimbursed for the test by Medicare under CPT code 87321 (capped at $49.04). In addition, Evan Jones, chairman and chief executive of Digene, tells *DTTR* that the test is now reimbursed by health plans covering more than 200 million lives in the U.S.

Acceptance of HPV testing among OB/GYNs got a boost with the recent publication of revised cervical cancer screening guidelines by the American Society for Colposcopy and Cervical Pathology (ASCCP—Hagerstown, MD) which now advocates routine use of HPV testing as a follow-up to any borderline Pap test.

The revised guidelines, published in the *Journal of the American Medical Association* in April 2002, state that, for managing women with ASCUS (equivocal) Pap results, HPV testing is the "preferred approach" when it can be performed directly from a liquid-based Pap test (i.e., reflex HPV testing) or when the HPV test specimen can be collected during the initial office visit. According to the guidelines, "Reflex HPV DNA testing offers significant advantages since women do not need an additional clinical examination for specimen collection, and 40% to 60% of women will be spared a colposcopic examination. Moreover, women testing negative for HPV DNA can rapidly be assured that they do not have a significant lesion."

Jones says follow-up HPV testing is quickly becoming the standard of care and he estimates that Digene's HPV test is approaching a 50% market share of all ASCUS cases in the U.S. He adds that approximately 225 labs in the U.S. and another 400-500 labs in Europe now use the Digene HPV test.

In the fiscal year ending June 30, 2003, Digene will generate $47.3 million from HPV test kit sales worldwide, including $37.3 million from North America, $5.7 million from Europe, and $4.3 million from the rest of the world, according to estimates from the investment firm Leerink Swann & Company.

The total potential annual market for HPV test kits for ASCUS cases in the U.S. is estimated at approximately $66 million (i.e., 55 million Pap tests multiplied by 6% ASCUS cases at $20 per HPV test kit=$66 million), and the global market is probably twice as big. However, the real potential for HPV testing lies in its promise to become part of a primary screening program for cervical cancer.

In October 2001, Digene submitted an application to the FDA to obtain market approval for the use of its HPV test as a cervical cancer screening test to be performed in conjunction with the Pap smear for women ages 30 and older. Digene calls the use of its HPV test in conjunction with the Pap smear as a primary screen the "DNA Pap." In March 2002, an FDA advisory panel recommended that the FDA approve, with conditions, Digene's DNA Pap application. Digene then received a letter from the FDA requesting additional information.

In September 2002, Digene resubmitted to the FDA its application for the DNA Pap. Questions that Digene addressed in the filing included: (1) recommendations for clinical use of the test with a demonstration of positive clinical outcomes; (2) an educational program and materials for physicians and patients; and (3) a post-market study plan designed to confirm the DNA Pap's performance in the U.S. and to measure clinical outcomes.

Jones says that data included in the resubmission showed that a negative HPV result, in conjunction with a normal Pap, conveys a level of protection equivalent to three consecutive annual cytology exams; data also showed that women who are persistently HPV-positive are at measurable risk for cervical cancer, compared to women who are HPV-negative. Jones anticipates that the FDA is likely to approve the DNA Pap by mid-2003.

Momentum for the DNA Pap got a boost in November 2002 when the American Cancer Society published new guidelines for cervical cancer screening in the cancer journal *CA*. This marked the first time that ACS guidelines had been revised since 1987. The new guidelines included a preliminary recommendation that, as an alternative to Pap smears alone, a combination of liquid-based cytology and HPV testing could be performed once every three years. This recommendation is in line with data that Digene provided in its resubmission to the FDA.

Digene—Revenue Break Out *($MM)*

	FY01	Change	FY02	Change	FY03E	Change
N. America HPV	$13.1	130%	$24.2	85%	$37.3	54%
N. America other tests	6.5	31%	6.4	0%	9.0	41%
Total N. America	19.6	105%	30.6	56%	46.3	51%
Europe HPV	5.2	46%	9.3	79%	5.7	-39%
Europe other tests	5.3	-18%	3.8	-28%	4.0	5%
Total Europe	10.5	6%	13.1	25%	9.7	-26%
ROW HPV	2.1	25%	3.1	48%	4.3	39%
ROW other tests	2.0	10%	2.0	0%	1.2	-40%
Total ROW	4.1	17%	5.1	24%	5.5	8%
Grand Total Digene	$34.2	48%	$48.8	43%	$61.5	26%

Source: Digene and Leerink Swann estimates

Private health insurance plans are expected to fall into line and cover the DNA Pap once it receives FDA clearance

Meanwhile, a survey of 10,000 OB/GYNs performed by the investment bank UBS Warburg (New York City) in May/June 2002 indicates that the DNA Pap, if approved by the FDA, will be well received among physicians. Specifically, 77% (524/684) of the respondents were aware of the DNA Pap, and of the total respondents, 82% (544/664) indicated they would use the test upon FDA approval. Of the respondents who were not familiar with the DNA Pap, 70% (105/150) said they would use the test if approved.

Jones says that assuming FDA clearance of the DNA Pap, existing Medicare reimbursement for each of the test's two components—liquid-based Pap test currently reimbursed at $28.31 and DNA-based HPV test currently reimbursed at $49.04—might be combined for a total Medicare reimbursement of $77.35 for the DNA Pap. He estimates that after FDA clearance it will take the Centers for Medicare and Medicaid Services about six to nine months to finalize a reimbursement method.

Approximately half of the 55 million Pap tests now performed each year in the U.S. are for women age 30 and over. The total potential market for HPV testing when used as part of a DNA Pap for screening for cervical cancer for women over age 30 could range from a low of approximately $300 million to a high of $500 million in revenue per year, depending on whether screenings are performed annually or once every three years. And the worldwide market for HPV testing for cervical cancer could be as high as $1 billion.

Competition Is On Its Way For HPV Testing

The prospects of an emerging $1 billion market were too much for **Roche Diagnostics** (Basel, Switzerland) to let pass by. In early 2001, Roche agreed to distribute Digene's HPV test in Europe. However, in June 2002, Roche announced that it had acquired a broad portfolio of patents pertaining to HPV from Institut Pasteur (Paris, France) for an undisclosed sum.

Shortly thereafter, Digene announced that it was terminating its distribution agreement with Roche. "It became evident that Roche did not have our [Digene's] best interest at heart," notes Jones. He says that Digene is now building up its own salesforce in Europe.

Heino von Prondzynski, head of the diagnostics division at Roche, tells *DTTR* that Roche plans to launch a home brew version of its own HPV test in the U.S. either later this year or in early 2004, thereby putting it in direct competition with Digene. But Jones says that several key HPV DNA types, including types 52 and 68, are exclusively licensed to Digene in the U.S. Jones says that without these HPV types, any potential Roche HPV test will fail to spot up to 4% of those women who are infected with HPV. Jones notes that Digene also has a huge lead over Roche because it already has an FDA-cleared test on the market with research from dozens of clinical trials behind it.

Prondzynski says that Roche has access to enough HPV types to develop an effective test. He believes that Roche has an advantage because there are more than 500 laboratories in the U.S. that are performing other gene-based tests

using the company's PCR (polymerase chain reaction) technology and instruments. Prondzynski says that Roche PCR customers will be able to run the company's planned HPV test on their existing instruments, thereby facilitating adoption.

DTTR also notes that within days of announcing plans to develop its own HPV test, Roche announced an agreement with Stressgen Biotechnologies (Victoria, British Columbia, Canada) to co-develop a drug (HspE7) to treat diseases linked to HPV. Stressgen's HspE7, which is in Phase II drug development, is an engineered protein that induces the body's immune system to destroy HPV-infected cells.

Ventana Medical Systems (Tucson, AZ) has also targeted HPV testing as a business opportunity. In September 2002, Ventana acquired the HPV business and assets of Beckman Coulter (Fullerton, CA) for $1 million in cash plus contingent payments of $750,000. The acquisition included assignment of the HPV intellectual property portfolio acquired by Beckman from Institut Pasteur through a 1991 sublicense agreement.

Digene has filed a lawsuit against Ventana seeking to block its use of types 52 and 68. Chris Gleeson, chief executive of Ventana, refused to comment on the lawsuit, but expressed confidence in Ventana's legal position.

Meanwhile, Ventana has been marketing a home brew version of its Inform HPV test for tissue-based specimens since the fourth quarter of 2001 and a version for liquid-based specimens since May 2002. Gleeson says Ventana plans to begin clinical trials of its Inform HPV test for both tissue and liquid-based specimens by mid-year 2003. Ventana hopes to submit an application to the FDA for Inform HPV test for use as a reflex test to ASCUS Pap tests by year-end 2003.

Gleeson believes that Ventana's Inform HPV test provides similar sensitivity as Digene's HPV test, but is more specific (i.e., fewer false positives). Gleeson says that Inform HPV is more specific because it is a slide-based test which allows the pathologist to view the HPV virus in the context of cell morphology changes. "Seeing the nuclear signal in the cells of interest provides strong clinical evidence that the virus has begun to take its course towards dysplasia," according to Gleeson.

An Overview of Various Cervical Cancer Testing Methods

Type of Test	*Test Manufacturer*	*Reagent Cost*	*CPT Code*	*2003 Medicare National Cap*
Traditional Pap Smear	Various	$1	88150, 88164	$14.76
Liquid-Based Pap Test	Cytyc, TriPath	$9	88142	$28.31
DNA-Based HPV Test	Digene	$20	87621	$49.04
Tissue Hybridization HPV Test	Ventana	$40	88365	$104.12
DNA Pap Test*	Cytyc, Digene	$29	88142+87621	$77.35

*The DNA Pap Test has not yet been cleared by the FDA and no formal Medicare reimbursement has been set. Figures in table assume that existing codes for liquid-based Pap test and DNA-based HPV test are combined.
Source: *DTTR*

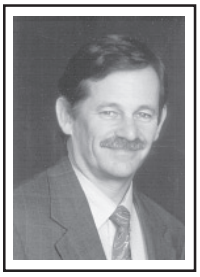
Cholestech To Take $5 Million Write-Off On Sale Of WellCheck

Cholestech Corp. (Hayward, CA) has sold its WellCheck testing service business to Impact Health (Wayne, PA) for an undisclosed sum. In addition, Cholestech and Impact Health have entered into a three-year supply contract involving the purchase of the Cholestech LDX System and test cassettes.

WellCheck manages cholesterol testing services at health fairs sponsored by pharmaceutical companies that market cholesterol-lowering drugs. WellCheck's top customer had been Pfizer (which sells Lipitor). However, Pfizer and other pharmaceutical companies have recently cut back on their sponsorship of cholesterol testing programs. As a result, revenue at WellCheck dropped to $682,000 in the six months ended Sept. 27, 2002 from $3.9 million in the same period a year earlier. In connection with the sale of WellCheck, Cholestech says it will record write-offs totaling $4.9 million in its fiscal third quarter (ended Dec. 31, 2002). Cholestech originally acquired WellCheck (previously known as Health Net) in January 2000 for $4.3 million in cash and stock.

Impact Health, a privately held company with approximately 45 employees, manages on-site test screening programs for pharmaceutical companies, employers, managed care companies, and drug stores—clients include Merck, Novartis, American Express, Coca-Cola, United Healthcare, and Walgreen's.

Norman Schwartz Fills Father's Shoes At Bio-Rad



Norman Schwartz

Norman Schwartz, 52, vice president and group manager of life science at Bio-Rad Laboratories (Hercules, CA), has assumed the position of president and chief executive. He replaces his father, David Schwartz, 78, who will remain as chairman of the board. David Schwartz has led Bio-Rad as president, chief executive and chairman since he and his wife Alice Schwartz, 72, a biochemist, co-founded the company in 1952. The Schwartz family owns approximately 30% of all outstanding shares of Bio-Rad and maintains control of the company via majority ownership of Class B shares with special voting rights.

Novitron To Acquire Elan Diagnostics For $15 Million

Novitron International (Newton, MA) has agreed to acquire Elan Diagnostics (EDx—Smithfield, RI), a subsidiary of the Irish pharmaceutical firm Elan Corp., for $14.6 million in cash. EDx, which employs 110 people, is a leading supplier of clinical chemistry instruments and reagents to physician office labs. As part of the transaction, Novitron will also acquire the assets of EDx's manufacturing facility in Brea, CA. In the nine months ended Sept. 30, 2002, EDx generated operating income of $1.6 million on revenue of $22.2 million. The acquisition of EDx comes on the heels of Novitron's recently announced plans to acquire Group Practice Services Inc. (Greensboro, NC), a POL management services company, for approximately $7 million.

Revenue At Bayer Diagnostics Slips 3%

Bayer Group (Leverkusen, Germany) reports that revenue at its diagnostics business fell by 3% to 483 million euros (US $506 million) in the three months ended Sept. 30, 2002. Bayer says the revenue dip was due mainly to declines in its self-testing and near-patient testing product segments. On the other hand, Bayer reports that its Advia Centaur laboratory system achieved good growth in the third quarter.

Overall, Bayer Group reported net income of 656 million euros (US $687 million) in the three months ended Sept. 30, 2002, compared with a net loss of 183 million euros (US $192 million) in the same period a year earlier; revenue was up 8% to 7.459 billion euros (US $7.8 billion).

Separately, Bayer management recently stated for the first time that it would be willing to give up majority control of a potential joint venture involving the company's pharmaceutical unit, removing what had been seen as a stumbling block to making a deal. *DTTR* speculates that completion of a deal for the pharma unit could result in a change of ownership for Bayer's diagnostics business as well.

Bayer Group At A Glance
(in millions of euros)

	3Q02	3Q01	Change
Bayer Group Revenue	7,459	6,931	+8%
Bayer Group Net Income	656	-183	NA
Health Care Revenue	2,279	2,397	-5%
Pharmaceuticals	846	902	-6%
Diagnostics	483	493	-3%
Consumer Care	457	528	-13%
Biological Products	270	241	+12%
Animal Health	223	230	-3%
Health Care Operating Profit	175	77	+127%

Source: Bayer

Bayer's pharmaceutical business has been struggling since last year when it was forced to recall its Baycol cholesterol-lowering medication after the drug was linked with patient deaths. In the quarter ended Sept. 30, 2002, for example, pharma revenue at Bayer declined 6% to 846 million euros (US $892 million).

For more than a year, Bayer has been considering combining its pharmaceutical business into a joint venture, but with the stipulation Bayer would hold majority control. Dropping the control requirement opens the door to Bayer taking a minority role in a partnership, or possibly selling the pharma business.

"We will proceed pragmatically and attempt to achieve the optimum scenario for our business and our stockholders," Werner Wenning, chief executive of Bayer, said in a November 12 press release. Wenning said the company is actively searching for a potential partner for the pharma unit. "We are currently involved in very good and constructive discussions along the lines I've mentioned, and we're confident that these discussions will lead to a value-enhancing solution for our pharmaceuticals business," said Wenning.

A Bayer spokeswoman declined to comment on potential partners, when a deal might be completed, and whether or not the diagnostics business would be packaged together with the pharma business under any potential transaction.

Immucor The Big Winner In Down Year For IVD Stocks

***Roche** non-voting equity shares, which trade on the Zurich stock exchange, fell 19% to 96.35 Swiss francs in 2002. Shares of **Bayer,** which trade on the German stock exchanges, closed the year at 20.45 euros, down 43% from 35.80 euros a year earlier*

Shares of **Immucor** (Norcross, GA), which sells blood banking instruments and reagents, vaulted 156% to $20.25 in 2002—a year in which most other IVD stocks suffered double-digit declines.

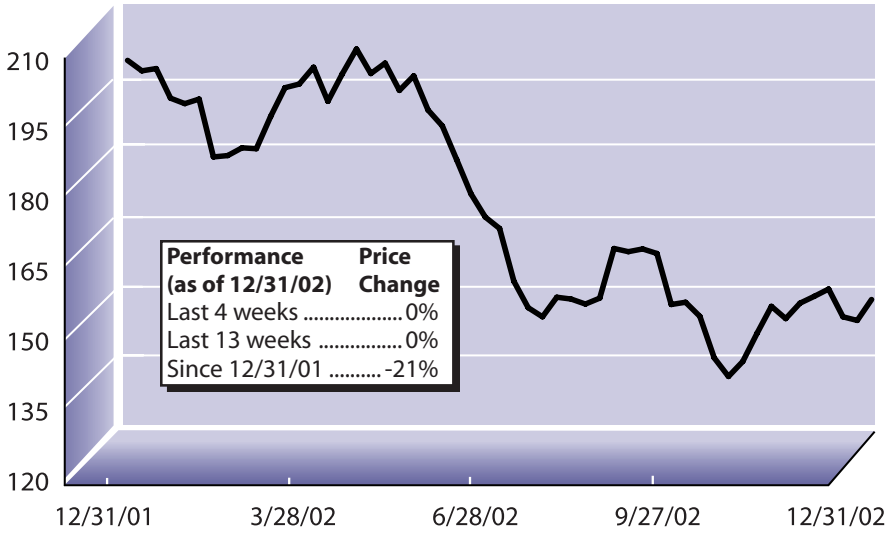
Propelling Immucor shares forward was the correction of performance-related issues surrounding its ABS2000 analyzer. The problems (discovered in mid-2000) caused errors in test results and forced Immucor to issue a "safety notification" on the product requiring customers to do manual back-up testing. A sharp decline in instrument placements and some refunds followed, with Immucor sinking to an all-time low of about $1 per share in late 2000. However, in September 2001, Immucor announced that, with FDA approval, it had lifted all safety notifications for the instrument. Revenue, profit growth, and a major stock advance followed in 2002.

Overall, the 21 stocks in the G-2 Diagnostic Stock Index fell an unweighted average of 21% in the year ended Dec. 31, 2002, with 15 stocks falling in price and six rising. This compared with a 23% decline for the S&P 500 and a 32% drop for the Nasdaq.

After Immucor, the next best-performing IVD stock last year was **Biosite** (San Diego, CA), which jumped 85% to $34.02 per share as a result of booming demand for its Triage BNP test. **Bio-Rad Laboratories** (Hercules, CA) was up 22% to $38.70 per share as sales of the company's test for mad cow disease boomed in Europe and Japan.

Meanwhile, shareholders in **Careside** (Culver City, CA) were wiped out after the company filed for Chapter 11 bankruptcy reorganization on Oct. 18, 2002. And **Cygnus Inc.** (Redwood City, CA), which makes a wristwatch type of monitor for self-testing of blood glucose, plunged 87% to $0.66 per share last year as its product failed to register meaningful sales in the marketplace.

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 diagnostic test and equipment makers.

% price change, 52 weeks ended 12/31/02

	Price	% Chg
UP		
Bio-Rad	$38.70	22%
Biosite	34.02	85%
Igen	42.85	7%
Immucor	20.25	156%
Meridian	6.88	14%
Ventana	23.05	2%
DOWN		
Abbott Labs	40.00	-28%
Becton Dickinson	30.69	-7%
Beckman Coulter	29.52	-33%
Careside	0.00	-100%
Cholestech	5.91	-5%
Cygnus	0.66	-87%
Cytyc	10.20	-61%
Diagnostic Products	38.62	-12%
Diametrics	1.65	-71%
Digene	11.46	-61%
Inverness Medical	13.15	-27%
i-Stat	4.00	-49%
Johnson & Johnson	53.71	-9%
Quidel	3.46	-55%
TheraSense	8.35	-66%

G-2 Insider

Becton Dickinson has launched two new blood glucose monitoring products (*see page 1*) and declared it can carve out a 10% market share over the next five years. The worldwide blood glucose testing market currently totals approximately $4.5 billion and is growing by some 10%-15% annually. If this rate of growth continues, the market will double in size in five years and a 10% share would mean some $900 million in annual revenue to Becton Dickinson.

Some market watchers say Becton Dickinson faces a major challenge and are wondering if the company can meet its goal. The most formidable challenge may be instituting its unique marketing strategy. Becton Dickinson plans to utilize an internal salesforce of about 50 people and will also rely on its partnerships with Medtronic and Eli Lilly to help with marketing. In the past, these types of relationships have generally not been productive.

The largest competitors in blood glucose testing include Roche Diagnostics and Johnson & Johnson's Lifescan unit, and they compete with a devoted salesforce of around 300 people each for their diabetes products. Furthermore, both of these companies use very aggressive direct-to-consumer marketing campaigns that include television and magazine advertisements, but Becton Dickinson says it has no immediate plans for such advertising. Furthermore, Becton Dickinson says it plans to price its products similar to the market leaders, so the company will not be using low prices to gain its market share goals.

If there is any reason to have confidence that Becton Dickinson will reach its market share goal, it may be TheraSense, which introduced its blood glucose testing product in June 2000 and has already reached a 4% market share. But then again, TheraSense employs a direct salesforce of about 150 people and has spent heavily on direct-to-consumer advertising.

Company References

Bayer Diagnostics
914-631-8000

Becton Dickinson
201-847-6800

Bio-Rad 510-724-7000

Celera Diagnostics
510-749-4200

Cholestech 510-732-7200

Digene 301-944-7000

Immucor 770-441-2051

Metrika 408-524-2255

Novitron 617-527-9933

OraSure 503-641-6115

Roche Diagnostics
317-849-9350

Ventana 520-887-2155

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