Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

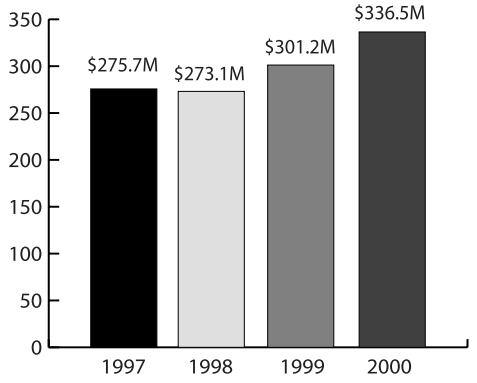
Will Cholesterol Testing Shift To The Point Of Care?

Diagnostic testing for cholesterol levels is a big and growing market. Medicare spending for it under Part B increased by 12% last year to $336.5 million, according to estimates by *Diagnostic Testing & Technology Report (DTTR)*. And this market growth should accelerate, given recent recommendations from the National Institutes of Health that all adults age 20 and older should get a complete lipid profile screening every five years.

Today, most testing for cholesterol levels is performed at centralized commercial or hospital labs with reagents supplied by the major IVD manufacturers. However, several smaller manufacturers, including Cholestech and Lifestream Technologies, have developed testing systems for use at the point of care or for over-the-counter sale. Proponents say that getting immediate results is convenient and improves compliance among patients on cholesterol-lowering drugs. Skeptics counter that high cholesterol does not pose an immediate risk, so a 2-3 day wait for test results from a central lab is fast enough.

For more on cholesterol point-of-care testing and profiles of leading vendors, see *Inside The Diagnostics Industry*, pp. 5-7.

Medicare Outlays: Cholesterol Tests*



*Includes all Part B allowed charges billed under CPT codes 80061 (lipid panel), 82465, 83718, 83721 & 84478.

Source: *DTTR* estimates from Medicare Part B Extract & Summary System files.

Roche Acquires Amira Medical

Roche Holding (Basel, Switzerland) has acquired Amira Medical Inc. (Scotts Valley, CA) for an undisclosed sum. Amira is a privately held company with 160 employees that specializes in blood glucose monitoring. The acquisition brings Roche a substantial patent portfolio of virtually pain-free blood sampling technology and integrated blood glucose systems.

Amira launched its first commercial product—the AtLast Blood Glucose System in January 2001. AtLast takes blood samples from

Continued on p. 2

▲ **Roche Acquires Amira,** *from page 1*

parts of the body that are less sensitive than the fingertips (*e.g.*, forearm, upper arm or thigh). Test strips are integrated with a hand-held reflectance meter that accepts samples of less than 3 µL. Starter kits, including the meter plus 25 test strips and lancets, sell for $62.95, and the company has been offering a mail-in rebate of $25, lowering the cost to $37.95.

The acquisition of Amira builds on lancing technology that Roche gained earlier this year through a licensing agreement with Kumetrix Inc. (Union City, CA). Privately held Kumetrix is developing a silicon micro-needle with a diameter smaller than that of a human hair.

Combining its internal research and development efforts with the technology newly acquired from Amira, plus technology licensed from Kumetrix, Roche aims to develop a pain-free blood glucose meter that integrates the measuring meter, lancet and testing strip. The system would involve meters that hold disposable cartridges combining the lancet and test strips. Patients would press the meter against the skin to draw minuscule samples of blood (*e.g.*, less than 100 nanoliters using Kumetrix's technology).

"There are no more acquisitions [needed]. We have everything in place now. What we have to do is our homework in terms of development of the product," a process that can take 3-4 years, Heino von Prondzynski, head of Roche's diagnostics division, told Reuters English News Service in a recent interview.

"It really gives us a significant advantage over the competition. Amira has the broadest intellectual property portfolio, so everybody else who would like to get access to integrated spot monitoring would have to approach us," von Prondzynski pointed out. He likened the deal to Roche's acquisition 12 years ago of PCR (polymerase chain reaction) technology that has become the fastest-growing division within Roche's diagnostics business.

Meanwhile, Roche reports that its worldwide diagnostics business generated revenue of 5.094 billion Swiss francs (US $3.062 billion) in the nine months ended Sept. 30, 2001, up 12% from 4.537 billion Swiss francs (US $2.727 billion) in the same period a year ago. Roche's glucose monitoring business, which includes the company's Accu-Chek line of products, now accounts for 34% of the sales of the diagnostics division and has grown by 18% year-to-date.

J&J Completes Purchase Of Inverness Diabetes Unit For $1.14B

Johnson & Johnson (New Brunswick, NJ) has completed its acquisition of the blood glucose monitoring business of Inverness Medical Technology (Waltham, MA). Inverness shareholders received $35 worth of J&J common stock for each Inverness share they owned, or a total of 19.6 million J&J shares worth $1.14 billion. Inverness shareholders now own 0.6% of the total outstanding J&J shares.

The glucose monitoring business purchased by J&J generated $4.695 million in EBITDA (earnings before interest, taxes, depreciation and amortization) in the three

Inverness At A Glance *($000)*

	3rd-Qtr 2001	3rd-Qtr 2000
Total revenue	$61,956	$42,043
—Glucose monitoring	50,297	29,407
—Women's health	9,130	10,002
—Clinical diagnostics	2,529	2,543
Operating income	1,803	4,680
Net income	526	3,078

Source: Inverness

months ended Sept. 30, 2001 vs. $5.335 million in the same period a year ago; revenue jumped 71% to $50.297 million. Based on these annualized figures, J&J paid 5.6 times revenue and 61 times EBITDA for the business.

The purchase caps a six-year relationship between the two companies. In 1995, Inverness and J&J-owned Lifescan (Milpitas, CA) entered into a development and global distribution agreement related to an electrochemical system for whole blood glucose meters and strips. Such a system requires a smaller sample size, has greater ease of use and provides results faster than J&J's in-house photometric technology. The first product from the partnership, One Touch FastTake, was launched in early 1998. A second-generation product, One Touch Ultra System, debuted late in 2000.

Inverness makes the FastTake test strips at its 103,500 square-foot plant in Inverness, Scotland; meters are subcontracted to a manufacturing firm in China. Lifescan markets the products worldwide. J&J reports that its Lifescan unit posted third-quarter revenue this year of $293 million, up 15% from $254 million in the same prior-year period. Sales were driven, the company says, by the One Touch Ultra blood glucose test system and could have been even higher if not for manufacturing capacity constraints.

Following the spin-off of its glucose monitoring business, Inverness has changed its name to Inverness Medical Innovations. Its remaining businesses include a women's health unit (nutritional supplements and over-the-counter pregnancy and ovulation tests) and a clinical diagnostics unit (point-of-care tests for HIV-1, HIV-2, hepatitis and chlamydia). As part of the terms of the transaction with J&J, Inverness Medical Innovations was left with $40 million in cash and zero debt. In third-quarter 2001, these remaining businesses generated a consolidated EBITDA of $1.262 million on revenue of $11.659 million vs. $2.429 million on revenue of $12.545 million in the same prior-year period. Ron Zwanziger remains chairman and chief executive of Inverness Medical Innovations, which now has 42 employees.

Lifescan To Pay Government $15 Million

The U.S. Justice Department has announced that Lifescan will pay the U.S. government $15 million to settle civil claims that it overcharged the Department of Veteran Affairs. The settlement resolves allegations that Lifescan failed to notify the VA that it had reduced prices to certain commercial customers below the cost negotiated by the agency. Under the government's contract with Lifescan, the company was required to notify the VA of any such reductions and pass them on to government customers. The overcharging was brought to the government's attention by Johnson & Johnson, which owns Lifescan, under the VA's voluntary disclosure program.

IMI International Seeks FDA Approval Of Cholesterol Skin Test

Cholesterol 1,2,3 is a painless test system that measures cholesterol in the skin and provides a quantifiable estimate of a patient's risk of developing heart disease. The test is a better predictor than traditional cholesterol tests which measure the amount of cholesterol circulating in the blood, according to IMI

IMI International Medical Innovations Inc. (Toronto, Canada) expects to gain approval from the U.S. Food & Drug Administration for its skin cholesterol test—Cholesterol 1,2,3—in the first quarter of 2002. The company's initial application to FDA was submitted in June 2001, and a revised submission will go to the agency by the end of the month, according to Andrew Weir, spokesman for IMI. The test was cleared for sale in Canada in January 2001.

IMI's test procedure involves placing a small foam pad with three wells (two for controls) on the palm of the hand. A drop of reagents is placed in the middle well and left for one minute. This drop contains digitonin, which binds to cholesterol in the top layer of skin. It also contains an enzyme (horseradish peroxidase) linked to the digitonin by a copolymer. After one minute, the area is blotted dry; some of the digitonin remains on the palm, bound to any cholesterol in the skin.

A second drop is then added, containing a substrate for the horseradish peroxidase enzyme. The enzyme bound to the skin reacts with the substrate and causes this second drop to turn a shade of blue. After two minutes, a hand-held spectrophotometer is placed over the drop and measures the precise blue color, which indicates skin cholesterol value.

The disposable foam pad and reagents for Cholesterol 1,2,3 are expected to sell for roughly $10 per test, according to Weir. IMI, which currently generates no revenue, reported a net loss of $1.725 million (Canadian) for the six months ended July 31, 2001; cash holdings totaled $9.415 million at the end of this period.

New Bill Seeks Medicare Coverage Of Cholesterol Screening

Preventive screening for cholesterol and other lipid levels would be covered by Medicare under legislation (HR 3278) introduced in the U.S. House of Representatives on Nov. 13 by Rep. Dave Camp (R-MI). The bill, entitled the "Medicare Cholesterol Screening Coverage Act of 2001," has 13 House co-sponsors and, if passed, would take effect on Jan. 1, 2002. The legislation does not specify the frequency of screening, but asks the U.S. Department of Health & Human Services to "establish standards … regarding the frequency and type of cholesterol and other blood lipid screening tests for individuals who do not otherwise qualify for coverage … based on established clinical diagnoses."

Cardiovascular diseases claim more than 950,000 lives each year—more than the next seven leading causes of death combined, according to the American Heart Association.

Medicare Part B reimbursement for cholesterol tests was an estimated $336.5 million in 2000. Assuming the entire Medicare population (34 million over age 65) were to receive a lipid panel each year (average Medicare payment of $18.51 per panel), this market could reach $629 million annually. However, with this session of Congress due to recess this month, passage of the bill seems unlikely in the near term.

The Outlook For Cholesterol Testing At The Point Of Care

The potential market for cholesterol testing was greatly expanded last May when the National Institutes of Health urged that all adults age 20 and older get a complete lipid profile to screen for high cholesterol every five years. Under NIH recommendations this profile includes total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.

Increased screening spurred by the NIH guidelines may make it more economically feasible for physicians to purchase a point-of-care (POC) cholesterol testing monitor to bring this testing in-house, rather than send it to a commercial or hospital lab. Cholestech, for example, charges $9.95 per test cassette for its CLIA-waived lipid panel, while Medicare carriers reimburse the panel at an average $18.51.

The increased screening is expected to substantially expand the number of Americans being treated for high cholesterol, including raising the number of people who are prescribed a cholesterol-lowering drug from about 13 million to about 36 million, according to NIH. In addition, NIH says that more screening could raise the number of Americans on dietary/exercise therapy from 52 million to 65 million.

This potential expansion of people on either dietary/exercise or drug therapy is expected to increase cholesterol testing to monitor compliance. Manufacturers of POC and home-use cholesterol monitors say their devices offer patients convenience and immediate feedback, thereby improving therapy compliance and clinical outcomes.

The NIH guidelines are also expected to spur more alliances between POC/home-use manufacturers and pharmaceutical companies that make cholesterol-lowering drugs. These pharma companies have an obvious economic interest in increasing the number of people who are prescribed their drugs and comply with the therapy regimen. Every patient prescribed a cholesterol-lowering drug generates approximately $500-$600 per year in revenue for the drug manufacturer. In total, pharma companies generated roughly $15 billion in worldwide revenue last year from the sale of cholesterol-lowering drugs. Not surprisingly, pharma companies have been eager financial supporters of cholesterol screening programs provided at health fairs, shopping malls, fitness clubs, etc.

Today, there are four IVD manufacturers with cholesterol testing analyzers on the market for physician office use or for over-the-counter sale.

Medicare Part B Payment For Cholesterol Tests

Code	*Description*	*Medicare Fee*
80061	Lipid panel	$18.51
82465	Total cholesterol	6.02
83718	HDL cholesterol	11.31
83721	LDL cholesterol	13.18
84478	Triglycerides	7.95
84460	Alanine aminotransferase (ALT)	7.32

Source: 2001 Lab Fee Schedule. The fee for 80061 is a national average; fees for the other codes are the national cap.

They are profiled below:

Cholestech Corp. (Hayward, CA) began marketing its LDX Analyzer in 1991 and has shipped more than 31,000 instruments to date. The LDX Analyzer is a telephone-sized instrument with CLIA-waived test cassettes for total cholesterol, a lipid profile, glucose and alanine aminotransferase (liver function) among others. The system performs tests on a single drop of whole blood and produces results in less than five minutes.

The LDX Analyzer has a list price of $1,995; prices for the disposable cassettes include $3.95 per total cholesterol, $9.95 per lipid panel, $4.50 per liver function and $10.95 per lipid profile plus glucose. In the fiscal year ended March 31, 2001, Cholestech sold more than 4.4 million cassettes (and in excess of 13 million over the past four fiscal years).

Cholestech employs 21 direct sales representatives and has distribution agreements with PSS World Medical and with General Medical, plus a recent agreement with Allegiance Healthcare (McGaw Park, IL). Target markets include the roughly 100,000 physician office laboratories throughout the country.

Cholestech also recently signed an agreement with Bayer Diagnostics to co-market its LDX Analyzer jointly with Bayer's DCA 2000+ Analyzer for diabetes management under a "Risk Management Program" that will run through the end of February 2002. The DCA 2000+ is a CLIA-waived device that provides both the hemoglobin A1c (HbA1c) and microalbumin-to-creatinine ratio in less than five minutes and lists for $2,500.

In addition, Cholestech operates a business unit named "WellCheck" that manages cholesterol and related testing services at health fairs sponsored by pharmaceutical companies which market cholesterol-lowering drugs. WellCheck is expected to perform more than 250,000 tests this year. Key contracts include Pfizer (which sells Lipitor), Bristol Myers Squibb (Pravachol) and Merck (Zocor and Mevacor).

Drugs Used To Lower Cholesterol

Pharma Co.	*Annual Cost Per Lipid Drugs*	*Patient*[1]
Pfizer	Lipitor	$599
Merck	Zocor	507
Bristol Myers	Pravachol	558
Novartis	Lescol	515
Merck	Mevacor	NA
AstraZeneca	Crestor[2]	NA

[1]Assumes typical 20 milligram dosage taken daily.
[2]Crestor is expected to be launched in mid-2002.

Source: *DTTR* with pricing information from *Planetdrugsdirect.com*

Warren Pinckert, president of Cholestech, tells *DTTR* that POC testing for cholesterol eliminates the time and cost of having a phlebotomist draw blood and reduces the potential risk of a sample mix-up at a central lab. Pinckert further notes that POC testing ensures that results are delivered at the "teachable moment," thereby "improving patient therapy compliance and the reaching of the therapeutic goal."

Pinckert points to the results of the *1999 Project Impact: Hyperlipidemia* study, which demonstrated average drug therapy compliance rates of more than 90% for 397 patients who were regularly monitored (monthly or quarterly) at 26 pharmacies for high lipid levels, using the LDX Analyzer over a two-year period. This compares with other recent studies showing that under traditional methods of care, only 40% remain on lipid-lowering medication after 12 months.

In the six months ended Sept. 28, 2001, Cholestech reported net income of $2.863 million vs. $978,000 in the same period a year ago; revenue increased 37% to $24.517 million.

Lifestream Technologies (Post Falls, ID) received clearance from the U.S. Food & Drug Administration for over-the-counter sale of its Lifestream Cholesterol Monitor in July 2000. The product is being marketed through the QVC television shopping network, The Sharper Image catalog and stores as well as Winn-Dixie, Eckerd, Longs, Sav-on and Osco drugstores.

The Lifestream Cholesterol Monitor has a suggested retail price of $129.95. The hand-held device tests total cholesterol levels from one drop of whole blood placed on disposable test strips. The strips are sold in packages of six for $19.95 (equal to $3.33 per test). Results are provided in about three minutes, and up to 200 results can be stored for trend analysis using a credit card-sized microprocessor that comes with the monitor.

The company markets a similar cholesterol monitor for use in physician offices at a list price of $299.95. This monitor includes a keypad to input 15 other cardiac risk factors (*e.g.*, age, weight, gender, tobacco use, etc.) to determine the likely overall cardiac condition of the patient.

Christopher Maus, chairman of Lifestream, says his company is focusing its marketing efforts on over-the-counter sales. Maus says at-home cholesterol monitors can provide motivation for patients to stick with cholesterol-lowering programs just as bathroom scales help those seeking to lose weight. He says Lifestream is in discussions with several pharmaceutical companies regarding possible marketing alliances.

In the three months ended Sept. 30, 2001, Lifestream recorded a net loss of $3.119 million vs. a net loss of $1.365 million in the same period a year ago; revenue increased to $879,845 from $26,974.

Polymer Technology Systems (Indianapolis, IN), a privately held company, makes a hand-held testing system named the BioScanner 2000. The system and five test cassettes (glucose, total cholesterol, HDL cholesterol, triglycerides and blood ketone levels) have received FDA clearance for both consumer and professional use. Company president Robert Huffstodt tells *DTTR* that clinical trials have begun for LDL cholesterol, creatinine and microalbumin tests. The BioScanner has a retail price of $149.95; test cassettes sell for approximately $3 each. The product is being sold over the Internet and at select Wal-Mart stores.

AccuTech, LLC (Vista, CA), a privately held company, launched its new "Cholestrak Plus" three-in-one cholesterol monitoring product in July 2001. The boxed set includes two complete, FDA-cleared rapid home total cholesterol tests (disposable analyzer and strips), plus one bottle of 80 "Super Red Rice Yeast" capsules which the company claims block the body's intake of cholesterol. The package has a suggested retail price of $44.50 and is being sold at Albertson's, CVS, Eckerd, Longs and Walgreens drugstores.

Hospital POC Testing Increasing Across-The-Board, Study Shows

The number of hospitals performing some portion of their testing at the point of care (POC) is growing for all disciplines, according to the *2001 U.S. Hospital Point-of-Care Survey* from Enterprise Analysis Corp. (EAC-Stamford, CT). "There has been some controversy about the rate of POC testing growth. Data from our survey suggest a double-digit growth rate," says Mark Hughes, an analyst at EAC.

The fast-growing segment of the market includes POC chemistry analyzers, now used by 36% of hospitals compared with only 18% two years ago. Penetration of POC blood gas and electrolyte analyzers has risen to 50% from 34% in 1999 and coagulation analyzers to 62% from 51%. All 584 hospitals participating in the latest survey said they use POC blood glucose monitors vs. 99% of 510 participants in the 1999 survey.

Satisfaction Rating With The POC Manufacturer, 2001

Overall	75
Purchase another	76
Service response time	75
Hotline support	77
Initial training	77
Sales rep responsiveness	68

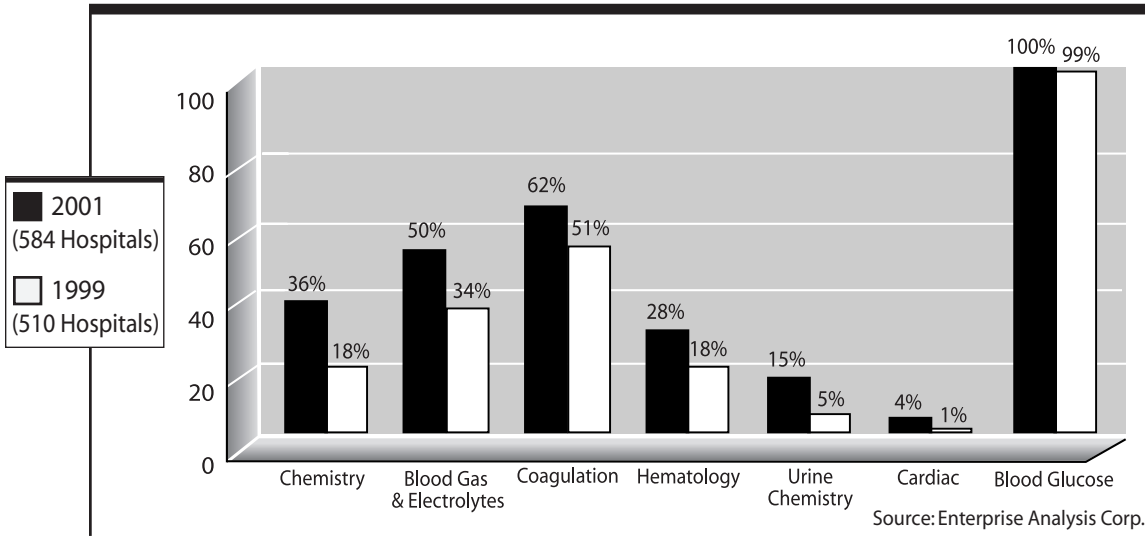
Ratings are on a scale of zero to 100.
Source: Enterprise Analysis Corp.

In terms of future growth, Hughes expects POC tests for myocardial infarction and congestive heart failure to quickly gain market share. He also anticipates that POC analyzers measuring platelet function aggregation (*e.g.*, Accumetrics' Ultegra system) will gain wider use. Hughes notes that the growing acceptability of POC testing is reflected in survey data indicating that 60% of hospitals now perform three or more types of POC testing vs. 40% in 1999.

The EAC report showed that hospital laboratory departments are deeply involved in the selection and management (accreditation and quality control) of POC equipment. Hospital labs are involved in the decision-making in more than 90% of the hospitals surveyed and are the sole decision-maker at 26% of hospitals.

On a scale of zero to 100, the 584 hospitals in the 2001 survey rated "overall satisfaction" with POC instruments at an average score of 75. "Sales representative responsiveness" got the lowest satisfaction rating (68). Hughes speculates that POC instruments may be a low priority for IVD sales reps—they may be more focused on sales and servicing of other "big ticket" items for central labs.

Percentage Of Hospitals With POC Instruments By Category



Source: Enterprise Analysis Corp.

Abbott Warns Physicians Of Limits Of B-hCG Test

Abbott Laboratories (Abbott Park, IL) has released a letter to thousands of physicians across the country warning them of the limitations of its B-hCG immunoassay. The B-hCG test is intended only for early pregnancy detection and "should not be used to diagnose any condition unrelated to pregnancy," said the letter dated November 2001 and signed by Dr. Frederick Axelrod, senior director of Abbott's division of medical and clinical affairs.

The Abbott test measures human chorionic gonadotropin, or hCG. Elevated hCG is recognized throughout the medical community as a reliable way to determine pregnancy. However, physicians also routinely interpret elevated hCG levels in the absence of pregnancy as evidence of trophoblast disease, a deadly form of cancer that starts in a women's reproductive system.

The letter comes on the heels of a recent jury decision in King County, WA, awarding $16.2 million to Jennifer Rufer, a 25-year-old woman who underwent a hysterectomy and had part of a lung removed after being incorrectly diagnosed with cancer based on the Abbott B-hCG test. Abbott and the University of Washington Medical Center (UWMC-Seattle), which treated Rufer, were found equally responsible and ordered to pay $8.1 million each.

Rufer's ordeal began in early 1998, when the Abbott test showed she had an elevated level of the hormone hCG, but was not pregnant. UWMC doctors repeated the test more than 40 times, and each time the result was positive. Rufer began several months of chemotherapy, underwent a hysterectomy and had part of her right lung removed. Finally, in January 1999, doctors realized she didn't have cancer. The jurors said Abbott "failed to warn" the UWMC doctors of the limitations of the test.

Abbott and UWMC each say they are appealing the June 29 decision. The UWMC doctors claim that Abbott's test was faulty; Abbott says the doctors should have done a simple urinalysis to confirm their diagnosis. Abbott is facing additional lawsuits based on similar claims from patients, including at least one class action.

Abbott's Purchase Of Vysis Clears Antitrust Review

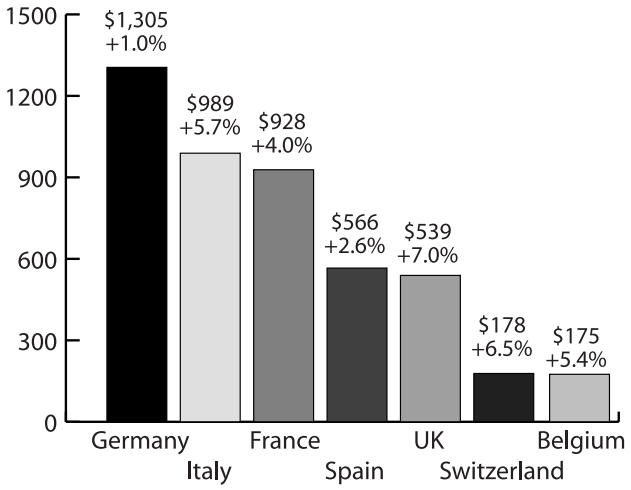
Abbott Laboratories says the antitrust waiting period for its pending $355 million acquisition of Vysis Inc. (Downers Grove, IL) has expired, thereby clearing the way for completion of the deal (*DTTR, Nov. '01, p. 3*). Abbott began a cash tender offer on Oct. 31, 2001 for all outstanding shares of Vysis at $30.50 per share. The tender offer was scheduled to have expired on midnight, Nov. 29. Completion of the tender is subject to receipt of at least 51% of the Vysis shares outstanding. Amoco Technology Co., a unit of BP Amoco (London, England), owns 65% of Vysis and has agreed to tender its stock.

Vysis makes the PathVysion HER-2 DNA Probe Kit, which detects amplification of the HER-2 gene in breast cancer patients. The company also makes the UroVysion Bladder Cancer Recurrence Kit, which detects genetic changes in bladder cancer cells found in urine.

European IVD Market Up 4.6% In 2000, Says IVD Makers Group

The European IVD market expanded by 4.6% at constant exchange rates to 6.295 billion euros (US $5.534 billion) in 2000, according to the latest market audit from the European Diagnostic Manufacturers Association (EDMA-Brussels, Belgium). "It seems that the market is recovering from the weak performance of the years 1992 to 1998, but it has still not reached the consistent growth that can support a growing industry sector. The result is continuing industry consolidation," stated EDMA in a press release.

Top 7 European IVD Markets, 2000*



*In U.S. millions, based on exchange rate of 1.00 euro = 0.8795 USD
Source: EDMA

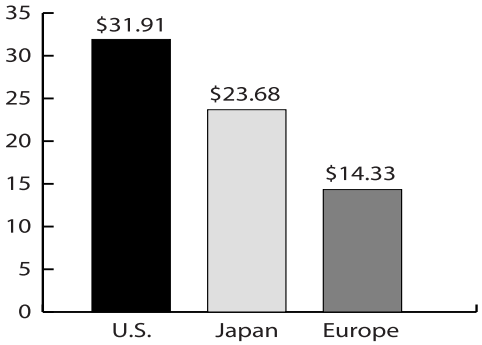
The fastest-growing market segment was rapid testing, which increased by 14.2% to 1.345 billion euros (US $1.182 billion). EDMA says patient self-testing for glucose and point-of-care tests for cardiac markers led this growth.

The core laboratory reagent market in Europe grew by only 1.3% to 4.083 billion euros (US $3.591 billion). EDMA indicated that test volume is rising, but is being offset by decreases in the average price per test. The strongest volume trends are occurring in nucleic acid-based tests and assays for D-dimer, osteoporosis and anemia. Instrument sales to core labs rose by 7.5% to 866 million euros (US $762 million).

The largest IVD market in Europe is Germany, where IVD sales in 2000 grew by just 1% at constant exchange rates to 1.485 billion euros (US $1.305 billion), according to EDMA. The next largest market is Italy, where IVD sales grew by 5.7% to 1.125 billion euros (US $989 million). Among the seven largest IVD markets in Europe, the United Kingdom grew the fastest last year—up 7% to 613 million euros (US $539 million).

The average amount spent on IVD tests in Europe in 2000 was 16.3 euros per person (US $14.33), according to EDMA. This compares to average spending of $31.91 per person in the U.S., based on an IVD market size of $8.98 billion (from Freedonia Group estimates) and a population of 281.4 million. In Japan, average spending is $23.68 per person, based on a market size of $3.05 billion (from Asiatic Research) and a population of 128.8 million. "Clearly, the amount spent on in vitro tests in Europe is too low," says EDMA.

Average IVD Test Spending Per Person, 2000 (U.S. $)



Source: *DTTR* from data from EDMA, Freedonia Group and Asiatic Research

IVD Stocks Dip 1% In Latest Four Weeks

Shares of Bayer, which trade on the German stock exchanges, have fallen 32% so far this year to 37.85 euros per share; Roche non-voting equity shares, which trade on the Zurich Stock Exchange, are down 24% year-to-date to 124.50 Swiss francs per share

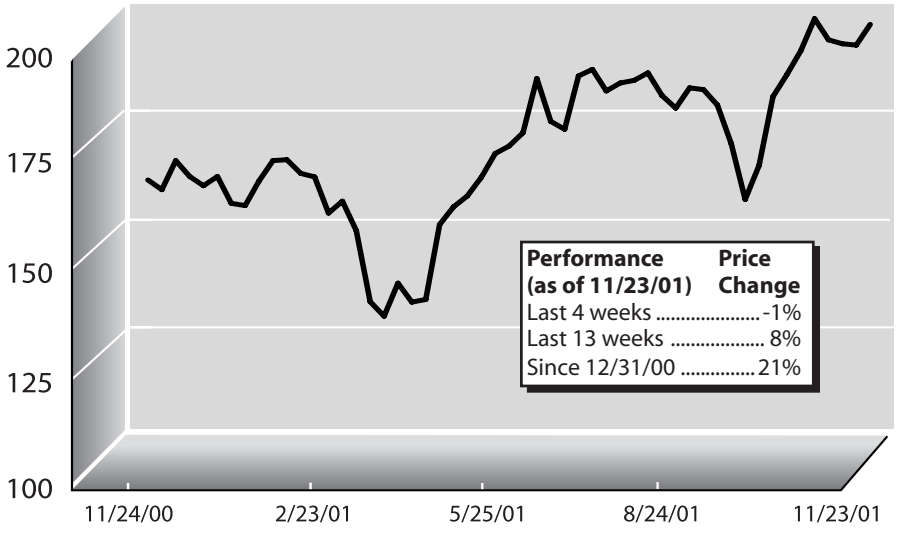
The G-2 Diagnostic Stock Index fell 1% in the four weeks ended Nov. 23. Eight stocks in our index went up in price, 12 declined. Since the start of the year, the index has risen 21%, while the S&P 500 is down 13% and the Nasdaq is down 23%.

Diametrics (St. Paul, MN) rose 38% to $5.75 per share, giving it a market capitalization of $154 million. The company reported a third-quarter loss of $924,591 vs. $487,271 in the same prior-year period; revenue fell 4% to $6.263 million. Diametrics also announced that Philips Medical Systems (a division of Royal Philips Electronics, based in Amsterdam, The Netherlands) is now the exclusive global distributor of Diametrics' IRMA Blood Analysis System. Agilent Technologies (Palo Alto, CA) had been the exclusive distributor, but Agilent assigned the agreement to Philips Medical Systems after Royal Philips Electronics acquired Agilent's Healthcare Solutions Group. IRMA is a point-of-care (POC) blood gas/electrolyte analyzer.

Meridian Bioscience (Cincinnati, OH) was up 25% for a market cap of $88 million. The company reported net income of $171,000 for the three months ended last Sept. 30 vs. net income of $1.908 million for the same period a year ago; revenue fell 3% to $13.501 million. Meridian also announced an agreement with Thermo Electron (Waltham, MA) to jointly distribute POC tests produced by each company. Meridian will distribute Thermo's POC tests for influenza and C. difficile bacteria. Thermo will market Meridian's POC tests for rotavirus (pediatric diarrhea) and E. coli.

Careside (Culver City, CA) fell 19% to $1.85 per share, giving it a market cap of $21 million. The company reported a third-quarter loss of $3.342 million vs. a loss of $4.103 million in the same period a year ago; revenue increased to $305,000 from $108,000. Careside says that more than 50 of its Careside Analyzers (for POC blood analysis) have been placed to date.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 20 diagnostic test and equipment makers.

% price change, 4 weeks ended 11/23/01

UP	Price	% Chg
Affymetrix	$37.13	17
Bio-Rad	62.50	2
Cholestech	23.62	18
Diametrics	5.75	38
Inverness Medical	39.44	4
Johnson & Johnson	60.97	4
Meridian	6.00	25
Quidel	6.67	7
DOWN		
Abbott Labs	53.95	-1
Beckman Coulter	42.32	-2
Becton Dickinson	32.30	-12
Biosite	16.00	-4
Calypte	0.21	-16
Careside	1.85	-19
Cygnus	5.51	-12
Cytyc	24.00	-15
Diagnostic Products	39.89	-17
Digene	32.00	-12
i-Stat	6.10	-6
Ventana	21.89	-5

G-2 Insider

"The largest driving force behind the movement toward point-of-care (POC) testing is economics," says Robin Felder, PhD, director of the Medical Automation Research Center at the University of Virginia in Charlottesville. "Ultimately, all high-volume tests will move from central laboratories to the point of care," he predicts.

Right now, many hospital labs are making decisions to keep certain testing in the central lab, based on the cost impact to their specific department—not to the overall hospital system, notes Felder. "Hospitals are very poor at analyzing the cost implications of any new technology whose benefits crossover to different [hospital] departments."

A comparison of the 15 cents in reagent costs for a test done in a central lab to the $3-$4 per cartridge cost for the typical POC test leads to an obvious decision. "Under this narrow view of costs, POC testing is a tough sell," says Felder. However, if other costs associated with core lab testing (sample handling, packaging, labeling and transport) are included in the equation, he says, the cost differential lessens.

To Felder, POC testing's greatest advantage is that it allows physicians to provide immediate therapy to patients, thereby reducing hospital stays and eliminating follow-up bureaucratic tasks. He estimates that 50% of the typical physician's time is spent on patient-related bureaucracy.

The system-wide economic advantages of POC testing are slowly being understood by hospital administrators, Felder notes, and that spells trouble for central labs. To replace testing that will move to the point of care, Felder believes central labs "better be gearing up fast for genetic testing and proteomics."

Company References

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