Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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CONTENTS

WASHINGTON G-2 REPORTS

Established 1979

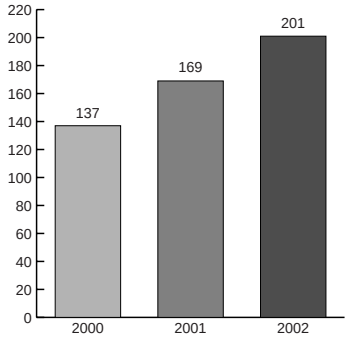
Upward Surge Seen In Lab Automation

Seven leading IVD vendors have installed laboratory automation systems at 201 hospital and independent lab facilities in the U.S. as of September 2002, according to an exclusive survey by *Diagnostic Testing & Technology Report* (*DTTR*). The survey further indicates that approximately 30 new labs per year are installing automation. Market leaders in this technology include Beckman Coulter (110 installed sites for a 55% market share) and Roche Diagnostics (40 sites for a 20% share).

Growth in the upcoming year is almost certain to accelerate since Bayer, Olympus and Dade Behring are each in the process of launching new automation products in the U.S.

Automation efforts to date have been focused on the most labor-intensive activity in the laboratory—the front end (*e.g.*, specimen accessioning, decapping, aliquoting, sorting). But vendors tell *DTTR* that demand is also growing for back-end functions (*e.g.*, re-capping, racking and storing tubes). For details, see *Inside The Diagnostics Industry*, pp. 5-7.

U.S. Lab Automation: Installed Sites*



*Totals include total lab automation and front-end installations.
Source: *DTTR* based on surveys in Dec. 2000 and Sept. 2002

PharmaNetics Gets FDA Clearance For Enox Test

In yet another example of the growing ties between diagnostic and pharmaceutical products, PharmaNetics Inc. (Raleigh, NC) has received clearance from the U.S. Food & Drug Administration to market its Enox Test, a point-of-care test that measures the anticoagulant effects of the blood-thinning drug, enoxaparin sodium. The drug, approved in the U.S. and Canada since 1993, is used to treat deep vein thrombosis (blood-clotting in the veins) as well as complications associated with unstable angina (a condition that precedes a heart attack) and full-blown heart attack. The Enox Test will be used to determine whether a patient's dosage of the blood-thinner needs to be adjusted.

Continued on p. 2

▲ **PharmaNetics Get FDA Clearance,** *from page 1*

The Enox Test was developed by PharmaNetics in collaboration with Aventis Pharmaceuticals Inc., the U.S. prescription drug business of Aventis (Schiltigheim, France). Aventis developed and markets enoxaparin, which its sells under the brand name Lovenox in the U.S. and Clexane throughout the rest of the world. Last year, Aventis generated an estimated $1 billion from sales of Lovenox and Clexane.

As a result of the Enox approval, PharmaNetics will receive a $1.5 million milestone payment from Aventis. It will get another $1.5 million payment from Aventis upon market launch of the test, expected in early 2003.

Mike Riddle, executive vice president of sales & marketing at PharmaNetics, says the company has contracted with Professional Detailing Inc. (PDI-Upper Saddle River, NJ) to help recruit a sales and technical service group of 18 representatives. The sales force will be employed by PDI and will be trained specifically to promote the Enox Test to cardiologists and intensive care specialists. Riddle says the sales force should be fully deployed by January 2003.

In the interim, according to Riddle, PharmaNetics plans to beta-test the Enox Test at 100 cardiac catheterization labs across the U.S. He estimates the total U.S. market for cardiac interventions at about 2.5 million tests annually. This estimate is derived by assuming that the approximately one million patients per year who have angioplasty would get two or three Enox Tests per year. PharmaNetics will sell the kits for $25-$30 each, indicating a total U.S. market potential of roughly $62-$75 million.

The Enox Test will run on PharmaNetics' Thrombolytic Assessment System (TAS), a telephone-sized instrument weighing about four pounds. Other tests that have been FDA-cleared to run on the system include prothrombin time, activated partial thromboplastin time and heparin management. Bayer Diagnostics (Tarrytown, NY), which owns 20% of PharmaNetics, is the global distributor of TAS and markets the product as the Rapidpoint Coag Analyzer.

In the three months ended June 30, 2002, PharmaNetics reported a net loss of $2.426 million vs. a net loss of $2.477 million in the same period a year earlier; revenue was $798,000 vs. $1.322 million. Cash holdings totaled $9.5 million as of June 30.

Safeguard Scientifics Takes Control Of ChromaVision

In desperate need of financing, ChromaVision (San Juan Capistrano, CA) has completed a refinancing transaction that makes investment firm Safeguard Scientifics (Wayne, PA) a majority owner with the power to elect all directors of the company. ChromaVision says it has also given Safeguard contractual rights which will enable it to exercise significant control over the company. ChromaVision's main product is the Automated Cellular Imaging System, an automated microscopy system intended for use at anatomic pathology labs to detect, count and classify cells. The U.S. Food & Drug Administration cleared it in July 1999, and 165 systems were in place as of June 30, 2002.

Under the deal, Safeguard purchased all of ChromaVision's outstanding Series D preferred stock for approximately $11 million, then immediately converted it into 7.142 million common shares of ChromaVision at a conversion price of $1.585 per share. In a related transaction, Safeguard has purchased 4.4 million common shares of ChromaVision for $7 million. Safeguard now holds 56% equity ownership in ChromaVision. Previously, it held a 32% stake.

ChromaVision At A Glance *($000)*

	2Q02	2Q01
Revenue	$2,194	$949
Net income	-3,372	-3,700
Cash holdings	6,418	2,722
Stockholder equity	3,965	6,320

Source: ChromaVision

The conversion of the Series D preferred stock eliminates ChromaVision's obligation to redeem the stock in July 2004 for $11.23 million and its obligation to pay the 5%-per-year preferred stock dividend. In addition, because of the common stock sale to Safeguard, ChromaVision has added almost $7 million to its working capital balance.

In the three months ended June 30, 2002, ChromaVision reported a net loss of $3.4 million (the cash burn was $2.5 million) vs. a net loss of $3.7 million in the same period a year earlier; revenue increased to $2.2 million from $949,423.

FDA To Create New Office To Regulate IVD Devices

The Center for Devices & Radiological Health (CDRH) at the U.S. Food & Drug Administration has announced plans to establish a new office-level unit called the Office for In Vitro Diagnostic Device Evaluation & Safety. The office will be formed this fall and will be headed by Steven Gutman, MD, who is currently director of clinical laboratory devices for CDRH.

The new office has been designed to consolidate all premarket, compliance and postmarket IVD regulatory activity into a single functional unit. CDRH says the goal is to develop a seamless, interactive regulatory process consistent with the total product life cycle. In doing so, CDRH aims to carry out its regulatory functions in a "least burdensome" manner with "decreased response times for all parts of the regulatory process."

FDA Clears A1c Test Collection Kit For OTC Sale

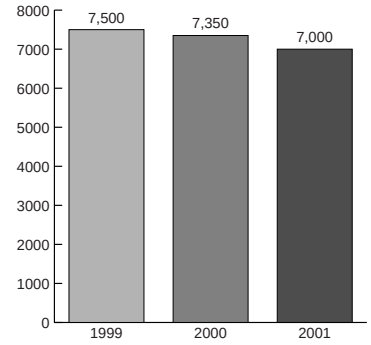
Diabetes Technologies Inc. (DTI-Thomasville, GA) has received clearance from the U.S. Food & Drug Administration for over-the-counter sale of its AccuBase A1c Test Collection Kit. Hemoglobin A1c testing provides a measure of a patient's average glucose level over the prior 60-90 days. The AccuBase A1c kit allows diabetes patients to collect a non-fasting, fingerstick blood sample at home, then mail the specimen to a designated laboratory for testing. Patients get the test results in about 5-7 days. DTI, a privately held company, is direct-marketing the kits for $20 through a toll-free telephone number.

Competitors include Metrika Inc. (Sunnyvale, CA), which sells its A1cNow disposable monitor for at-home testing (with a prescription) for $22.95 per test, and Biosafe Laboratories (Lincolnshire, IL), which sells an A1c home specimen collection kit for $29.95.

Bayer To Cut 4,700 More Jobs Worldwide

Bayer Group (Leverkusen, Germany) says it will cut 4,700 more jobs—or about 4% of its global workforce of 127,000—by 2005. The latest planned cuts are on top of 10,300 job reductions over the next four years that Bayer had previously announced. Those cuts—including 1,800 positions already eliminated—came largely at Bayer Pharmaceuticals last year when the company was forced to withdraw its cholesterol-lowering drug Lipobay/Baycol after finding that the drug may have been linked to patient deaths.

Bayer Diagnostics: Pruning The Staff



Source: Bayer

A spokeswoman at Bayer Diagnostics (Tarrytown, NY) tells *DTTR* that the number of cuts, if any, for the diagnostics group has not yet been revealed. Over the past two years, Bayer Diagnostics has reduced its workforce by 7% to 7,000 employees. A statement from Bayer Group said that 40% of the latest announced cuts will be made in Germany, but did not specify where the rest of the cuts would be made.

Overall, Bayer Group reported first-half 2002 net income of 816 million euros (US $798M), down from 1.006 billion euros for the same period a year ago; revenue was down 8% to 14.737 billion euros (US $14.4B).

PathVysion Test Approved For Herceptin Product Labeling

The U.S. Food & Drug Administration has given Genentech (South San Francisco, CA) approval to include information about the PathVysion breast cancer gene-detection test in its product labeling insert for Herceptin, which is used to treat metastatic breast cancer in patients who overexpress HER2 protein. The PathVysion test uses FISH (fluorescence in situ hybridization) to identify women who are HER2-positive and candidates for treatment with Herceptin.

Until now, the Herceptin package insert had included only information about immunohistochemistry (IHC) testing methods. The HercepTest, made by DakoCytomation, is the most common IHC test for determining HER2 status.

The PathVysion FISH assay is made by Vysis Inc. (Downers Grove, IL), which was acquired by Abbott Laboratories in December 2001.

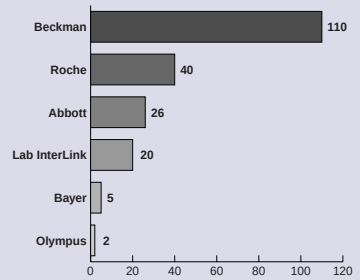
U.S. Military Orders 20 More Abaxis Piccolo Analyzers

Abaxis Inc. (Union City, CA) has received an order from the Defense Logistics Agency for 20 Abaxis Piccolo blood chemistry analyzers for the U.S. military. This order brings to 62 the number of Piccolo analyzers purchased by the U.S. armed forces over the past six months. The Piccolo is a portable instrument that provides test results from whole blood in less than 14 minutes. Test cartridges include several different blood chemistry panels and a basic metabolic panel. Abaxis generates approximately $13-$14 on average per panel cartridge sold.

Labs Pursue Productivity Gains Through Automation

Laboratory budgets across the board are being squeezed tighter and tighter due to a convergence of several critical factors: rising testing volume fueled by an growing population base and a wealth of newly developed tests, and a shrinking supply of qualified laboratory personnel that is not likely to be reversed for some time. To meet staffing needs, labs are raising salary levels and offering sign-on bonuses. Still, most labs report vacancy rates of more than 10% and are forced to require current staff to work overtime.

U.S. Lab Automation: Installed Sites*



*Includes total lab and front-end automation
Source: *DTTR* from companies

As lab budgets get devoured by higher wages, sign-on bonuses and overtime pay, more labs are turning to automation to improve productivity. Most IVD vendors are deploying their automation products as loss-leaders with the aim of locking-in clients to long-term chemistry and immunoassay reagent contracts. On the downside, this limits a client's ability to take advantage of new instrument technology or negotiate better reagent contracts in future years. On the upside, a client generally has lower initial costs to get an automated system up and running and gets quicker installations.

Here's an update on the latest developments at seven leading automation vendors.

Beckman Coulter (Fullerton, CA) has installed its automation products at 110 sites, up from 85 in December 2000. New installations include Sacred Heart Hospital (Pensacola, FL), Baptist Hospital of East Tennessee (Knoxville) and Northwestern Memorial (Chicago, IL). The company's lead product is its Power Processor (lists for $450,000), which has throughput of up to 300 tubes per hour.

Ron Berman, director of sales & marketing for lab automation, says that while the greatest interest from hospital customers remains automating the front end, more and more labs are now automating the back end (*e.g.*, re-capping, racking and storing tubes). Back-end automation lowers labor costs associated with locating tubes that need to be re-tested. In total, Berman estimates, manual back-end work represents about 25%-30% of the typical lab's overall labor costs.

The majority of Beckman's new automation installations are at current Beckman clients, Berman says, but some 30%-35% represent instrument conversions from competing IVD vendors.

Roche Diagnostics (Indianapolis, IN) has installed its automation systems at 40 laboratories in the U.S., including 15 sites with its Modular Pre-Analytics (MPA) total lab automation system. Recent MPA installations include William Beaumont Hospital (Royal Oak, MI) and Saint Elizabeth Health Center (Youngstown, OH). However, Chris Demeris, marketing manager for laboratory integration, says the company's most popular task-targeted products are PSD I for sorting, decapping and archiving and VS II for aliquoting and archiving.

Demeris says hospital lab budgets remain under pressure and anticipates this will intensify in coming years. "Capital spending is tight….Customers want fast turnaround on their investments."

Roche's automation products are designed to work only with its own analyzers. Demeris says that what customers give up in terms of flexibility, they gain back in terms of efficiency. Installation of Roche automation systems can typically be completed in about two weeks, he points out, adding that Roche has smoothed the process of interfacing with existing laboratory information systems by hiring an IT services group, Data Innovations (Burlington, VT), to help with installations.

Lab InterLink (Omaha, NE) has completed the "best of breed" integration of software and hardware from its original Lab-Frame system and the Labotix RRush system. The resulting product, called Lab-Frame Trax 2000, was formally introduced to the marketplace at the recent American Association for Clinical Chemistry convention in Florida.

Lab InterLink's automation systems are installed at 20 sites in the U.S., according to Mary Newcomb, chief operating officer. Roughly half of these are through Ortho-Clinical Diagnostics' enGen product. OCD has non-exclusive rights to market the Lab InterLink product line under the enGen trademark. Lab-InterLink has four installations outside the U.S. The largest installed system is at the Maccabi Health Services laboratory in Rehovot, Israel.

Lab InterLink has the only truly "open" automation system platform on the market, Newcomb says, compared with most instrument vendors that provide closed automation systems to compete for market share in reagents. She notes that the company's systems can interface with any instrument vendor that is cooperative and willing to comply with the lab automation standards formulated by the National Committee for Clinical Laboratory Standards.

Bayer Diagnostics (Tarrytown, NY) has installed its Advia WorkCell Modular Automation System at 32 sites worldwide, including five in the U.S. Rodney Day, marketing director for lab automation, says Bayer has contracts to install Advia WorkCell at another six U.S. hospitals within the next 60 days. The majority of new installations are replacing competing products, he adds.

Advia Workcell, launched in the U.S. in June at a list price of $300,000-$600,000, integrates front-end processing with Bayer's Advia Centaur immunoassay system and the Advia 1650 chemistry system. Throughput is as high as 3,300 chemistry tests per hour and 500 immunoassay tests per hour. The first U.S. installation of Advia WorkCell was at Abington Memorial Hospital (Abington, PA).

Bayer also has 10 worldwide installations of its Advia LabCell TLA (total lab automation) system, including one in the U.S. at Memorial-Sloan Kettering in New York City.

Abbott Laboratories (Abbott Park, IL) began marketing its Tecan Genesis FE 500 in the U.S. in July 2000 and now has installations at 26 sites, according to Brian Syverson, product manager for U.S. marketing. The system automates sorting, centrifuging, decapping, serum volume verification, aliquoting, bar code labeling and racking of samples at a rate of up to 500 tubes per hour. A key benefit of the system, says Syverson, is its combination of preanalytical capabilities and small footprint (approximately 7.5 feet by 4 feet). Hospital labs that beta-tested the system include Evanston Northwestern Memorial Hospital (Evanston, IL) and Penn State University Hospital-Hershey Medical Center.

Some IVD vendors are aiming to make their systems as flexible as possible because lab customers are becoming more hesitant about tying themselves down to just one IVD vendor

Olympus America (Melville, NY) recently completed beta-testing of its OLA1500 system at two laboratories in the U.S. earlier this year, according to Stephen Wasserman, group vice president for diagnostic systems. The OLA1500 operates as a stand-alone unit that sorts, decaps and archives up to 1,500 samples per hour. Wasserman says the system sorts tubes by either bar code or by tube cap color. At a list price of $250,000 per unit, the OLA1500 is intended for use at blood banks, large hospitals and independent labs.

The company plans to roll out its OLA2500 system in the U.S. in a matter of weeks, Wasserman notes. This system, which was shown at the recent AACC convention, is already in use at approximately 80 laboratories in Europe. The OLA2500 sorts by bar code, decaps, aliquots and archives, and is intended for use at independent labs and at hospitals with 250 or more beds.

Wasserman says Olympus is working with Lab InterLink to bring to market a "universal interface" robotic unit. The unit is designed to connect Olympus analyzers with any manufacturer's lab automation system as long as it follows NCCLS protocols. Wasserman says the robotic unit is already in use at a laboratory in Israel and will soon be installed at a U.S. site for beta-testing.

Dade Behring (Deerfield, IL) has installed its StreamLab automation system at two sites in Italy. The first U.S. installation will be completed within the next few weeks at Methodist Hospital (Peoria, IL), according to Bob Brightfelt, president of global research and development.

Brightfelt says StreamLab will have a list price of $400,000-$500,000 and can process up to 2,000 tests per hour when connected to four of Dade's Dimension RxL chemistry analyzers. StreamLab eliminates the need to split samples, giving labs more flexibility, according to Brightfelt. He notes that the Dimension RxL with its unique sample transfer module and internal aliquoting capability allows StreamLab to immediately release the primary tube to the next destination.

StreamLab will be capable of linking to the Immulite 2000, a high-volume immunoassay analyzer made by Diagnostic Products Corp. (Los Angeles, CA). Brightfelt says Dade has discussed similar arrangements with other companies. Dade also has talked, he adds, with Lab InterLink about creating smoother linkages between Dade's analyzers and Lab InterLink's automation systems.

LGC Says POC Genetic Test Could Be On Market Within A Year

LGC Ltd. (London, England) is working with Agile Technologies Ltd. to produce a new genetic testing analyzer for point-of-care use that could be commercially available within a year, according to Paul Debenham, PhD, director of life sciences at LGC.

Speaking at the annual meeting of the British Association for the Advancement of Science in Leicester, England on Sept. 13, Debenham said the instrument will be about the size of a shoebox and will provide DNA test results from saliva, blood or urine samples in about 15-25 minutes. The instrument will utilize LGC's DNA probe technology called HyBeacons and Agile Technologies' novel ultra rapid thermal cycling technology. Further details about the technology were not available.

Agile Technologies is building a prototype, which will likely sell for about 4,000 pounds (US $6,200), according to Debenham. He envisions that the instrument could be used at physician office locations or during surgeries for a wide range of testing needs, including infectious diseases and pharmacogenomics.

LGC was formerly Britain's Laboratory of the Government Chemist which was privatized in 1996. The company is the largest independent laboratory in the U.K., with 600 employees and four major lab facilities (plus five more throughout the rest of Europe). Annual revenue at LGC exceeds 27 million pounds (US $42 million).

FDA Clears Hutchinson Cancer Research Center's Lupus Test

Hutchinson has filed for patent protection and is actively seeking a commercial partner to help bring the lupus test to market, according to spokeswoman Kristen Woodward

The U.S. Food & Drug Administration has cleared a new screening test for systemic lupus erythematosis (SLE) developed by researchers at the Fred Hutchinson Cancer Research Center in Seattle, WA. The test is expected to pick up the 20% of SLE cases that fall through the cracks because they cannot be detected by the most widely used standard screening test (antinuclear antibody test).

Lupus is a chronic disorder in which a person's immune system attacks the body. The Lupus Foundation of America (Rockville, MD) estimates that 1.4 million Americans (mostly women) have it. SLE is the most serious and common form of the disease, which causes inflammation of connective tissue throughout the body, from the joints to the kidneys. Because symptoms range from skin rash and mild fatigue to organ failure, diagnosis can be difficult.

While the majority of lupus patients produce antibodies to their own tissue that can be detected by the antinuclear antibody test, about one-fifth of patients do not make such antibodies and often go undiagnosed, explains Kristen Woodward, spokeswoman at Hutchinson. Woodward says Hutchinson's test, called the anti-SR protein antibody assay, helps close that diagnostic gap.

Funding for development of the test came from the National Institutes of Health and Fred Hutchinson's New Technology Development Fund.

LipoScience To Attempt IPO Despite Loss Of Largest Client

LipoScience Inc. (Raleigh, NC) is moving forward with plans for an initial public offering despite the loss of its largest client, Quest Diagnostics (Teterboro, NJ).

In a recent filing with the Securities & Exchange Commission, LipoScience said it plans to sell five million shares at an estimated price of $14-$16 apiece. If completed at the high end of this range, LipoScience will raise gross proceeds of $80 million and have an initial market capitalization of about $233 million (based on 14.6 million total shares outstanding). Proceeds from the IPO will be used, the company says, for sales & marketing expansion and for possible acquisitions.

The company, which was profiled in the April 2002 issue of *DTTR*, makes a test named the NMR LipoProfile that gauges a person's risk of cardiovascular disease. In the six months ended June 30, 2002, LipoScience recorded a net loss of $3.293 million vs. a net loss of $1.248 million in the same period last year; revenue jumped from $6.893 million to $14.083 million. LipoScience performed a total of 200,000 tests in the six months ended June 30, 2002, including 165,000 NMR tests.

LipoScience's clinical laboratory in Raleigh is the only lab that performs the NMR LipoProfile, which is sold at an average price of $77 across all payers (including governmental, managed care and lab customers).

However, the company revealed in its SEC filing that Quest, which accounts for 27% of its total revenue, has chosen to stop offering the NMR LipoProfile and will instead use a competing test. LipoScience says it hopes to make up the lost revenue from increased sales to other customers.

BioMerieux, Pierre Fabre Have Officially Parted Ways

BioMerieux (Marcy-l'Etoile, France) and Pierre Fabre (Castres, France), a pharmaceutical and cosmetics firm, have officially split back into two separate companies. The "de-merger" became effective June 27, following shareholder approval from each company. A breakup had been anticipated (*DTTR, May 02, p. 3*) because the two were never able to achieve any synergies following their merger in January 2001. BioMerieux says Alain Merieux will remain its chairman. He retains a majority ownership stake. Minority stakes are held by Wendel Investissement (formerly CGIP) and the Dassault Group.

The de-merger will have zero impact on BioMerieux's U.S. operations, according to Bob Bokerman, manager of marketing & communications for BioMerieux (Durham, NC). Bokerman says BioMerieux employs about 1,500 people and will generate approximately $250 million of revenue in the U.S. this year (worldwide employment is 5,400 and revenue is about $825 million). He notes that after BioMerieux's $263 million acquisition of Organon Teknika in July 2001, the company moved most of its U.S. operations from St. Louis, MO to Organon's base in Durham, NC.

DakoCytomation Acquires CytoLogix's Artisan Business

DakoCytomation (Copenhagen, Denmark) has purchased the Artisan tissue-staining instrument business from CytoLogix Corp. (Cambridge, MA) for an undisclosed sum. Artisan had been CytoLogix's primary product, and its sale indicates that the company may soon shut down operations. Stephanie Marrus, spokeswoman for CytoLogix, says the company's board is currently mulling its options.

Privately held CytoLogix was founded in 1996 by its president Steven Bogen, MD, PhD. It has raised a total of $40 million to date, including $26 million from a private equity placement that closed in January 2001 and included investments from EGS Healthcare Capital Partners, Société Financière D'Innovation (SOFINOV) and Oxford Bioscience Partners.

The money was to be used by CytoLogix for new product development, manufacturing and international expansion. But the company was never able to launch any new products of significance, and sales of its Artisan product never expanded outside the U.S.

Meanwhile, CytoLogix is continuing its long-running, far-reaching legal battle with Ventana Medical Systems (Tucson, AZ). Included in the various lawsuits is an allegation by CytoLogix that Ventana improperly obtained a confidential business plan and used information from the document to its advantage. CytoLogix further alleges that Ventana infringes on its slide-heating patents through the manufacture and sale of the Benchmark and Discovery instruments. Gitte Sjorslev, spokeswoman for DakoCytomation, tells *DTTR* that DakoCytomation will not be involved in these ongoing legal actions.

To increase the customer base for Artisan, Sjorslev says DakoCytomation will use its existing salesforce. Plans include getting a CE marking so the instrument can be introduced in Europe where DakoCytomation has a particularly strong presence, according to Sjorslev. She says DakoCytomation will retain the CytoLogix facility in Cambridge, along with a number of CytoLogix employees in research & development and sales & marketing.

Hycor Retains Seidler Companies To Find "Strategic Alternatives"

Hycor Biomedical (Garden Grove, CA) has hired The Seidler Companies (Los Angeles, CA) to assist in ongoing efforts to identify strategic alternatives, including product distribution deals and possible divestiture. Hycor generates about 56% of its revenue from its Kova Microscopic Urinalysis System, 29% from allergy diagnostics, 9% from autoimmune diagnostics and the rest from "other" diagnostics.

Hycor In Brief *($000)*

	2Q02	2Q01
Revenue	$4,694	$4,290
Net income	408	166
Long-term debt	1,000	11
Cash & securities	4,157	2,097

Source: Hycor

In the three months ended June 30, 2002, Hycor reported net income of $408,343 vs. $165,766 in the same period a year ago; revenue was up 9% to $4.694 million.

IVD Stocks Rise 9% In Latest Four Weeks

Roche non-voting equity shares, which trade on the Zurich stock exchange, are down 12% to 104.25 Swiss francs year-to-date. Shares of Bayer, which trade on the German stock exchanges, are down 39% at 21.88 euros per share year-to-date

The 21 stocks in the G-2 Diagnostic Stock Index were up an unweighted average of 9% in the four weeks ended Sept. 6, 2002, with 14 stocks rising in price, two unchanged and five falling. Year-to-date, the G-2 Index has fallen 22%, compared with a 21% decline for the S&P 500 and a 32% drop for the Nasdaq.

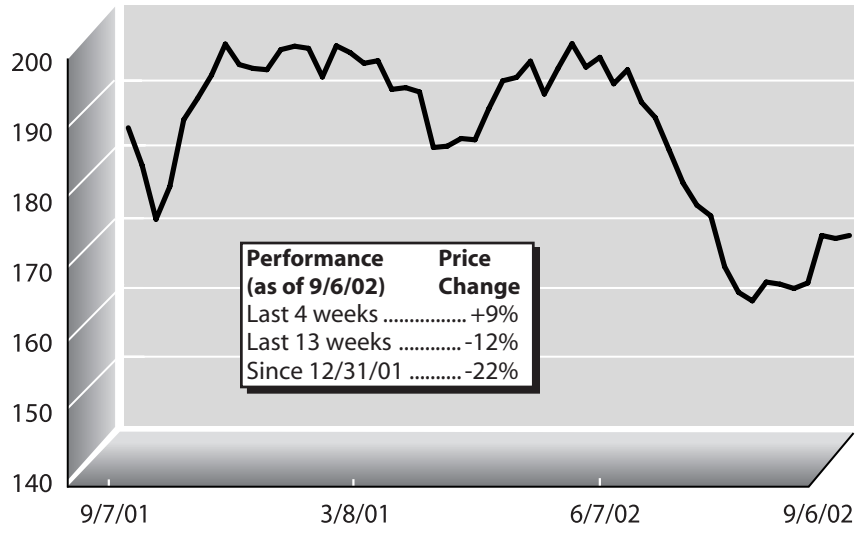
Shares of **Cygnus** (Redwood City, CA) rose 68% to $1.66 for a market capitalization of $63 million. The company's GlucoWatch G2 Biographer recently received clearance from the U.S. Food & Drug Administration for prescription use by children and adolescents (ages 7-17). GlucoWatch is worn on the wrist and automatically displays glucose levels continuously up to every 10 minutes. It collects glucose non-invasively through the skin, not from blood. The device, cleared by FDA for adult use in April 2002, is being marketed in the U.S. by Sankyo Pharma (Parsippany, NJ) with a specialty salesforce of 100.

Digene (Gaithersburg, MD) was up 21% to $8.26 per share for a market cap of $149 million. The company recently announced that it has completed establishment of direct sales units in Germany and Switzerland, thus expanding its presence in Europe to 18 countries. Previously, Digene's products were marketed in Europe by Roche and Abbott.

Among the other rising stocks: **Immucor** (Norcross, GA) was up 29% to $27.08 per share for a market cap of $222 million; **Cholestech** (Hayward, CA) was up 15% to $13.96 per share for a market cap of $190 million.

i-Stat Corp. (East Windsor, NJ) tumbled 29% to $2.26 per share for a market cap of $45 million. The stock continues to suffer from news that it is ending its distribution agreement with Abbott (*DTTR, Sept. 02, p. 10*).

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, 4 weeks ended 9/06/02

	PRICE	% CHG
UP		
Beckman Coulter	$40.35	+4
Becton Dickinson	30.45	+2
Bio-Rad	44.25	+6
Biosite	20.37	+2
Careside	0.08	+14
Cholestech	13.96	+15
Cygnus	1.66	+68
Diametrics	3.50	+30
Digene	8.26	+21
Diagnostic Products	40.70	+10
Immucor	27.08	+29
Johnson & Johnson	54.92	+1
TheraSense	15.76	+5
Ventana	21.26	+1
UNCHANGED		
Igen	32.16	0
Inverness Medical	16.00	0
DOWN		
Abbott Labs	37.50	-7
Cytyc	9.70	-2
i-Stat	2.26	-29
Meridian	5.90	-4
Quidel	5.15	-4

G-2 Insider

Next big thing in IVD sales & marketing?.....Some industry experts predict that as more and more high-priced genetic tests are introduced, the sales & marketing practices of IVD companies will increasingly mimic those used by pharmaceutical companies. Introduction of new point-of-care testing technologies is also expected to push this trend.

Like the highly successful marketing programs that Big Pharma has fielded for drugs such as Viagra, Prozac and Rogaine, some IVD companies are trying to create branded products that either patients or office-based physicians will request by name. This represents a dramatic shift from the traditional IVD corporate focus on sale of routine reagents to hospital labs.

To capitalize on this trend, Professional Detailing Inc. (PDI-Upper Saddle River, NJ) last year formed a new division called PDI Medical Devices & Diagnostics. The new division has 110 FTEs and has already won marketing contracts with Becton Dickinson, Roche, certain Johnson & Johnson divisions and PharmaNetics (*see this issue, pp. 1-2*).

Lloyd Fishman, general manager for PDI Medical Devices & Diagnostics, tells *DTTR* that the interest level in its services is high among both large and small diagnostics companies. This year, the division is expected to generate $10-$15 million in revenue.

PDI, which employs more than 3,000 sales & marketing staff, previously had focused solely on providing product-specific support to drug companies like Pfizer and Allergan. Total revenue for PDI in 2001 was $697 million. Services offered by PDI include sales support, recruiting and management along with medical education programs for target audiences.

Company References

Abaxis 510-675-6500
Abbott Labs 847-937-6100
Bayer Diagnostics 914-631-8000
Beckman Coulter 714-871-4848
ChromaVision 888-443-3310
CytoLogix 888-425-6449
Dade Behring 847-267-5300
Diabetes Technologies 888-872-2443
Hycor Biomedical 714-933-3000
Lab InterLink 402-595-3767
LipoScience 877-547-6837
Olympus America 631-844-5690
PharmaNetics 919-582-2600
Roche Diagnostics 317-849-9350

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