Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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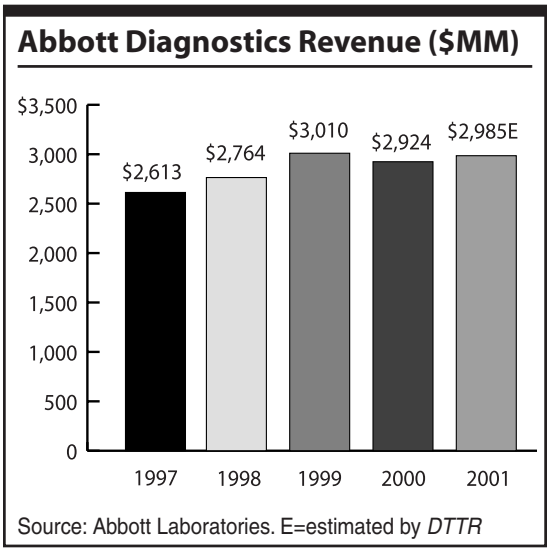
WASHINGTON G-2 REPORTS

Established 1979

Abbott Labs Plans Diagnostics Comeback

Abbott Laboratories (Abbott Park, IL) expects its sagging diagnostics division to get back on a growth track later this year after it gets the green light to reintroduce some 60 test kits banned under its November 1999 consent decree with the U.S. Food & Drug Administration. In a July 12 conference call, John Thomas, division vice president/investor relations, said Abbott Diagnostics would likely post a double-digit rate of growth in the fourth quarter. This would mark a decisive turnaround for the division, which saw its revenue decline by 3% in 2000 to $2.924 billion, while operating earnings plunged from $561 million to $331 million. "Clearly, the diagnostics division has been a drag on Abbott," notes Robert Dunne, analyst at Dresdner Kleinwort Wasserstein (New York City). *Diagnostic Testing & Technology Report* estimates that reintroduction of the banned products, plus several new initiatives, could help Abbott Diagnostics finish this year with $2.985 billion in revenue. For an in-depth analysis of the world's second largest IVD manufacturer, see pp. 5-7.



Will HDI Force Glucose Test Strip Price Decline?

Early last year Home Diagnostics Inc. (HDI—Fort Lauderdale, FL) began selling low-priced blood glucose testing supplies under a new co-branding model that threatens to decimate the ultra-high profit margins the major IVD manufacturers now reap from this market. Under the HDI model, packaging for the company's "Prestige" glucose meters and strips includes the retail store's name, and retail prices for the strips are 30-40% lower than competing strips from Lifescan, Medisense, Roche, and Bayer. "Our goal is to lower the cost of diabetes diagnosis and treatment," says Dick Damron, HDI's chief executive. He says that privately held HDI doubled its revenue to approximately $85 million last year and was profitable. *Continued on p. 2*

▲ **Will HDI Force Glucose Test,** *from page 1*

Prior to early 2000, HDI sold its products mainly through mail-order houses and wholesale distributors. It began shipping co-branded meters and strips to its first national customer, Walgreens, in April 2000, Damron says. Since then, HDI has added about 40 more drugstore chains to the program, including Eckerd, CVS/Pharmacy, Longs Drug Stores Pharmacy, Duane-Reade, and Osco Drug. Supermarket chains in the program include Albertson's, Shop Rite, Weis Markets, and Winn-Dixie.

Retail Prices For 50 Test Strips

Roche Accu-Check	$39.99
Bayer/Glucometer	$39.99
Lifescan FastTake	$39.99
Medisense Sof-Tact	$44.99
Prestige/Walgreens	$24.99

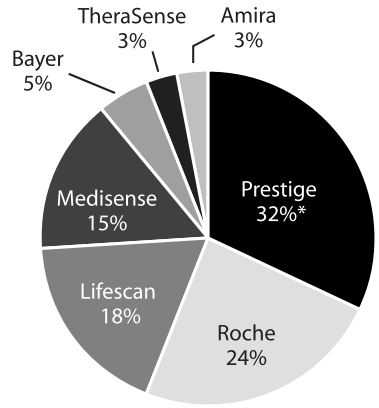
Source: Walgreens.com

Collectively, the Prestige meter and strips are now being sold at about 25,000 chain-store outlets, plus another 6,000 independent drug stores, according to Damron. He says HDI recently signed several co-marketing agreements with retailers in England and will soon expand into Canada as well.

Damron says co-branding with HDI allows chain stores to sell a box of 50 test strips at approximately $24.99 vs. the leading national brands' prices of $36-40 per box. Under the HDI program, retailers are also selling a combination package of 100 test strips, plus a meter, for $50. Despite the low prices to consumers, Damron says retailers earn a higher profit margin by selling co-branded Prestige meters and strips than by selling higher-priced supplies from the major diagnostics companies. He estimates that drugstores earn a pretax profit margin of 10-15% on every package of strips they sell from the major diagnostics vendors. In contrast, he says, pretax profit margins earned by retailers are 3-5 times higher under HDI's co-branding program.

According to data from A.C. Nielsen, HDI's Prestige line accounted for 32% of the 330,000 blood glucose meters sold at U.S. drugstore chains in the first quarter of 2001. Next was Roche with a 24% share, followed by Lifescan with an 18% share. Prestige was fourth in terms of test strips sold, with 8% of the 2.3 million 50-count packages sold in the first quarter. Lifescan was first, with a 39% share of test strips sold, followed by Roche, 31% and Bayer, 12%. Damron notes that HDI's increasing share of meter sales should lead to a greater share in test strips as well.

Blood Glucose Meters:
Share of Sales At Chain Drugstores



*Includes some combo meter/test strip package sales
Source: A.C. Nielsen Report, Chain Drug Channel, First-Quarter 2001

Other avenues for growth for HDI include contracts with managed care companies. Damron says negotiations with third-party payers are underway. He expects HDI to be added to managed care formularies at the lowest end of the co-pay scale. For example, HMO members might pay a $5 co-pay when purchasing a box of 50 Prestige strips vs. a $15-25 co-pay when buying a competing box from Lifescan or Medisense.

HDI manufactures its strips at a facility in Fort Lauderdale with 260 employees. The company also owns a manufacturing plant with 140 employees in Taiwan that makes the Prestige meters. "We may be the lowest-cost producer in the industry. We are a low overhead operation," notes Damron.

Radiometer Buys Accumetrics For $10 Million

Radiometer (Copenhagen, Denmark) has purchased privately held Accumetrics Inc. (San Diego, CA) for approximately 85 million krona (US $10 million). Radiometer expects Accumetrics and its 80 employees to generate revenue of roughly 40 million krona (US $5 million) in the fiscal year ending April 30, 2002, with an operating loss of about 100 million krona (US $11 million). Radiometer does not expect the acquired business to contribute positive profits until the fiscal year ending April 30, 2004.

The acquisition brings Radiometer into the immunoassay market. It was previously focused on blood gas/electrolytes

Accumetrics, founded in 1996, has developed a point-of-care analyzer and disposable cartridges for use at hospital cath labs, where patients with heart attacks are brought. The device, named the Ultegra System, measures a patient's response to the GPIIb/IIIa inhibitor class of intravenous antiplatelet drug therapy. GPIIb/IIIa inhibitors have demonstrated benefits in treating patients undergoing coronary interventions (such as stent placement) and acute coronary syndromes (unstable angina and non-Q-wave myocardial infarction).

Drugs currently available in this new and rapidly growing class include ReoPro (Centocor), Integrilin (Cor Therapeutics), and Aggrastat (Merck). Accumetrics estimates that more than 2.5 million patients per year are candidates for intravenous antiplatelet therapy.

The Ultegra System uses whole blood samples directly from Becton Dickinson's Vacutainer. Test results are provided at the bedside/operating table in less than two minutes vs. the traditional method of sending specimens to a central laboratory. The instrument was introduced in the U.S. one year ago and is currently being used by 100 of the Nation's 500 biggest cath labs.

BioMerieux Buys Organon Teknika For $263 Million

BioMerieux Pierre Fabre (Marcy l'Etoile and Castres, France) has completed the acquisition of Organon Teknika from Dutch chemical group Akzo Nobel NV. The purchase price was 311.3 million euros (US $263 million). With the addition of Organon Teknika, BioMerieux will generate approximately 900 million euros (US $761 million) from diagnostic sales, 82% of which will be generated outside of France.

TheraSense To Try Again For IPO

TheraSense (Alameda, CA), which makes the "Freestyle" blood glucose meter, has refiled with the U.S. Securities & Exchange Commission to raise up to $115 million from an initial public offering. The company withdrew plans for an IPO last December, citing volatile market conditions. In the three months ended March 31, 2001, TheraSense recorded a net loss of $35.483 million vs. a net loss of $21.679 million in the same period a year earlier; revenue increased to $7.677 million from $500,000. (For more on TheraSense, see *DTTR, Nov. '00, p. 10*).

Broadlane Contracts Indicate Continued Pricing Pressure

The group purchasing organization Broadlane Inc. (San Francisco, CA; Dallas, TX) recently signed contracts (effective Aug. 1, 2001) to have Bayer Diagnostics and Ortho-Clinical Diagnostics become its preferred providers of immunoassay analyzers and reagents. Robert McDaniel, an associate at Broadlane, says the contracts provide Broadlane members with savings of more than 25% from previous contracts. The six-year agreements have fixed reagent prices with no annual adjustments for inflation. Despite the contract's tough terms, McDaniel says additional companies are seeking to be added to Broadlane's list of preferred immunoassay vendors.

McDaniel says that, in general, pricing for reagents in the core laboratory remains under pressure. "Prices have been decreasing for the past 10 years, and I've seen no recent changes in this trend." In particular, hospital labs that own their own instruments (as Tenet and Kaiser generally do) have the most leverage in negotiating reagent prices, he says.

Broadlane's Lab Contracts

Chemistry	Roche Diagnostics
Hematology	Beckman Coulter
Coagulation	Dade Behring
Immunoassay	Bayer, Johnson & Johnson
Glucose	Roche Diagnostics
Reference lab	Quest Diagnostics

Source: Broadlane

Earlier this year, Kaiser Permanente (Oakland, CA) outsourced most of its supply chain and contracting functions to Broadlane. Formed in December 1999, Broadlane handles purchasing for Tenet Healthcare (Santa Barbara, CA), Universal Health Services (King of Prussia, PA), Community Health Systems (Brentwood, TN), Cleveland Clinic Foundation, and others. Including Kaiser, Broadlane purchases roughly $4 billion per year for 572 acute care hospitals and 2,335 other facilities.

TCPI Files For Chapter 11 Bankruptcy Protection

To avoid liquidation proceedings and continue operations, TCPI Inc. (Pompano Beach, FL) on July 3 filed for Chapter 11 bankruptcy protection with the U.S. Bankruptcy Court in the Southern District of Florida (Fort Lauderdale). The company says it will soon file a plan of reorganization.

TCPI markets point-of-care tests for pregnancy, ovulation, urinary tract infections, diabetes, and cholesterol through its HealthChek brand as well as OEM (original equipment manufacturer) and private label agreements. The company also markets a patented skin permeation enhancer for drug delivery and is developing a non-invasive glucose meter that uses a patch to collect interstitial fluid from the forearm.

In the three months ended March 31, 2001, TCPI reported a net loss of $1.233 million vs. a net loss of $2.638 million in the same period a year earlier; revenue increased to $1.601 million from $1.187 million. In full-year 2000, the company lost $9.151 million on revenue of $7.462 million. Since its inception in January 1992, TCPI (formerly named Technical Chemicals and Products Inc.) has accumulated losses of $43.9 million.

Abbott Working To Put FDA Consent Decree Behind It

Nearly two years after signing a consent decree with the U.S. Food & Drug Administration over manufacturing quality concerns at its Lake County, IL diagnostics facility, Abbott Laboratories (Abbott Park, IL) is still working to put the matter behind it.

Abbott is currently making final changes to its manufacturing process validation documentation and preparing for FDA's final inspection of its Lake County facility anticipated in late August or early September, according to John Thomas, division vice president/investor relations. "We expect the inspection to go well and [we] project reintroduction of our products on a rolling basis, beginning later in the second half of this year," Thomas told investors and analysts during a July 12 conference call.

"We've expended tremendous effort in not only fulfilling our obligations and responsibilities under the agreement, but also in establishing best-in-class quality systems," Thomas said. As a result of the consent decree, Abbott recorded a one-time charge of $168 million in the third quarter of 1999, including a $100 million payment to the U.S. Government and charges of $44 million for contractual obligations and inventory exposures, plus $24 million for long-term asset write-offs.

As part of the consent decree, Abbott was forced to stop selling approximately 60 tests, including anemia tests using B12, ferritin, and folate assays on its TDx, Imx, and AxSym analyzers. Sales of the company's TestPack line of pregnancy and Strep A tests were also halted. In addition, the consent decree has delayed Abbott's ability to get new immunoassays on the market (*e.g.*, free PSA and HCV) and has cut sales of its latest generation immunoassay system, the Architect i2000 (launched in January 1999). In fact, Abbott reports its sales were reduced by approximately $250 million last year, and earnings by $0.10 per share (or a total of $155 million), because of the consent decree.

Abbott's Consent Decree Milestones

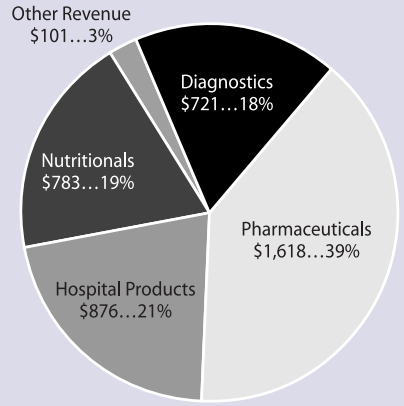
Nov 99	Abbott signs consent decree with FDA and agrees to pay $100 million fine
Jan 00	Abbott pulls 60 tests from the market
Mar 00	Third-party consultant, Quintiles Transactional, validates Abbott's Corrective and Preventative Action (CAPA) plan
Jun 00	Abbott gets FDA sign-off on CAPA plan
Mar 01	Abbott submits the 14th and final common manufacturing validation package to FDA
Jul 01	Abbott makes final changes to its process validation documentation
Aug/Sep 01	FDA is expected to conduct final inspections of Abbott's Lake County diagnostics manufacturing facility over a 2-4 week period
Sep/Oct 01	With FDA okay, Abbott will begin reintroducing banned products on a rolling basis

Abbott reports that at one point last year it had nearly 1,000 employees focused on meeting the demands of the consent decree. The company also has reimbursed labs that were forced to outsource certain tests because they had lost their supply of certain reagents from Abbott.

In the latest reported quarter ended June 30, 2001, worldwide diagnostic sales at Abbott declined 4.3% to $721 million from $752 million a year earlier. U.S. diagnostic sales were down 5% to $291 million, and international sales were down 4% to $430 million.

Worldwide revenue from Abbott's Medisense glucose monitoring unit, which is part of Abbott Diagnostics, were down 12.6% to $106 million. Abbott executives attribute the decline in Medisense to a tough year-over-year comparison—last year's second quarter was particularly strong because of the U.S. launch of the company's Precision Xtra glucose monitor. In this year's second quarter, Abbott says Medisense sales were hurt by non-recurring adjustments to trade inventories.

Abbott Labs' Revenue, 2Q01*



*$MM Source: Abbott Laboratories

Overall, Abbott reported company-wide net income of $529 million in the three months ended June 30, 2001, down 23% from $685 million in the same period a year earlier; revenue was up 22% to $4.099 billion. Top-line growth was lifted by the acquisition of the pharmaceutical business of BASF (Ludwigshafen, Germany) for $6.9 billion in cash.

The stagnation of Abbott's diagnostics division, combined with the expansion of its pharmaceutical business, means that diagnostics now comprise only 18% of Abbott's overall revenue, down from 22% a year ago.

And Abbott has clearly stated that its main focus is its prescription drug business. "Our second-quarter results show that we have delivered on our most important strategic objective—the scientific and commercial expansion of our global pharmaceutical business," said Abbott's chairman and chief executive Miles White in a press release.

Meanwhile, Abbott's loss has been gain for many of its competitors, including Diagnostic Products Corp. (Los Angeles, CA), which posted a 15% revenue gain last year to $247.9 million, propelled by increased sales of its Immulite immunoassay analyzer. Other beneficiaries of Abbott's FDA problems include Bayer Diagnostics, Beckman Coulter, Roche, and Dade Behring. "I expect them [Abbott] to come back strong … In the past they haven't sought market share with cut-throat pricing. They realize that once you offer a lower price, it's nearly impossible to raise it later," a top marketing executive at a competing firm tells *DTTR*.

Abbott Labs In Brief*

	2Q01	2Q00	% Chg
Total revenue	$4,099	$3,370	22%
Worldwide Diagnostics	721	752	-4%
—U.S. diagnostics	291	305	-5%
—International diagnostics	430	447	-4%
—Medisense	106	94	-13%
Pharmaceuticals	1,618	912	77%
Hospital products	876	850	3%
Nutritionals	783	769	2%
Other revenue	101	87	16%
Total net income	529	685	-23%

*$MM. Source: Abbott Laboratories

Despite Abbott Diagnostics' lackluster performance over the past 18 months, the unit is expected to achieve year-over-year revenue growth in excess of 10% in the coming fourth quarter. Abbott executives say a number of factors will drive this anticipated rebound:

1 Abbott anticipates reintroducing test kits banned under FDA's consent decree on a rolling basis in September/October.

2 Medisense (Bedford, MA) is expected to pick up growth in the second half of the year. The unit is expanding the distribution of its Sof-Tact glucose meter to U.S. wholesalers and retailers. The virtually pain-free testing device was officially launched in the U.S. via mail order only in April, and Abbott says demand has been double the initial expectations. Marketing in Germany and Japan has begun, and the product will next be rolled out in Scandinavia. In addition, Medisense will soon launch a luminous glucose meter to ease patient testing at night in the dark.

3 Several new assays should soon be cleared for marketing. For example, on Feb. 8, Abbott received an approvable letter from FDA for hepatitis A assays run on its AxSym analyzer. And on May 8, approvable letters were received for hepatitis C and hepatitis B assays run on Abbott's Prism system.

4 Abbott recently gained exclusive rights to distribute DNA-based breast and bladder cancer tests made by Vysis Inc. (Downers Grove, IL; *see DTTR, May '01, p. 1*). Abbott expects Vysis' UroVysion assay (used to detect bladder cancer cells in urine) to gain final clearance from FDA in the near future. Vysis' PathVysion breast cancer test was cleared in 1998.

5 Abbott is in the process of launching two tests for "mad cow" disease under a distribution agreement with Enfer Scientific Ltd. (Tipperary, Ireland; *see DTTR, April '01, p. 8*).

Who's To Blame?

Abbott Diagnostics' fracas with FDA didn't hit the front pages until late 1999. However, the consent decree and the record $100 million settlement were a long time in the making. FDA had cited Abbott's Lake County facility for alleged manufacturing deficiencies every year since 1993.

Interestingly, Abbott's current chairman and chief executive Miles White was elected vice president of diagnostics systems operations in 1993 as well. White advanced to senior vice president of diagnostics operations in 1994 and executive vice president in February 1998. The diagnostic division's growth to a $3 billion-a-year operation contributed to White's elevation to chief executive of Abbott Laboratories in January 1999.

When FDA clamped down later that same year, White did not admit any wrongdoing or take blame for any of the problems at the division he had headed only months earlier. Last year, he received total compensation (including options) of $28.2 million (*DTTR, April '01, p. 8*).

Roche, DeCode Finalize 5-Year Development, Marketing Alliance

Under the deal, DeCode will identify genes linked to diseases for which Roche will develop DNA-based diagnostic and predisposition screening products

Roche Holding (Basel, Switzerland) and DeCode Genetics (Reykjavik, Iceland) have finalized a five-year agreement covering the development and marketing of DNA-based diagnostic tests. A preliminary agreement was first announced in March (*DTTR, March '01, p. 3*). The agreement calls for Roche to pay DeCode an upfront fee of $5 million, plus approximately $15 million per year in fixed funding. Roche will also pay royalties to DeCode on sales of products developed from the alliance. The companies estimate the total value of the collaboration to DeCode could exceed $300 million. The first diagnostic product is expected to be developed by the end of next year.

Under a separate five-year agreement signed in 1998, DeCode has the opportunity to earn up to $200 million in research and milestone payments from Roche in exchange for supplying new drug targets from its gene research. The companies have already announced that DeCode has identified genes linked to schizophrenia and peripheral arterial occlusive disease (causes narrowing of the arteries).

DeCode has a treasure trove of genetic information derived from Iceland's unique genetic composition which has remained stable since the Vikings arrived in the 9th and 10th centuries. In January 2000 the Ministry of Health and Social Security granted the company a 12-year license to collect and analyze data from the medical records of the island's healthcare institutions. The purpose is to create a centralized database containing non-personally identifiable information that can be studied to uncover the genetic basis of disease. Although DeCode was initially criticized for not seeking the consent of its studies' subjects, it now does so. Only 7% of Iceland's population of 280,000 have opted out of the research.

In the three months ended March 31, 2001, DeCode recorded a net loss of $16.087 million vs. a net loss of $9.278 million in the same period a year earlier; revenue (nearly all from Roche) was up 9% to $5.033 million. In July 2000, DeCode raised gross proceeds of $198.7 million from an IPO. As of March 31, 2001, the company had approximately $172.1 million in cash holdings. Roche owns 10% of DeCode.

Roche Seeking More R&D Collaborations

Franz Humer, chief executive of Roche, has stated that Roche will continue to pursue collaborations with other companies in areas such as genetics and diagnostics. "We're spending about 10% to 20% of our research budget on external cooperation now, and my inclination is to say we'll see it rising," Humer told Dow Jones Newswires on June 21. "The joint work we're doing with DeCode, for example, makes a lot of sense … we couldn't do the work that DeCode is doing." Humer noted, however, that collaboration requires careful management. "If you don't manage it properly, it's not an external collaboration, it's a waste of money … You have to have significant in-house expertise in the fields in which you collaborate." Roche's company-wide spending on research and development last year totaled 3.95 billion Swiss francs (US $2.25 billion) or 14% of revenue; R&D spending for the diagnostics division was 558 million Swiss francs (US $317 million) or 9% of division sales.

Roche To Sell CombiMatrix Microarrays

CombiMatrix Corp. (Mukilteo, WA) has signed a non-exclusive worldwide license, supply, research and development agreement with Roche Diagnostics (Indianapolis, IN). Terms allow Roche to market CombiMatrix's biochips (a.k.a microarrays), which are used by researchers at academic labs and pharmaceutical companies to analyze genes and proteins for the development of new drugs. Roche also expects to develop the CombiMatrix microarray system into a broader tool for use at clinical labs for early detection of a variety of diseases.

The agreement includes an undisclosed revenue-sharing arrangement and has a term of 15 years. Over the first three years, Roche will make minimum payments to CombiMatrix, including royalties, payments for products, and R&D projects.

Microarrays are a collection of miniaturized test sites arranged on a silicon wafer that permit many tests to be performed simultaneously, or in parallel, in order to achieve higher throughput or speed—a necessity for large-scale DNA screening and analysis. CombiMatrix's technology provides a single integrated platform for both genetic testing and protein research. In addition, the company customizes the microarrays within a couple of days of receiving an order. Most competitors focus on selling standardized microarrays.

CombiMatrix is owned by Acacia Research Corp. (Pasadena, CA), a publicly traded holding company that develops and invests in new biotechnology companies.

LabCorp To Market Exact Sciences' Colorectal Tests

Exact Sciences Corp. (Maynard, MD) and Laboratory Corp. of America (Burlington, NC) have signed an agreement whereby LabCorp will be the only national clinical laboratory to offer Exact's DNA-based testing technology for the detection of colorectal cancer. Exact will receive an upfront payment and licensing fees on the amount of testing performed.

LabCorp will market Exact's PreGen-26 test for detecting colorectal cancer in stool samples from people with known or suspected hereditary non-polyposis colorectal cancer (HNPCC). There are an estimated 280,000 people in the U.S. with this inherited predisposition. Those with HNPCC have an 80% lifetime risk of developing colorectal cancer. LabCorp will perform ProGen-26 as a "home-brew" test with an expected list price of several hundred dollars. Over time, Exact and LabCorp expect to offer broader testing services based on Exact's genomics-testing technologies.

Separately, Exact has announced that its testing technology will be the subject of a study by the Mayo Clinic (Rochester, MN) for which Mayo has received a $4.9 million grant from the National Cancer Institute of the National Institutes of Health. The study will involve 4,000 patients at average risk for developing colorectal cancer and compare the results of Exact's DNA-based test with those of the fecal occult blood test. Exact will process all the stool samples at its CLIA-certified lab in Maynard. In addition to the Mayo study, Exact expects to initiate its own two-year clinical trial of 5,000 patients in the fourth quarter.

J&J's Diagnostics Revenue Edges Up 3% In Second-Quarter

Johnson & Johnson (New Brunswick, NJ) generated total worldwide IVD revenue of $519 million in the three months ended June 30, 2001, up 3% from $502 million in the same period a year ago. The company's blood glucose monitoring subsidiary Lifescan (Milpitas, CA) reported a 6% gain in worldwide revenue to $266 million. J&J's Ortho-Clinical Diagnostics (Raritan, NJ) unit increased its worldwide revenue by 1% to $253 million. Overall, J&J reported second-quarter net income of $1.584 billion vs. $1.363 billion in the same prior-year period; revenue was up 9% to $8.342 billion.

Diagnostics Revenue At J&J*

	2Q 2001	2Q 2000	% Chg
Lifescan			
US	$182	$171	7%
International	84	81	4%
Worldwide	266	252	6%
Ortho-Clinical Diagnostics			
US	132	125	6%
International	122	126	-3%
Worldwide	253	250	1%

* $MM. Source: J&J

Sysmex To Boost IRC Stake To 51%

Sysmex Corp. (Kobe, Japan) says it will make a tender offer to buy 4.2 million shares of International Reagents Corp. (IRC, also headquartered in Kobe) for 2.604 billion yen (US $21 million). The purchase, if completed, will boost Sysmex's stake in IRC to 50.8%. Sysmex currently owns 33.3% of IRC, which it purchased from Japanese drug maker Welfide Corp. earlier this year for 4.96 billion yen (US $40 million). [For more on the Sysmex/IRC alliance, see *DTTR, Feb. '01, p. 1.*]

Separately, Sysmex recently reported net income of 1.363 billion yen (US $11 million) on revenue of 38.816 billion yen (US $310.5 million) for the fiscal year ended March 31, 2001. IRC reported net income of 162 million yen (US $1.3 million) on revenue of 10.43 billion yen (US $83 million) in fiscal year 2001.

Sysmex/IRC In Brief*

	FY 2001	FY 2000	% Chg
Sysmex			
Revenue	38.816	37.243	4%
Net Income	1.363	1.838	-26%
International Reagents Corp.			
Revenue	10.430	10.135	3%
Net Income	0.162	0.305	-47%

*In billions of yen. Source: Wright Investors' Service

ZstatTx Sells 100,000 ZstatFlu Tests To Japanese Distributor

ZymeTx Inc. (Oklahoma City, OK) says it has finalized the sale of 100,000 ZstatFlu diagnostic tests to its Japanese distributor, the Nichirei Corp. (Tokyo). The sale represents the single largest bulk order received by ZymeTx for its ZstatFlu test, which received CLIA-waived status from the U.S. Food & Drug Administration in December 2000. The 20-minute point-of-care flu test detects influenza types A and B within 20 minutes, using a simple throat swab.

The sale to Nichirei gives a much-needed boost to ZymeTx, whose sales have been hurt by the lightest flu season on record in the U.S. In the nine months ended March 31, 2001, ZymeTx recorded a net loss of $4.143 million vs. a net loss of $4.068 million in the same period a year earlier; revenue fell to $832,129 from $1.245 million. Cash and securities totaled $844,456 as of March 31.

IVD Stocks Rise Another 4% In Latest Four Weeks

The G-2 Diagnostic Stock Index rose 4% in the four weeks ended July 13. Twelve stocks in the index gained in price, eight fell. Since the start of the year, the index has risen 12%, while the S&P 500 is down 8% and the Nasdaq is down 16%.

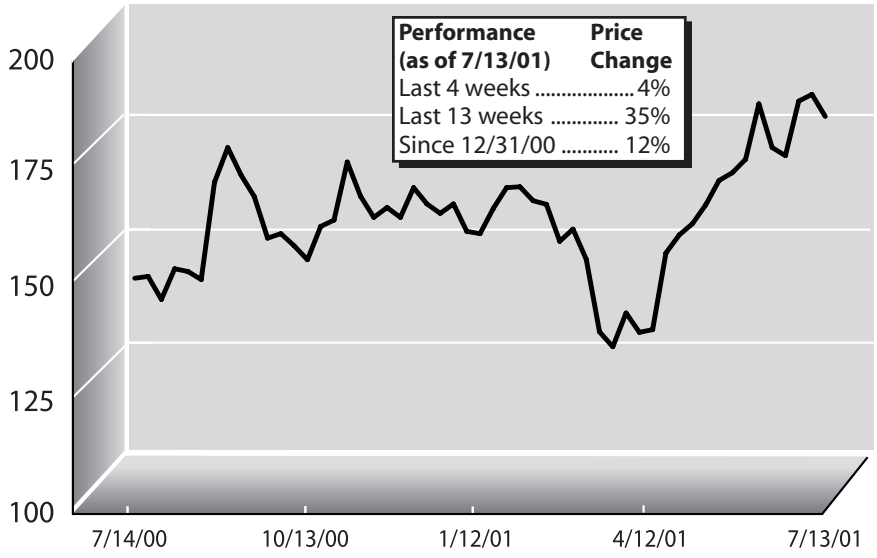
Shares of Bayer, which trade on the German stock exchanges, have fallen 21% so far this year to 43.99 euros per share; Roche non-voting equity shares, which trade on the Zurich Stock Exchange, are down 19% year-to-date to 132.50 Swiss francs per share

Shares of **Digene Corp.** (Gaithersburg, MD) were up 40% to $36.55 per share to reach a market capitalization of $610 million. A study in the June 27 *Journal of the American Medical Association* supported use of the company's Hybrid Capture 2 HPV (human papillomavirus) DNA test for cervical cancer screening in low-resource settings. Specifically, the study showed that a single screening with HPV using Digene's test reduced the risk of cancer incidence by 27% vs. 19% for the traditional Pap smear. On a cost basis, HPV testing totaled $39 per year for each life saved vs. $81 per year for traditional Pap testing. The study's analysis team was headed by professors from the Harvard School of Public Health and Columbia University.

Shares of **Careside** (Santa Clara, CA) were up 33% to $3.19 per share for a market cap of $35 million. The company says it has overcome its initial instrument reliability problems and is now placing nearly one Careside analyzer per day. In addition, the company has announced new distribution agreements with three distributors of medical and laboratory supplies: Alaska Scientific Inc. (Anchorage), Kem Surgical Supply Inc. (Bakersfield, CA) and Hankins Surgical Supply Co. (Springfield, MO). The Careside Analyzer is a point-of-care blood testing system with a menu of approximately 55 tests in clinical chemistry, electrochemistry, coagulation, and hematology.

Meanwhile, shares of **Johnson & Johnson** (New Brunswick, NJ) split two-for-one on June 13; those of **Diagnostic Products** (Los Angeles, CA) split two-for-one on June 19.

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.

Avg. % Price Change, 4 weeks ended 7/13/01

UP	PRICE	%CHG
Bio-Rad	$47.12	2%
Biosite	42.30	2%
Beckman Coulter	44.22	10%
Becton Dickinson	36.10	3%
Calypte	0.34	6%
Careside	3.19	33%
Cholestech	9.00	18%
Digene	36.55	40%
Cytyc	25.24	3%
Inverness Medical	36.86	1%
Johnson & Johnson	53.05	2%
Ventana	29.50	12%
DOWN		
Abbott Labs	$49.60	-2%
Affymetrix	20.31	-13%
Cygnus	8.40	-3%
Diagnostic Products	32.65	-12%
Diametrics	4.10	-6%
i-STAT	12.85	-10%
Meridian	4.54	-5%
Quidel	4.16	-16%

G-2 Insider

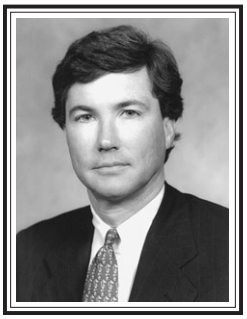
As strange as it may sound, Twyford Bathroom (Cheshire, England) has produced a prototype of a futuristic toilet that can monitor human waste and spot health problems. The product, dubbed the Versatile Interactive Pan (VIP), is yet another sign that diagnostic testing is moving out of the lab and closer to consumers.

Using built-in diagnostic technology, the VIP will perform tests on urine and stool samples for a range of physical anomalies from colorectal cancer to diabetes. The device will also measure nutrient levels for dietary concerns. Although the VIP is not yet in production, Twyford predicts it could be on the market within the next five years. In the meantime, a model has been donated to the Gladstone Pottery Museum (Stoke-on-Trent, England) and will be featured in an exhibition there this autumn.

Separately, Matsushita of Japan has developed the "Health Monitoring Toilet System." A prototype is on display in a Tokyo showroom, and rollout could begin within two to five years, according to the company.

Company References

Abbott Labs 847-937-6100
Accumetrics 858-643-1600
BioMerieux (St. Louis, MO) 314-731-8500
Broadlane 866-276-2356
Careside 310-338-6767
CombiMatrix 425-493-2000
DeCode Genetics 354-570-1900
Digene 301-944-7000
Exact Sciences 978-897-2800
Home Diagnostics Inc. 954-677-9201
Johnson & Johnson 732-524-0400
LabCorp 336-584-5171
Radiometer America 800-736-0600
Roche Diagnostics 317-849-9350
Sysmex 81-78-265-0500
TCPI 954-979-0400
TheraSense 888-522-5226
ZymeTx 405-271-1314



THOMAS SCULLY, the new administrator of the Centers for Medicare & Medicaid Services (formerly HCFA), will discuss issues crucial to the healthcare industry—Medicare reform, as well as CMS reform—at this year's Lab Institute to be held Oct. 24-27 in Arlington, VA.

The program also features major presentations by prominent lab industry executives, **Kenneth Freeman**, chairman & CEO of Quest Diagnostics, and **James Koziarz**, Abbott Labs' VP/diagnostics products R&D. For details, see the Lab Institute 2001 program booklet enclosed with this issue.

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