Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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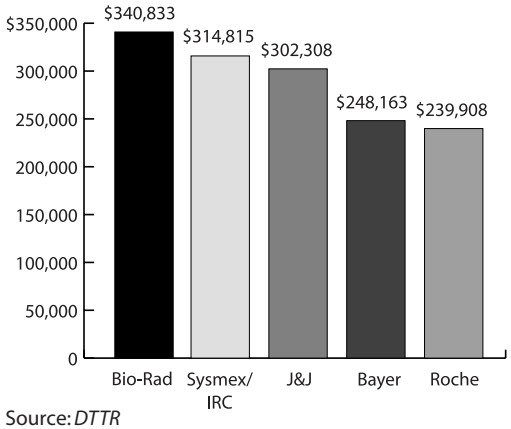
WASHINGTON G-2 REPORTS

Established 1979

Measuring Efficiency At Leading IVD Companies

The world's 10 largest in vitro diagnostics manufacturers generated an average $216,856 in revenue per employee last year, according to data compiled by *Diagnostic Testing & Technology Report* (*DTTR*). By this measure, the most efficient company was Bio-Rad Clinical Diagnostics (BRCD—Hercules, CA), a unit of Bio-Rad Laboratories Inc. With approximately 1,250 employees, BRCD generated $409 million in revenue last year for an average $340,833 per employee. Sysmex/International Reagents Corp. (Kobe, Japan) was the next most efficient, with $314,815 of revenue per employee. Johnson & Johnson (New Brunswick, NJ), which employs about 6,500 at its Lifescan and Ortho-Clinical Diagnostics units, also surpassed the $300,000 revenue-per-employee mark. For full details, see p. 9.

Revenue Per Employee At Select IVD Companies



Source: *DTTR*

Abbott To Distribute Vysis Cancer Tests

Vysis Inc. (Downers Grove, IL) says Abbott Laboratories (Abbott Park, IL) has agreed to distribute its DNA-based breast and bladder cancer tests. The deal gives Abbott exclusive distribution rights in North America and Europe for Vysis' PathVysion HER-2 assay (used to detect amplification of the HER-2/neu gene in breast cancer tissue specimens) and UroVysion assay (used to detect bladder cancer cells in urine). The agreement also gives Abbott an exclusive option for distribution rights for both tests in Asia (excluding Japan) and South America. Vysis has a marketing partnership in Japan with Fujisawa Pharmaceutical Co. of Osaka.

The agreement will greatly expand Vysis distribution capabilities for the two tests. The company's current workforce totals 133. Robert Koska, vice president for sales and marketing, oversees seven technical sales representatives in the U.S.; Paul Steuperaert, president of European *Continued on p.2*

▲ **Vysis Cancer Tests,** *from page 1*

operations, oversees a nine-person salesforce. In contrast, Abbott's diagnostics division employs approximately 16,000 worldwide, including thousands of on-the-ground salespeople.

Ron Opel, analyst at H.C. Wainwright (Boston, MA), notes that the deal marks an unusual incursion on Abbott's part into anatomic pathology. Up until now, it has been an active marketer primarily in the non-AP diagnostic lab market. "So, to some extent, the Abbott/Vysis deal will be a mutual leveraging, despite their size difference," Opel adds.

Vysis won approval from the U.S. Food & Drug Administration to market its PathVysion test in December 1998. It submitted a 510(K) application for its bladder cancer test in October 2000 and expects FDA approval by mid-year, according to chief executive John Bishop.

Vysis also markets four other genetic tests cleared by FDA, including its AneuVysion test for detection of Trisomy 13, 18, 21 (Down syndrome) and chromosome X and Y aneusomies (such as Klinefelter and Turner syndromes).

Sales of genetic tests to the clinical market accounted for 25% of Vysis' total revenue last year. The company also sells more than 200 analyte-specific reagent products (*i.e.*, DNA probes) to the research market, accounting for 47% of total revenue. Subsidiary Gene-Trak Systems Industrial Diagnostics makes products for the detection and identification of food-borne pathogens for food processors and quality control labs. These products include DNA probes and antibody kits for detection of organisms found to contaminate food, such as Salmonella, E. coli, and Listeria.

Vysis At A Glance ($000)

	2000	*1999*
Revenue	$23,991	$21,695
Operating income	-2,219	-12,645
Net income	-460	-9,842
Long-term debt	0	0
Cash & securities	11,388	9,037

Source: Vysis

Vysis completed its initial public offering in February 1998, selling three million shares at $12 each. Currently, the company trades at about $10 per share and, with 11 million shares outstanding, has a market capitalization of $110 million. BP Amoco owns a 66% stake in Vysis.

Will Shareholders Vote For Bayer Breakup?

At 49.09 euros per share, the stock of Bayer AG (Leverkusen, Germany) is essentially unchanged since mid-December 2000 when the New York-based investment firm of Tweedy, Browne Co. officially proposed that the German giant split into three separate companies (*DTTR, April '01, p. 1*). Tweedy, Browne believes that Bayer could be worth roughly 75 euros per share if broken up. However, the sluggish trading activity of Bayer stock indicates that investors may not believe the breakup proposal will pass. Approximately 55-60% of Bayer's 730 million outstanding shares are held by German investors, many of whom are expected to vote against the breakup. The next issue of *DTTR* will provide a summary of Bayer's April 27 shareholder meeting and the voting results on the breakup proposal.

Top Japanese IVD Executive Says Consolidation Is "Unavoidable"

Tatsuo Tokumitsu, president of Fujirebio Inc. (Tokyo, Japan), recently told Bloomberg News that the 100+ in vitro diagnostics manufacturers in Japan are feeling the urge to make acquisitions in order to survive in the stagnant domestic market. "Whenever people in the industry gather, someone brings up the topic … Consolidation among diagnostic makers is unavoidable." Tokumitsu said Fujirebio has a five-year business plan to more than double annual sales to 50 billion yen (US $400 million), including adding 20 billion yen through acquisitions.

With estimated worldwide annual revenue of roughly $200 million, Fujirebio is among the top five IVD companies based in Japan. The company, which is focused on the immunoassay reagent market, acquired Centocor Diagnostics (Malvern, PA)—oncology diagnostics—in November 1998. In June 2000, Fujirebio sold its pharmaceutical business ($40-50 million in annual revenue) to UCB SA, a Belgium-based chemical and pharmaceutical company, for five billion yen (US $47.5 million). Fujirebio is now focused exclusively on diagnostics.

Sizing Up The Japanese IVD Market

Sysmex Corp. (Kobe, Japan) became the largest shareholder (33.4%) of International Reagents Corp. (IRC—also headquartered in Kobe) when it added eight million shares to its small existing stake in IRC in March. The two companies have agreed to form a comprehensive business alliance that could result in a full merger within two years. A full merger would make Sysmex/IRC the largest diagnostic company in Japan, with about $425 million in worldwide sales.

Other large Japanese diagnostics companies include Arkray (Kyoto), formerly Kyoto Daiichi (estimated annual revenue, $386 million); Olympus Optical Co. (Tokyo), which gets about $225 million from its diagnostic unit; and Eiken Chemical Co. (Tokyo), about $179 million. Dainabot (Tokyo), a joint venture between Daiichi Pharmaceuticals and Abbott Laboratories, generates an estimated $275-300 million in annual revenue, mainly from placing AxSYM analyzers (this venture is really the Japanese face of an American company and thus not in the table below).

Chiharu Yokoyama of Asiatic Research (San Francisco, CA) pegs total revenue generated by Japanese IVD companies at roughly $2.4 billion per year, with about 70% coming from the domestic market and 30% from exports. Of the 100+ IVD manufacturers, seven are primarily open instrument producers, six are primarily closed system producers, and well over 100 are primarily producers of open reagents, according to Yokoyama.

Michael Farmer, also with Asiatic Research, says the sale of Fujirebio's non-IVD business to a European firm may jumpstart the consolidation process in Japan. "Nobody wanted to be the first to sell to foreigners, because of the potential loss of face. Now that Fujirebio has broken the ice, other CEOs can broach the same subject to their boards."

Top Five Japanese IVD Companies

Company	*Est'd Annual Sales ($MM)*
Sysmex/IRC	$425
Arkray	386*
Olympus Optical	225
Fujirebio	200**
Eiken Chemical	179

*Includes clinical LIS business
**Excludes divested pharmaceutical business
Source: Asiatic Research

Cygnus GlucoWatch Cleared By FDA

The U.S. Food & Drug Administration has granted Cygnus Inc. (Redwood City, CA) approval to market its GlucoWatch Biographer as a prescription device for adults with diabetes. GlucoWatch is a non-invasive, continuous monitoring device that is worn like a wristwatch and tests interstitial fluid found just beneath the skin.

Cygnus now plans to launch a pilot marketing program which will be the first time that U.S. patients can use GlucoWatch outside of controlled clinical studies. Cygnus is working toward finalizing a large-scale manufacturing process for the product's consumable AutoSensors.

In March, Cygnus signed a market research agreement with Johnson & Johnson's Lifescan Inc. (Milpitas, CA). Terms give Lifescan exclusive access for a limited period to data from Cygnus's pilot program. Lifescan also has the right of first refusal with respect to a comprehensive collaboration agreement to distribute and support GlucoWatch in the U.S. Further details about the agreement were not disclosed.

Cash and securities at Cygnus totaled $24.5 million as of Dec. 31, 2000. In full-year 2000, Cygnus posted a net loss of $37.033 million on revenue of $1.052 million. As of year-end 2000, the company had accumulated net losses of $215.823 million.

Careside Signs Distribution Accords With Labsco, Fisher

Careside Inc. (Culver City, CA) has signed separate non-exclusive agreements for national distribution of its Careside Analyzer system with Laboratory Supply Co. (Labsco—Louisville, KY), which has 80 lab-specialty salespeople, and Fisher Healthcare (Hampton, NH), which has more than 200 physician office salespeople. In addition, Careside has signed distribution agreements with regional distributors: Kreisers Inc. (Sioux Falls, SD) and Medico-Mart Inc. (Milwaukee, WI), each with 8-12 salespeople.

Careside received FDA approval of its Careside Analyzer—a point-of-care blood testing system for use in doctors' offices—in December 1999. However, manufacturing glitches hampered the launch of the product throughout last year. Careside chairman W. Vickery Stoughton tells *DTTR* that reliability trials at several beta sites were successfully concluded late last year. Installed instruments are now functioning with high reliability in all test modes (blood chemistry, electrochemistry, coagulation, and hematology), according to Stoughton. The Careside system, including the H-2000 hematology analyzer, lists for approximately $30,000; reagent cartridges sell for $3-5 each.

The U.S. Navy recently completed an evaluation of the Careside system on a Navy support ship. Stoughton says the evaluation was positive, but can't predict whether or not the Navy will actually make a purchase. A final decision is expected by the end of May.

Careside reported a loss of $4.674 million in fourth-quarter 2000. As of Dec. 31, 2000, the company had $1.789 million in cash and current liabilities of $4.744 million. Stoughton says Careside is in the process of raising additional cash.

Nucleic Acid Probes Are Fastest-Growing Segment Of IVD

With annual sales growth of more than 20% for each of the past three years, nucleic acid probes are easily the most vibrant segment of the diagnostics market. Estimates from Merrill Lynch and SG Cowen peg the worldwide market for nucleic acid testing at $800-850 million last year, up 20-25% from 1999.

A nucleic acid probe is a DNA strand (with a labeled detector molecule) that is synthesized in the laboratory. Its purpose is to seek out and hybridize (*i.e.*, bind) with the target nucleic acid molecule in the patient sample being tested. When the hybridization occurs between the probe and the target organism's nucleic acid, the hybrid can be detected through the detector molecule.

Roche and its patented PCR technology dominate the nucleic acid probe market. As of year-end 2000, Roche had 744 PCR licensees, including 650 in the U.S.

Infectious disease testing represents the majority of clinical nucleic acid probe testing, and tests for chlamydia and HIV viral load are two leading applications. In comparison to traditional alternatives (*e.g.*, microscopy, cell culture, and immunoassay), nucleic acid probes are quicker and have greater sensitivity.

The three primary types of DNA probe assays used for detecting infectious organisms are:

1. Culture Identification: The organism is grown in a culture, after which its nucleic acid is detected by DNA probes.

2. Direct Probe: The DNA probe detects the organism's nucleic acid directly in the specimen.

3. Nucleic Acid Amplification: The nucleic acid is enzymatically amplified in a test tube to a very high level so that DNA probes can be used to identify the organism present in the sample. Amplification is used for organisms such as viruses, which exist in too few numbers to be directly detected with DNA probes.

Analysts say the market for nucleic acid probes could grow even faster if not for the complex and labor-intensive sample preparation required. To address this opportunity, Becton Dickinson and Qiagen NV have formed a joint venture named PreAnalytix to develop sample collection tubes for nucleic acid testing. The joint venture recently introduced its first product, the Paxgene Blood RNA System. It integrates blood sample collection, stabilization, and purification, making it easier and faster to analyze RNA (ribonucleic acid). RNA is less stable than DNA, and Paxgene eliminates the need to freeze blood samples immediately. (For more on Qiagen, see p. 8.)

In addition, Merck KgaA (Darmstadt, Germany) and Swiss-based Tecan AG recently formed a strategic alliance to develop and distribute flexible, high-throughput nucleic acid extraction and purification kits. Under the deal, Merck will supply special reagents to Tecan that are optimized for use in Tecan's automated nucleic acid analyzer.

The latest news from the seven leading manufacturers of nucleic acid probe kits follows on pp. 6-7.

The PCR patents have provided Roche with a lucrative royalty stream, but are due to expire in mid-2004

Roche Holding AG (Basel, Switzerland) is far and away the market share leader in nucleic acid probes by virtue of its patents on PCR (polymerase chain reaction) testing. PCR is the first nucleic acid amplification technique to be developed and remains the molecular diagnostic method most widely used in both research and clinical laboratories. Roche's largest single customer for its PCR technology is Laboratory Corp. of America (Burlington, NC), which currently conducts 30,000-40,000 viral load tests for HIV and hepatitis C per month.

Revenue at Roche's Molecular Diagnostics unit (formerly Molecular Systems) increased by 26% last year to 750 million Swiss francs (US $450 million). The unit markets a line of PCR products, including the Cobas Amplicor automated system and test kits for HIV viral load, chlamydia, tuberculosis, and hepatitis C. New products expected to be launched this year include Cobas AmpliPrep, an automated PCR sample preparation machine.

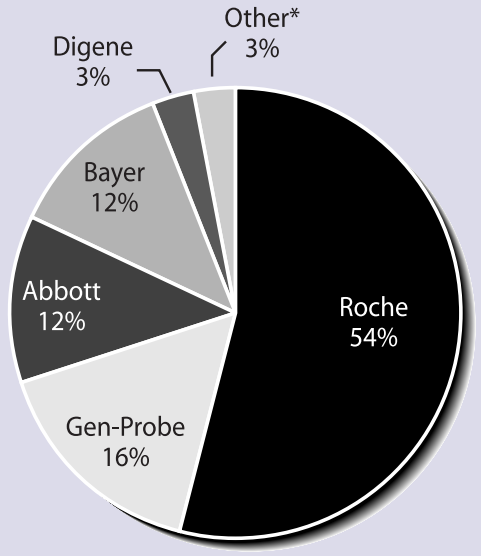
Gen-Probe (San Diego, CA), a subsidiary of Chugai Pharmaceutical Co. (Tokyo, Japan), makes the most widely used molecular culture identification tests under its AccuProbe line. These tests detect clinically relevant bacteria, mycobacteria, and fungi. Gen-Probe also makes direct probe assays for detection of chlamydia or gonorrhea under its Pace 2 brand. Annual sales at Gen-Probe, which has more than 650 employees, are estimated at more than $100 million and are growing at approximately 5-10% per year.

Gen-Probe has developed a combination transcription mediated amplification (TMA) test system designed to detect HIV-1 and hepatitis C in whole blood and plasma and is working through a collaboration with Chiron Corp. to commercialize the system worldwide. The assay has been in trials at the American Red Cross, America's Blood Centers (ABC), and the Association of Independent Blood Centers since April 1999. Roche is also developing nucleic acid probes for blood banks and is conducting trials at ABC as well.

Gen-Probe is currently being reimbursed under co-development agreements in the U.S., significantly below expected commercial prices. The U.S. Food & Drug Administration is reviewing the Gen-Probe/Chiron assay system (trade name: Procelix); once approved for use on automated systems, the price is expected to be raised to around $10 per donation. With approximately 12-14 million units of whole blood collected and tested each year in the U.S., this market could represent up to $140 million annually. The worldwide market (50 million units) could be as high as $500 million per year.

Nucleic Acid Probe Market Share, 2000E

Total sales: $825 million



*Includes bioMerieux, Becton Dickinson, Organon Teknika, and others

Source: *DTTR* based on company reports and estimates from Merrill Lynch and SG Cowen

Abbott Laboratories (Abbott Park, IL) currently markets nucleic acid amplification tests for chlamydia and gonorrhea on its LCx Analyzer. Sales for 2000 are estimated at $75-100 million. Tests for retroviruses and viral load for HIV and hepatitis C are under development.

Bayer Diagnostics (Tarrytown, NY) and Innogenetics NV (Ghent, Belgium) recently signed an agreement that gives Bayer exclusive worldwide rights to market Innogenetics' products for nucleic acid based HCV genotyping and HIV drug resistance assays. Terms call for a payment of 10.4 million euros, a future milestone payment, and R&D funding for the next five years. Bayer will also pay to Innogenetics a percentage of the end-user price for supply of the products, and will make an equity investment of 10 million euros in Innogenetics.

Bayer currently has an estimated 12% of the worldwide market for nucleic acid probes as a result of its November 1998 acquisition of Chiron's diagnostics business. In May 2000, Bayer filed a pre-market application to the FDA for its HIV-1 RNA 3.0 viral load assay, which utilizes the company's proprietary branched DNA (bDNA) assay technology (gained from the Chiron acquisition). The test, if approved, will be Bayer's first proprietary nucleic acid test cleared for clinical use in the U.S.

Digene Corp. (Gaithersburg, MD) makes a proprietary line of nucleic acid probe tests, including its Hybrid Capture 2 HPV Test—the only FDA-approved test for human papillomavirus, or HPV, which is associated with more than 90% of cervical cancer cases. The company also makes DNA tests for chlamydia and gonorrhea. Abbott is the distributor for Digene's product line in Europe, as well as chlamydia and gonorrhea tests in the U.S. In the six months ended Dec. 31, 2000, Digene reported a net loss of $3.493 million vs. a net loss of $2.704 million in the same period a year earlier; revenue increased 43% to $14.927 million.

bioMerieux-Pierre Fabre (Marcy l'Etoile and Castres, France) is collaborating with Gen-Probe to offer nucleic acid probes on bioMerieux's Vidas immunoassay analyzer. Recently, bioMerieux launched a gonorrhea test in Europe, and a tuberculosis test is under development. Nucleic acid probe sales for 2000 are estimated at less than $10 million. In addition, bioMerieux has agreed to acquire the diagnostics business of Organon Teknika (Boxtel, The Netherlands) from Akzo Nobel NV (Arnhem, The Netherlands). Organon Teknika has developed a proprietary nucleic acid sequence-based amplification (NASBA) technology to compete with Roche's PCR. In September 1999, Organon received FDA clearance for its NucliSens CMV assay for diagnosis of human cytomegalovirus.

Becton Dickinson (Franklin Lakes, NJ) launched its nucleic acid probe system, BDProbeTec, in the U.S. in late 1999 with a combination chlamydia/gonorrhea test. The company reports 148 worldwide placements as of November 2000 and expects to reach about 300 placements by the end of this year. The system is based on BD's proprietary amplification technology (strand displacement amplification) and can be run in about one hour vs. 4-6 hours for Roche or Abbott systems.

Qiagen Reports Full-Year 2000 Profit Of $20 Million

Qiagen NV (Venlo, The Netherlands), which makes kits to extract and purify nucleic acids for use in DNA sequencing, posted a net profit of $20.106 million for the year ended Dec. 31, 2000, up from $13.889 million in 1999; revenue increased 29% to $204.031 million.

To date, the company's products have been sold primarily to the academic research market and to pharmaceutical and biotechnology companies. However, Qiagen is positioning its products for sale in developing commercial markets, including molecular testing at clinical labs for genetic or infectious diseases such as tuberculosis, hepatitis, and HIV.

For example, in August 1999, Qiagen formed PreAnalytix, a joint venture with Becton Dickinson (Franklin Lakes, NJ) to develop and market integrated systems for clinical labs to extract and purify nucleic acids for molecular testing. Qiagen also has an agreement to supply Visible Genetics (Toronto, Canada) with nucleic acid sample preparation products for VGI's HIV TruGene HIV-1 genotyping kits. In addition, Qiagen supplies Abbott Laboratories with nucleic acid sample preparation products for use with Abbott's LCx probe-based diagnostic system.

Qiagen generated $117.2 million in revenue from the U.S. last year. As of year-end 2000, Qiagen employed 1,315 individuals, primarily in Germany (647) and the U.S. (454). Its sales and distribution operations for the U.S. are based in Valencia, CA. Qiagen also owns Qiagen Genomics (Bothell, WA), which makes the Masscode system for screening single nucleotide polymorphisms (SNPs). And Qiagen is building a new research and manufacturing facility in Germantown, MD, that is expected to be completed next year.

On June 28, 2000, the company acquired Operon Technologies Inc. (Alameda, CA) for 2.392 million shares of stock (worth $104 million at the time of the acquisition). Operon makes synthetic nucleic acids, DNA microarrays, and synthetic genes. Earlier this year, Qiagen also acquired Sawady Group (Tokyo, Japan) in exchange for 855,000 shares of its common stock worth approximately $18.8 million. Privately held Sawady—comprised of Sawady Technology Co., Omega Co., and a majority owner of Accord Co.—is a supplier of synthetic nucleic acids in Japan, with $10 million in annual revenue and more than 40 employees.

With 144.4 million shares outstanding and currently priced at $22 per share, Qiagen has a market capitalization of $3.177 billion—down 36% since the start of the year. Investors have dumped shares of gene analysis equipment makers on news that instrument sales are beginning to slow. For example, executives at Applied Biosystems (Foster City, CA) recently said that sales over the next few quarters would rise by about 10-13%, considerably below its previous growth target of 20%. Applied Biosystems, which makes a number of gene sequence detection systems under its TaqMan product line, has seen its stock plummet 69% to $28.86 per share year-to-date.

Qiagen At A Glance ($000)

	2000	*1999*
Revenue	$204,031	$158,155
Operating income	34,872	23,348
Net income	20,106	13,889
Cash and securities	58,807	44,413
Long-term debt	10,547	4,845

Source: Qiagen

▲ **Measuring Efficiency,** *from page 1*

With 15,631 employees, Roche Holding AG (Basel, Switzerland) generated diagnostic sales of 6.252 billion Swiss francs (US $3.75 billion) in 2000 for an average $239,908 per employee. Abbott Laboratories (Abbott Park, IL) had $182,750 of revenue per employee and Bayer AG (Leverkusen, Germany) produced $248,163 per employee.

Top 10 IVD Manufacturers

Company	Revenue ($MM) Calendar 2000	Employees	Revenue Per Employee
1. Roche	$3,750	15,631	$ 239,908
2. Abbott	2,924	16,000	182,750
3. Johnson & Johnson	1,965	6,500	302,308
4. Bayer	1,824	7,350	248,163
5. Becton Dickinson	1,652	8,000	206,500
6. Beckman Coulter	1,472	8,100	181,728
7. Dade Behring	1,184	6,500	182,154
8. bioMerieux	525E	3,700	141,892
9. Sysmex/IRC	425E	1,350	314,815
10. Bio-Rad	409	1,250	340,833
Total, 10 companies	16,130	74,381	
Average, 10 companies			$ 216,856

E=estimated by *DTTR*

Source: *DTTR* and company reports

Among some of the smaller IVD manufacturers, Diagnostic Products (Los Angeles, CA) had 1,767 employees and $248 million in 2000 revenue for an average $140,351 per employee. Inverness Medical Technology (Waltham, MA), with 871 employees and $170.3 million in revenue, averaged $195,522 per employee. Cytyc Corp. (Boxborough, MA), with 457 employees and revenue of $142.1 million, averaged $310,941 per employee. And Quidel Corp. (San Diego, CA), with 350 employees and revenue of $68.4 million, averaged $195,429 per employee.

Idexx Labs Launches Combo Test Kit For Canines

Idexx Laboratories (Westbrook, ME) has begun marketing its new Canine Snap 3Dx test kit, an on-site diagnostic test that screens dogs simultaneously for three diseases: heartworm, Ehrlichiosis, and Lyme disease. Over 15 million dogs are tested for heartworm disease each year, according to Idexx. By combining tests for Ehrlichiosis and Lyme disease with a heartworm test, the Snap 3Dx test enables veterinarians to test efficiently and economically for three diseases that are difficult to diagnose from clinical signs alone, says Idexx. The test kit has an introductory price of $225 per box of 30 tests.

Idexx At A Glance ($000)

	1Q01	1Q00
Revenue	$91,426	$91,389
Pretax income	11,889	12,854
Net income	7,609	8,034
Cash and securities	53,105	75,203

Source: Idexx

Idexx is the leader in veterinary diagnostic tests, with roughly 50% of the $700+ million worldwide market for animal testing, according to estimates from Merrill Lynch.

In the first quarter ended last March 31, Idexx reported net income of $7.609 million, down from $8.034 million in the same period a year earlier; revenue was $91.426 million vs. $91.389 million.

Veterinary test kits and laboratory services account for about 80% of sales at Idexx. The company also makes immunoassay kits to detect livestock diseases and test systems for contaminants in water and antibiotics in milk. In addition, it is expanding into veterinary drug development.

First-Quarter Sales Creep Up At Abbott Diagnostics

Worldwide diagnostics sales at Abbott Laboratories (Abbott Park, IL) edged up 0.1% to $704 million in the first quarter ended March 31, 2001. First-quarter revenue from MediSense glucose monitoring products (part of Abbott's diagnostics division) was up 10.6% in the U.S. to $50 million and up 19.8% in the rest of the world to $64 million. Overall, Abbott reported a first-quarter net loss of $223.613 million vs. net income of $692.957 million in the same period a year ago; revenue was up 6% to $3.56 billion. Excluding write-offs associated with its $6.9 billion purchase of Knoll, the drug unit of German conglomerate BASF AG, and litigation expenses, Abbott had net income of $734.877 million in first-quarter 2001.

In a conference call discussing first-quarter results, Abbott executives said the company had submitted all the necessary paperwork to the U.S. Food & Drug Administration to prove that it has corrected problems related to diagnostic kits made at its Lake County, IL facility. FDA inspectors are expected to visit the plant in late May or early June, and Abbott could begin returning affected products to the market in the second half of this year.

Revenue Falls 10% At Dade Behring

Dade Behring (Deerfield, IL) reports that its revenue for full-year 2000 fell by 10% to $1.184 billion from $1.32 billion in 1999. The company says revenue was unfavorably affected by foreign currency, sold businesses, and the impact of SAB 101, a new accounting standard issued by the Securities & Exchange Commission. For 2000, EBITDA (earnings before interest, taxes, depreciation, and amortization) was $195 million vs. $266 million in 1999. Dade did not report net income figures and says that because it has fewer than 300 securities holders, it is no longer required to file 10-K and 10-Q reports and thus will no longer do so.

Meanwhile, the company says it is in discussions with its banking group and bondholders regarding long-term modifications to its capital structure. Dade had a total of $1.394 billion in long-term debt and notes as of Sept. 30, 2000 (the latest date of available figures). "Long-term, our goal is to de-leverage the company, and we are considering a variety of strategic options that will allow us to that," Jim Reid-Anderson, president and chief executive, said in a press release.

Cytyc Forms Healthcare Venture Unit

Cytyc Corp. (Boxborough, MA), which makes the ThinPrep system for Pap smears, has formed a venture capital subsidiary named Cytyc Healthcare Ventures to make private equity investments in early-stage healthcare companies. "Our financial success and strong cash position allow us to create an entity that will focus on long-term strategic opportunities and business development," according to Patrick Sullivan, president and chief executive. In the three months ended Dec. 31, 2000, Cytyc earned $14.787 million vs. $2.863 million in the same period a year earlier; revenue was up 72% to $42.553 million.

IVD Stocks Edge Up 0.4% In Latest Four Weeks

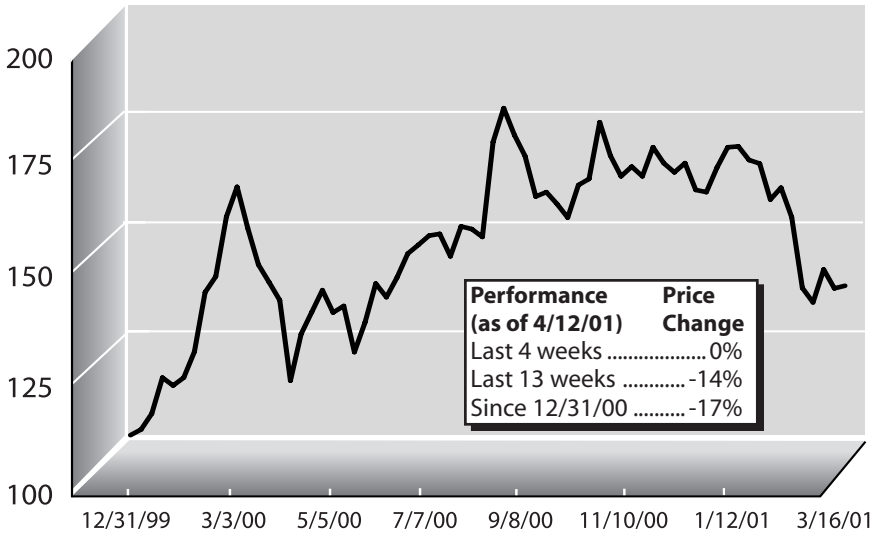
The G-2 Diagnostic Stock Index rose 0.4% in the four weeks ended April 12. Eleven stocks in the index went up in price, eight fell, and one was unchanged. Since the start of the year, the index has dropped 17%, while the S&P 500 is down 10% and the Nasdaq is down 21%.

Shares of **Calypte Biomedical Corp.** (Alameda, CA), which manufactures urine-based tests for HIV-1, plunged 79% to $0.18 per share, giving the company a market capitalization of $4.6 million. The company recently warned that it does not believe that its currently available financing will be adequate to sustain operations through June 30. During the first quarter of 2001, cash expenditures exceeded cash receipts by approximately $1 million. As of March 31, Calypte's cash-on-hand was $89,000. Nancy Katz, president, says that "due to the decline in the price of Calypte shares, our ability to access needed operating capital through our equity line has diminished substantially." In full-year 2000, the company recorded a net loss of $12.364 million on revenue of $3.296 million.

Cygnus Inc. (Redwood City, CA) saw its stock rise 37% to $6.86 per share for a market capitalization of $189 million. The company's GlucoWatch Biographer was recently cleared by the U.S. Food & Drug Administration as a prescription device for adults with diabetes (*see story, p. 4*).

Biosite Diagnostics (San Diego, CA) was up 27% to $38 per share for a market capitalization of $537 million. Biosite recently agreed to conduct an evaluation of Copiague, NY-based **American Biogenetic Sciences'** Thrombus Precursor Protein (TpP) diagnostic marker and antibodies for potential use with Biosite's rapid Triage Meter (for detecting heart attacks). The TpP test is approved for use in aiding in the risk assessment of thrombosis and the monitoring of anticoagulant therapy.

G-2 Diagnostic Stock Index



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

Avg. % Price Change, 4 weeks ended 4/12/01

	Price	% Chg
UP		
Abbott Labs	$45.67	1%
Becton Dickinson	34.46	6%
Bio-Rad	37.10	3%
Biosite	38.00	29%
Careside	2.33	14%
Cygnus	6.86	37%
Diametrics	4.60	13%
Digene	16.04	2%
Inverness Medical	23.40	11%
i-STAT	18.95	9%
Ventana	22.25	5%
DOWN		
Affymetrix	32.15	-13%
Calypte	0.18	-79%
Cholestech	4.72	-3%
Cytyc	17.08	-1%
Diagnostic Products	53.07	-1%
Johnson & Johnson	90.95	-1%
Meridian	2.92	-3%
Quidel	3.30	-18%
UNCHANGED		
Beckman Coulter	37.25	0%

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Wall Street has turned off the money spigot. With the Nasdaq Composite Index down 41% in the 12 months ended April 20, investors have become less willing to fund money-losing companies with no near-term path to profitability.

The inability to raise fresh cash could lead some fledgling IVD companies to be sold to larger rivals or force them out of business altogether. For example, HIV test kit maker Calypte Biomedical (*see p. 11*) warned in its recent 10-K annual report that "any failure to raise additional financing will likely place us in significant financial jeopardy." As of Dec. 31, 2000, Calypte had a working capital balance (current assets minus current liabilities) of -$875,000. Other IVD companies low on cash include Careside (*see p. 4*) which had a year-end working capital balance of $21,000; TCPI Inc. (Pompano Beach, FL) -$876,000; and World Diagnostics (Miami Lakes, FL), $1.269 million.

IVD Companies With Low Working Capital *($MM)*

Company	Current Assets	Current Liabilities	Working Capital
BICO	$12.449	$11.395	$1.054
Calypte	3.212	4.087	-0.875
Careside	4.765	4.744	0.021
TCPI	3.963	4.839	-0.880
World Diagnostics	1.949	0.680	1.269

Source: *DTTR* (based on data as of 12/31/00)

And then there's BICO Inc. (Pittsburgh, PA), formerly named Biocontrol Technology. BICO, which makes a non-invasive glucose meter, had $1.054 million in working capital as of Dec. 31, 2000; however, it lost $42.5 million last year on revenue of $345,874.

Likewise, the IPO market has come to a standstill. Among the victims have been TheraSense (Alameda, CA), which makes a blood glucose meter, and American Medical Laboratories (Chantilly, VA). Both companies recently cancelled plans to go public, citing market conditions.

Think I'm all wet? You can write me at *labreporter@aol.com.*

Jondavid Klipp, *managing editor*

Company References

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Bio-Rad Labs 510-724-7000
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Careside 310-338-6767
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