Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Vol. II, No. 5/January 2002

CONTENTS

WASHINGTON G-2 REPORTS

Established 1979

Outlook For 2002: *Reagent Pricing Pressure Offset By Growth Of Molecular Diagnostics, Glucose Markets*

To get a firsthand picture of what may be in store for the IVD industry this year, *Diagnostic Testing & Technology Report (DTTR)* interviewed top executives at 10 of the world's leading diagnostics manufacturers. Industry trends gleaned from these conversations include expectations for continued pricing pressure on reagents for core laboratories with low single-digit volume growth. But double-digit growth in both molecular diagnostics and glucose self-testing markets is expected to raise overall IVD industry growth to roughly 6% per year.

IVD executives say success in the industry will be determined by the ability to bring higher-margin testing technologies (both in molecular diagnostics and in point-of-care) to the market. With healthcare budgets tight all over the world, executives emphasize that product launches must be accompanied by clinical studies documenting cost-effectiveness and the ability to improve clinical outcomes.

Highlights of our exclusive interviews are featured in *Inside The Diagnostics Industry*, pp. 3-9.

IVD Industry At A Glance

Segment	2001 Revenue	Annual Growth
Core lab reagents	$15.8B	0-3%
Molecular diagnostics	$1.2B	15-20%
Glucose self-testing	$3.8B	10-13%
Total	$20.8B	4-7%

Roche To Buy Controlling Stake In Chugai Gen-Probe To Be Spun Off As Independent Co.

Roche Holding AG (Basel, Switzerland) has announced plans to acquire a 50.1% stake in Chugai Pharmaceuticals (Tokyo, Japan) for between 155-198 billion yen (US $1.23-$1.58 billion). The deal calls for Chugai (annual revenue, 203 billion yen) to be merged with Roche's Japanese unit, Nippon Roche (annual revenue, 66 billion yen). Completion of the transaction is expected in the fourth quarter of 2002 and will make Roche the world's 9th largest drug maker (up from 12th) with overall annual pharmaceutical sales of 30.4 billion Swiss francs (US $18.4 billion). Terms of the deal call for Chugai to first spin-off its molecular diagnostics unit, Gen-Probe Inc.

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▲ **Roche To Buy Controlling Stake In Chugai,** *from page 1*

(San Diego, CA), which Chugai originally acquired in December 1989 for $110.6 million.

Chugai shareholders will receive shares of Gen-Probe, which will be listed on the American Stock Exchange and remain under current management. Investment bankers working with Roche and Chugai have appraised Gen-Probe's value at 80 billion yen (US $635 million)—or approximately five times Gen-Probe's estimated revenue of $125-130 million in calendar 2001.

Henry Nordhoff, president of Gen-Probe, tells *DTTR* that Gen-Probe is being spun off as a separate company to avoid potential antitrust concerns. Gen-Probe makes molecular diagnostics for clinical laboratories and blood screening centers that compete with Roche's PCR business.

Gen-Probe's FDA-cleared nucleic acid probes include tests for chlamydia/gonorrhea, tuberculosis, strep throat, pneumonia and fungal infections. In addition, Gen-Probe has developed a semi-automated instrument and is finalizing a fully automated DNA amplification system for screening the blood supply for HIV-1 and hepatitis C. Gen-Probe is working in collaboration with Chiron to commercialize these systems worldwide.

Chugai shareholders will vote on the merger with Roche in late June 2002. Assuming their approval, Chugai will spin off Gen-Probe to existing shareholders in July/August and the company will begin trading on the American Stock Exchange. Gen-Probe's listing will not involve an IPO or the raising of any new funds. However, Nordhoff notes that after trading has been established, Gen-Probe will have the opportunity to raise funds through equity offerings. *(For more on Gen-Probe, see page 6.)*

Gen-Probe's Timeline

1983—Founded as a partnership by Dr. David Kohne, Dr. Thomas Adams and Howard Birndorf

1985—Received first FDA clearance for a clinical diagnostic test using a genetic probe technology

1987—Sells 2.5 million shares at $7 per share in IPO

1989—Acquired by Chugai for $6.25 per share ($110.6 million)

1998—Formed strategic alliance with Chiron Corp. to develop, manufacture and market nucleic acid probe assay systems for blood screening

2002—To be spun off from Chugai as independent company with appraised value of $600+ million

Source: DTTR

All Immucor Directors Re-Elected By Shareholders

Immucor makes blood screening instruments and supplies for hospitals and blood donor centers

Following an annual meeting of stockholders held on Nov. 30, 2001, Immucor Inc. (Norcross, GA) has announced that all six of its current directors have been re-elected to the board. The election had been contested, with Immucor's current directors (including chairman Edward Gallup) being challenged for board seats by a shareholder group led by Kairos Partners (New York City), which sought to have three of its nominees elected *(DTTR, Nov. '01, p. 8)*.

In a press release, Kairos Partners said that despite losing the shareholder vote, it had achieved its objective of making Immucor more accountable to shareholders. It also noted Immucor's recently announced plans to add two more independent outside directors to its board.

As of mid-October 2001, Kairos Partners, a healthcare investment firm controlled by Aim High Enterprises (Norwell, MA), had owned as much as 819,770 shares of Immucor for an 11.6% stake, according to documents filed with the SEC.

Outlook For IVD Industry In 2002: CEO Perspectives

IVD executives uniformly tell *DTTR* that the biggest challenge facing the industry is the ability to secure reasonable reimbursement rates for the highly sensitive molecular assays that are being developed and for advances in point-of-care (POC) testing technologies. Executives expect to devote more resources toward clinical studies that justify increasing diagnostic expenditures to lower downstream health care costs. In addition, more marketing collaborations are expected between diagnostic manufacturers, clinical laboratories and pharmaceutical companies—each of which has a vested interest in speeding the introduction of new diagnostic technologies. Highlights from our exclusive interviews with executives at 10 leading companies begin below:

Heino von Prondzynski, head of the diagnostics division at Roche (Basel, Switzerland), expects worldwide diagnostic sales at Roche to increase by 10% to 15% for both 2001 and 2002, including 20+% annual growth from molecular diagnostics and 15% to 20% annual growth from blood glucose testing.

He believes that molecular diagnostics will increasingly be linked to the introduction of pharmaceutical products tailored for individual patients. "Diagnostic tools will be used to avoid useless treatments and reduce adverse drug events," says von Prondzynski. He cites HER-2/neu assays, which are used to determine Herceptin treatment for breast cancer patients, as the model for future pharmacogenomics products. "Reimbursement for this test was never an issue. The reimbursement for molecular tests will be there, and it may be quite large."

Top 10 IVD Manufacturers, Estimated Revenue For 2001

Company	*Revenue ($MM)*	*% Growth*	*% Share*
Roche Diagnostics	$4,100	12	20
Abbott Diagnostics	2,895	-1	14
Johnson & Johnson	2,125	8	10
Bayer Diagnostics	1,900	5	9
Becton Dickinson	1,780	8	9
Beckman Coulter	1,525	4	7
Dade Behring	1,290	9	6
BioMerieux*	825	8	4
Bio-Rad	402	-2	2
Arkray	395	3	2
Total Top 10	17,237	6	84
Total IVD Market	$20,500	6	

*Pro forma including Organon Teknika (acquired July 2001).
Source: *DTTR* estimates based on company reports.

Meanwhile, von Prondzynski says that central lab volumes are growing in the low single digits, but are being offset by lower prices. However, he adds, "There's not too much room left to cut prices, given that routine reagents now typically sell for 10 cents per test vs. a couple of dollars each in the early 1990s."

He believes that there is little chance of consolidation between the top seven or eight IVD companies given product overlap and potential antitrust concerns. But von Prondzynski does expect the major IVD companies to step up their purchases of smaller companies with new technologies (*e.g.*, Abbott's purchase of Vysis and Roche's acquisition of Amira).

Over the next 12 months, POC testing for coagulation will accelerate due to reimbursement changes in the U.S. and Europe, according to von Prondzynski. Over the next five to 10 years, he believes that advances in POC tests that allow patients to self-monitor cancer therapies could become a bigger market than glucose monitoring.

Martin Madaus, PhD, head of Roche's U.S. diagnostics operations (Indianapolis, IN), says Roche's recently signed agreement with Quest Diagnostics (Teterboro, NJ) is aimed at reducing the time it takes Roche to bring new molecular tests to market. The collaboration will focus on clinical trials and commercialization of genetic tests that are being developed by DeCode Genetics (Reykjavik, Iceland). Roche's pharmaceutical and diagnostics divisions each have agreements with DeCode covering the development and marketing of DNA-based diagnostic tests and drug therapies. Under these arrangements, DeCode has already identified genes linked to rheumatoid arthritis, schizophrenia and obesity.

In terms of securing adequate reimbursement for new and expensive genetic assays, Madaus says, "It will be a test by test battle, but I'm convinced this market will grow. Those [IVD] companies that do not participate will get left behind."

In full-year 2000, Roche generated 2.191 billion Swiss francs (US $1.3 billion) from diagnostic sales in the U.S. Madaus says that U.S. diagnostic sales grew by roughly 12% in 2001. He expects similar growth in 2002.

New products that are driving growth include the company's Accu-Chek Active and Accu-Chek Compact blood glucose meters. Accu-Chek Active is billed as the first full-featured metered system at a value price. It offers a five-second test and memory with time and date and averaging components.

Accu-Chek Compact features a drum with 17 test strips that are easily loaded into the meter and calibrate automatically. With the touch of a button, a strip slides out ready for testing; another button touch ejects the used strip.

Madaus also expects Roche's new E170 module for Modular Analytics to spur growth. The E170 is a high-volume heterogeneous immunochemistry analyzer that can be combined with Roche's existing chemistry modules such as D2400, P800 and ISE 900/1800 into a consolidated workstation.

Rolf Classon, president of Bayer Diagnostics (Tarrytown, NY), says that Bayer Group's new operating structure will allow its Health Care Segment (includes pharmaceuticals, consumer products and diagnostics) to improve its competitiveness, to better exploit synergies between the different groups and to align the business for potential strategic partnerships. "These advantages also apply to the diagnostics business and we intend to expand our activities in the areas of alliances and partnerships," says Classon.

Bayer Group recently announced plans to transform its current organizational structure into a management holding company with four legally independent corporate units for Health Care, Agrochemicals, Polymers, and Chemicals. Subject to stockholders' approval, the new structure is to be operational effective Jan. 1, 2003.

Worldwide revenue at Bayer Diagnostics totaled 1.965 billion euros (US $1.77 billion) in 2000. Classon forecasts 5% revenue growth for 2001 and he projects 5-6% growth for 2002, in line with the industry.

Classon says that price pressures will continue for the most commoditized tests. Currently, Europe has the weakest pricing for routine reagents, followed by Japan and then the U.S., according to Classon. However, he believes that overall health care benefits, demonstrated by outcome studies, will result in improved reimbursement rates for

newer high-value assays such as Bayer's serum HER-2/neu oncoprotein test. The HER-2/neu oncoprotein can be elevated in the blood of women with metastatic breast cancer, and changes in concentration reflect treatment progression. Bayer's blood test measures circulating HER-2/neu oncoprotein to help oncologists treat patients with metastatic breast cancer.

The American Medical Association recently approved a unique CPT code for the serum HER-2/neu oncoprotein test. The CPT code 83950 becomes effective Jan. 1, 2002 and the Center for Medicare & Medicaid Services has proposed that the test be reimbursed by Medicare at $89.01, starting in January 2002.

Meanwhile, Classon says that although POC testing has been slower to be adopted than many people had previously anticipated, he predicts an acceleration in the hospital critical care segment of POC during the next 2-3 years, especially in the U.S. In addition to blood gas/electrolytes, the greatest opportunities will include coagulation and cardiac markers (once POC analyzers are able to give quantitative results similar to central lab results), according to Classon.

Jim Reid-Anderson, chief executive of Dade Behring (Deerfield, IL), says that after a strategic review of its product lines completed by Goldman Sachs in early 2001, Dade Behring has concluded that "all of its businesses are strong and worth staying in." However, Reid-Anderson notes that the company is still working on restructuring its $1+ billion in debt to take advantage of today's current low interest rates.

He points out that in 2001, Dade Behring was able to regain its sales momentum after several years of flat-to-lower sales. Through the nine months ended Sept. 30, 2001, Dade posted revenue of $927 million, an increase of 9% over the same period in 2000; EBITDA was up 25% to $157 million. He says that sales of the company's Dimension RxL platform are growing by 20% per year. Dimension RxL, which integrates clinical chemistry and heterogeneous immunoassay testing on one workstation, is now installed at approximately 1,500 laboratory facilities worldwide, according to Reid-Anderson. He also cites strong growth in the company's Stratus CS, a POC immunoassay system for cardiac testing.

"Far and away the biggest need at hospital labs is for productivity improvement," says Reid-Anderson. He expects capital expenditures at hospital labs to be targeted at workstation consolidation, automation and information technology aimed at improving the purchasing process.

In terms of reagent pricing, he notes that although vendor "consolidation has driven out some overcapacity," pricing in the U.S. remains competitive. Approximately 50% of Dade Behring's sales come from outside the U.S. and Reid-Anderson notes that there is "still some pricing pressure that has not yet run its course in Europe and Japan." As for volume trends in the core laboratory market, Reid-Anderson anticipates 2% to 4% annual growth in the U.S. and worldwide for the next few years.

Finally, Reid-Anderson is skeptical that Medicare and managed care will be willing to reimburse the flood of high-priced DNA-based tests that some industry analysts predict will hit the market over the next few years. "Test volumes and overall market size will be hindered by high prices," says Reid-Anderson.

Michael Ziering, president of Diagnostic Products Corp. (DPC-Los Angeles, CA), says that reagent pricing for the core laboratory market remains very competitive with one or two very aggressive vendors. "I look at some of the pricing being offered by some of our competitors and wonder how they make any money."

Ziering says that the prospects for DNA testing have been over-hyped. However, he does expect the market for DNA testing to broaden as more automated test systems are introduced and the links between diagnostic testing and drug therapies grow. "Eventually, we want to get involved in this market, but we're in no rush."

In the nine months ended Sept. 30, 2001, DPC reported a net profit of $27.692 million vs. $19.717 million in the same period a year earlier; revenue increased 14% to $208.461 million. The company shipped approximately 1,100 Immulite immunoassay instruments in full-year 2001, bringing its total installed base to roughly 7,000 (including 5,400 moderate-volume Immulite-1 and 1,700 high-volume Immulite 2000 systems). Sales of Immulite products (instruments and reagents) now account for 81% of DPC's overall revenue. Specific reagent test kits that are showing strong growth include troponin, homocysteine and PSA.

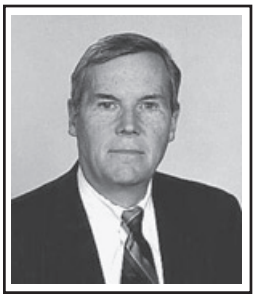
Ziering notes that DPC has benefited to some degree from Abbott's consent decree with the FDA, which forced Abbott to stop selling approximately 60 tests in the U.S. in early 2000, including eight products that compete directly with DPC. He also attributes increased domestic sales to continued penetration of group purchasing organizations and notes a new contract with Broadlane signed in third-quarter 2001. He adds that DPC is recording double-digit sales growth in international markets where it competes against Abbott's full menu of products. Ziering expects to place an additional 1,000 Immulite instruments in 2002 and post revenue growth of 10% to 15%.

Patrick Sullivan, president of Cytyc Corp. (Boxborough, MA), expects the acquisition of Pro-Duct Health (Menlo Park, CA) to generate some $9 million to $15 million in revenue for Cytyc in 2002 and $35 million to $45 million in 2003. The purchase of Pro-Duct, which has an FDA-approved procedure for evaluating the risk of breast cancer, was closed on Nov. 30, 2001; Cytyc paid five million shares (worth $125 million) plus $38.5 million in cash.

Cytyc is currently generating about $24 million to $25 million in net free cash flow per quarter and currently has about $130 million of cash on its balance sheet, according to Sullivan. He says that Cytyc is looking for other acquisitions that can leverage its on-the-ground salesforce of 150 people focused on OB/GYN practices and pathology labs. The company is also seeking co-marketing agreements with pharmaceutical companies to sell certain drug therapies to its existing physician client base.

Meanwhile, Sullivan says that more than half of the 50 million Pap tests performed in the U.S. annually are now done using Cytyc's ThinPrep method vs. 33% a year ago. In addition, Cytyc has clinical trials for ThinPrep underway in the United Kingdom (five million Pap tests per year) and will soon begin trials in Germany (12-15 million Pap tests per year).

In the nine months ended Sept. 30, 2001, Cytyc reported net income of $49.59 million, up from $23.376 million in the same period a year earlier; revenue was up 58% to $157.713 million. Revenue for full-year 2002 is expected to climb to about $300 million from $219 million in full-year 2001.



Henry Nordhoff, president of Gen-Probe Inc. (San Diego, CA), says his company will likely receive FDA clearance for its Procleix semi-automated system for nucleic acid amplification testing in early 2002. Under an investigational new drug application, Procleix is currently being used to test for HIV-1 and HCV at all five American Red Cross blood screening centers, plus three America's Blood Centers sites and one facility for the Association of Independent Blood Centers. Gen-Probe's HIV-1/HCV assay is currently used to test roughly 70% of the 13 million

annual whole blood donations in the U.S., according to Nordhoff. Roche has the remaining 30% marketshare.

Gen-Probe is currently being reimbursed on a cost recovery basis only that averages about $3 to $4 for an HIV/HCV test result. However, Nordhoff notes that this reimbursement is likely to be raised to $10 to $15 per donation after Procleix gets FDA clearance.

Procleix was developed by Gen-Probe under its strategic relationship with Chiron Corp. (Emeryville, CA), under which Gen-Probe is responsible for development and manufacturing and Chiron handles marketing and distribution. Under this relationship, Gen-Probe has also developed a fully-automated system for diagnostics and blood screening named Tigris, which is expected to begin clinical testing for the diagnostics market in 2002.

In addition, Nordhoff notes that Gen-Probe is developing a nucleic acid amplification test to simultaneously detect HIV-1, HBV and HCV and recently launched an amplified diagnostics test that detects chlamydia/gonorrhea in urine.

To date, Gen-Probe has generated more than 75% of its revenue from the sale of direct probe assays for sexually transmitted diseases (primarily chlamydia/gonorrhea). In calendar-year 2001, revenue is estimated to have grown by roughly 10% to $125-$135 million.

Nordhoff says that despite spending 42% to 44% on research and development, Gen-Probe is "comfortably profitable." He anticipates that Gen-Probe's growth rate and profitability will rise following commercialization of Procleix.

Nordhoff is confident that Medicare and managed care are willing and able to pay for more expensive molecular diagnostics, given the high sensitivity of these tests. He believes that automation is the key driver that will expand the growth of molecular diagnostics.

Mark Chandler, PhD, chairman of Luminex Corp. (Austin, TX), expects his company's Luminex 100 analyzer to play a key role in shifting immunoassays, genetic tests and cellular tests from the large central reference labs to smaller satellite labs that can provide physicians with same-day results.

The company's Luminex 100 is a benchtop analyzer that performs up to 100 tests (including enzymatic, genetic and immunologic tests) simultaneously on one drop of fluid. Since its commercial launch in 1999, the Luminex 100 has been placed at nearly 1,000 sites—55% of which are IVD manufacturers or clinical laboratories, according to Chandler. He expects to sell another 1,200 to 1,400 Luminex 100s in 2002. The Luminex 100 system has a list price of $55,000.

Chandler says that the key to increased penetration of the Luminex 100 in the clinical lab market is test menu expansion. The company has licensed its technology to 32 companies, including 19 IVD manufacturers or clinical labs that are working to commercialize tests that run on the Luminex 100 (another 13 pharmaceutical companies are using the Luminex 100 for drug development research). IVD/clinical lab partners include Bio-Rad and Dynacare.

Last Aug. 1, privately held Inova Diagnostics (San Diego, CA) announced clearance from FDA for the first clinical diagnostic application (an autoimmune panel) based on Luminex's technology.

In addition, privately held Zeus Scientific (Branchburg, NJ) recently announced FDA clearance for its new Athena Multi-Lyte ANA Test System, which is also based on Luminex's technology. Marketing for Zeus's test system, an autoimmune panel that detects nine separate analytes simultaneously, will begin in the first quarter of 2002 through a distribution partnership with Wampole Laboratories, a MedPointe company (Cranbury,

NJ). Over the next 12 months, Chandler expects other partners to gain FDA approval for Luminex-based tests in the areas of infectious disease (HIV and hepatitis C), cardiac markers (including C-reactive protein) and endocrinology.

In the nine months ended Sept. 30, 2001, Luminex reported a net loss of $11.939 million vs. a net loss of $8.985 million in the same period a year earlier; revenue was $14.764 million, up from $5.099 million. Cash holdings totaled $56.11 million as of Sept. 30.

Chandler anticipates that Luminex will generate $40 million to $55 million in full-year 2002, including $7 million to $9 million from the sale of microspheres, royalties and other revenues, with the remainder from instrument sales. He says profitability could be achieved in the fourth quarter of 2002.

Evan Jones, chairman of Digene Corp. (Gaithersburg, MD), notes that gaining reasonable reimbursement from Medicare and managed care companies may be the biggest challenge facing the burgeoning molecular diagnostics market. He notes that "politically important" new tests, such as those in the area of women's health (*e.g.*, breast and cervical cancer) and infectious disease (HIV and hepatitis C), have had a leg up in securing adequate fee levels. "Payers have been receptive to new technologies, but you need solid evidence that they improve outcomes and reduce costs," he adds.

Jones says that managed care companies (including Aetna, UnitedHealth and Kaiser) covering 80% of women with health insurance coverage now reimburse Digene's DNA-based Hybrid Capture2 HPV test for use as a reflex test for inconclusive Pap test results.

Digene's HPV test, which was launced in 1999, is the only FDA-cleared test for human papillomavirus (HPV). HPV is the primary cause of cancer and is found in 99% of all cervical cancer cases.

Most recently, Digene announced that Arkansas Blue Cross Blue Shield has instituted and approved a formal coverage policy for Hybrid Capture2 HPV. With 750,000 members, Arkansas BCBS is the largest health plan in the state. Over 30 BCBS plans, covering 55+ million members, now offer formal coverage for HPV testing.

Of the total 50 million Pap tests performed in the U.S. each year, approximately 7% (or 3.5 million) are borderline and require follow-up testing. Jones says Digene now has approximately 30% penetration of this market. In addition, Jones says that Digene recently filed a PMA supplement with the FDA so that the company's HPV test can be used as a primary screen for cervical cancer in conjunction with the Pap smear to increase the effectiveness of Pap smear screening.

Digene charges laboratories about $20 per specimen tested using its HPV test (high and low risk). Medicare reimbursement to laboratories is capped at $97 per specimen tested (CPT code 87621—HPV Amplified Probe technology billed x 2 for high and low risk).

Digene reported a net loss of $535,000 for its fiscal first quarter ended Sept. 30, 2001 vs. a net loss of $1.916 million in the same period a year earlier; revenue increased 45% to $10.382 million.

Digene generates 80% of its revenue from its Hybrid Capture2 HPV test, with the remainder coming from its DNA-based tests for chlamydia, gonorrhea, cytomegalovirus and hepatitis B. In addition, Jones says Digene is developing a DNA-based test for herpes with $1.1 million in funding from the National Institute of Allergy & Infectious Diseases.

Jones expects Digene to increase its revenue by approximately 50% in fiscal year 2002 (ends June 30) to roughly $50 million and achieve profitability in fiscal year 2003.

Clint Severson, chairman of Abaxis, Inc. (Union City, CA), expects nearly all routine testing to migrate to the point-of-care, but anticipates that the transition will occur gradually over the next 10 years. "The key is the technology that allows medical staff to push a button and get a result."

Abaxis currently generates about 85% to 90% of its $30 million in annual revenue from the sale of POC analyzers and cartridges to the veterinary market under the brand names Vetscan (for blood chemistry) and Vetscan HMT (for hematology). However, Severson says that sales of the company's Piccolo blood chemistry analyzer for the human diagnostics market are increasing along with its test menu.

The Piccolo is a POC instrument weighing 6.9 kilograms for use at CLIA-licensed labs. Test results from whole blood are provided in less than 13 minutes. Over 300 Piccolo analyzers have been placed to date at an average selling price of about $10,000 per instrument (list price is $15,000). Primary customers include urgent care/walk-in medical clinics, small hospitals and the U.S. Army and Navy.

Abaxis offers a total of seven different blood chemistry panels for the Piccolo, including liver, general chemistry, electrolyte, chem.-7, chem.-6 and most recently Metlyte 8 (chloride, creatine, kinase, creatinine, glucose, potassium, sodium, total carbon dioxide and urea nitrogen) and basic metabolic panels. Abaxis generates an average of $13.78 in revenue per panel cartridge sold.

Severson says Abaxis is aiming to introduce renal, lipid and comprehensive metabolic panels within the next 12 months. The company also plans to add 12 new sales people to its current human diagnostics marketing team of three people.

In the six months ended Sept. 30, 2001, Abaxis reported net income of $221,000 vs. $903,000 in the same period a year earlier; revenue was $14.253 million vs. $14.471 million.

Larry Cohen, president of International Technidyne Corp. (ITC-Edison, NJ), a subsidiary of Thoratec Corp. (Pleasanton, CA), notes that successful introduction of new diagnostic testing technologies" boils down to outcomes. You need to put together the right clinical studies. If you can prove that your test shortens length of stay and improves outcomes, then Medicare and managed care will reimburse it."

Cohen observes that hospital lab budgets remain under a great deal of pressure and that the focus of hospital labs remains on cutting costs and working more efficiently. As a result, he sees continued pressure on pricing for routine laboratory test reagents. "The opportunities for better pricing lie in new molecular tests and POC tests where there is value and proven cost-effectiveness," according to Cohen.

He notes that shifts to testing at the point-of-care are not guaranteed just because technological advances allow for it. "A point-of-care test needs to provide a result that physicians can act on immediately," says Cohen. He also cites the need for POC devices with built-in quality controls and connectivity solutions for integrating test results into patient records and hospital billing systems.

Cohen says that ITC continues to record brisk sales of its ProTime Microcoagulation System for prothrombin time testing to manage Coumadin therapy at home and in physician offices. ProTime is currently used by several thousand physician offices plus approximately 1,000 self-testing patients, according to Cohen. ITC, which has about 350 employees, also makes the Hemochron line of analyzers (15,000+ placements) for performing whole blood activated clotting time at the point-of-care for monitoring heparin therapy.

Abbott Completes Purchase Of Vysis—Who's Next?

Abbott Laboratories (Abbott Park, IL) completed its purchase of Vysis Inc. (Downers Grove, IL) for $30.50 per share, or approximately $355 million, on Nov. 30, 2001. In its last quarter (ended Sept. 30, 2001) as an independent publicly traded company, Vysis reported net income of $2.519 million vs. net income of $950,000 in the same prior-year period; revenue was up 51% to $7.087 million.

Based on these annualized results, Abbott paid approximately 13 times revenue and 35 times net income for Vysis, which makes DNA probe kits for detecting cancer. The purchase price of $30.50 per share represents a 154% premium over Vysis' IPO price of $12 per share (completed in February 1998).

Aside from the stunning purchase price, Abbott's acquisition of Vysis is yet another example of a large IVD company acquiring a new technology just after it has proved its viability in the marketplace. "Let them [the startup companies] pave the road. We'll pick up the winners," an Abbott executive (who wishes to remain anonymous) tells *DTTR*. This strategy results in the major IVD companies paying steep multiples for companies with proven new technologies, but it also reduces the risk of acquiring a clunker.

A brief overview of eight "new technology" IVD companies that have gone public over the past seven years shows current stock market valuations averaging 14 times annual revenue. None of the eight is currently profitable, and the accumulated losses (since inception) at these firms total $631.1 million through Sept. 30, 2001. The average age of the companies is approximately six years.

Of these eight companies, investors have placed the highest market capitalization ($701.2 million) on Igen International Inc. (Gaithersburg, MD). Igen has developed a proprietary electrochemiluminescent detection technology (called "Origen") for immunoassays and high-throughput screening. More than 50% of Igen's revenue comes from Roche (with whom the company is in a licensing dispute). Roche uses Origen technology in its Elecsys immunoassay product line. In the three months ended Sept. 30, 2001, Igen reported a net loss of $12.515 million vs. a net loss of $9.307 million in the same period a year earlier; revenue was up 43% to $9.396 million; cash and short-term investments totaled $21.753 million. Igen is 23% owned by chairman and founder Samuel Wohlstadter, who also founded Amgen (Thousand Oaks, CA).

Potential Acquisition Targets *($MM)*

Company	Market Cap*	Annual Revenue**	Market Cap/ Revenue	Accumulated Losses	Stock Price From IPO	IPO Date
Cepheid	$121.7	$11.2	10.9	-$38.6	-24%	6/00
Digene	508.0	41.5	12.2	-62.5	164%	5/96
Exact Sciences	178.0	0.0	NA	-39.9	-29%	1/01
Igen	701.2	37.6	18.7	-181.5	216%	2/94
Luminex	499.0	24.8	20.1	-47.4	2%	3/00
Third Wave	255.0	32.8	7.8	-68.1	-39%	2/01
ViroLogic	55.1	17.6	3.1	-72.3	-60%	5/00
Visible Genetics	163.3	11.5	14.2	-120.8	-13%	6/96
Total, 8 cos.	$2,481.3	$177.0	14.0	-$631.1	27%	

*Based on closing share prices for Dec. 18, 2001.
**Based on annualized results for three months ended Sept. 30, 2001.
Source: *DTTR* from company reports

IVD Stocks Dip 3% In Latest Three Weeks

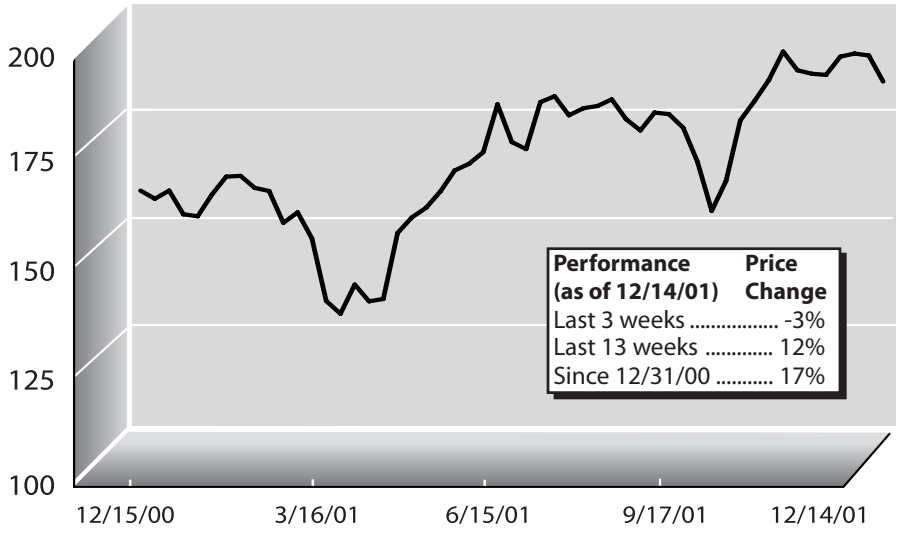
The G-2 Diagnostic Stock Index fell 3% in the three weeks ended Dec. 14, 2001. Eleven stocks in the index declined in price, eight gained, one was unchanged. Since the start of 2001, the index has risen 17%, while the S&P 500 is down 15% and the Nasdaq is down 21%.

Quidel Corp. (San Diego, CA) was up 20% to $8 per share, giving it a market capitalization of $226 million. In a recent final rule from the Centers for Medicare & Medicaid Services, collagen crosslinks was one of 23 analytes for which national Medicare coverage was established, effective Nov. 25, 2002. The decision is a boon to Quidel, which markets a collagen crosslinks test under the trade name, MetraDPD. It is intended to identify elevated bone resorption associated with osteoporosis and other metabolic bone diseases in both men and women. Medicare's national fee cap for a collagen crosslinks test in 2002 is $25.83. MetraDPD can be used by physicians to monitor patient response to anti-resorptive medications, such as Merck's Fosamax, Proctor & Gamble and Aventis Pharmaceutical's Actone, Eli Lilly's Evista and American Home Product's Premarin.

Shares of Bayer, which trade on the German stock exchanges, fell 38% through Dec. 14, 2001 to 34.75 euros per share; Roche non-voting equity shares, which trade on the Zurich Stock Exchange, were down 31% to 112.50 Swiss francs per share

i-Stat (East Windsor, NJ) was up 19% to $7.25 per share for a market cap of $140 million. The company recently raised $30 million from Cerberus Capital Management (New York City) from the sale of 30,000 shares of a new series D convertible preferred stock at $1,000 per share. The series D shares pay an 8% dividend and come with warrants to purchase up to 937,500 shares of i-Stat common stock at a price of $8 per share. i-Stat also announced that it has elected to redeem all of its series C convertible preferred stock (issued in August 2001 to institutional investors) for a redemption price of approximately $20.5 million. The net effect of these two transactions was to add $9.5 million in new funds to i-Stat, while reducing the number of i-Stat common shares issuable upon exercise of warrants from 1.3 million to 937,500.

G-2 Diagnostic Stock Index



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

% price change, 3 weeks ended 12/14/01

	Price	% Chg
UP		
Abbott Labs	$54.40	1
Beckman Coulter	43.88	4
Becton Dickinson	32.47	1
Biosite	16.83	5
Diagnostic Products	41.20	3
i-Stat	7.25	19
Quidel	8.0	20
Ventana	22.82	4
UNCHANGED		
Bio-Rad	62.25	0
DOWN		
Affymetrix	33.65	-9
Calypte	0.20	-5
Careside	1.00	-46
Cholestech	17.43	-26
Diametrics	5.45	-5
Inverness Medical	16.95	-10
Cygnus	5.24	-5
Cytyc	24.00	-15
Digene	28.70	-10
Johnson & Johnson	56.30	-8
Meridian	5.97	-1

G-2 Insider

Quest Diagnostics (Teterboro, NJ), with $3.6 billion in annual revenue, and Laboratory Corp. of America (Burlington, NC), with $2.2 billion, are the two largest laboratory testing companies in the country. Below are key strategic directions disclosed in our recent interviews with the top execs at these two lab giants.

Kenneth Freeman, chairman of Quest, says his company aims to increase its presence in the esoteric testing/molecular diagnostics market, which currently accounts for about 13% of the company's overall revenue. To meet this end, Quest is seeking to work closer with more IVD manufacturers to commercialize their genomics-based tests. For example, Quest recently obtained exclusive rights from diaDexus Inc. (Santa Clara, CA) to commercialize genomics-based tests made by diaDexus for osteoporosis and colorectal cancer. In October 2000, Quest signed an agreement with Roche Diagnostics to help commercialize genomics-based tests expected to be created from Roche's alliance with Decode Genetics. "Labs must stay current with the full range of new tests being developed, or risk getting left behind … Gene-based tests could become the predominant form of testing in our lifetime," says Freeman.

Thomas Mac Mahon, chairman of LabCorp, says his company is adding new testing technologies by acquiring esoteric testing labs (such as ViroMed in Minneapolis and National Genetics Institute in Los Angeles). LabCorp has also struck exclusive marketing agreements with Myriad Genetics (Salt Lake City, UT) and Exact Sciences (Maynard, MA). Mac Mahon adds that the cost of performing molecular testing is "escalating rather quickly" and LabCorp is seeking to exert more pressure on IVD manufacturers for better pricing.

Note: For complete highlights of interviews with Freeman and Mac Mahon, plus eight other heavyweight lab testing company executives, see the January 2002 issue of *DTTR's* sister publication, *Laboratory Industry Report*. For a free sample, call 202-789-1034.

Company References

Abaxis 510-675-6500
Abbott Labs 847-937-6100
Bayer Diagnostics 914-631-8000
Cytyc Corp. 978-263-8000
Dade Behring 847-267-5300
Diagnostic Products 310-645-8200
Digene 301-944-7000
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Diagnostic Testing & Technology Report (ISSN 1531-3786) is published by Washington G-2 Reports, 1111 14th St NW, Ste 500, Washington DC 20005-5663. Tel: 202-789-1034. Fax: 202-289-4062. Order line: 212-629-3679. Website: *www.g2reports.com*

Publisher: Dennis W. Weissman. Editor: D.J. Curren. Managing Editor: Jondavid Klipp, *labreporter@aol.com*