Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

Experts Predict Gene-Based Testing Wave, But Can 3rd-Party Payers Afford To Ride The Crest?

New high-priced gene-based tests are entering the market almost every month, and experts forecast that the current drizzle of new product introductions will turn into a torrent over the next five years. Experts say the clinical benefits will include earlier detection of disease and personalized pharmaceutical therapies that reduce adverse drug reactions. For well-positioned IVD companies and clinical laboratories, analysts predict, the benefit of the spread of gene-based testing will be substantially higher profit margins.

Some simple arithmetic suggests, however, that widespread utilization of even just one gene-based test could put significant strains on the nation's healthcare budget. Consider Exact Sciences (Maynard, MA), which is developing a gene-based test named PreGen-Plus to screen for early detection of colon cancer among 80 million Americans over age 50. The test is expected to be on the "home brew" market within 12 months with anticipated reimbursement of several hundred dollars per test. In contrast, the fecal occult blood test, currently the most common screening test for colon cancer, is capped nationally by Medicare at $3.50 per test.

Prospects for the "genetic revolution" and associated profit opportunities for IVD manufacturers and clinical labs were the focus of a specialized investor conference hosted by Bank of America Securities on March 20 in New York City. For conference highlights, see *Inside The Diagnostic Industry*, pp. 5-7.

Legislation Would Loosen Gene Patents

Bipartisan legislation that would give physicians and medical researchers unrestricted access to patented genes for use in clinical testing and non-commercial genetics research was introduced recently in the U.S. House of Representatives by Reps. Lynn Rivers (D-MI) and Dave Weldon (R-FL). "Evidence is mounting that the patenting of human genes is both inhibiting important biomedical research and interfering with patient care," Rivers noted in a related statement. The proposal comes as dozens of research labs and biotechnology companies are investing millions of dollars in a race to discover and patent genes and thus gain control of related diagnostic tests and therapies.

Continued on p. 2

▲ **Legislation Would Loosen Gene Patents,** *from page 1*

Current guidelines from the U.S. Patent & Trademark Office (PTO) require that a company seeking to patent a "discovered" gene must include on its application evidence of credible, specific and substantial use for that gene. PTO has already issued more than 1,500 patents on human genetic material and more than 10,000 additional patent applications are pending.

Major Holders Of Gene-Based Patents

Organization	*# Patents*
Incyte Pharmaceuticals	356
University of California	265
Glaxo SmithKline	197
Genentech	175
Eli Lilly	145
Novo Nordisk	142
Chiron	129
American Home Products	117
Isis Pharmaceuticals	108
Massachusetts General Hospital	108

Source: Biotechnology Industry Organization (as of 12/31/99)

The Rivers/Weldon argument against gene patents is based on the premise that genes are part of nature and have not been invented by anyone, thus should not be owned by anyone. Rivers says gene patents can prevent physicians from doing associated clinical testing and can stifle research to improve a genetic test. Key provisions of the legislation are highlighted below:

H.R. 3967—The Genomics Research & Diagnostic Accessibility Act of 2002
• Research: Would exempt from patent infringement those individuals who use patented genetic sequence information for non-commercial research purposes.
• Diagnostic use: Would exempt medical practitioners utilizing genetic diagnostic tests from patent infringement remedies.

H.R. 3966—The Genomic Science & Technology Innovation Act of 2002
• Authorizes an in-depth study by the White House Office of Science & Technology Policy into the impact of federal policies, especially patent policies, on the rate of innovation, cost and availability of genomic technologies. Rivers says that despite ample justification for the reforms proposed in H.R. 3967, further study is needed before any additional and more dramatic changes are made (such as making the diagnostic use exemption retroactive).

Several professional groups have come out for the legislation. Among them: the College of American Pathologists (CAP), the Academy of Clinical Laboratory Physicians & Scientists, and the American College of Medical Genetics. CAP president Paul Raslavicus, MD, notes: "When patents are granted, subsequent exclusive license agreements and excessive licensing fees prevent researchers, physicians and laboratories from providing genetic-based diagnostic services. As a result, patient access to care is limited, quality is jeopardized and training of healthcare providers

is restricted. This sets an extraordinary and dangerous precedent for patients and all of medicine."

"In the history of Western medicine there has never been a restriction placed on how a qualified physician can use a piece of information for practicing medicine," David Korn, senior vice president for biomedical and health sciences research at the Association of American Medical Colleges tells *Diagnostic Testing & Technology Report (DTTR)*. AAMC supports HR 3966 and is reviewing HR 3967.

Opponents of the legislation contend that without significant investment—made possible only by the prospect of total control of the diagnostic revenue—gene-based tests would never be developed in the first place.

George Poste, PhD, chief executive of Health Technology Networks (Gilbertsville, PA) and former chief science and technology officer at SmithKline Beecham, tells *DTTR* that the diagnostics industry is becoming more and more like the pharmaceutical industry. Poste notes that gene-based tests take longer and are more expensive to develop than traditional diagnostics. "Companies will stop investing if patent protection is not available," he predicts.

FDA Clears Procleix HIV-1/HCV Assay

The U.S. Food & Drug Administration has approved the Procleix HIV-1/HCV Assay, a nucleic acid amplification test for early detection of HIV-1 and hepatitis C in donated blood. Procleix was developed by Gen-Probe (San Diego, CA) under its strategic relationship with Chiron Corp. (Emeryville, CA). Gen-Probe is responsible for development and manufacturing, while Chiron handles marketing and distribution.

FDA approval allows Chiron to begin charging blood banks its full price of $10-$15 per donation. Under an investigational use drug application, Procleix has been sold since 1999 on a cost recovery basis of approximately $3-$4 per test result. Sales of Procleix totaled $48 million in 2001, Chiron reports. This year, sales are estimated to jump to $140 million, according to estimates from Merrill Lynch.

The higher prices should have a dramatic financial impact on Gen-Probe, which posted a net profit of $4.6 million on revenue of $130 million in 2001. The HIV-1/HCV assay is currently used to test roughly 70% of the 13 million annual whole blood donations in the U.S. Roche has the remaining 30% share of this market. Gen-Probe is a unit of Chugai Pharmaceuticals (Tokyo, Japan), but is expected to be spun off as a publicly traded company later this year (*DTTR, Jan. '02, p. 1*).

Nucleic acid testing (NAT) reduces the number of days between the time when a person contracts HIV or HCV and when the virus can be detected. Traditional serological tests can catch HIV at 16 days after initial infection. NAT trims it to 12 days. The window for HCV using serological testing is about 72-82 days, but with NAT it's down to 25 days, according to America's Blood Centers, which has been using NAT tests from both Gen-Probe and Roche since March 1999 as part of a clinical trial.

BioMerieux, Pierre Fabre To Separate

Only a year after their merger, French companies BioMerieux (Marcy-l'Etoile) and Pierre Fabre (Castres) are headed for a breakup because of a lack of synergies, according to reports in *Le Monde* and *Les Echos*. BioMerieux is among the 10 largest IVD companies in the world with annual revenue of some $800 million; Pierre Fabre, which specializes in drugs and cosmetics, has annual sales of roughly $1.2 billion. The former respective owners, Alain Merieux and Pierre Fabre, reportedly will resume control of their companies. Merieux is currently the executive chairman of the combined companies; Fabre is chairman of the supervisory board. A public announcement of the split-up is expected within weeks.

New Microscope Could Mark End Of Pap Smears

Royal Women's Hospital (Melbourne, Australia) will soon begin testing a new, miniature microscope that could revolutionize cervical cancer screening, according to reports from the Australian Associated Press. Developed by Optiscan Imaging Ltd. (Dandenong, Australia), the device, known as a rigid endomicroscope, is about the size of a ballpoint pen and uses laser light in conjunction with optical fiber to examine tissue at the cellular level. The device allows physicians to immediately see several layers of cells below the tissue surface of the cervix, thus removing the need to extract samples for testing at a lab.

Bayer Diagnostics Revenue Edges Up 2.2%

Bayer Group (Leverkusen, Germany) reports that Bayer Diagnostics (Tarrytown, NY) generated revenue of 2.009 billion euros (US $1.773 billion) in 2001, up 2.2% from 1.965 billion euros in 2000. A small restructuring in early 2001 cut employment at Bayer Diagnostics from 7,350 at year-end 2000 to 7,000 currently.

Expansion of nucleic acid testing led the growth, Bayer says. According to the company's annual report, Bayer paid 12 million euros (US $10.6 million) in March 2001 for exclusive worldwide distribution and marketing rights for HIV and hepatitis C tests made by Innogenetics (Ghent, Belgium), a biotech company. In addition, in June 2001, Bayer paid 116 million euros (US $102 million) to Ortho-Clinical Diagnostics (Raritan, NJ) and Chiron Corp. (Emeryville, CA) for the right to develop, manufacture and sell Ortho/Chiron HIV and HCV antibody assays for Bayer's ADVIA Centaur Immunoassay System and other systems.

Overall, Bayer Group reported net income of 965 million euros (US $851 million) in 2001, down from 1.816 billion euros in 2000; revenue fell 2.2% to 30.275 billion euros (US $26.7 billion).

Bayer Group At A Glance *(Euros MM)*

	2001	2000	Chg
Total revenue	30,275	30,971	-2.2%
Net income	965	1,816	-46.9%
Healthcare revenue	9,833	10,028	-1.9%
—Pharmaceuticals	4,784	4,930	-3.0%
—Biological products	945	1,210	-21.9%
—Consumer care	2,095	1,923	+8.9%
—Diagnostics	2,009	1,965	+2.2%
Healthcare operating profit	392	1,337	-70.7%

Source: Bayer

Company Execs Have Different Takes On Genetic Testing's Future

The main message DTTR *took away from this conference: reimbursement issues—rather than technological innovation—will probably be the key factor in the success or failure of the new diagnostic technologies*

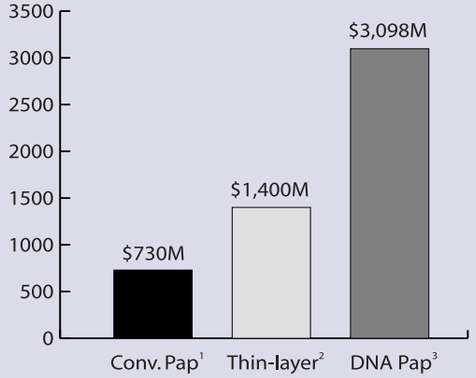
At a March 20 conference in New York City convened by Bank of America Securities, more than two dozen executives from biotechnology, IVD manufacturing, commercial laboratory and managed care companies came together to offer their views on the outlook for gene-based testing to an audience of some 200 analysts and investors.

In a panel discussion of lessons that can be learned from the widespread adoption of thin-layer Pap testing, **R. Derek Prentice**, MD, senior medical director/medical resource management at **Blue Cross Blue Shield of North Carolina** (Durham), noted: "This was not a positive embrace of a new technology on the part of the HMO industry." The more expensive thin-layer methods (capped nationally by Medicare at $28 per test) provide only a marginal benefit to low-risk women already getting periodic conventional Pap tests (reimbursed by Medicare nationally at no less than $14.60 per test), he said. The greater need, he stressed, is for high-risk women who never get tested to have access to the traditional Pap smear. The HMO industry was "harangued" by patients, providers and legislators into covering thin-layer Pap testing, he contended.

Prentice's biggest concern about the anticipated widespread use of new technologies, such as gene-based testing, is indiscriminate usage that results in higher costs with limited clinical benefits. "As a society, we do a poor job of evaluating new technology … healthcare costs are exploding again … the pie is only so big that we can spend on healthcare."

To illustrate, consider the transition from traditional Pap testing to thin-layer testing to the new "DNA Pap." A 100% adoption of thin-layer testing (already at about 60% market penetration) for the 50 million Pap tests currently done per year in this country would result in roughly $670 million in additional healthcare expenditures.

Estimated Reimbursement For U.S. Cervical Cancer Testing



1Assumes 50M conventional Pap tests/yr at $14.60/test
2Assumes 50M thin-layer tests/yr at $28/test
3Assumes 15M thin-layer tests at $28/test, plus 35M "DNA Pap" tests at $76.50/test
Source: *DTTR*

Meanwhile, on March 8, the U.S. Food & Drug Administration's Microbiology Devices Panel advised FDA to approve Digene Corp.'s submission to market its gene-based Hybrid Capture2 HPV Test (high-risk probe) in conjunction with the Pap test for primary cervical cancer screening of women age 30 and older. More than 35 million U.S. women in that age group have Pap smears annually. Digene expects a final FDA decision by year's end.

If FDA accepts the recommendation and current Medicare reimbursement levels are maintained, labs performing the combined thin-layer Pap test and the human papillomavirus (HPV) test (aka DNA Pap) could be reimbursed up to a maximum of $76.50 per speci-

men. Assuming 100% market penetration of the DNA Pap plus thin-layer tests for women under age 30, the U.S. cervical cancer testing market would be roughly $3.1 billion—a fourfold increase from conventional Pap testing.

Remember, this illustration applies to only one test. If potential costs for new gene-based tests for colorectal and prostate cancer, melanoma, etc., are added up, major fiscal and policy concerns arise, given that the size of the U.S. clinical lab testing market today is approximately $35 billion, of which only about $4 billion is attributed to Medicare Part B spending.

Reimbursement Levels For Selected Tests

Common Routine Tests	
Fecal occult blood	$4
Prothrombin time	5
Complete blood count	12
Traditional Pap	15
Lipid panel	19
PSA, total	25
Gene-Based Tests	
Cytyc/Digene's "DNA Pap"	77
Abbott/Vysis' HER-2 DNA Test	216
Genzyme Genetics' Cystic Fibrosis	240
Exact's PreGen-26	495
Myriad's Melaris	745
Myriad's BracAnalysis	2,580

Source: *DTTR* based on data from companies and Medicare payment rates

In his presentation at the conference, **George Poste**, PhD, chief executive of **Health Technology Networks** (Gilbertsville, PA) and former chief science and technology officer at SmithKline Beecham, said the fundamental challenge facing healthcare is demographics. "There is a growing imbalance between the infinite demand for healthcare vs. finite resources."

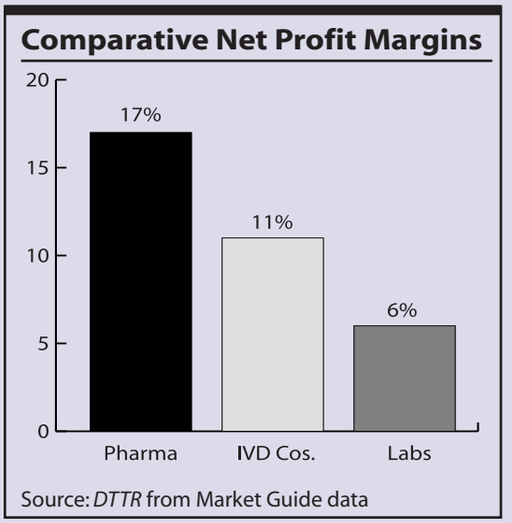
To Poste, the pharmaceutical industry is the healthcare sector most vulnerable to cost containment pressures. "I don't think pharmaceutical margins are sustainable. Pharma's soft underbelly is its promotional practices. How can you [pharma] justify these drug prices when you spend more on marketing than on research and development?"

Poste expects the advent of pharmacogenomics (personalized therapeutics determined by gene-based testing) will exert downward pressure on pharmaceutical company margins, while the margins for diagnostics improve. The value of diagnostics will rise as gene-based testing gets linked to new drugs targeted to specific patient populations to improve outcomes, eliminate futile therapies and reduce adverse drug reactions, according to Poste.

Certainly, any shift in value away from pharmaceuticals toward diagnostics would have a huge positive impact on IVD companies and clinical labs, given that the nation spent about $180 billion on prescription drugs last year and only $35 billion on clinical lab services (including about $9 billion for IVD supplies). The largest pharmaceutical companies also enjoy net profit margins averaging about 17% (Merck, Glaxo SmithKline, Pfizer, Schering-Plough, Pharmacia), compared with 11% for IVD companies (Diagnostic Products, Beckman Coulter, Becton-Dickinson) and 6% for the largest U.S. commercial lab companies (Quest Diagnostics and Laboratory Corp. of America).

Despite likely reimbursement hurdles, biotech, IVD and commercial lab companies are forging ahead to bring expensive gene-based diagnostics to the market. Here are some highlights of company presentations at the conference.

Heino von Prondzynski, global head of **Roche Diagnostics** (Basel, Switzerland), noted that Roche's molecular diagnostics business (PCR-based products



and services) grew 17% in 2001 to 877 million Swiss francs (US $523 million). New products include a home-brew test for cystic fibrosis (kit clearance expected in about 18 months). Roche also plans to bring to market early next year a gene-based test to guide warfarin dosage levels.

Patrick Plewman, president of **diaDexus Inc.** (Santa Clara, CA), expects the company's PLAC Test (which measures a novel risk factor for coronary heart disease) and Cathepsi-K (for detection of osteoporosis) to be on the home-brew market by year's end. Plewman also anticipates market introduction of Colon-101 (to detect colon cancer) in early 2003. "Screening is where the money is in diagnostics," he says. Glaxo SmithKline and Incyte Genomics each own 20% of diaDexus, which has filed with the U.S. Securities & Exchange Commission to go public.

Gregory Critchfield, MD, president of **Myriad Genetics Laboratories** (Salt Lake City, UT), says the list price for Myriad's newest genetic test, Melaris, is $745. The test is used to assess an individual's risk of developing malignant melanoma. Myriad's fastest-growing test is Colaris, he says, a predictive test for colon cancer priced at $1,950. The company's predictive testing business posted a 69% revenue increase, to $11.9 million, in the six months ended Dec. 31, 2001; gross margins are approximately 60%, according to Critchfield.

Kari Stefansson, chairman of **Decode Genetics** (Reykjavik, Iceland), expects his company to begin introducing gene-based tests for rheumatoid arthritis, Parkinson's disease, stroke, diabetes, obesity and anxiety within the next 2-3 years. "The scarce resource in human genetics is population data," he says. Decode has access to the Icelandic genealogy database, which enables the company to do thorough population genetics studies to discover markers.

Bruce Huebner, executive vice president and chief operating officer of **Gen-Probe** (San Diego, CA), believes automation is a key to expanding the molecular diagnostics market. Gen-Probe's Tigris system (an automated nucleic acid probe instrument system) will be introduced to the clinical diagnostics market sometime next year, he says, and to the blood screening market shortly thereafter. (For more on Gen-Probe, see p. 3)

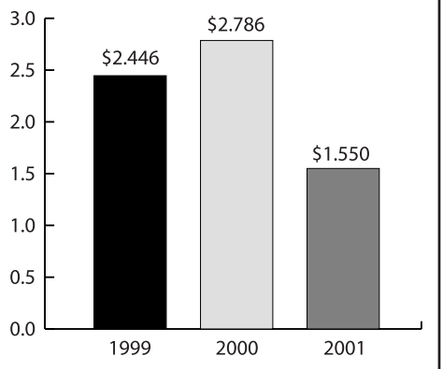
Lance Fors, chairman of **Third Wave Technologies** (Madison, WI), says ease of integration into existing equipment and workflow is necessary for the successful launch of a new assay in the clinical laboratory market. Last year, Third Wave introduced nine new DNA-based tests. Recently, the company announced an agreement with Daiichi Pure Chemical Co. Ltd., an affiliate of Daiichi Pharmaceutical Company (Tokyo, Japan), under which Third Wave will develop and supply genetic analysis products for development of a diagnostic test to determine an individual's predisposition to side effects from Irinotecan, a powerful colorectal/rectal cancer therapy marketed by Daiichi and Yakult Honsha (Tokyo).

Abbott's Miles White Earns $46 Million In 2001

Abbott Laboratories (Abbott Park, IL) awarded its chairman and chief executive, Miles White, total compensation of $46.3 million last year (up 64% from $28.2 million in 2000), according to the company's latest shareholder proxy statement.

White's 2001 compensation included 10-year options to purchase 525,000 shares of Abbott stock at a base price of $48.36 per share. These options could be worth $40.5 million if Abbott's stock price were to appreciate 10% annually until their expiration date in February 2011. White also got a salary of $1.4 million in 2001, plus a bonus of $2.1 million, restricted stock worth $2.1 million and other compensation totaling $172,966.

Net Income At Abbott *($B)*



Source: Abbott Laboratories

Richard Gonzalez, president and chief operating officer for Abbott's medical products group (including diagnostics), received total 2001 compensation of $20.6 million, more than double his total of $8.8 million in 2000. His compensation for 2001 included options to buy 250,000 shares of Abbott stock potentially worth $19.3 million. Gonzalez also got a salary of $593,754, a bonus of $642,000 and other compensation totaling $79,580.

Abbott's net income fell 44% in 2001 to $1.55 billion from $2.786 billion in 2000; revenue rose 18% to $16.285 billion. Its stock rose 15% last year to $55.75 per share.

Fujirebio Diagnostics To Commercialize Bladder Cancer Test

Fujirebio Diagnostics Inc. (FDI-Malvern, PA), a unit of Fujirebio Inc. (Tokyo, Japan), has acquired worldwide rights to commercialize tests for bladder cancer using a gene-based assay discovered by scientists at the Yale University School of Medicine (New Haven, CT). The agreement gives FDI rights to the cancer-specific gene Survivin, which has been shown to be abundant in the urine of patients with new or recurring bladder cancer, according to published preliminary clinical studies led by Dario Altieri, MD, professor of pathology at Yale University School of Medicine.

The agreement also gives FDI the right to develop and commercialize other cancer diagnostic tests utilizing Survivin. In return, FDI will pay Yale undisclosed license fees, milestone payments and royalties on future product sales. FDI, formerly known as Centocor Diagnostics, was acquired by Fujirebio Inc. in November 1998.

Separately, Fujirebio Inc. recently announced an agreement with Ribozyme Pharmaceuticals Inc. (RPI-Boulder, CO) to commercialize clinical diagnostic products using RPI's ribozyme-based diagnostic technology. Fujirebio will fund research for clinical diagnostics in human viral diseases and cancer. Fujirebio will get exclusive commercial rights for East Asia (including Japan) for any resulting products from this collaboration. In addition to research funding, RPI will get licensing fees and royalties.

Under another agreement signed in late 2001, Fujirebio Inc. is working with diaDexus Inc. (San Francisco, CA) to develop and sell cancer diagnostic tests in Japan. (See page 7 for more on diaDexus.)

Fujirebio Inc. recently reported consolidated net income of 3,033 million yen (US $23 million) for the year ended Dec. 31, 2001 vs. a net loss of 2,595 billion yen in 2000; revenue fell to 26,030 million yen (US $200 million) from 26,139 million yen the year before. The company divested its pharmaceutical business in June 2000 to focus on its diagnostics business—infectious disease testing and cancer markers. Fujirebio employs more than 800 people worldwide, including approximately 80 at U.S.-based Fujirebio Diagnostics.

Fujirebio At A Glance *(Japanese Yen, MM)*

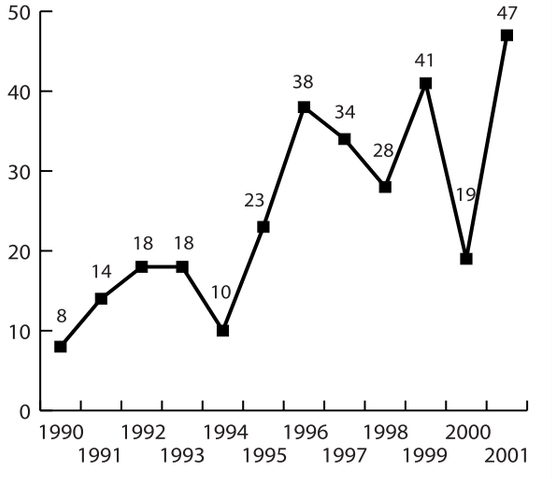
	1999	2000	2001
Revenue	29,737	26,139	26,030
EBITDA	3,340	16,848	16,830
Net income	1,795	-2,595	3,033

Source: Fujirebio Inc.

FDA Approves A Record 47 OTC Kits In 2001

The U.S. Food & Drug Administration's clinical laboratory devices division cleared 47 in vitro diagnostic devices for over-the-counter sale in 2001, breaking the previous record of 41 approvals in 1999. Among the home-test devices approved in 2001 were 21 glucose tests, 15 drugs-of-abuse tests and seven pregnancy or ovulation tests.

FDA Home-Test Approvals*



*Totals exclude approvals for devices available for home use by prescription only, but include collection devices that require samples to be mailed to a lab.

Source: U.S. Food & Drug Administration

Other test kits cleared for OTC sale in 2001 included the URS-1K (Ketone Test) urine reagent strip made by Teco Diagnostics (Anaheim, CA); the Ease-A-Cult fecal occult blood test made by Diagnostica Inc. (Las Vegas, NV); the Phem-Alert test for vaginal pH levels made by FemTek (Rockville, MD); and the FertilMarq test for male infertility made by Embryotech Laboratories (Boston, MA–see *DTTR, Nov. '01, p. 9*).

Since approving the first home pregnancy test in 1977, the FDA division has cleared more than 450 test kits for OTC sale. Gaining FDA approval allows a test to be sold directly to consumers at drugstores or through online distributors. Sales of OTC diagnostic tests to U.S. consumers are growing at better than 10% per year and reached roughly $2.3 billion in 2001, including approximately $2 billion from blood glucose testing and $300 million from other tests (primarily pregnancy), according to *DTTR* estimates.

LipoScience Seeks Up To $100 Million From IPO

LipoScience Inc. (Raleigh, NC), which makes a test to gauge a patient's risk of cardiovascular disease, has registered with the U.S. Securities & Exchange Commission to raise up to $100 million from an initial public offering. Merrill Lynch, U.S. Bancorp Piper Jaffray, Thomas Weisel Partners and Pacific Growth Equities have been hired to manage it. The number of shares to be sold and the share price have not yet been determined. Proceeds from the IPO will be used to expand the company's sales force, purchase inventories and for operating expenses.

LipoScience's main product is its NMR LipoProfile test, which contributed 83% of the company's $18.5 million in revenue in 2001. LipoScience says the patented test utilizes nuclear magnetic resonance spectroscopy to provide detailed information about the concentration and size of lipoprotein particles that carry cholesterol in the blood stream. The test enables physicians to diagnose cardiovascular disease risk more accurately than traditional lipid panel testing, the company asserts.

LipoProfile has been marketed to the clinical research market since 1997 and to the patient care market since early 1999. Medicare reimburses it under CPT code 83716; payment is capped nationally at $34.30. The average selling price per LipoProfile test across all payers (Medicare, managed care, and commercial lab customers) was approximately $85 in 2001, the company says.

LipoScience's clinical laboratory in Raleigh is the only lab that performs the LipoProfile test. Last year, it performed a total of 249,000 tests, including 179,000 LipoProfile tests. The remaining volume came from non-proprietary cardiovascular tests, including lipoprotein, homocysteine, and high-sensitivity C-reactive protein. LipoScience says it is also developing a proprietary test for insulin resistance, a precursor of type 2 diabetes.

In the year ended Dec. 31, 2001, LipoScience reported a net loss of $3.413 million vs. a net loss of $3.238 million in 2000; revenue increased to $18.479 million from $6.226 million. Since its inception in 1997, the company has incurred $10.4 million in accumulated losses.

James Otvos, PhD, is the founder and chief scientific officer at LipoScience; he also is an adjunct professor of biochemistry at North Carolina State University. Otvos holds an 18% stake in the company. Richard Franco, R.PH, is company chairman and holds a 7% stake. The largest shareholder is venture firm Three Arch Capital (Menlo Park, CA), which holds a 20% stake.

LipoScience At A Glance *($000)*

	2001	2000	1999
Revenue	$18,479	$6,226	$1,398
Gross profit	13,525	4,226	539
Net income	-3,413	-3,238	-2,147

Source: LipoScience

IVD Stocks Rise 8% In Latest Four Weeks

After falling 36% in 2001, Bayer stock has risen 9% so far this year to 39.13 euros per share; Roche non-voting equity shares, which fell 28% in 2001, have jumped 31% so far this year to 155.25 Swiss francs per share

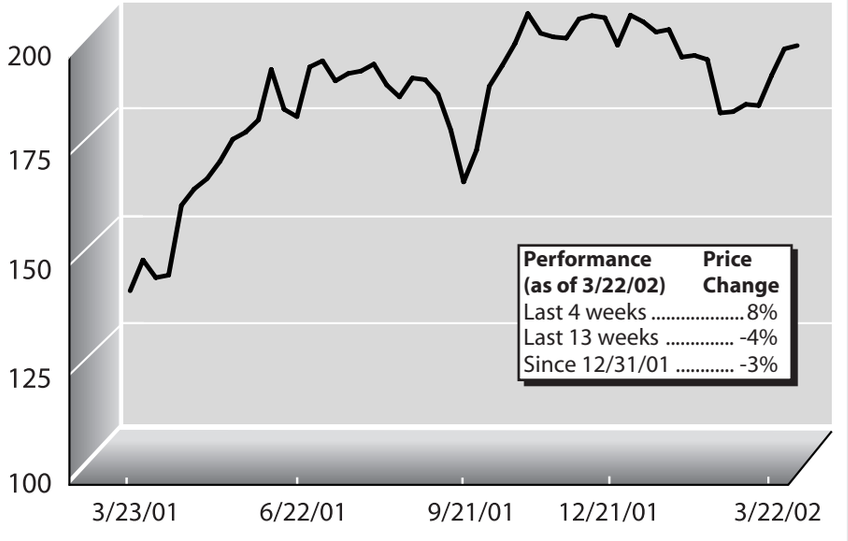
The 21 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 8% in the four weeks ended March 22, 2002, with 12 stocks moving up in price, six falling and three unchanged. Year-to-date, the G-2 Index has declined by 3%, compared with a 1% gain for the S&P 500 and a 5% drop for the Nasdaq.

Shares of **Immucor** (Norcross, GA) jumped 52% to $14.86 per share, giving the company a market capitalization of $108 million. Immucor recently announced a letter of intent to transfer all its commercial activities in France to **Bio-Rad Laboratories** (Hercules, CA), effective April 2, 2002 through April 1, 2007. Over the life of the agreement, Immucor expects revenue growth of approximately $9 million (or $1.8 million per year). For the six months ended Nov. 30, 2001, Immucor posted net income of $3.5 million vs. a net loss of $828,000 in the comparable period a year earlier; revenue rose 17% to $39.6 million.

Shares of **Biosite** (San Diego, CA) rose 21% to $24.40 per share for a market capitalization of $356 million. Biosite recently announced a three-year agreement with **Amgen** (Thousand Oaks, CA) to generate high-affinity antibodies to targets provided by Amgen. Biosite will receive undisclosed development fees as well as potential royalties if Amgen successfully commercializes products. Biosite also will retain certain diagnostic rights to targets in the collaboration.

Other IVD stocks moving up in price over the past four weeks included **Cholestech** (Hayward, CA), up 41% to $16.50 for a market capitalization of $190 million; **Diagnostic Products** (Los Angeles, CA), up 15% to $42.96 per share for a market cap of $1.2 billion; and **Cytyc** (Boxborough, MA), up 14% to $26.19 per share for a market cap of $3.2 billion.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 21 diagnostic test and equipment makers.

% price change, 4 weeks ended 3/22/01

	Price	% Chg
UP		
Biosite	$24.40	21
Bio-Rad	37.20	10
Cholestech	16.50	41
Cytyc	26.19	14
Diagnostic Products	42.96	15
Digene	34.99	12
Immucor	14.86	52
Inverness Medical	21.65	9
Johnson & Johnson	64.85	9
Meridian	6.89	13
Quidel	6.26	10
Ventana	20.50	8
UNCHANGED		
Beckman Coulter	48.30	0
Cygnus	3.90	0
i-Stat	6.30	0
DOWN		
Abbott Labs	53.70	-7
Becton Dickinson	36.28	-2
Careside	0.31	-23
Diametrics	4.03	-3
Igen	38.18	-14
Therasense	19.00	-5

G-2 Insider

Roche Diagnostics (Basel, Switzerland) has begun the appeal process in its patent dispute with **Igen International** (Gaithersburg, MD; see *DTTR, March '02, p. 3*).

Heino von Prondzynski, global head of Roche Diagnostics, tells *DTTR* that he believes the jury's decision to award $505 million in damages to Igen "is way out of line." Roche would like to maintain access to Igen technology, he says, but must reach an agreement that allows Roche to remain competitive in the marketplace.

Igen says it has notified Roche that the license agreement terminates once the final judgment is affirmed by the Court of Appeals (expected sometime in the second half of 2003). Furthermore, Igen says it is establishing a project team to manage the transfer of Roche's Elecsys products and improvements to Igen. Unless the judgment is amended or stayed pending appeal, Roche will be obligated to commence the process of transferring all improvements to Igen during the second quarter of 2002.

Publicly, Roche Diagnostics and Igen each have indicated a willingness to end their relationship, but **Larry McGrath**, president of McGrath & Associates (Grass Valley, CA) believes too much is at stake for both companies not to work out a new agreement. "Roche must have an immunoassay product line in order to compete in the core laboratory market, and I believe it would be extremely difficult for Igen to start over with a new partner."

Concessions that Roche might need to make to pacify Igen include higher licensing fees (currently at 9%) or transfer of additional technologies to Igen (in addition to transfers required under the judgment), according to McGrath.

Company References

Abbott Labs 847-937-6100
Biosite 858-455-4808
Chiron 510-655-8730
Decode Genetics 354-570-1900
diaDexus 650-246-6400
Exact Sciences 978-897-2800
Fujirebio Diagnostics 610-240-3800
Gen-Probe 858-410-8000
Health Technology Networks 610-705-0828
Igen 301-869-9800
Immucor 770-441-2051
LipoScience 877-547-6837
McGrath & Assoc. 530-477-0577
Myriad Genetics 801-584-3600
Roche Diagnostics 317-849-9350
Third Wave 608-273-8933

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