



Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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CONTENTS

TOP OF THE NEWS

Blood gas/electrolyte testing moves to the point of care 1
Medtronic to buy MiniMed 1

M&A/PARTNERSHIPS

J&J finalizes agreement to purchase Inverness unit 3
Bayer, Matsushita to develop IVD products 4
IRIS strikes deal with Arkray 8

INSIDE DIAGNOSTICS INDUSTRY

POCT has become standard for blood gas tests 5
Companies featured: *Bayer, Radiometer, Instrumentation Laboratory, Roche, Nova Biomedical* 5-6
Hand-held market growing 7

TECHNOLOGY

Matsushita launches Tele-Homecare System" 4
Roche launches AmpliPrep in Europe 9
Gen-Probe gets FDA okay for CT/NG test 9
Beckman introduces rapid heart attack test 10
Decode seeks DNA test for arthritis 10

FINANCIAL NEWS

Profit up at Tecan 8
IVD stocks up 4% 11

G-2 INSIDER

Pharmacogenomics interests diverge 12



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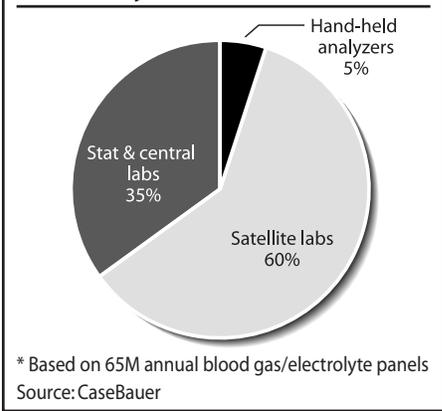
New Products May Boost POCT For Blood Gas

Approximately 65 million blood gas/electrolyte test panels are performed in the U.S. each year, representing some \$260 million in annual revenue to IVD manufacturers. That's a sizable market, and for the past 10 years it has been shifting from stat and centralized laboratories to "satellite" labs equipped with miniature analyzers (<35 lbs) located in emergency departments, operating rooms, and intensive care units. Hand-held analyzers for testing at the bedside are also gaining market share. In fact, the research and consulting firm, CaseBauer (Irving, TX), estimates that 65% of all blood gas/electrolyte testing is now being performed by mini-analyzers in satellite labs and by hand-held instruments.

The long-term trend toward point-of-care testing for blood gas/electrolytes should get a boost from the re-launch of Bayer's Rapidpoint 400 Critical Care Analyzer for satellite labs. Problems with Rapidpoint's pO₂ sensor thwarted the initial launch in 1998. But kinks have been ironed out, says James Tordella, worldwide marketing manager for Rapidpoint, and a full marketing campaign is now underway. In addition, rival Radiometer began marketing its 25-pound NPT7 blood gas instrument for satellite lab testing earlier this year.

For an overview of the competitive landscape, see *Inside The Diagnostics Industry*, pp. 5-7. 🏠

U.S. Blood Gas/Electrolyte Testing Volume By Location, 2001



Purchase Of MiniMed/MRG Will Add Deep-Pocket Competitor To Glucose Testing Market

The competition to provide blood glucose testing devices to some 16 million diabetics in the U.S. is expected to get tighter now that Medtronic Inc. (Minneapolis, MN) has agreed to acquire MiniMed Inc. (Northridge, CA) and its sister company, Medical Research Group Inc. (MRG—Sylmar, CA), for a combined \$3.7 billion.

Continued on p.2

▲ **Medtronic's Purchase Of MiniMed/MRG**, *from page 1*

MiniMed is the world's leading maker of insulin delivery pumps and has also developed a continuous glucose monitoring system. Medtronic will pay \$3.28 billion in cash (or \$48 per MiniMed share) to acquire MiniMed. In a related deal, Medtronic has agreed to pay \$420 million in cash and stock for MRG, a privately held company that is working to integrate implantable insulin pump and glucose testing technologies to create an "artificial pancreas" that monitors blood glucose levels, then automatically delivers the appropriate amount of insulin.

The combined purchase is expected to close within the next 90 to 120 days. At a price of \$3.7 billion, Medtronic is paying 9-10 times the estimated \$375-400 million in revenue that MiniMed/MRG will generate this year. However, coughing up the cash should be no problem for Medtronic. The diversified medical device maker had \$1.7 billion in cash on its balance sheet as of April 27 and is generating an additional \$350 million in cash each quarter. In the fiscal year ended April 27, Medtronic reported net income of \$1.282 billion vs. \$1.096 billion a year earlier; revenue was up 11% to \$5.552 billion.

The purchase of MiniMed/MRG brings Medtronic into a whole new market. Medtronic was founded in the 1950s as a heart pacemaker company and branched out into cardiac defibrillators. Through \$8.3 billion worth of acquisitions over the past three years, it has moved into ear/nose/throat surgery products (its Xomed unit), spinal surgery devices (Sofamor Danek), emergency defibrillators used by paramedics (Physio Control), and stents and aneurysm grafts (Arterial Vascular Engineering).

In a conference call announcing the MiniMed/MRG deal on May 30, Arthur Collins, chief executive of Medtronic, said: "Diabetes represents an exciting, new rapidly growing platform for Medtronics ... We have been contemplating these two acquisitions for some time ... This is the best way to enter the large and growing diabetes market."

"Artificial Pancreas" Could Unsettle Glucose Testing Market

An estimated \$3.5 billion was generated by the worldwide sale of blood glucose testing devices last year. And this market is expected to grow by 10-15% over the next few years. Market share leaders include Roche, Johnson & Johnson, Bayer, and Abbott. The market is quickly shifting from traditional finger-prick testing systems to less-painful systems that can draw small quantities of blood (less than 3µL sample size) from the forearm or thigh. In addition, companies like Cygnus Corp. (Redwood City, CA) have developed wrist-worn devices that monitor glucose levels without breaking the skin.

Looking farther out, some industry observers believe MRG's implantable "artificial pancreas," which monitors blood glucose levels and delivers insulin, will revolutionize diabetes care. The device has been successfully tested on animals, and Medtronics' chief executive Arthur Collins has stated that a product could be ready for the consumer market in about five years.

MiniMed derives nearly all its revenue from the sale of insulin delivery pumps and related consumables to patients with diabetes. Its virtually painless pumps deliver hundreds of tiny infusions of insulin via soft tubes or mini-catheters.

The company has an 85% market share for insulin pumps in the U.S. Its primary market is the 800,000 to one million individuals who suffer from Type 1 diabetes—a severe form characterized by a complete lack of insulin secretion by the pancreas. In addition, it markets an implantable pump that has been approved for distribution in Europe, but has not yet been cleared in the U.S.

MiniMed has also developed a continuous glucose monitoring system approved for use by physicians treating patients with diabetes. The company sub-

mitted an application for consumer use in August 2000 and expects clearance sometime this year. The system utilizes a small, thin, pliable sensor inserted just below a patient's skin (but above the nerve level) in the abdomen, upper arm, or thigh. It measures glucose in fluid found just under the skin, which contains glucose molecules in levels similar to those found in blood.

Each sensor lasts about three days, after which it must be replaced with another sensor in a different location. The system records the average glucose levels over five-minute intervals. Physicians review the data and adjust therapy accordingly.

MiniMed In Brief (\$000)			
	1Q2001	1Q2000	% Chg
Total Revenue	\$80,007	\$60,338	33%
☐ External insulin pumps	75,107	56,278	33%
☐ Implantable insulin pumps	351	300	17%
☐ Other diabetes supplies	3,185	2,345	36%
☐ Glucose monitoring systems	690	650	6%
☐ Pharmacy products	674	765	-12%
Pretax income	14,125	9,761	45%
Net income	9,751	6,247	56%
Source: MiniMed			

In the three months ended March 31, MiniMed reported net income of \$9.751 million, up 56% from \$6.247 million in the same period a year earlier; revenue was up 33% to \$80.007 million. MiniMed, which employs 1,600 people, was founded by its chairman and chief executive, Alfred Mann, in 1983. Mann owns 17.9 million shares, or 27%, of MiniMed worth \$859 million.

Mann is also founder of MRG, which he created by purchasing the rights to implantable pump technology from MiniMed in September 1998 for \$3.6 million. Less than three years later, Mann is selling MRG to Medtronic for \$420 million. Mann's 34% stake in MRG is worth \$143 million. 🏠

J&J Finalizes Agreement To Purchase Inverness Unit

Johnson & Johnson (New Brunswick, NJ) has reached a definitive agreement to purchase the blood glucose testing business of Inverness Medical Technology (Waltham, MA) for \$1.33 billion worth of J&J common stock. The deal is expected to close in the fourth quarter. Shareholders of Inverness will receive \$35 worth of J&J common stock for each Inverness share they own. They will also get shares in the new company formed from the remaining Inverness product line (nutritional supplements, over-the-counter tests, and infectious disease kits—\$50 million in combined annual revenue).

Inverness' blood glucose testing business will generate an estimated \$160 million in revenue this year, indicating that J&J is paying 8.3 times revenue (*i.e.*, \$1.33 billion/\$160 million=8.3). Inverness currently manufactures electrochemical glucose monitoring meters and strips for J&J's One Touch Ultra product. Sales of Inverness products were 20% of J&J's Lifescan sales in 2000.

The acquisition will bring J&J two FDA-approved products to test for fructosamine: one in the physician office (named Duet); the other for consumer use (named In Charge). J&J will also gain Inverness' development-stage products for insulin pumps and continuous glucose monitoring. 🏠

Bayer, Matsushita To Jointly Develop Diagnostic Products

Bayer Corp. (Tarrytown, NY) and Matsushita Electric Industrial Co. Ltd. (Osaka, Japan), best known for its Panasonic brand, have announced plans to enter into a long-term, strategic business relationship to jointly develop, manufacture, and market diagnostic products. Under the agreement, Bayer Corp., through its business group Bayer Diagnostics, would acquire rights for the sale and marketing of newly developed diagnostic products, while Matsushita will be primarily responsible for the development and manufacturing of new products.

“This relationship will leverage our combined strengths ... We have already begun work on products for blood glucose monitoring through our self-testing segment in Elkhart, Indiana, and future opportunities are limitless,” commented Rolf Classon, president of Bayer Diagnostics.

Matsushita is one of the world’s largest manufacturers of electronics products. In the fiscal year ended March 31, 2001, the company increased revenue by 5% to 7.682 trillion yen (US \$62.3 billion). 🏠

Matsushita Introduces “Panasonic Tele-Homecare System”

Matsushita Electric Industrial Corp. of America (a.k.a. “Panasonic”—Secaucus, NJ), the principal North American subsidiary of Matsushita of Japan, has begun marketing its new Panasonic Web-based tele-homecare system. The system allows remotely located patients to measure their vital signs and other physiological data and transmit the information to physicians and nurses by telephone service over the Internet.

The Panasonic system is comprised of three components: a patient terminal, network server software, and doctor terminal software. The patient terminal weighs 17 lbs. and measures vital signs using a thermometer; sensors for blood pressure/pulse, blood glucose, and oxygen saturation; a stethoscope; an electrocardiograph device; and a scale. The network server informs the patient which sensor to use to monitor which vital sign at a particular time, based on the personalized plan drawn up by the patient’s doctor. The physician terminal software enables physicians and nurses to view patient data stored on the server as well as communicate with the patient via e-mail and video/phone camera.

The Panasonic system is being leased to healthcare institutions at a list price of \$15,000 per three-year period (\$5,000 per year per unit). The system has been tested at Focused Health Solutions Inc. (Northbrook, IL), which provides health services to self-insured employers, and the VA Connecticut Healthcare System (West Haven), which serves veterans in Connecticut.

The system uses a Panasonic-developed and manufactured blood glucose testing device which has been branded by Bayer. The system is currently being sold by Panasonic’s internal salesforce. A spokesman tells *DTTR* that Bayer’s involvement in the Panasonic tele-homecare system is separate from a recent agreement between Bayer and Matsushita of Japan (*see article above*). 🏠

inside the diagnostics industry

Point-Of-Care Has Become The Standard For Blood Gas/Electrolyte Testing

The standard of care dictates that physicians and nurses receive blood gas (e.g., oxygen, carbon dioxide, and acidity) and electrolyte (e.g., sodium, potassium, and ionized calcium) test results as fast as possible when using these analytes to assess vital tissue oxygenation, perfusion, and substrate status in critically ill patients. Point-of-care devices for such testing allow attending clinicians to implement therapy almost immediately for unstable patients. As a result (despite the higher per-test cost), hospitals have sought to bring blood gas/electrolyte testing closer to patients.

For the estimated 22.7 million annual blood gas/electrolyte test panels done each year in the U.S. at stat or centralized labs, reagent costs are roughly \$1 per panel or less. For the estimated 42.3 million such tests done each year using mini-analyzers and hand-held instruments, reagent/cartridge costs average roughly \$3-7 per test panel. These figures suggest a total current market size of \$260 million in annual revenue to IVD vendors.

Bayer Diagnostics (Tarrytown, NY) and **Radiometer** (Copenhagen, Denmark) are the leaders in traditional blood gas/electrolyte analyzers for stat and centralized labs. To protect their market share, each company has recently launched new mini-analyzers for use in satellite labs within emergency departments, operating rooms, and intensive care units.

According to James Tordella, worldwide marketing manager for Bayer's Rapidpoint 400 analyzer, there are more than 7,500 traditional blood gas/electrolyte analyzers (i.e., 70+ lbs) in place at stat and centralized labs in U.S. hospitals. He estimates that about 1,500 of these are being replaced each year, with more than 500 of this amount transitioning to mini-analyzers such as Bayer's Rapidpoint 400.

Tordella says Bayer has placed about 55 Rapidpoint 400 analyzers in the U.S., the United Kingdom, and Germany since re-launching the instrument earlier this year. The 34-pound instrument has a list price of \$38,000. Each disposable reagent system sells for about \$3,000 and can test 750 samples for an average cost of \$4 per test panel, according to Tordella. Rapidpoint 400 has an automatic quality control system and is maintenance-free; test results are provided in approximately 60 seconds.

Radiometer began marketing its 25-pound NPT7 blood gas instrument for satellite lab testing earlier this year. NPT7 is an all-dry system that performs blood gas testing in single-use measuring chambers. It automatically loads and prepares a new measuring chamber from a cartridge containing 30 chambers prior to each test. NPT7 has an integrated quality control system and is maintenance-free; test results are provided about two minutes. It lists for \$18,500.

Late last year, Radiometer launched its ABL77 blood gas analyzer. The 16-pound instrument is designed for satellite lab testing and measures pH, blood gases,

The decentralization of blood gas/electrolyte testing has been pushed by the expanded menu breadth (e.g., electrolytes, glucose, and lactate) of mini- and hand-held analyzers, says Robert Bauer, president of CaseBauer

three electrolytes, and hematocrit on 85 microliters of blood. The ABL77 is manufactured by Radiometer's subsidiary, SenDx Medical Inc. (Carlsbad, CA), acquired in 1998. It lists for \$15,900.

Radiometer also makes the 66-pound ABL700 series, a high-end instrument (list price: \$28,700-\$68,150, depending on configuration options) geared more for traditional stat and centralized labs. In the nine months ended Jan. 31, 2001, Radiometer reported a net profit of 96.2 million krona (US \$11 million) vs. 79.6 million krona (US \$9 million) in the same period a year earlier; revenue was up 11% to 1.223 billion krona (US \$140 million).

Instrumentation Laboratory (IL—Lexington, MA and Milan, Italy) began marketing its GEM Premier 3000 blood gas/electrolyte analyzer last year. The 30-pound instrument provides test results in less than 100 seconds and is maintenance-free. Scott LaNeve, executive director of sales and national accounts, tells *DTTR* that more than 1,000 GEM Premier systems are in operation worldwide, including 800 in the U.S.

Also last year, IL launched the GEM 3100, which includes the capability to perform clotting assays. IL expanded its expertise in coagulation through acquisition of Hemoliance (Pleasantville, NY) in early 1999. Hemoliance was a coagulation testing joint venture between Ortho Clinical Diagnostics (Raritan, NJ) and Medical Laboratory Automation (Pleasantville, NY).

IL, which is a subsidiary of C.H. Werfen (Barcelona, Spain), generated an estimated \$300 million in revenue last year.

Roche (Basel, Switzerland) gained a position in the satellite lab market for blood gas/electrolyte testing when it acquired the medical instruments business from AVL (Graz, Austria) in June 2000. AVL Medical Instruments sells the Opti and Omni systems and has more than 15,000 analyzers placed worldwide; annual revenue is more than \$100 million per year. New products include the Opti R Critical Care Analyzer.

Privately held **Nova Biomedical** (Waltham, MA) launched its Stat Profile pHox Plus blood gas/electrolyte analyzer last year. The 18-pound device (list price: \$29,000) provides test results in 45 seconds.

Recently Introduced Near-Patient Blood Gas/Electrolyte Analyzers

Vendor/System	Weight	TAT*	List Price
Bayer's Rapidpoint 400	34 lbs	60 seconds	\$38,000
Radiometer's NPT7	25 lbs	120 seconds	\$18,500
Radiometer's ABL77	16 lbs	90 seconds	\$15,900
IL's GEM Premier 3000	30 lbs	90 seconds	\$39,995
IL's GEM 3100	32 lbs	90 seconds**	\$45,995
Roche/AVL's Opti R	11 lbs	60 seconds	NA
Nova Biomed's Stat Profile Plus	18 lbs	45 seconds	\$29,000

*Turnaround time (TAT) from sample introduction to results availability.
 **TAT for blood gas/electrolyte approx. 90 seconds; coagulation is under 5 min.
 Source: *DTTR* from companies and *CAP Today* (August 2000)

Hand-Held Blood Gas/Electrolyte Testing Growing By 30+%

i-Stat Corp. (East Windsor, NJ) and **Diametrics Medical** (St. Paul, MN) are the global leaders in the market for hand-held blood gas/electrolyte analyzers. In the first quarter ended March 31, 2001, the two companies sold a combined worldwide total of 3.1 million test cartridges. This indicates annualized worldwide volume of 12.4 million cartridges, including about 10 million sold to U.S. hospitals. Test cartridge volume at both i-Stat and Diametrics is growing by more than 30% per year.

The i-Stat hand-held analyzer weighs less than two pounds, making it the lightest blood gas/electrolyte testing device on the market today. Abbott Laboratories markets the analyzer under a five-year agreement that became effective in 1999. In first-quarter 2001, i-Stat shipped 900 analyzers, bringing its worldwide base to more than 22,000. Also in the first quarter, the company shipped 2.76 million test cartridges, up 34% from 2.065 million in the same period a year earlier. The company's average selling price per cartridge was \$3.39, and the U.S. accounted for approximately 75% of cartridge volume.

The i-Stat analyzer currently runs all of the standard tests for blood gas and electrolytes, plus glucose, creatinine, BUN, ACTc, and lactate. In addition, William Moffitt, chairman of i-Stat, says three additional tests for the measurement of coagulation (kaolin ACT, partial thromboplastin time, and prothrombin time) should be added to the menu in the first half of 2002. Point-of-care coagulation testing will greatly reduce the hour-long waits for lab results that most patients on Coumadin (blood thinner) treatment are now subject to when visiting outpatient clinics, says Moffitt.

Diametrics' IRMA Blood Analysis System (approximately four pounds) is marketed by Agilent's Healthcare Solutions Group. In the first quarter of this year, Diametrics shipped 750 analyzers, bringing its estimated worldwide base to more than 6,000. Also in the first quarter, the company shipped 330,000 test cartridges, up 42% from 235,950 in the same period a year earlier. David Giddings, chairman of Diametrics, says the company, in collaboration with Agilent, is planning to launch a one-pound blood gas/electrolyte analyzer by year's end. The palm-sized device will connect by cord to Agilent's CMS bedside monitors. Meanwhile, Agilent's Healthcare Solutions Group, which generates \$1.4+ billion in annual revenue, is being acquired by Royal Philips Electronics (Amsterdam, The Netherlands) for \$1.7 billion. ▲

"We believe Philips will be committed to point-of-care testing and Diametrics," says Giddings

Leading Manufacturers Of Hand-Held Blood Gas Analyzers

	i-Stat	Diametrics
Device name:	i-Stat System	IRMA System
Marketing partner:	Abbott Labs	Agilent Technologies
Worldwide analyzers placed ¹ :	22,000+	6,000+
Worldwide cartridge volume ² :	11+M	1.35+M
Avg. annual cartridge volume per analyzer:	500	225

¹Figures are estimated as of March 31, 2001.

²Figures for cartridge volume are estimated for full-year 2001, based on annualized first-quarter results.

Source: DTTR

First-Quarter Net Income Up 47% At Tecan

Tecan Holding AG (Maennedorf, Switzerland) reports that its net income rose to 11.1 million Swiss francs (US \$6.2 million) for the first quarter ended March 31, up 47% from 7.5 million (US \$4.2 million) earned in the same period a year earlier. Revenue increased 43% to 84.2 million Swiss francs (US \$47 million) from 58.7 million (US \$32.7 million).

Tecan's fastest-growing division is Genomics/Proteomics, which increased first-quarter revenue by 118% to 18.5 million Swiss francs (US \$10.3 million). Growth was spurred by increasing sales of Tecan's automated DNA sample preparation systems (e.g., MolBio workstation) to the gene and protein research markets. The Genomics/Proteomics division now accounts for 22% of Tecan's overall revenue.

Diagnostic division revenue increased 53% to 38 million Swiss francs (US \$21.2 million). Growth was driven by sales of Tecan's Genesis FE 500 workcell, with first-quarter sales of this instrument for front-end automation (e.g., pre-sorting, centrifugation, decapping, aliquoting, etc.) exceeding total sales in full-year 2000. Tecan has an agreement to co-market the Genesis FE 500 with Abbott Laboratories (Abbott Park, IL).

	1Q2001	1Q2000	% Chg
Total Revenue	84.2	58.7	43%
—Diagnostics	38.0	24.8	53%
—Drug Discovery	27.7	25.4	9%
—Genomics/Proteomics	18.5	8.5	118%
Pretax income	16.4	11.7	40%
Net income	11.1	7.5	47%

Source: Tecan

Tecan's drug discovery division increased first-quarter revenue by 9% to 27.7 million Swiss francs (US \$15.5 million). This division sells high-throughput screening equipment and ADME (absorption, distribution, metabolism, excretion) toxicology assays that help pharmaceutical and biotech companies identify the most promising drug candidates more rapidly.

Tecan, which has 690 employees worldwide, maintains its U.S. headquarters at Research Triangle Park,

NC. First-quarter revenue from U.S. customers increased 48% to 42.1 million Swiss francs (US \$23.4 million). In full-year 2000, Tecan posted net income of 39.45 million Swiss francs (US \$22 million), up 41%, on total revenue of 273.532 million Swiss francs (US \$152.2 million), up 42%. Revenue and net income for full-year 2001 are each expected to grow by 30-35%, according to chief executive Emile Sutcliffe. ▲

IRIS Enters U.S. Distribution Agreement With Japan's Arkray

International Remote Imaging Systems Inc. (IRIS—Chatsworth, CA) has entered into an exclusive agreement with Arkray Inc. (Kyoto, Japan) to distribute the Arkray Model AX-4280 Automated Urine Strip Analyzer and related consumables in the U.S. IRIS will assist Arkray in obtaining clearance for these products from the U.S. Food & Drug Administration and begin distribution immediately thereafter. The agreement marks Arkray's entrance in the U.S. market. IRIS is a leading manufacturer of urinalysis workstations with 450 placements worldwide. In the three months ended March 31, IRIS posted net income of \$361,000 vs. \$637,000 in the comparable period a year ago; revenue was up 8% to \$7.228 million. ▲

Roche Launches AmpliPrep In Europe

Roche Molecular Systems (Pleasanton, CA) has begun European marketing of its Cobas AmpliPrep System (list price: US \$100,000). AmpliPrep automates the entire sample preparation process of nucleic acid extraction for PCR analysis on Roche's Cobas Amplicor analyzer. Technologist hands-on time is reduced to loading samples, reagents, and reaction vessels onto the AmpliPrep system. Patient orders can be manually entered via Roche's AmpliLink software or downloaded from the laboratory information system. The introductory assay menu includes qualitative and quantitative assays for HCV and a quantitative assay for HIV-1.

Roche is planning to begin U.S. clinical trials of AmpliPrep later this year. The company could gain approval from the Food & Drug Administration and begin marketing the product in the U.S. as soon as the first quarter of 2002, according to Clelia Baur, spokeswoman for Roche.

An independent study has demonstrated the labor savings that AmpliPrep can produce. Total hands-on technician time for PCR-based testing of batches of 24 specimens can range from 70 minutes for chlamydia/gonorrhoeae (urine samples) to up to 200 minutes for hepatitis C assays, according to the study published in the August 1998 edition of *Clinical Chemistry* (Klapper, P.E. *et al*, Multicenter International Work Flow Study Of An Automated PCR Instrument). The study focused on workflow timing for PCR-based testing at five laboratories in Italy, Germany, The Netherlands, England, and the U.S.

The study found that, on average, 60-84% of hands-on time for a PCR-based assay is related to specimen preparation, with the remainder being related to steps involving the Amplicor analyzer. The hands-on time savings achieved with AmpliPrep were a significant 60% for a batch of 24 specimens, increasing up to 76% for the largest batch of 72 specimens, according to the study. 🏠

Gen-Probe Gets FDA Okay For Chlamydia/Gonorrhoeae Test

Gen-Probe Inc. (San Diego, CA) has received FDA clearance to begin marketing its target-amplified nucleic acid probe test ("Aptima Combo 2 Assay") for the qualitative detection of ribosomal RNA from chlamydia/gonorrhoeae in endocervical and male urethral swab specimens and urine samples.

Gen-Probe says its "target capture" technology selectively pulls the nucleic acid target out of the specimen to allow larger volumes of specimen to be tested. By using ribosomal RNA targets that are present in 2,000 or more copies per bacterium instead of DNA targets present in only a few copies per cell, Aptima Combo 2 Assay achieves greater sensitivity more reliably than competing technologies, says Gen-Probe.

By coupling this "natural amplification" with its transcription-mediation amplification method, Gen-Probe is able to make billions of copies of the target nucleic acid in the test tube in minutes. Detection of the amplified target is achieved using

two light-producing labels that allow the detection of both chlamydia and gonorrhoeae with a single test.

Gen-Probe was acquired by Chugai Pharmaceutical Co. (Tokyo, Japan) for \$110 million in 1989. Chugai derives more than 90% of its annual revenue from prescription drug sales. In the fiscal year ended March 31, 2001, the company reported a net profit of 15.5 billion yen (US \$126 million) vs. 8.76 billion yen (US \$71 million) in fiscal 2000; revenue was up 4% to 203.01 billion yen (US \$1.65 billion). Revenue at Gen-Probe grew by 13.6% in fiscal 2001 to 15.047 billion yen (US \$122 million). ▲

Beckman Coulter Gets FDA Nod To Sell Heart Attack Test

Beckman Coulter (Fullerton, CA) has received FDA clearance to market its new Access AccuTnl test for the diagnosis of myocardial infarction (or heart attack) and cardiac muscle damage. The test measures levels of cardiac troponin I, a protein released into the bloodstream following a heart attack. The test is designed for use by hospitals in routine and emergency situations and can be run in about 12 minutes. More than six million people in the U.S. have a heart attack or report chest pain every year, and more than 300,000 die of heart attack, according to the American Heart Association. IVD manufacturers with competing heart attack tests include Biosite Diagnostics ("Triage Cardiac"), Dade Behring ("Stratus CS"), and Spectral Diagnostics ("Cardiac Status"). Medicare reimbursement for the heart attack test (CPT 84484: Troponin, quantitative) is capped at \$13.60. ▲

Decode Genetics Seeks DNA Test For Rheumatoid Arthritis

Decode Genetics (Reykjavik, Iceland) has announced an agreement to work with Genmab (Copenhagen, Denmark) to develop a DNA-based test to determine a patient's likely response to HuMax-CD4—Genmab's injectible antibody treatment for rheumatoid arthritis (RA). Exclusive of potential sales royalties, Genmab will pay Decode an undisclosed amount for research funding, plus potential milestone payments.

Decode and its pharmacogenomics and clinical trials subsidiary will conduct studies aimed at identifying key genetic factors that can accurately predict clinical response to treatments for moderate to severe RA. Genmab's HuMax-CD4 is currently in Phase 2 clinical trials for treating RA and is not expected to come to market until 2004 or later. Decode is already working with Roche to identify genes linked to RA, schizophrenia, and other diseases for the purpose of developing diagnostic tests and drug treatments (*DTTR, March '01, p. 3*).

The big question is whether genetic research and development companies such as Decode will have the wherewithal to fund continuing losses before meaningful revenue from products and royalties are achieved. In the three months ended March 31, Decode reported a net loss of \$16.1 million on revenue of \$5 million. Decode's spending on research and development was \$20.2 million in the first quarter and is expected to total \$80 million for the full year. Cash holdings as of March 31 totaled \$172 million, down from \$192 million at year-end 2000. ▲

IVD Stocks Up 4% In Latest Four Weeks

Shares of Bayer, which trade on the German stock exchanges and are not part of the G-2 Diagnostic Stock Index, have fallen 18% so far this year to 46.12 euros per share; Roche (non-voting equity shares), which trades on the Zurich Stock Exchange, is down 19% year-to-date to 133 Swiss francs per share

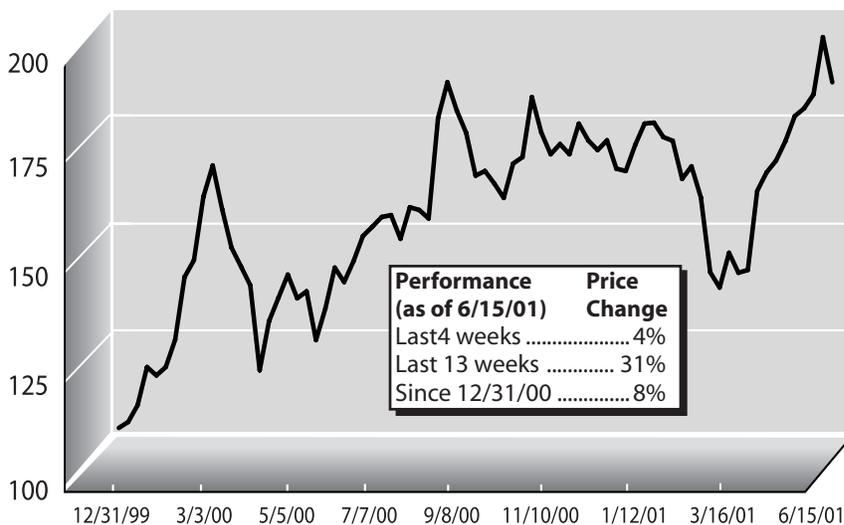
The G-2 Diagnostic Stock Index rose 4% in the four weeks ended June 15. Ten stocks in the index went up in price, 10 fell. Since the start of the year, the index has risen 8%, while the S&P 500 is down 8% and the Nasdaq is down 18%.

Diametrics (St. Paul, MN), which traded as low as \$2.40 per share last month, rebounded 82% to \$4.36 per share in the latest four weeks (for more on the company, see *Inside The Diagnostics Industry*, p. 7).

Gene analysis equipment maker **Affymetrix** (Santa Clara, CA) declined 34% to \$23.25 per share for a market capitalization of \$1.325 billion. The company recently announced it would fall short of analysts' expectations for the second quarter ended June 30. The company says it will report second-quarter revenue of \$40-47 million and record a loss (excluding write-offs) of \$4-7 million due to weak demand for its GeneChip product line. Analysts had expected the company to generate roughly \$57 million of revenue and break-even bottomline results. The company's newly revised revenue expectations for second-quarter 2001 indicate stagnant growth when compared with the \$45.411 million in revenue booked in second-quarter 2000.

Biosite (San Diego, CA) was down 25% to \$41.34 per share. On June 13, the company announced that the U.S. District Court in San Francisco has declined to grant a temporary restraining order barring Xoma Ltd. (Berkeley, CA) from purporting that three licenses granted to Biosite in 1998 and 1999 are terminated. The licenses relate to the bacterial expression of antibodies and are critical technology for Biosite's rapid triage meter for detecting heart attacks. "We believe we are in full compliance with the license agreements and that we have not breached our obligations. We look forward to the next hearing and having this matter resolved ultimately in our favor," stated Kim Blickenstaff, president of Biosite, in a June 13 press release. 🏠

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, 4 weeks ended 6/15/01		
UP	PRICE	%CHG
Calypte	\$0.32	60
Cholestech	7.65	6
Cygnus	8.66	8
Cytc	24.42	1
Diagnostic Products	74.40	4
Diametrics	4.36	82
Inverness Medical	36.36	3
Johnson & Johnson	52.04	3
Quidel	4.98	10
Ventana	26.45	7
DOWN		
Abbott Labs	50.56	-5
Affymetrix	23.25	-34
Bio-Rad	46.39	-3
Biosite	41.34	-25
Beckman Coulter	36.49	-2
Becton Dickinson	30.84	-11
Careside	2.40	-2
Digene	26.03	-16
i-Stat	14.30	-17
Meridian	4.80	-7

G-2 Insider

Genetic testing research, equipment manufacturers, and laboratory service companies have all touted "pharmacogenomics" as an inexorable trend that will soon provide each of them with a multitude of new high-margin products and services to sell. For patients, advances in pharmacogenomics will mean personalized drug prescriptions based on their specific genetic test profiles. This should help reduce side effects and make drug therapies more potent.

However, as noted in an article in the June 18 *Wall Street Journal*, some pharmaceutical companies are resisting personalized treatments for fear that it could limit the market for some of their blockbuster prescription drugs. Weeding out patients not suitable for existing drugs is not in the economic interest of the pharmaceutical giants. And make no mistake, their economic interests are huge. For example, four of the top pharmaceutical firms generated \$29.2 billion in pretax profits on \$115.9 billion of revenue last year.

As one would expect, pharmaceutical companies seem more eager to use genomics information to help target new drugs for development, rather than discover the limitations of their existing drugs. 🏠

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- Affymetrix 408-731-5000
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714-871-4848
- Biosite 858-455-4808
- CaseBauer 972-869-2500
- Decode Genetics
354-570-1900
- Diametrics 651-639-8035
- Gen-Probe 858-410-8000
- Instrumentation Laboratory
781-861-0710
- IRIS 818-709-1244
- i-Stat 609-443-9300
- Medtronic 763-514-4000
- MiniMed 818-362-5958
- Nova Biomedical
781-894-0800
- Panasonic Telecare
201-392-6124
- Radiometer America
800-736-0600
- Roche Diagnostics
317-849-9350

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Major Drug Makers Have High Profits To Protect (For 12 months ended 12/31/00; \$ in billions)

Company	Revenue	Pretax Profit	Pretax Margin
Merck	\$40.636	\$9.824	24%
Pfizer	29.574	5.781	20%
GlaxoSmithKline*	25.517	8.509	33%
Novartis*	20.127	5.099	25%
Total	\$115.854	\$29.213	25%

*Figures for GlaxoSmithKline and Novartis are in U.S. dollars, based on exchange rates as of 6/22/01. Source: DTTR

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