Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

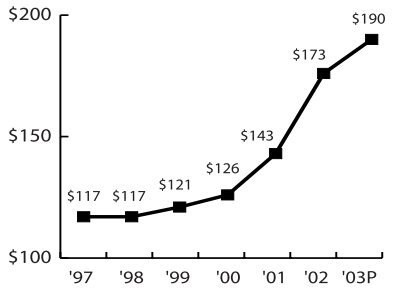
The Rising Price Of Blood Could Force Change In Blood-Screening Market

Over the past three years, the average price of a "unit" (roughly half a pint) of leukoreduced red blood cells has risen by 15% per year to $190, according to figures from America's Blood Centers (ABC). The American Red Cross has pushed through similar increases and now charges an average of $175 to $225 per unit.

Both ABC and the Red Cross, which together screen more than 90% of the nation's blood supply, say the price hikes are necessary given the increased marketing costs needed to attract donors and the introduction of expensive new molecular diagnostics for HIV, hepatitis C, and West Nile Virus.

Nonetheless, it looks like the high cost of blood could force major changes in the blood-screening market. For example, a group of hospitals in Massachusetts are talking about setting up their own centralized blood center to compete with the Red Cross. And a group of biotechnology companies are racing to develop a substitute for human blood. For details, see *Inside The Diagnostics Industry*, pp. 5-8.

Average Price Per Unit of Blood*



*Fee per unit of leukoreduced red blood cells
Source: America's Blood Centers

Can The Healthcare System Afford A $795 Colorectal Cancer Screen?

Exact Sciences (Marlborough, MA) and its distribution partner, LabCorp (Burlington, NC), have announced the commercial roll out of PreGen-Plus, a proprietary DNA-based stool assay for the early detection of colorectal cancer. The "homebrew" test is being offered at a list price of $795 (or an estimated $400 to $600 after discounts).

That's a lot of money for a lab test, especially when you consider that Exact and LabCorp are positioning PreGen-Plus as a "first line screen" for the over-50 population. It remains to be seen whether Medicare or managed care companies will pay for the test, but Exact and LabCorp are pushing hard and have dedicated a combined team of roughly 50 people to work on reimbursement issues. ➥ *p. 2*

The American Cancer Society estimates that 57,100 men and women will die from colorectal cancer, and the most common screening method—the fecal occult blood test—is cheap, but has low patient compliance and low sensitivity.

▲ PreGen-Plus Test Launch, *from page 1*

As with any new lab test, physician adoption rates for PreGen-Plus are difficult to predict and executives at Exact and LabCorp were unwilling to hazard a guess. But a lot is at stake. Since being formed in February 1995, Exact has accumulated $92.2 million in net losses and PreGen-Plus is the company's first commercial product.

Meanwhile, LabCorp paid $15 million to Exact in June 2002 for an exclusive five-year license to the PreGen-Plus technology and recently made another $15 million payment in connection with the commercial launch of the test. Furthermore, LabCorp will need to shell out a total of $45 million more if Exact reaches goals related to scientific acceptance, reimbursement approval, and revenue thresholds for the test.

LabCorp will also pay Exact a royalty fee for each PreGen-Plus test it performs. *DTTR* estimates that this fee will be roughly $100 per test, or about 20% of the average realized revenue (~$500) collected by LabCorp.

With so much at stake, it's no wonder that LabCorp is working hard to speed adoption. The company has trained its entire 800-person salesforce on Exact's technology and they are now spreading the word to tens of thousands of primary-care physicians across the nation. In addition, LabCorp is handing out PreGen-Plus marketing brochures to patients that visit its more than 1,000 specimen collection centers. A print advertising campaign in professional journals, popular magazines, and newspapers is set to begin soon too.

PreGen-Plus detects colorectal cancer by analyzing DNA in stool samples. Patients collect samples for the test by placing a special collection bucket over their toilets and then defecating into it. The entire bowel movement is sent to LabCorp's Center for Esoteric Testing (Burlington, NC), where the DNA is extracted and then shipped to LabCorp's Center for Molecular Biology and Pathology (Research Triangle Park, NC) for DNA analysis. Results are provided back to the ordering physician in two to three weeks.

Exact has helped fund a number of small-scale clinical studies that have shown that PreGen-Plus is significantly more sensitive (with less false positives) than conventional guaiac-based fecal occult blood tests (FOBT). But the biggest advantage may be that PreGen-Plus does not require patients to follow any dietary or prescription drug restrictions prior to being tested (unlike the conventional FOBT). This may help overcome the biggest problem in colorectal cancer screening, which is patient non-compliance.

Even so, the cost of PreGen-Plus is likely to be a major barrier to market acceptance. An abstract (#102381-The Cost-Effectiveness of Fecal DNA Testing for Colorectal Cancer. Ness, Klein, and Dittus) presented at the *Digestive Disease Week Conference* in Orlando earlier this year showed that the best modality may still be the conventional FOBT.

The study compared the cost-effectiveness of PreGen-Plus versus other testing methods using a computer simulation model. The sample base was a hypothetical population of 1 million 50-year-old, average-risk patients.

The analysis showed that an annual FOBT was the most cost-effective strategy, reducing the mortality of colorectal cancer by 50% at a cost per life-year saved of just $5 to $45. The simulation assumed a 70% compliance rate and proper diet modification prior to FOBT screening.

In contrast, the study showed that the use of PreGen-Plus every three years reduced mortality by 55% with a cost per life-year saved of $1,025 to $1,271. Alternating between colonoscopy and PreGen-Plus every five years reduced mortality by 60% at a cost per life-year saved of between $14,528 and $17,095, according to the study.

Don Hardison, president of Exact, tells *DTTR* that his company is positioning the test as an option, not a replacement, to other colorectal cancer screening methods. He points out that although the American Cancer Society recommends that all men and women over the age of 50 get an annual FOBT, only about one in four people actually get screened. "The worst test is the one that never gets done. Fifty-seven thousand people will die of colorectal cancer this year despite current testing options. If people use our test, it will save lives," adds Hardison.

Hardison notes that one key to future adoption rates will be the results from a 5,500-patient study, which is designed to compare the sensitivity of PreGen-Plus to the traditional FOBT. Smaller-scale studies have shown PreGen-Plus to yield sensitivities of 65% to 70% versus 25% to 35% for the traditional FOBT. Results of the large-scale study are expected by year's end. Hardison says Exact will use the study to try to get Medicare coverage for PreGen-Plus, but says the company has no immediate plans to seek FDA clearance for kit sale.

It appears that the biggest concern from hospital labs regarding expensive proprietary tests like PreGen-Plus is that they'll get stuck with the bill for tests ordered by their outreach clients. "We're working very hard with payers to get coverage so that client billing becomes less of an issue, but unfortunately it's going to happen sometimes to hospitals," says Hardison.

Meanwhile, Quest Diagnostics (Teterboro, NJ) has announced that it has begun offering InSure, an FDA-cleared fecal immunoassay for early detection of colorectal cancer made by Enterix Inc. (Falmouth, ME). Quest is expected to price the test at somewhere in the range of $25 to $75. The test is already covered by Medicare for diagnostic purposes, and a coverage decision for screening purposes is expected to be announced by the end of the year (see *DTTR*, June 2003, pp. 1-2).

Wampole To Distribute Efoora's Rapid HIV Test

The competition to provide rapid HIV-1 tests is heating up. Wampole Laboratories (Princeton, NJ), a division of Inverness Medical Inc. (Waltham, MA), has signed an agreement with Efoora Inc. (Buffalo Grove, IL) that makes Wampole the exclusive distributor of Efoora's rapid HIV test in the United States. The deal puts the Wampole/Efoora team in direct competition with Abbott Diagnostics, which distributes a rapid HIV test made by OraSure Technologies (Bethlehem, PA).

John Bridgen, president of Wampole, tells *DTTR* that clinical trials for the Efoora rapid HIV test were completed in March of this year and the test is now pending FDA clearance with the intent to also gain a CLIA waiver for whole blood. Bridgen says the test, which will be manufactured by Efoora at its Buffalo Grove plant (just north of Chicago), provides visually read, color results in 20 minutes or less from either serum, plasma, venous whole blood, or fingertip samples.

Meanwhile, OraSure reports that its revenue increased 21% in the second quarter to $9.6 million, led by increased sales of the company's OraQuick rapid HIV test. OraQuick, which is sold by Abbott at approximately $10 to $12 per test, received FDA clearance for HIV testing on fingertip whole blood samples in November 2002 and a CLIA waiver in January 2003. In addition, OraSure recently received FDA approval of a venous whole blood claim for OraQuick and the company expects to file for clearance of oral-fluid and plasma samples in the near future.

Finally, Medmira Inc. (Halifax, Canada) has announced that it has shipped more than 250,000 of its Reveal Rapid HIV tests to its U.S. distributor, Cardinal Health (Dublin, OH). The Medmira test provides results from serum, plasma, or whole blood in less than three minutes and was cleared by the FDA this past April.

A Glance at the Rapid HIV-1 Test Market

Test Name	*Manufacturer*	*Distributor*	*FDA Clearance*
Efoora Rapid HIV Test	Efoora	Wampole	Pending
OraQuick Rapid HIV-1	OraSure	Abbott Diagnostics	November 2002
Reveal Rapid Rapid HIV-1	Medmira	Cardinal Health	April 2003

Source: *DTTR* from companies

Calypte Raises $12.5 Million To Stay In Business

Calypte Biomedical Corp. (Alameda, CA), which had announced plans to go out of business last year due to cash constraints, says it has raised a total of $12.5 million from the Marr Group (London, England), an investment firm run by Marat Safin. The cash investment will keep Calypte in operation and involves the purchase of 28.3 million restricted Calypte shares at an average price of $0.44 per share.

Calypte makes urine-based HIV-1 tests for both screening and confirmation. Both products are cleared by the FDA for laboratory-based testing and the company plans to file an investigational device exemption with the FDA for a urine-based rapid test within the next six months. In addition, Anthony Cataldo, chairman of Calypte, says the company ultimately hopes to get its tests approved for over-the-counter sale for home testing. He notes that HIV infection cannot be transmitted through urine.

Skyrocketing Blood Costs Have Hospitals Looking For Alternatives

Blood in the U.S. is collected by FDA-licensed collection centers. Approximately half of the blood is collected by the Red Cross, and the other half by independent collection centers loosely banded by an organization known as America's Blood Centers.

Approximately 13 million to 15 million units of blood are transfused each year in the United States to accident victims, cancer patients, transplant recipients, and other patients. Hospitals now pay an average of around $200 per unit from the country's two main suppliers, America's Blood Centers (ABC) and the American Red Cross, indicating a total annual expense of about $2.8 billion (i.e., 14 million units multiplied by $200). That's big money, and hospitals are now struggling to find ways to curb this fast-growing expense.

In Massachusetts, where the average price of blood is now over $200 per unit, hospitals want to know how much of that is spent to recruit, collect, test, and process blood. But the Red Cross, the dominant blood bank in the state, has been unwilling or unable to provide any detailed answers. When *DTTR* contacted the Red Cross, a spokeswoman would only say, "The American Red Cross sets its fee for products and services at rates sufficient to cover operating costs of the business and headquarters."

This kind of fuzzy response has spurred hospitals in Massachusetts to consider working together to form a cooperative venture for centralized blood screening to bring competition into the market. In order to do that, the Massachusetts Hospital Association (MHA) is lobbying for passage of a bill (S638/H1862) that would allow entities other than hospitals and the Red Cross to collect and distribute blood products in Massachusetts.

As the law stands today, "The American Red Cross has a virtual monopoly in Massachusetts, and from a safety standpoint, it isn't necessary," according to Leslie Kirlie, the association's senior director of clinical policy.

Massachusetts is the only state that has such restrictions on who can collect blood. The current law was not intended to give the Red Cross a monopoly, but rather to keep the blood supply safe. But the MHA argues that this is not necessary given all of the federal guidelines that are in place. Michael Freedman, chief of business management for the Red Cross in New England, says his organization will not oppose the MHA proposal.

Meanwhile, a group of 10 hospitals in North Carolina has already gone ahead and opened their own blood bank and hired Greg Ball, an ex-Red Cross executive, to run it. Community Blood Center of the Carolinas (CBCC—Charlotte) opened for business this year in response to the escalating cost of blood and a lack of product choice from the Red Cross, according to spokeswoman Mary Alice Rogers.

In particular, Rogers says there was disagreement over whether or not white blood cells, or leukocytes, should be filtered from all donated blood. An FDA advisory committee has recommended that all blood be leukoreduced because it helps reduce adverse reactions to transfusions. The Red Cross has chosen to follow that recommendation, but leukoreduction raises the cost of producing a unit of blood by some $30 to $40 and this cost has been passed on to hospitals.

The North Carolina hospitals have argued that doctors are licensed for a reason and should be able to customize patients' care, says Rogers. By not leukoreducing all units of blood and with other operating efficiencies, CBCC expects to charge about $150 per unit. With an annual need for roughly 60,000 units among the 10 participating hospitals, they expect to collectively save more than $3 million per year.

CCBC occupies a 31,000-square-foot freestanding building in Charlotte and has about 50 employees. The operation cost $1 million to get up and running, according to Rogers. Virginia Blood Services (Richmond), a community blood bank and an ABC member, served as an advisor in the formation of CCBC.

CCBC handles the collection and "manufacturing," or separation of each donation into platelets, plasma, and red blood cells. Laboratory testing has been contracted out to Blood Service Labs (Dallas). The biggest challenge for CCBC will be attracting donors, and Rogers says it will be looking at channels overlooked by the Red Cross, such as small businesses. Other potential donors include the 23,000 employees of the 10 participating hospitals, which include Carolinas Medical Center and its three affiliates, Presbyterian and its two affiliates, Gaston Memorial, NorthEast Medical Center, and Piedmont Medical Center.

Charlotte is not the only city in recent years to start a community blood bank. In 1995, Red Cross staff members in Springfield, Missouri, angry over national demands that siphoned blood from the region, walked off the job and started their own blood center. Their new organization, Community Blood Center of the Ozarks, received funding from local hospitals and now supplies about 85% of the blood to 36 hospitals in Missouri, Kansas, and Arkansas.

Jim MacPherson, chief executive of ABC, says there are at least six other groups of hospitals in different regions of the country that are thinking about forming their own blood banks. "The group in Missouri has been successful, and if the group in Charlotte succeeds, then others will follow," says MacPherson.

Gateway Community Blood Bank Shuts Down

Even as some hospitals are questioning where all the money they pay for blood is going and wondering if they can do it more cheaply themselves, operating a blood-screening center does not come without risks. Consider Gateway Community Blood Bank, an independent blood center that had been one of the two major blood suppliers in St. Louis.

The increasing cost of finding and keeping blood donors, combined with the expense of adding molecular diagnostic testing capabilities, forced the company to borrow heavily to sustain itself over the last three years. In July, facing debts of more than $1.5 million, Gateway was forced to shut down operations and laid off its 60 employees. Things got so bad that direct deposit paychecks put in employee bank accounts in late July had to be taken back by

Infectious Disease Tests Performed On Donated Blood

Hepatitis B surface antigen (HBsAg)
Hepatitis B core antibody (anti-HBc)
Hepatitis C virus antibody (anti-HCV)
HIV-1 and HIV-2 antibody (anti-HIV-1 and anti-HIV-2)
HTLV-I and HTLV-II antibody (anti-HTLV-I and anti-HTLV-II)
Serologic test for syphilis
Nucleic acid testing for HIV-1 and HCV
Nucleic acid testing for West Nile Virus

Source: American Association of Blood Banks

the company a few days after being deposited. Gateway is now selling off assets to pay off its lenders.

Why Are Blood Prices Rising So Fast?

Jed Gorlin, M.D., medical director for Memorial Blood Centers (Minneapolis), which provides blood to 36 hospitals in Minnesota and Wisconsin, says that hospitals seeking to create their own blood banks may not fully understand the risks involved. He estimates that his blood center spends an average of roughly $40 to $50 per unit of blood just for lab testing (reagents plus labor), which has been one of the fastest-growing areas of expense.

Blood banks currently perform a total of 13 to 14 tests on every unit of blood that is donated. In addition to blood type, Rh type, and tests for unexpected red blood cell antibodies, blood centers perform 10 to 11 infectious disease tests (see table on p. 6).

The cost of lab testing has roughly doubled over the past few years because of the introduction of expensive nucleic acid testing for hepatitis C and HIV at blood banks. Nucleic acid tests are able to detect small amounts of viral nucleic acid in blood before antibodies or viral proteins such as HIV-1 antigen or HCV core antigen reach levels that are detectable by traditional screening methods.

Nucleic acid HIV/HCV tests from Gen-Probe (marketed by Chiron) and Roche were introduced to U.S. blood banks in 1999 under FDA-approved investigational new drug (IND) applications. The initial reagent price had been set at a cost-recovery basis of approximately $3 to $5 for the combined HIV/HCV test. But products from both manufacturers have now been approved for commercial sale, and the reagent price has risen to approximately $10 to $12 for a total cost per HIV/HCV test (including labor) of about $16, according to Gorlin.

In addition, Gorlin notes that in June of this year, Gen-Probe and Roche each received IND clearance for nucleic-acid tests for West Nile Virus for use at blood banks. The initial cost for reagents is $3 to $5 per unit tested and with labor the cost rises to $7 to $10, but Gorlin estimates that the total cost will rise to around $16 (including labor) after Gen-Probe and Roche get commercial clearance from the FDA.

"Hospitals complaining about rising prices are yelling at the wrong people. We are told by the FDA what we need to test for, and the reagent manufacturers are setting the price," adds Gorlin.

MacPherson believes that the price of blood will continue to rise in the coming years as more new and expensive testing techniques are adopted. On the immediate horizon is bacterial testing, which will add about $10 to the price of blood, according to MacPherson. He notes that the FDA is expected to issue guidelines related to bacterial testing within the next 90 days.

Over the next three to five years, MacPherson says that new pathogen inactivation technologies could double the price of blood. Pathogen inactivation involves adding and then removing toxic chemicals to donated blood in order to kill viruses and bacteria. Baxter International (Deerfield, IL) is working with Cerus Corp. (Concord, CA) to bring a pathogen-inactivation product to market, and Vitex Technologies (Watertown, MA) is developing a competing technology.

Finally, Kathy Connolly, spokeswoman for the Rhode Island Blood Center (Providence), which collects 82,000 units of blood per year, says that the cost to recruit

blood donors has risen substantially given new restrictions issued by the FDA. For example, there are now restrictions on potential donors that have visited or lived in Europe because of fears of "mad cow" disease.

Only about 3% of the population donates blood each year and the mad cow restriction alone eliminated roughly one out of every ten existing donors, according to MacPherson. As a result, blood banks have had to increase expenditures for advertisements to attract donors and this cost has contributed to higher blood prices. On average, he estimates that 15% of the price of blood, or about $30 per unit, is now related to marketing and donor recruitment efforts.

Are Blood Substitutes the Answer to the Shortage?

Scientists searching for a substitute for human blood have experimented since at least as far back as the mid-1600s, when English physicians injected sheep's blood into wounded soldiers in a futile attempt to save their lives. But recent developments suggest that the first artificial blood substitute product could soon receive FDA clearance.

For more information on the growing blood crisis be sure to listen in on the upcoming G-2 teleconference "Managing The Sticker Shock of Blood & Blood Products" on Oct. 29. Go to www.g2reports.com *for details.*

In August, Biopure Corp. (Cambridge, MA) announced that the FDA, responding to the company's application ahead of schedule, did not request additional clinical trials on its blood substitute product. Instead, the FDA asked for clarification of clinical data and included some comments on labeling, according to Jeffrey Tarmy, spokesman for Biopure. He says the company is hoping to respond to the questions within a month or two, and final clearance could be obtained by the end of the year.

Biopure's blood product, called Hemopure, is derived from purified cow blood. The company is seeking initial clearance for the product for anemic patients undergoing orthopedic surgery, which represents a U.S. market size of approximately 1.5 million units of blood per year.

When administered intravenously, Hemopure increases oxygen delivery to the body. The product does not require refrigeration and is stable for three years. Hemopure is also universally compatible for patients with any blood type and does not require lab testing for infectious diseases.

However, once inside the body, Hemopure has a half-life of only 24 hours versus 90 days for human blood. Tarmy says Hemopure is meant to be used as a bridge in emergencies when human blood is not available.

Another drawback is the projected cost of Hemopure, which is expected to fall somewhere in the range of $500 to $800 per unit. That's pretty cheap when you consider that Biopure has incurred more than $400 million in accumulated losses just to get Hemopure to the brink of commercial availability, *DTTR* observes. But when compared to the $200 per unit for traditional blood, it looks pricey.

Tarmy says the price for Hemopure will be competitive once you consider all of the additional costs associated with traditional leukoreduced blood, including the need for refrigerated storage and patient blood-type testing. Meanwhile, the ABC's MacPherson observes, "The best thing about blood substitutes is that they highlight how relatively inexpensive traditional donated blood remains.

i-Stat Gets FDA Clearance For Troponin And KaolinACT Tests

The i-Stat handheld system now runs a total of 17 tests and calculates another six parameters.

i-Stat Corp. (East Windsor, NJ) has received FDA clearance to market its 10-minute i-Stat System Cardiac Troponin I test. The test detects troponin I, which is released in the blood when an acute myocardial infarction, or heart attack, has occurred. Bill Moffit, chief executive of i-Stat, says the company will begin shipping the test, which will be priced at less than $10 each, to customers by the end of September.

The American College of Cardiology's preferred protocol for assessing patients with heart attack symptoms includes a troponin I measurement within 30 minutes of patient presentation at the emergency department. About 8 million people visit emergency rooms with chest pain each year in the United States. The i-Stat Troponin I test (and competing tests, see below) is expected to save hospitals money by rapidly identifying the 10% to 15% of patients who are admitted with chest pain but aren't suffering a heart attack, and often undergo unnecessary testing and hospitalization.

Competitors with rapid troponin I tests already on the market include Biosite (San Diego, CA), which markets the Triage Cardiac Panel. The Biosite panel includes tests for troponin I, creatinine kinase-MB (CK-MB), and myoglobin, which are run on a portable telephone-size analyzer with results provided in 15 minutes. Another competitor is Spectral Diagnostics (Toronto, Canada), which makes Cardiac Status, a self-contained disposable test panel that provides results for troponin I, CK-MB, and myoglobin in 15 minutes.

In addition, i-Stat recently announced FDA clearance to market its kaolin-based activated clotting time (kaolinACT) test. More than 15 million kaolinACT tests, representing an $80 million market, are performed in support of cardiac interventions in cardiovascular surgery and catheterization labs, worldwide, each year, according to Moffit. He anticipates market introduction of the kaolinACT cartridge in the fourth quarter this year at a price between $2.60 and $5 pert test.

TheraSense FreeStyle Featured At Wal-Mart Screening Event

Wal-Mart Stores (Bentonville, AR) offered free blood-glucose tests at all of its 2,900 stores nationwide on September 6, as part of a month-long campaign to raise awareness of diabetes. An estimated 300,000 to 500,000 customers were tested using FreeStyle blood-glucose meters made by TheraSense (Alameda, CA), according to Matt Lucas, an executive at Novartis Consumer Health (Parsippany, NJ), which helped sponsor the campaign. Interfit Inc. (Houston, TX), which manages health-screening events for corporations, staffed and managed the one-day event.

In addition to the public good, Wal-Mart is hoping that increased awareness of diabetes will prompt sales of the over-the-counter treatments (many of which are made by Novartis) available at its stores. Wal-Mart says it is considering future companywide health screenings, including bone-density tests for osteoporosis and cholesterol-level checks.

Roche Diagnostics Sales Dip 1% In First-Half 2003

Roche Group (Basel, Switzerland) reports that revenue at its diagnostics division fell by 1% to 3.6 billion Swiss franc (US $2.5 billion) in the six months ended June 30, 2003. (In local currencies, Roche says that its diagnostic revenue was up 7%.)

Roche At A Glance *(in millions of Swiss franc)*

	First-Half 2003	Change
Roche Group Revenue	15,327	4%
Roche Group Net Income	1,289	-28%
Diagnostic Revenue	3,569	-1%
Blood Glucose Testing	1,280	4%
Near-Patient Testing	271	-9%
Centralized Diagnostics	1,286	-1%
Molecular Diagnostics	481	-2%
Applied Science	251	-15%
Diagnostic Operating Profit	650	16%

Source: Roche

The worst-performing unit at Roche Diagnostics was Applied Science, which supplies testing systems and supplies to the pharmaceutical development market and reported a first-half revenue drop of 15% (down 6% in local currencies) to 251 million Swiss franc (US $178 million). The best performing unit was blood glucose self-testing, where revenue grew 4% (up 14% in local currencies) to $1.3 billion Swiss franc (US $907 million).

Overall, Roche Group reported that first-half net income fell by 28% to 1.3 billion Swiss franc (US $914 million); revenue was up 4% to 15.3 billion (US $10.9 billion).

Bayer Diagnostics Revenue Off 9% As Ascensia Lags

Bayer Group (Leverkusen, Germany) reports that revenue at its Bayer Diagnostics (Tarrytown, NY) unit fell by 9% to 908 million euros (US $988 million) in the six months ended June 30, 2003. (In local currencies, *DTTR* estimates that revenue at Bayer Diagnostics was up approximately 2% to 4%.)

Diagnostic revenue was hurt by intense competitive pressure in the blood glucose self-testing market, where the company's Ascensia Elite business saw its first-half revenue decline by 22% to 199 million euros (US $217 million), according to Bayer. The company says the weakness in self-testing contributed to a sharp decline in earnings at its diagnostics business (although no specific number was reported). Bayer says it is seeking to regain market share in the self-testing market through new product launches.

Bayer Group At A Glance *(in millions of euros)*

	First-Half 2003	Change
Bayer Group Revenue	14,612	-1%
Bayer Group Net Income	714	-13%
Healthcare Revenue	4,312	-9%
Pharmaceuticals	1,811	-6%
Biological Products	510	2%
Consumer Care	690	-26%
Diagnostics	908	-9%
Animal Health	393	-5%
Healthcare Operating Profit	859	80%

Source: Bayer

On a more positive note, Bayer reported that revenue generated from its Advia Centaur immunoassay system grew 13% to 180 million euros (US $196 million) in the first half of the year. The company also cited strong growth from its DCA 2000 and Rapidpoint 400 point-of-care systems.

Overall, Bayer Group reported that first-half net income fell by 13% to 714 million euros (US $777 million); revenue was down 1% to 14.612 billion euros (US $15.9 billion).

IVD Stocks Up 7% In Latest 6 Weeks; i-Stat Jumps 37%

***Roche** non-voting equity shares, which trade on the Zurich stock exchange, are up 15% to 111 Swiss francs so far this year. Shares of **Bayer**, which trade on the German stock exchanges, are down 2% at 20.04 euros.*

The 20 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 7% in the six weeks ended Sept. 5, 2003, with 12 stocks up in price, two unchanged, and six down. Year to date, the G-2 Index is up 64%, while the S&P 500 Index is up 16% and the Nasdaq is up 39%.

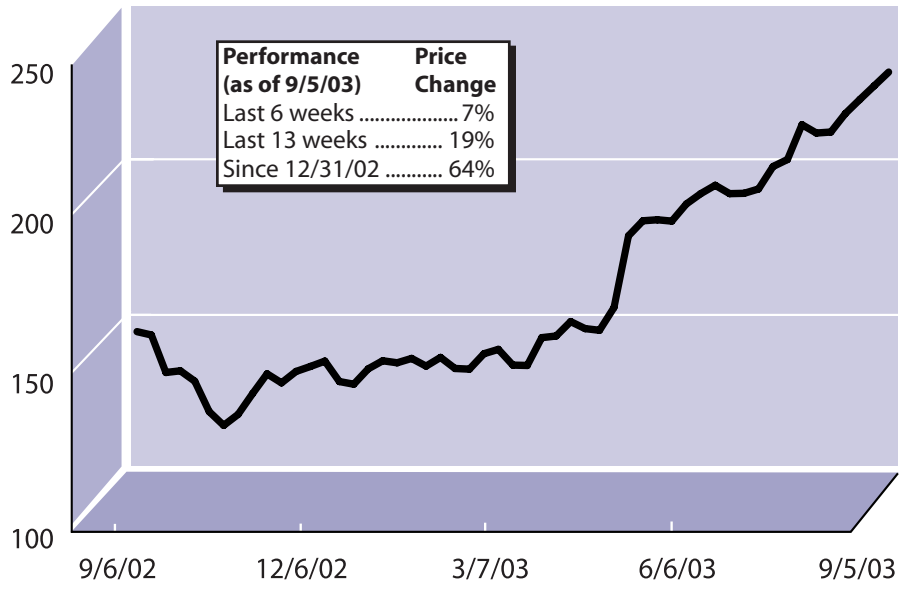
Shares of **i-Stat Corp.** (East Windsor, NJ) jumped 37% to $12.58 per share for a market cap of $253 million. The company recently received FDA clearance for a 10-minute cardiac troponin I test that will run on its handheld analyzer (see page 9).

Digene (Gaithersburg, MD) was up 35% to $37.07 per share for a market cap of $729 million. The company recently reported its first profitable quarter, earning $260,000 in the three months ended June 30, 2003, versus a net loss of $4.5 million in the same period a year earlier; revenue increased 50% to $19.1 million. Growth was driven by sales of Digene's DNA-based HPV test, which increased 68% to $16 million.

Gen-Probe (San Diego) was up 10% to $59.51 per share for a market cap of $1.45 billion, an amount that is equal to seven times the company annual revenue of $202.7 million and 44 times its net income of $32.6 million (based on annualized result for the second quarter of 2003). Meanwhile, Gen-Probe has announced plans for a 2-for-1 stock split effective September 30.

Exact Sciences (Marlborough, MA), which is not part of the G-2 Index, climbed 16% over the past six weeks to $16.92 per share for a market cap of $325 million. The company recently launched commercialization efforts for its PreGen-Plus colorectal cancer test (*see page 1*).

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 IVD companies.

% Price Change, 6 weeks ended 9/5/03

UP		
Abbott Labs	$42.00	4%
Beckman Coulter	45.19	6%
Biosite	49.26	7%
Cytyc	13.35	5%
Dade Behring	27.00	12%
Digene	37.07	35%
Gen-Probe	59.51	10%
Immucor	25.96	25%
Inverness Medical	24.46	22%
i-Stat	12.58	37%
TheraSense	15.32	15%
Ventana	41.93	14%
UNCHANGED		
Cholestech	9.18	0%
Igen	59.35	0%
DOWN		
Bio Rad	52.00	-16%
Diagnostic Products	37.10	-5%
Becton Dickinson	36.13	-3%
Johnson & Johnson	50.50	-3%
Meridian	10.46	-1%
Quidel	6.07	-10%

G-2 Insider

There's still time to register for Washington G-2 Reports' 21st annual Lab Institute this Oct. 8-11 at the Crystal Gateway Marriott in Arlington, VA. This year's Institute features some of the lab industry's most influential business and government leaders, including:

- ❑ Ron A. Andrews, senior vice president, marketing and business development of Roche Molecular Systems, will offer his views on the next generation of diagnostic technologies.
- ❑ Alan Mertz, president of the American Clinical Lab Assn.; Thomas Barker, senior advisor to the Administrator at CMS; and David Feigal, Jr., M.D., director for the Center for Devices & Radiological Health at the FDA, will offer their views of crucial topics such as the proposed Medicare lab copay and the potential for increased regulation of 'homebrew" testing.
- ❑ Rick Brajer, president of LipoScience; Don Hardison, president of Exact Sciences; and Doug Harrington, M.D., chief executive of Specialty Labs, will discuss the future of proprietary testing.
- ❑ Doug Jaciow, lab director at Baystate Health Systems; Scott Liff, executive director of lab services at John Muir/Mt. Diablo Health System; and David Wilkinson, M.D., Ph.D., chairman of the department of pathology at Medical College of Virginia, will offer advice on building a competitive lab outreach program.

In all, the Lab Institute conference will feature over 35 presentations and panel discussions from more than 50 laboratory experts and government officials. For more details and to sign up go to www.g2reports.com or call 202-789-1034.

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