Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

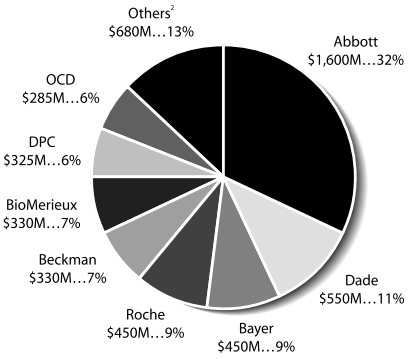
Beckman Enters High-Volume Immunoassay Market

Beckman Coulter (Fullerton, CA) has begun shipping its UniCel DxI 800 Access immunoassay system, marking the company's entrance into the high-volume immunoassay market. Up until now, Beckman has been somewhat of a bit player in the immunoassay market, with approximately $330 million in annual revenue (including $220 million from Access systems and $110 million from protein plasma testing) out of a total estimated worldwide market of $5 billion.

But Jim Rigo, global market manager for immunoassay at Beckman, tells *DTTR* that the DxI 800 launch should help Beckman gain share. Rigo says that Beckman shipped 10 DxI 800s in June, and he anticipates that it will have roughly 100 worldwide placements by the end of the year. "Given Abbott's continuing problems with the FDA and Roche's litigation with Igen, Rigo says, "This is absolutely the perfect time to be hitting the market with a new immunoassay system."

Naturally, Abbott, Bayer, Roche, and other vendors have a different perspective on how the immunoassay market is shaping up. For more details, see *Inside The Diagnostics Industry*, pp. 5-7.

The $5 Billion Worldwide Immunoassay Market[1], 2002



[1]Excludes blood banking, but includes protein plasma, and TDM/DOA
[2]Includes Tosoh, Bio-Rad, Fujirebio, Pharmacia, and others
Source: *DTTR*

Court Reverses Most Of $505M Igen Award; Igen Terminates Roche's License To Origen Technology

On July 9, the U.S. Court of Appeals for the Fourth Circuit reversed $486 million out of $505 million in damages awarded to Igen International (Gaithersburg, MD) in its immunoassay licensing battle with Roche Holding (Basel, Switzerland). However, the court affirmed Igen's right to terminate Roche's license to its Origen electrochemiluminescence technology and immediately following the court decision, Igen did just that. Igen chairman Sam Wohlstadter says that Roche can no longer sell Origen-based immunoassay products or service the more than 9,000 immunoassay systems (*i.e.*, Elecsys 1010, 2010, and E170) it has already placed worldwide. *Continued on p. 2*

▲ **Court Reverses Most Of $505M Igen Award,** *from page 1*

Furthermore, Wohlstadter says that Igen has filed patent infringement lawsuits against Roche in the U.S. and Germany to ensure that Roche ceases any further sales of products that incorporate Igen's Origen technology.

"We have been in intense negotiations with Roche forever. They have held off getting this matter resolved. Their lawyers have told them the termination would get overturned," Wohlstadter told analysts on a July 10 conference call. Wohlstadter added that any effort by Roche to seek a rehearing was "pie in the sky" given the history of the Appellate Court.

In a July 10 press release, Roche touted the $486 million reversal in damages and Heino von Prondzynski, head of Roche Diagnostics, stated, "We have made it clear to Igen through the course of this case that we wish to continue our partnership. We strongly believe it is in the best interest of both parties to continue the collaboration started 12 years ago." Roche spokesman Joel Reuter says Roche will continue to service its customers as it evaluates all legal options, including a request for a rehearing from a larger group of judges at the Appellate Court. Reuter adds that Roche has been in touch with all of its immunoassay customers to assure them that service will continue.

The dispute between Igen and Roche goes back to 1997, when Igen filed its original lawsuit alleging that Roche breached a licensing agreement for Igen's Origen technology, which uses light-emitting compounds to detect and measure biological substances. Igen said Roche willfully shortchanged its licensing fees, sold Igen technology in markets outside the contract, and plotted to drag down Igen's stock price so that Roche could acquire the firm.

Biosite And Beckman Sign BNP Test Deal

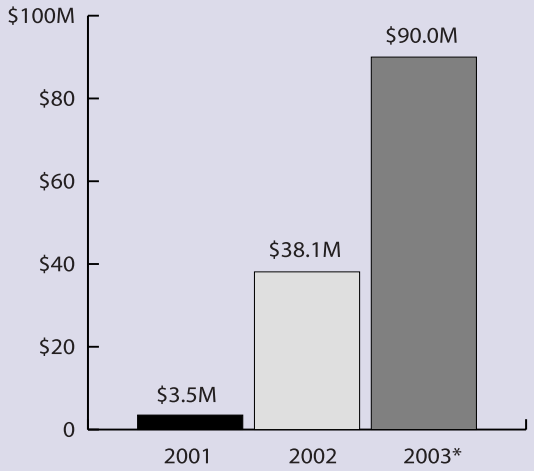
Biosite Inc. (San Diego, CA) and Beckman Coulter have signed a 10-year agreement that will make Biosite's b-type natriuretic peptide (BNP) testing technology available for use on Beckman's immunoassay systems.

Biosite's Triage BNP Test for diagnosing heart failure is currently used by approximately 1,700 hospitals in the U.S. To date, the test has been available solely on Biosite's Triage MeterPlus point-of-care device and not on traditional automated lab analyzers. The new agreement with Beckman should help Biosite better defend its market position given new BNP product launches from Roche (*i.e.*, proBNP) and Bayer (*see chart, p. 3*).

Terms of the Biosite/Beckman agreement call for Beckman to manufacture BNP test reagents for use on its immunoassay systems, including its Access and Access 2, Synchron LXi 725, and UniCel DxI 800 platforms. Biosite will pay Beckman for its manufacturing services and retain sole control of promotion, pricing, sales, and support for the new test.

On a June 25 conference call, Kim Blickenstaff, president and CEO of Biosite, said the company was aiming to submit a 510K for the test to the FDA by the end of this year and begin marketing in the first quarter of 2004. Biosite currently employs a 45-person direct salesforce in the U.S. that will be expanded in the future, according to Blickenstaff. In addition, Biosite has contracted with Fisher HealthCare to help distribute the test. Blickenstaff expects to price the automated test at the same level as its rapid version (*i.e.*, $20 to $25 per test).

Biosite's Revenue From Triage BNP *($MM)*



*Based on annualized first-quarter results
Source: Biosite

Biosite generated $38.1 million from sales of its Triage BNP Test in 2002, and sales are currently running at nearly $90 million per year, based on annualized results for the three months ended March 30, 2003. The test currently accounts for roughly 56% of Biosite's overall annualized sales of $160 million.

Bayer Gets FDA Clearance For Automated BNP Test

Bayer Diagnostics announced FDA clearance for its BNP test on the Advia Centaur high-volume immunoassay system in June. The average selling price to labs for the new test will fall in the range of $18 to $22 per test, according to Nino Totino, vice president of marketing for the U.S. at Bayer. He says that Bayer's salesforce has already been trained to sell the test and a quick launch is expected.

Meanwhile, Roche gained FDA clearance for its proBNP Test, which runs on its Elecsys analyzer, late last year and is marketing it at an average selling price of $15 to $20. Furthermore, Roche has licensed its proBNP technology to Dade Behring, and Mark Wolsey-Paige, senior vice president, strategy and technology at Dade, says the company is aiming to have an FDA-cleared test on the market later next year.

Don Braakman, spokesman for Abbott, says Abbott is working with Axis Shield (Dundee, Scotland) to develop a BNP test that will run on Abbott's AxSym system. European launch is expected later this year; FDA clearance and U.S. launch are anticipated for early 2004. Braakman says Abbott is aiming to have a BNP test for its Architect system in 2005.

BNP Test Launch Schedule

Company	*FDA Clearance*
Biosite	November 2000
Roche	December 2002
Bayer	June 2003
Abbott	expected early 2004
Beckman	expected early 2004
Dade	expected late 2004
DPC	no plans yet
OCD	no plans yet

Source: *DTTR* from companies

In fact, the only major immunoassay vendors that haven't yet announced plans to introduce an automated BNP test are Diagnostic Products Corp. (DPC), which says it has had trouble gaining access to the necessary licenses to develop the test, and Ortho-Clinical Diagnostics (OCD).

DakoCytomation Launches Aperio's Virtual Microscopy System

DakoCytomation (Glostrup, Denmark) has announced the marketing launch in the U.S. and Europe of a virtual microscopy system named ScanScope that is made by Aperio Technologies (Vista, CA).

Virtual microscopy is the digital equivalent of traditional microscopy, Dirk Soenksen, president and founder of Aperio, tells *DTTR*. Instead of looking at a glass slide through the eyepieces of a microscope, a pathologist views a digital image of an entire slide on a computer screen, with full panning and zooming capabilities, he explains.

Soenksen says Aperio's proprietary line-scanning technology allows slides to be scanned in approximately five minutes. The digitized slide picture is then archived on a server and can then be retrieved from a remote location by a pathologist for viewing on a computer screen. He says that the ScanScope system has a resolution of 100,000 pixels per square inch. This compares with, for example, resolution of 300 to 600 dots per square inch (DPI) on the typical laser printer.

Soenksen says that installation of a ScanScope system costs labs roughly $100,000, including the purchase of a server, scanner, software, and personal computer. He says that initial demand for the system has been "incredibly strong," although he would not provide any projections for the number of expected placements in the coming 12 months. Marketing of the system is being handled by DakoCytomation, which holds a 46% ownership stake in Aperio.

DakoCytomation Preparing For IPO

Separately, *DTTR* has learned that DakoCytomation is making preparations to soon file a registration statement with the Securities & Exchange Commission for an initial public offering (IPO).

Jes Ostergaard, president and CEO of DakoCytomation, had announced his intention to seek an IPO last year after the company acquired the flow cytometry maker Cytomation (*see DTTR, August 2002, p. 8*). It appears that the U.S. stock market's resurgence this Spring has opened the door for a DakoCytomation IPO, although a company spokeswoman was not available for comment.

DakoCytomation In Brief (in Danish kroner, 000)

	1999/00 *	2000/01 *	2001/02 *	2002 (6 months)
Revenue	870,211	1,044,769	1,187,006	715,337
Pretax income	50,100	65,954	263,069	26,241
Net income	42,402	45,949	186,121	19,410
Employees	816	956	1,036	1,240

*For fiscal years ending June 30

Source: DakoCytomation

In addition to flow cytometry, DakoCytomation specializes in cancer diagnostic reagents. Key products include the Dako HercepTest, which helps physicians determine appropriate drug therapies for breast cancer patients. In the six months ended December 31, 2002, DakoCytomation reported net income of 19.4 million Danish kroner (US $3 million) on revenue of 715.3 million (US $109 million).

IVD Vendors Battle To Gain Share In The Immunoassay Market

DTTR estimates that the worldwide market for immunoassay testing (excluding blood banking, but including plasma protein, and therapeutic drug monitoring/drugs of abuse testing-TDM/DOA) represented a total of $5 billion in revenue to IVD vendors last year and is growing at a 5% to 7% annual clip. The combination of size and growth of the immunoassay market have made it a key focus in the strategic plans of nearly every major IVD company.

Abbott's Decimated Immunoassay Menu*

Fertility/Pregnancy	*Thyroid*
Estradiol	Free T3
FSH	Free T4
LH	Total T3
Progesterone	Total T4
Prolactin	TSH
Total B-hCG	

*For Architect i2000

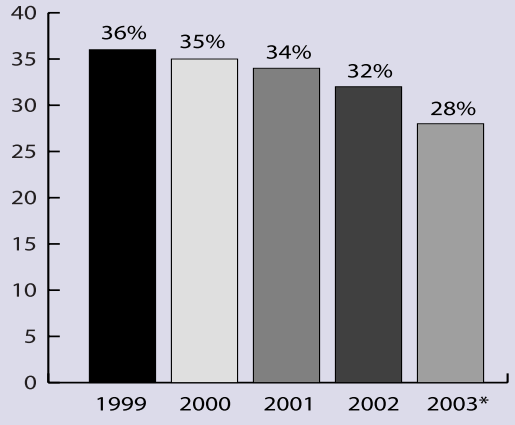
Source: Abbott

Of course, the driving force for change in the immunoassay market for the past three and a half years has been **Abbott Diagnostics'** consent decree with the FDA, which has forced it to suspend U.S. distribution of 60 immunoassay test kits produced at its Lake County, Illinois, manufacturing plant since January 2000. Among the important tests suspended are vitamin B12, ferritin, folate, and cortisol. In addition, the consent decree has shut down Abbott's ability to introduce new immunoassays manufactured at the Lake County facility.

As a result, Abbott's immunoassay test menu has been stymied. This is particularly evident in Abbott's Architect i2000 high-volume immunoassay system, which currently offers a menu of only 11 tests.

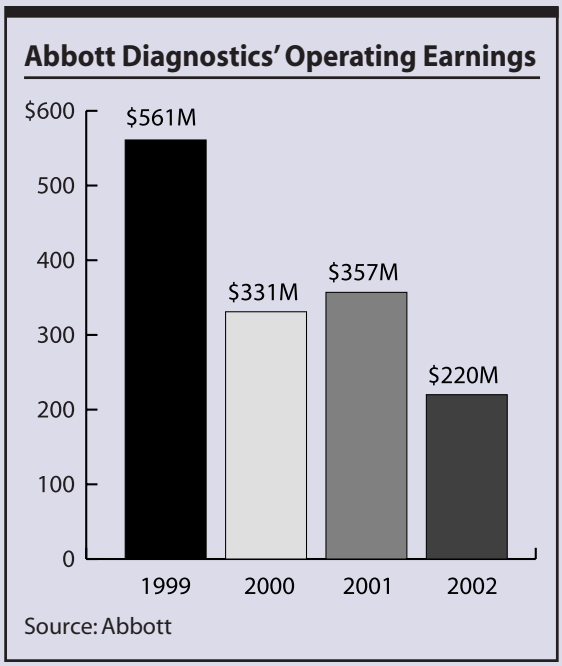
Following initial news of the consent decree, Abbott had aimed to get back in compliance within 12 months (*see DTTR, August 2000, p. 12*). But things haven't worked out that way. The biggest setback occurred in May of 2002, when, following a six-month inspection and review process, the FDA notified Abbott that the Lake County facility was still not in compliance with quality system regulations. Prior to the FDA's follow-up inspection, Abbott had hoped to begin reintroducing the suspended products, which had represented an estimated $250 million in annual sales, back onto the market by year-end 2002.

Abbott's Shrinking Share of the $5 Billion* Global Immunoassay Market



*Excludes blood banking, but includes protein plasma, and TDM/DOA testing
**As of June 2003
Source: *DTTR* estimates based on data from Abbott

Now the company has become a bit more hesitant to make predictions. Don Braakman, spokesman for Abbott Diagnostics, says the company hopes to be ready for another inspection by September or October. The FDA would then schedule the time, determine the length of the inspection, and when to issue its report. *DTTR* estimates that the earliest that Abbott could be found to be back in compliance would be in the first quarter of 2004. But even under this optimistic scenario it would still probably take



Abbott the full year to get all its suspended products back on the market.

Although the consent decree has badly hurt Abbott's market share in the U.S. immunoassay market, the company has offset part of the damage by international growth. Even so, Braakman tells *DTTR* that Abbott's share of the global immunoassay market had fallen to the 26% to 29% range as of June 2003 from 31% to 33% at year-end 2002.

The effect on the bottom line has also been pronounced. Last year, operating profits at Abbott's diagnostic division fell to $220 million from $357 million in 2001. They had been as high as $561 million in 1999, the last year before the effects of the consent decree kicked in.

Meanwhile, Abbott is trying to cope with the Lake County product suspensions by farming out the development and manufacturing of new immunoassays for its AxSym system to the European IVD manufacturer Axis-Shield (Dundee, Scotland). Axis-Shield is developing BNP and testosterone tests for Abbott that should be ready for the European market later this year and for the U.S. market early next year.

Under another contract, Axis-Shield recently agreed to develop and manufacture 12 new immunoassays for the AxSym system, including cardiovascular disease and autoimmune tests.

Nino Totino

Nino Totino, vice president of marketing for the U.S. at **Bayer Diagnostics** (Tarrytown, NY), believes that the switchover of Abbott immunoassay customers to other vendors accelerated in mid-2002 when Abbott failed its second inspection. "There is the potential for major shifts in market share. Time will tell, but who would have ever thought that Abbott's problems with the FDA would last this long," notes Totino.

Totino says that Bayer's Advia Centaur high throughput immunoassay system was the standout performer at Bayer Diagnostics last year, growing revenue by 31% to 340 million euros (US $375 million). And *DTTR* estimates that Bayer's worldwide immunoassay business generated a total of roughly $450 million in revenue last year, including $375 million from Centaur plus another $75 million from Bayer's older systems (*i.e.*, Immuno-1 and ACS:180)

Totino says the Centaur currently has a menu of 54 immunoassays; recent additions include homocysteine, CA19-9, serum Her-2/neu, and automated BNP (*see p. 4*). Tests for hepatitis B and C are expected to be added in September or October, and HIV 1&2 tests should be cleared by early 2004, according to Totino.

Dade Behring (Deerfield, IL) generated more than $500 million from its im-

munoassay business last year, according to Mark Wolsey-Paige, senior vice president, strategy and technology. Dade's immunoassay business consists of three major segments: 1) the Dimension platform (*i.e.*, Dimension RxL and Dimension XPand); 2) protein plasma testing (aka, nephelometry); and 3) Stratus Cardiac point-of-care testing.

Mark Wolsey-Paige

Dade's Dimension RxL can perform up to 175 heterogenous immunoassays per hour. Its menu includes 13 heterogenous immunoassays plus plasma protein and TDM/DOA tests for a total of approximately 30 tests. Test menu expansion is the key that will allow Dade's Dimension business to expand, notes Wolsey-Paige. He says that Dade is also gearing up for the launch of its next-generation chemistry/immunoassay system named Dimension Vista (formerly known as Project Epsilon). Dimension Vista will consolidate chemistry and immunoassay testing on a single homogeneous testing format with throughput of 2,800 tests per hour. Commercialization is set to begin in 2005, according to Wolsey-Paige.

Regarding Abbott, Wolsey-Paige notes that the sales process for labs switching to a new immunoassay system typically occurs over a one- to two-year time frame, so the impact of Abbott failing its second inspection last year is just now being felt. He adds that while Abbott has probably seen a precipitous drop in its new placements in the U.S., it seems to be competing effectively in the international market where it is unaffected by the consent decree.

Roche Diagnostics' immunoassay business grew by roughly 20% in 2002 to reach $450 million, but the business is in doubt now that Igen has terminated Roche's licence to Igen's Origen technology, which is the backbone of Roche's Elecsys and high-volume E-170 Modular platform (*see pp. 1-2*).

Of all the IVD manufacturers, **Diagnostic Products Corp.** (DPC—Los Angeles, CA), which generates 100% of its sales from immunoassay systems, has probably benefited the most from Abbott's problems. DPC introduced its Immulite 2000 immunoassay system for mid- and high-volume labs in late 1998—only one year before Abbott's signed its consent decree with the FDA.

Last year, DPC booked record sales and profits, with revenues of $324.1 million, up 15% from 2001, and net income of $47.3 million, up 21%. And this year, James Brill, chief financial officer for DPC, says the company is anticipating another double-digit gain in both revenue and net income.

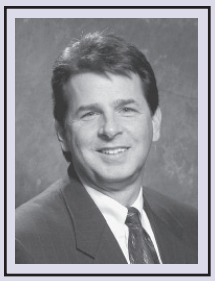
Brill says that Abbott's problems have made more hospitals willing to use multiple vendors and allowed DPC to shed its image as a small esoteric test vendor.

A big key to DPC's growth has been its wide menu (100 tests for Immulite; 85 tests for Immulite 2000). New tests that will be added soon include an automated ANA screen, D-dimer, and Epstein Barr, according to Brill. He adds that DPC is aiming to have its next generation immunoassay system, Immulite 3000, on the market in the 2005-2006 time frame.

BioMerieux (Marcy-l'Etoile, France) has approximately 13,000 Vidas immunoas-

say systems placed worldwide, including about 2,000 in the U.S. Last year, the company generated more than $300 million from its immunoassay business. New products under development include Vidas Probe, a dual platform that will allow existing Vidas immunoassay customers to add DNA probe technology and thus perform both immunoassays and molecular diagnostics on a single platform.

Ortho-Clinical Diagnostics (New Brunswick, NJ) generated an estimated $285 million in sales from immunoassay systems last year (excluding blood banking). The company's key growth driver is the Vitros Eci immunoassay system (90 tests per hour) and its broad infectious disease menu, which includes new tests for anti-HBs, HBsAg, and anti-HCV.



Jim Rigo

Jim Rigo, global market manager for immunoassay at **Beckman Coulter**, tells *DTTR* that launch of the high-volume DxI 800 Access immunoassay system should help Beckman accelerate the growth rate for its Access business to 20% to 25% this year, up from 15% growth in 2002. That translates into expected revenue of $265 million to $275 million for Access this year. Beckman's other immunoassay business, protein plasma testing, is expected to grow 1% to approximately $111 million.

Rigo says the DxI 800, which can perform up to 400 tests per hour, is aimed at the 1,000 or so labs in the U.S. that do more than 100,000 immunoassays per year. He estimates that the U.S. market for high-volume immunoassay systems totals roughly $600 million while the worldwide market is $1.4 billion annually.

Beta testing for the DxI 800 took place at the Mayo Clinic, Duke University Medical Center, London Health (Toronto), and Centre hospitalier de l'Universite de Montreal (aka, CHUM).

Rigo says the DxI 800 has been launched with Beckman's full immunoassay menu of 40 tests. The system uses the same reagent packs, calibrators, and assay protocols as Beckman's other Access system, thus providing consistent patient test results across all immunoassay platforms. New immunoassays that Beckman has launched include the tumor marker CA125. Tests for CA15-3 and CA19-9 will be added to the menu in the fourth quarter and a BNP test licensed from Biosite (*see p. 3*) will be available early next year, according to Rigo.

High-Volume Immunoassay Systems

Company	System Name	Throughput	U.S. Test Menu Size
Abbott	Architect i2000	200 tests/hour	11
Bayer	Advia Centaur	240 tests/hour	54
Beckman	UniCel DxI 800	400 tests/hour	40
Dade	Dimension RxL	175 tests/hour	13*
DPC	Immulite 2000	200 tests/hour	85
Roche	E-170	170 tests/hour	33

*heterogenous immunoassays only

Source: *DTTR* from companies

In regard to the Abbott situation, Rigo notes that labs have seven other vendors to choose from. "We have done extremely well in gaining our share from Abbott, probably better than most," he says. He adds that pricing in immunoassay is getting competitive, especially from group purchasing organizations, but he doesn't expect it to reach the "give away" level that's now common practice in routine chemistry.

Roche Launches AmpliChip CYP450 Microarray

In addition to CYP450, Roche is planning to introduce microarrays for HIV genotyping, p53 cancer resequencing, colorectal cancer risk, cystic fibrosis, and HPV genotyping

Roche Diagnostics (Basel, Switzerland, and Indianapolis, IN) has announced the launch of its AmpliChip CYP450 microarray in the U.S. Roche will sell the gene chip and reagents on an analyte-specific-reagent (ASR) basis at a starting price to laboratories of $350 to $400 per test (with potential for volume discounts), according to Thomas Metcalfe, senior vice president for genomics business at Roche. Metcalfe would not speculate on the price that labs will bill to run the test, but *DTTR* estimates that they are likely to charge payers more than $1,000 per test.

The AmpliChip CYP450 microarray is the first test to come to market from Roche's recent alliance with DNA chip maker Affymetrix (*see DTTR, March 2003, p. 1*). The microarray identifies polymorphisms in two genes in the cytochrome P450 family, the CYP2D6 and CYP2C19 genes, which play a major role in drug metabolism. Variations in these genes can affect the rate at which an individual metabolizes many drugs used to treat cardiovascular disease, high blood pressure, depression, and other diseases. Knowledge of these variations can help a physician select the best drug and set the right dose for a patient.

In order to perform the AmpliChip CYP450 test, Metcalfe says labs will need four key pieces of equipment, including nucleic acid isolation equipment and a thermocycler. These tools are fairly common at the roughly 400 labs certified under CLIA to perform high-complexity testing. Less common are the necessary hybridization station and microarray scanner, and Metcalfe estimates that only about 10 of these CLIA high-complexity labs in the nation currently own the two pieces of equipment. Among these 10 is Quest Diagnostics' Nichols Institute in San Juan Capistrano, California. Metcalfe says that Roche is currently working with Quest to set up a beta site at Nichols to begin CYP450 testing.

Many labs have been performing CYP450 testing on a homebrew basis for years. However, they have generally used a testing method called capillary electrophoresis and directed their work toward the research and pharmaceutical development markets; Roche's test is the first to employ microarray technology for CYP450 aimed at the clinical market.

The benefit of microarray technology is that it allows a very wide range of genetic variances to be analyzed in a single, more reproducible, high-throughput test, according to Metcalfe. He says it also offers workflow advantages compared to the capillary electrophoresis platform. For example, he notes that the AmpliChip CYP450 tests for a total of 33 polymorphisms (thirty-one 2D6 and two 2C19 polymorphisms), including insertions and deletions, something that has not been possible in other multiplexed high-throughput tests to date.

Metcalfe expects the AmpliChip CYP450 microarray to generate revenue of more than $100 million per year for Roche by 2008. "Developing demand will be a challenge, but we're not going to sit by and wait for things to happen," he says. The key to gaining market acceptance will be the publication of studies that show the clinical and financial benefits of using AmpliChip CYP450, according to Metcalfe. He says that Roche is currently laying the groundwork for a clinical study that will examine the benefits of the test when used in conjunction with prescriptions for antidepressant and schizophrenia drugs.

In addition, Metcalfe says that Roche is working to put together a plan for submitting an application to the FDA to gain clearance to market AmpliChip CYP450 in kit form. "We are breaking new ground here. It's difficult to predict when we might have our application ready," he says.

Finally, Metcalfe notes that Roche is planning to introduce five other microarray-based assays by the end of 2004. These will include ASR tests in the areas of HIV-1 resistance genotyping, p53 cancer resequencing, colorectal cancer risk prediction, cystic fibrosis, and human papillomavirus (HPV) genotyping.

TM Bioscience Launches P450-2D6 Test

TM Bioscience Corp. (Toronto, Canada) has announced the U.S. launch of its Tag-It Mutation Detection Kit for P450-2D6 in a research-use-only (RUO) format. The test uses bead-based liquid microarray technology and runs on instruments made by Luminex Corp. (Austin, TX).

The TM Bioscience launch came just days after Roche announced the availability of its AmpliChip CYP450 microarray. James Smith, spokesman for TM Bioscience, says that the company will sell its test to lab customers at a price of less than $100 per test mix. "That's a fraction of the price that Roche is selling its CYP450 test for," notes Smith.

TM Bioscience is a start-up company that is working to bring several genetic tests to market. In December 2002, the company began offering a Factor V genetic test, and it's planning to introduce a cystic fibrosis test soon. Smith says that TM Bioscience expects to get ISO 13485 and QSR certification by year's end, so that it can offer its tests in ASR form.

Pharmacia Diagnostics Up For Sale

Pfizer Inc. (New York City), the world's biggest drugmaker, has announced that it is exploring strategic options for its Pharmacia Diagnostics business, including its possible sale. The Pharmacia Diagnostics business became a part of Pfizer in April 2003, with Pfizer's $60 billion acquisition of Pharmacia.

In a press release, Pfizer chairman and CEO Hank McKinnell stated, "The Pharmacia Diagnostics business is a successful and growing business, with an outstanding reputation and strong position in its industry. However, this business is not aligned with Pfizer's strategic focus on our three core businesses of human pharmaceuticals, consumer healthcare, and animal health."

The Pharmacia Diagnostics business is headquartered in Uppsala, Sweden, and U.S. operations are based out of Kalamazoo, Michigan. It has 1,100 employees worldwide and generated revenue of approximately $220 million in 2002. Pharmacia Diagnostics has a line of microwell autoimmune and allergy tests along with a semi-automated allergy system. Its main product is ImmunoCap, a blood test for allergies. The majority of sales come from Europe, where allergy testing is more prevalent than in the U.S.

IVD Stocks Up 1% In Latest 4 Weeks; Ventana Jumps 18%

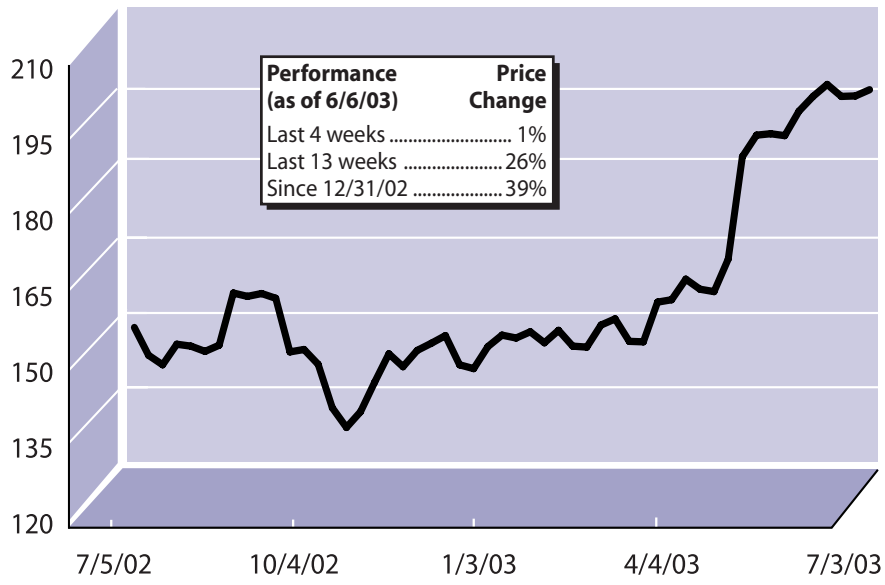
***Roche** non-voting equity shares, which trade on the Zurich stock exchange, are up 11% to 107 Swiss francs so far this year. Shares of **Bayer**, which trade on the German stock exchanges, are down 4% at 19.60 euros*

The 21 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 1% in the four weeks ended July 7, 2003, with 10 stocks up in price, two unchanged, and nine down. Year to date, the G-2 Index is up 39%, while the S&P 500 Index is up 12% and the Nasdaq is up 25%.

Shares of **Ventana Medical Systems** (Tucson, AZ) were up 18% to $31.21 per share for a market cap of $520 million. **i-Stat Corp.** (East Windsor, NJ) was up 17% to $9 per share for a market cap of $181 million. i-Stat Corporation recently announced its submission of a 510(k) pre-market notification with the FDA for its new 10 minute cardiac troponin I test. Cardiac troponin I is a protein marker used by physicians to help determine if a patient has suffered a heart attack. **Biosite** (San Diego, CA) was up 12% to $49.34 per share for a market cap of $794 million on news that it is developing a BNP test that will run on Beckman Coulter's automated immunoassay systems (*see p. 3*).

Shares of **Cholestech Corp.** (Hayward, CA) fell 8% to $9.91 per share for a market cap of $135 million. The company recently announced that it is in discussions with Roche regarding a complaint that alleges it is violating three of Roche's U.S. patents for measuring cholesterol. In a press release, Cholestech said it believes the complaint is without merit, but that it expects defense of this matter will likely be costly and time-consuming. The complaint was filed in March in the U.S. District Court for the Southern District of Indiana. Roche's suit seeks a preliminary and permanent injunction, damages, and attorney's fees. In February, a German court barred Cholestech from distributing some cholesterol tests in that country that correspond to Roche's patents.

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 IVD companies.

% Price Change, weeks ended 7/3/03

UP	Price	% Chg
Biosite	49.34	12%
Diagnostic Products	40.55	4%
Digene	27.91	6%
Gen-Probe	43.64	9%
Immucor	22.25	10%
Inverness Medical	19.35	5%
i-STAT	9.00	17%
Meridian	9.27	2%
Quidel	6.01	1%
Ventana	31.21	18%
UNCHANGED		
Johnson & Johnson	52.99	0%
Dade Behring	23.35	0%
DOWN		
Abbott Labs	$44.22	-2%
Beckman Coulter	40.81	-3%
Becton Dickinson	39.51	-2%
Bio Rad	59.20	-5%
Cholestech	9.91	-8%
Cytyc	10.50	-5%
Diametrics	0.85	-35%
Igen	33.76	-4%
TheraSense	10.31	-10%

G-2 Insider

Survey Shows Labs Want Folate On Their Menus

Folate is the most popular test that will be added to test menus this year, according to an exclusive survey of hospital and independent labs conducted by Washington G-2 Reports (publisher of *DTTR*). Of the total 171 survey respondents, 10% cited folate as being among the tests they plan to bring in-house in 2003. Other top tests on the "to add" list: Vitamin B12 (9%), Hepatitis C antibody (9%), and BNP (7%).

Survey finding are contained in a new 100+ page report titled: "U.S. Laboratory Reference Testing: Market Profile & Pricing Trends." The report provides a detailed look at the $2.5 billion reference testing market and includes key data on pricing for esoteric tests, benchmarks for average referral volume and expense by lab size and type, and ratings of the national reference labs by turnaround time, pricing, and overall best value.

For more information go to *www.g2reports.com* and click on "publications." For additional information contact the report's author, Jondavid Klipp, at *labreporter@aol.com*.

Top 10 Tests Expected To Be Brought In-House, 2003

Test	*% labs citing they will add to menu*
Folate	10
Vitamin B12	9
Hepatitis C antibody	9
BNP	7
Chlamydia/GC DNA probe	7
Hemoglobin A1c	7
Hepatitis B surface antigen	7
Cystic fibrosis (genetic mutations)	5
Hepatitis B antibody	5
Ferritin	6

Source: U.S. Laboratory Reference Testing: Market Profile & Pricing Trends

Company References

Abbott Labs 847-937-6100
Aperio Technologies 760-539-1100
Bayer Diagnostics 914-631-8000
Beckman Coulter 714-871-4848
BioMerieux (Durham, NC) 800-654-0331
Biosite 858-455-4808
Cholestech 510-732-7200
Dade Behring 847-267-5300
Diagnostic Products 310-645-8200
Igen 301-869-9800
Pharmacia Diagnostics 800-818-0979
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